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Application Proof of

Sichuan Biokin Pharmaceutical Co., Ltd.

四川百利天恒藥業股份有限公司

(the “Company”)

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

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Sichuan Biokin Pharmaceutical Co., Ltd.

四川百利天恒藥業股份有限公司

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

[REDACTED]

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

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

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

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

Nominal value : RMB1.00 per H Share

[REDACTED] : [REDACTED]

*Joint Sponsors, [REDACTED], [REDACTED],
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[REDACTED]

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[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

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SUMMARY

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

OVERVIEW

We are an integrated pharmaceutical group with capabilities spanning early-stage research and development, clinical development, manufacturing and commercialization. We operate two major businesses: innovative biologics business, and generics and traditional Chinese medicine business.

Ten years ago, in 2014, we established SystImmune in Seattle, U.S., embarking on the development of BL-B01D1, the world’s first and only clinical-stage EGFR × HER3 bispecific ADC to date. A decade later, we entered into a global strategic license and collaboration agreement for BL-B01D1 with BMS, with a US\$800 million upfront payment and a total deal value worth up to US\$8.4 billion — being the largest ever for a single-asset collaboration transaction in the ADC space in terms of total deal value. Our endeavors in the U.S. over the past decade have led to the creation of (i) an innovative ADC drug development platform, from which we have successfully advanced eight clinical-stage, innovative ADC candidates, including BL-B01D1, into approximately 50 clinical studies, including eight Phase III clinical trials for late-line cancer treatment and 12 Phase II clinical trials for first-line cancer treatment; and (ii) a multi-specific T cell engager platform, from which we have successfully advanced four innovative Guidance Navigation & Control (GNC) multi-specific antibodies, including GNC-077, to clinical stage, which have been evaluated in 13 clinical studies.

Through years of dedicated effort since 1996, we have cultivated expertise in generics and traditional Chinese medicine. Our generics and traditional Chinese medicine business has a product portfolio in anesthesia, parenteral nutrition, anti-infection, pediatrics and other therapeutic areas. We have accumulated rich experience in R&D, production and marketing of special preparations such as emulsion injections and effervescent preparations, and have formed a competitive product portfolio. During the Track Record Period, we generated revenue from the sales of 29 approved drug products with over 100 specifications, which includes 25 generics products and four traditional Chinese medicine products. Revenue from these products has played a crucial role in funding our innovative drug development.

As of the Latest Practicable Date, all of our innovative drug candidates remained in clinical and preclinical development. In the nine months ended September 30, 2024, we recorded revenue of RMB5,661.2 million, among which 94.2% represented the license fee income generated under our license and collaboration agreement with BMS, and 5.8%

SUMMARY

represented sales of generics and traditional Chinese medicines. In 2021, 2022 and 2023, we generated a revenue of RMB795.0 million, RMB701.8 million, and RMB560.4 million, respectively, from sales of generics and traditional Chinese medicines. Sales of generics and traditional Chinese medicines decreased over the Track Record Period as certain of our major marketed products are generic drugs that were adversely impacted by the VBP schemes, which resulted in (i) a significant reduction in selling prices for products included in the VBP schemes, despite an increase in sales volume under those VBP schemes; in some cases, a corresponding decrease in sales volumes to hospitals outside the VBP schemes, (ii) a decrease in sales volumes for products that belong to a drug class subject to the VBP schemes but did not participated in such schemes, and (iii) a decrease in sales volumes of certain product due to increased competition from its competing drug class which was included in the VBP schemes. We incurred net losses of RMB107.6 million, RMB282.4 million, RMB780.5 million in 2021, 2022 and 2023, respectively, and achieved a profit of RMB4,065.4 million in the nine months ended September 30, 2024. Our net losses recorded in the first three years of the Track Record Period were primarily in relation to: (i) our substantial investment in R&D activities for innovative drug candidates, and (ii) the reduction of revenue from sales of generics and traditional Chinese medicines. In particular, the profitability of our generics and traditional Chinese medicines was affected by the implementation of VBP schemes relating to our products. Our net profit achieved in the nine months ended September 30, 2024 was primarily due to the recognition of the license fee income generated under our license and collaboration agreement with BMS. In addition, we experienced net operating cash outflow of RMB137.5 million, RMB256.6 million and RMB618.0 million in 2021, 2022 and 2023, respectively, which was primarily due to our losses before tax, while we generated net operating cash inflow of RMB4,430.6 million in the nine months ended September 30, 2024, primarily due to our profit before tax.

OUR JOURNEY TO DATE

Inception and Growth (1996-2010)

Our history can be traced back to 1996, when Dr. Zhu Yi, our chairman of the Board, general manager and Chief Scientific Officer, established Baili Pharmaceutical, which is the predecessor of our Company and currently one of our key subsidiaries. Through years of dedicated effort, we have cultivated expertise in complex generics and traditional Chinese medicine. Our generics and traditional Chinese medicine business has a product portfolio in anesthesia, parenteral nutrition, anti-infection, pediatrics and other therapeutic areas. We have accumulated rich experience in R&D, production and marketing of special preparations such as emulsion injections and effervescent preparations, and have formed a competitive product portfolio. As of the Latest Practicable Date, our portfolio of marketed products comprised 19 generics products and three traditional Chinese medicine products.

More importantly, we have grown into an integrated pharmaceutical corporate group with capabilities spanning early-stage research, clinical development, manufacturing, and commercialization.

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Strategic Pivot (2010-2014)

To realize long-term growth and enhance patient outcomes, we made the strategic move into the innovative drug business in 2010 and commenced the independent development of innovative drugs. To support this shift, we reinvested most of our revenue from our generic drug and traditional Chinese medicine business into innovative drug research and development. In 2014, we established SystImmune in Seattle, the U.S., to lead the 0-to-1 innovation of therapeutic modalities and discovery of novel drug pipelines. In the same year, we commenced the independent development of bispecific antibodies and ADCs. SystImmune also spearheads our global clinical development and future commercialization in global markets. Our presence in the U.S. has given us access to a highly skilled talent pool with expertise in drug discovery, development and clinical research. Immersion in the global biotech innovation epicenter also offers valuable networking opportunities and insights into emerging trends. At the same time, we have built a team of scientists and specialists in innovative drug development in China over the years.

Substantial Investments in Discovering and Developing Innovative Oncology Drugs (2014-2024)

Since 2014, discovering and developing innovative drugs has been our business focus. We have dedicated substantial resources to the development of ADC, bispecific as well as multi-specific antibody drugs: including establishing the SEBA and HIRE-ADC technology platforms in 2014, followed by the GNC multi-specific platform in 2015. These initiatives have enabled us to achieve a number of “firsts” in the industry, including the world’s first and only clinical-stage EGFR × HER3 bispecific ADC, and the first and only three tetra-specific antibodies to enter into clinical development to date. In 2021, 2022 and 2023 and the nine months ended September 30, 2024, our research and development expenses for innovative drug candidates accounted for 71.5%, 85.9%, 92.9% and 96.3% of our total research and development expenses, respectively.

Our dual R&D centers in the U.S. and China consist of highly experienced professionals specializing in drug discovery, preclinical development, CMC, clinical development, and regulatory affairs. These teams cover the entire R&D cycle for innovative drugs, comprising both exceptional scientists who have grown within our Company and top-tier professionals recruited from the industry. As of September 30, 2024, our R&D teams in the U.S. and China comprised 1,006 members, representing approximately 41.9% of our total workforce. Many of these individuals have extensive experience leading drug discovery and development projects at renowned multinational and domestic biopharmaceutical companies, as well as research institutions such as MD Anderson Cancer Center and Fred Hutchinson Cancer Center, and/or have worked with the FDA. This combination of talent and expertise has equipped us with the requisite R&D capabilities to advance our innovative drug development efforts.

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While as a private company, we received investment from leading healthcare investors such as OrbiMed. We successfully completed a listing of our Company on the SSE STAR Market in January 2023 and commenced a new chapter in our corporate development as a publicly traded company.

In December 2023, we entered into a global strategic license and collaboration agreement with BMS to co-develop and co-commercialize BL-B01D1, in which BMS agreed to pay to the Group a US\$800 million upfront payment and a total consideration of up to US\$8.4 billion. This collaboration is the culmination of years of dedication to innovative drug development and marks our first step toward generating revenue from our innovative oncology drug portfolio.

OUR GENERICS AND TRADITIONAL CHINESE MEDICINE BUSINESS

All of our revenues in 2021, 2022 and 2023 and a portion of our revenue in the nine months ended September 30, 2024 were generated from the sale of generics and traditional Chinese medicine drug products. During the Track Record Period, we generated revenue from the sales of 29 approved drug products with over 100 specifications, which includes both generics (covering a wide range of therapeutic areas such as anesthesia, parenteral nutrition, anti-infective and pediatrics) and traditional Chinese medicine products. Revenue from our marketed products has played a crucial role in funding our innovative drug development. The following table summarizes our major marketed products as of the Latest Practicable Date:

Therapeutic Areas	Name of Products
Generic Drugs	
Anesthesia Drugs	Leweijing 乐维静® (Propofol Injectable Emulsion (丙泊酚乳狀注射液)) Loweitai 乐维泰® (Propofol Medium and Long Chain Fat Emulsion Injection (丙泊酚中/長鏈脂肪乳注射液)) Youmeining 右美宁® (Dexmedetomidine Hydrochloride Injection (鹽酸右美托咪定注射液))
Parenteral Nutrition Drugs	Tianze 天泽® (Medium and Long Chain Fat Emulsion Injection (中/長鏈脂肪乳注射液))
Anti-Infective Drugs	Xinbolin 新博林® (Ribavirin Granule (利巴韋林顆粒)) Aobolin 奧博林® (Ornidazole Capsule (奧硝唑膠囊))
Pediatric Drugs	Dulabao 杜拉宝® (Racecadotril Granule (消旋卡多曲顆粒)) Leyeping 乐液平® and Pujikang 朴吉康® (Glucose Electrolyte Effervescent Tablet (葡萄糖電解質泡騰片))
Traditional Chinese Medicine	
	Astragalus Granule (黃芪顆粒) Chaihuang Granule (柴黃顆粒)

For details, see “Business — Our Marketed Products.”

SUMMARY

OUR INNOVATIVE BIOLOGICS BUSINESS

First-in-class EGFR × HER3 Bispecific ADC: BL-B01D1

BL-B01D1 is the world’s first and only clinical-stage EGFR × HER3 bispecific ADC. EGFR and HER3 are broadly overexpressed in numerous types of epithelial tumors. The bispecific structure of BL-B01D1 is designed to target a wide range of solid tumors and achieve greater enrichment within tumor tissues, thereby enhancing tumor killing activity and reducing on-target off-tumor toxicity.

We initiated the first-in-human Phase I clinical study for BL-B01D1 in November 2021 and have since enrolled over 2,000 patients across multiple clinical trials, covering over ten tumor types, including lung cancer, breast cancer (BC), head and neck squamous cell carcinoma (HNSCC), nasopharyngeal cancer (NPC), esophageal cancer (EC), gastric cancer (GC), colorectal cancer (CRC), biliary cancer, urothelial carcinoma (UC), prostate cancer (PC), ovarian cancer (OC), endometrial cancer, and cervical cancer (CC). BL-B01D1 has demonstrated promising efficacy and manageable safety in these tumor types, including one of the most promising clinical data profiles for late-line non-small cell lung cancer (NSCLC) to date.

As of the Latest Practicable Date, we had conducted approximately 30 clinical trials for BL-B01D1, including (i) seven Phase III clinical trials evaluating BL-B01D1 as monotherapy for late-line treatment of various cancers, including two NSCLC indications, SCLC, two BC indications, ESCC, and NPC, (ii) eight Phase II clinical trials evaluating its combination with PD-(L)1 therapies for 1L treatment of nine cancer indications (*SCLC, NSCLC, NPC, HNSCC, EC, GC, CRC, BC, and UC*), (iii) two Phase II clinical trial evaluating its combination with TKI for 1L treatment of lung cancer, and (iv) six Phase Ib clinical trials.

For a wide range of solid tumor indications currently treated with PD-(L)1 therapies in 1L settings, BL-B01D1 has the potential to replace the chemotherapy component where PD-(L)1 combo therapies are the current standard of care. For cancer indications primarily treated with TKIs in 1L settings — such as EGFRmut NSCLC currently treated with the TKI osimertinib — BL-B01D1 also demonstrates potential for combination use with TKIs to establish a new standard of care. Furthermore, BL-B01D1 could advance into earlier lines in the treatment regimen for these cancers as neoadjuvant and adjuvant therapy. It has also shown promising efficacy and manageable safety profiles as late-line treatment for these cancers. Therefore, BL-B01D1 has the potential to become a next generation backbone cancer therapy and a super blockbuster drug after PD-(L)1 immunotherapies.

SUMMARY

On December 11, 2023, we reached a global strategic license and collaboration agreement with BMS to co-develop and co-commercialize BL-B01D1. Under the agreement, both parties will jointly develop and commercialize BL-B01D1 in the U.S. We are exclusively responsible for the development, commercialization, and manufacturing of BL-B01D1 in mainland China, and will be responsible for manufacturing certain drug supplies for use outside of mainland China. BMS has an exclusive license for BL-B01D1 in the rest of the world. This collaboration is expected to generate substantial global revenues for the Company, while also allowing us to extend our biopharmaceutical capabilities beyond early-stage drug discovery and development to include global clinical development and commercialization.

Innovative ADC Drug Development Platform

In the course of developing BL-B01D1 (EGFR × HER3 bispecific ADC), we have also made significant advancements in our technology platforms:

- (1) We have established the SEBA (Specificity Enhancement Bispecific Antibody) platform for iterative innovations in antibody discovery and engineering, safeguarded by a global patent portfolio. This platform has successfully identified and advanced a number of antibodies that specifically target and enrich in tumor cells, such as the EGFR × HER3 bispecific antibody. These antibodies are also used in our portfolio of ADC drug candidates, such as BL-B01D1.
- (2) We have established a technology platform for developing payloads with different mechanistic approaches that effectively overcome tumor heterogeneity and enable extensive and efficient tumor cell killing.
- (3) We have developed a linker and conjugation technology platform that enables stable conjugation of varying numbers of payloads to antibodies.
- (4) Our innovative ADC drug development platform possesses fully in-house, end-to-end capabilities. This platform has accrued a large volume of foundational research data, enabling continuous iteration of our innovative ADC technologies and development of innovative drug portfolio, thereby ensuring our capacity for sustained innovation.

GNC-077 and Innovative Multi-specific Antibody Development Platform

GNC-077 is an innovative multi-specific antibody molecule, representing a novel class of “targeted immunotherapy” for cancer treatment. We have initiated Phase I clinical trials for GNC-077 for the treatment of BC, NSCLC, GIC and other solid tumors as of the Latest Practicable Date. Its molecular structure features antibody domains targeting T cell CD3 and T cell immune checkpoints, as well as antibody domains targeting tumor antigens. GNC-077

SUMMARY

can effectively induce activation, differentiation, and proliferation of naive T cells and guide these activated T cells to specifically target and kill antigen-bearing cancer cells. In our *in vivo* studies, GNC-077 has demonstrated robust “targeted immune” tumor-killing activity in multiple solid tumors.

GNC (Guidance Navigation & Control) is our proprietary multi-specific antibody development platform. It is designed to develop multi-specific antibody with symmetrical/asymmetrical structures that can simultaneously target multiple different antigens. Multi-specific GNC molecules developed on this platform coordinate interactions among several tumor/immune-related protein domains to synergistically and comprehensively activate several mechanisms of the immune system of cancer patients. These GNC compounds guide, navigate, and control T cells, ultimately leading to a stimulatory “targeted immune” attack against the tumors.

In addition to GNC-077, we are developing three other GNC drug candidates at Phase Ib stage, GNC-038 (CD3 × 4-1BB × PD-L1 × CD19), GNC-035 (CD3 × 4-1BB × PD-L1 × ROR1), and GNC-039 (CD3 × 4-1BB × PD-L1 × EGFRvIII). These three GNC molecules are the world’s first and only tetra-specific antibodies in clinical development.

INSIGHTS AND STRATEGIES

Focused on oncology, we are committed to continuously innovating and developing new breakthrough cancer drugs.

In the realm of innovative drug development, North America’s innovation ecosystem excels at pioneering 0-to-1 breakthroughs, while China’s ecosystem is notably efficient at 1-to-100 innovative scale-ups. Through SystImmune, we embed ourselves in North America’s vibrant innovation ecosystem. Meanwhile, our R&D team leverages the China-efficiency to scale up and accelerate translational research, preclinical development, and proof-of-concept clinical development. Operating dual R&D centers in the U.S. and China allows us to advance innovations rapidly, efficiently and economically. This strategy has been instrumental in our development of innovative ADCs and multi-specific antibodies.

The ideal oncology therapies selectively target tumors without harming normal tissues. We believe ADCs, as “targeted chemotherapy,” and GNCs, as “targeted immunotherapy,” will become two of the most crucial types of weapons in our arsenal against cancer. Leveraging our proprietary ADC, GNC and other technology platforms, we have systematically built a pipeline of potential treatments across multiple modalities that target major tumor types. Going forward, we aim to continue to make substantial investments in discovering and developing innovative drugs with blockbuster potential while realizing the commercial value of our pipeline assets. As many pipeline assets in our innovative drug portfolio are expected to rapidly advance into late-stage development and commercialization in the coming years, we expect that revenue from this business to be the primary driver of our top-line growth in the future.

SUMMARY

BUSINESS SUSTAINABILITY

We recorded net losses of RMB107.6 million, RMB282.4 million and RMB780.5 million in 2021, 2022 and 2023, respectively, primarily in relation to: (i) our substantial investment in R&D activities for the development of ADC, bispecific as well as multi-specific antibody drugs, and (ii) the reduction of revenue from the sale of pharmaceutical products. Going forward, we aim to continue to make substantial investments in discovering and developing innovative drugs with blockbuster potential while realizing the commercial value of our pipeline assets. For a detailed analysis of the sustainability of our innovative drug business and generics and traditional Chinese medicine business, see “Financial Information — Business Sustainability.”

Our near-term priority is to further accelerate the clinical development for BL-B01D1 both in China and around the globe by leveraging our global strategic collaboration with BMS. We will (i) proactively advance BL-B01D1’s development in combination with PD-(L)1 therapies, aiming to replace the chemotherapy component in 1L treatment for solid tumors where PD-(L)1 combo therapies are the current standard of care; (ii) proactively advance BL-B01D1’s development in combination with TKIs as the new standard of care for cancer indications currently treated with TKI monotherapy in 1L settings; and (iii) continue to develop BL-B01D1 in late-line settings, as well as in neoadjuvant and adjuvant settings across over ten epithelial cancers where BL-B01D1 has shown promising efficacy and manageable safety. We expect NDA submission to the NMPA for BL-B01D1 in its first indication by 2026, and the first BLA submission to the FDA in as early as 2028. Over the next three to five years, BL-B01D1 is anticipated to have multiple regulatory approval applications submitted for various indications in China, the U.S., Europe and other regulatory regions.

We reasonably anticipate near-term revenue from our strategic collaboration with BMS. In addition to the US\$800 million upfront payment we have already received in March 2024, we are eligible to receive a nonrefundable milestone payment of US\$250 million upon the initiation of the first Phase II or Phase III trial of the Licensed Product as 1L or 2L treatment in the U.S. on or before December 31, 2025, and another nonrefundable milestone payment of US\$250 million upon the initiation of the first Phase III trial of the Licensed Product as 1L treatment in the U.S. on or before December 31, 2026. Such milestones were established through mutual agreement. In the U.S., we initiated a Phase I clinical trial for BL-B01D1 in August 2023 for various solid tumors including NSCLC, BC, SCLC, EC, and NPC, and a Phase I/IIa clinical trial for BL-B01D1 in combination with osimertinib/pembrolizumab in December 2024 for advanced solid tumors. Based on the current pace of clinical progress, we reasonably anticipate that we will be eligible to receive the contingent near-term payments. We and BMS have conducted a Type B end-of-Phase I meeting with the FDA to discuss the clinical development strategy for a registration-enabling study of BL-B01D1 as a 2L treatment of a certain solid tumor, which we and BMS plan to initiate in 2025. Furthermore, we and BMS have conducted a Type B pre-IND meeting with the FDA to discuss the clinical development strategy for a registration-enabling study of BL-B01D1 as a 1L treatment of a certain solid tumor, which we and BMS also plan to initiate in 2025. The initiation of these registration-enabling studies will potentially qualify as the milestone events that will trigger the foregoing

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two contingent near-term payments by BMS. According to CIC, Type B meetings are typically held at critical junctures in the development process to align development strategies with regulatory expectations, reduce the risk of delays, and ensure readiness for transitioning to the next clinical phase.

In addition to BL-B01D1, we are committed to advancing the global clinical development of our other ADCs and GNC multi-specific antibodies, aiming to establish a robust and diverse pipeline of ADCs and GNC molecules.

As many of our pipeline assets are rapidly advancing into late-stage development and commercialization, in the medium to long term, we expect our revenue to come primarily from two sources: (i) sales of innovative drugs and (ii) out-licensing deals, partnerships, and co-development and co-commercialization agreements. As our lead asset, BL-B01D1, and other key candidates receive marketing approvals, sales of innovative drugs are expected to be an increasingly significant source of revenue for the Group. We believe our co-development and co-commercialization arrangement with BMS will contribute to fully realizing the global commercial potential of BL-B01D1. Under our global strategic collaboration with BMS, (i) we expect to generate revenue from the sales of BL-B01D1 in mainland China, where we have the exclusive right to commercialize BL-B01D1, while paying BMS a royalty of a mid-single-digit percentage of aggregate annual net sales; (ii) we and BMS will share the net profits/losses related to BL-B01D1 sales in the U.S. according to certain agreed-upon percentages; (iii) BMS is required to pay us tiered royalties based on a percentage of aggregate annual net sales of BL-B01D1 in the rest of the world, excluding the U.S. and mainland China, subject to certain customary reductions and a royalty floor; and (iv) for commercialization in the U.S. and the rest of the world, we will take on certain manufacturing responsibilities, which provides an additional source of revenue.

In addition, we will strategically explore out-licensing deals, partnerships, and co-development and co-commercialization agreements based on the unique circumstances surrounding each asset. Under the BMS Agreement, we are eligible to receive up to an aggregate of US\$7.1 billion contingent payments upon the achievement of certain specified regulatory and sales performance milestones. In addition, we believe our pipeline of innovative drug candidates across multiple modalities that target major tumor types are attractive targets for additional collaborations. Building on the BMS deal, we aim to establish out-licensing, partnerships, and co-development and co-commercialization arrangements as a sustainable source of revenue.

During the Track Record Period, our business has focused on discovering and developing innovative drugs. This has resulted in substantial research and development expenses, which were RMB278.6 million, RMB375.0 million, RMB746.2 million and RMB931.7 million in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively. Our research and development expenses for innovative drug candidates accounted for 71.5%, 85.9%, 92.9% and 96.3% of our total research and development expenses during these periods, respectively. As of September 30, 2024, we had an R&D team of 1,006 members across our offices in China and the U.S., with 69.9% focusing on innovative drug discovery and

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development. Our substantial investments in innovative drug development partially led to our net losses of RMB107.6 million, RMB282.4 million and RMB780.5 million in 2021, 2022 and 2023, respectively. In the nine months ended September 30, 2024, we recorded a profit of RMB4,065.4 million, primarily due to an US\$800 million upfront payment received in March 2024 under the BMS Agreement, which represented our first revenue recorded from our innovative drug portfolio.

To meet our future business needs, we plan to further expand our global operating footprint in manufacturing and commercialization. We expect that greater investments in clinical development, expanded manufacturing capabilities, and increased sales and marketing efforts are required for our future success. We are confident that enhancement of our manufacturing, commercialization and operational capabilities will facilitate our integration with global quality systems, expedite market entry, and fully realize the commercial potential of our pipeline. Successfully launching and marketing our innovative drug products could result in substantial revenue growth, contingent on market acceptance and adequate demand. Our risk profile will also evolve, with heightened regulatory, market, and operational risks during the commercialization phase. In addition to the inherent risks in discovering and developing innovative drugs, we will face uncertainties in obtaining regulatory approvals, achieving consumer acceptance, and competing with other treatments. Effective management of these factors will be crucial for sustaining growth and achieving long-term success.

OUR DISTRIBUTORS

We generate revenue from the sale of pharmaceutical products primarily by selling our products to distributors who, in turn, sell our products to hospitals, pharmacies and other medical institutions. We believe our distribution strategy helps extend our coverage in a cost-effective manner while retaining proper control over our distribution network and marketing and promotion process. We also sell directly to retail pharmacy chains. Our sales strategy is in line with the industry norm in the pharmaceutical industry, according to CIC. The following table sets forth a breakdown of our revenue from the sale of pharmaceutical products by distribution channels for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
<i>(RMB in thousands, except for percentages)</i>										
<i>(unaudited)</i>										
Distributors	788,031	99.1	697,712	99.4	554,687	99.0	371,489	98.6	325,030	99.4
Direct sales to retail pharmacies	6,924	0.9	4,121	0.6	5,729	1.0	5,110	1.4	1,906	0.6
Total	794,955	100.0	701,833	100.0	560,416	100.0	376,599	100.0	326,936	100.0

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We maintain strong relationships with our customers, including hundreds of nationally known pharmaceutical distributors. As of the Latest Practicable Date, our distribution network comprised of more than 1,000 distributors across more than 30 provinces and over 200 cities. This extensive network and close collaboration with distributors have cultivated a dynamic, open marketing system that effectively stimulates cooperation and sales, ensuring strong sales capabilities across various regional and local markets. In 2021, 2022, 2023 and the nine months ended September 30, 2023 and 2024, sales to our distributors amounted to approximately RMB788.0 million, RMB697.7 million, RMB554.7 million, RMB371.5 million and RMB325.0 million, which approximately accounted for 99.1%, 99.4%, 99.0%, 98.6% and 99.4% of our revenue from the sale of pharmaceutical products in 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, respectively. For details, see “Business — Sales and Marketing.”

OUR SUPPLIERS AND CUSTOMERS

During the Track Record Period, our suppliers primarily consisted of CROs and suppliers of raw materials, equipment, devices and construction services. Purchases from our five largest suppliers were RMB108.8 million, RMB111.5 million, RMB165.2 million and RMB151.0 million in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively, representing 16.8%, 16.2%, 16.8% and 17.3% of our total purchases for the corresponding periods. Purchases from our largest supplier in 2021, 2022 and 2023 and the nine months ended September 30, 2024, were RMB32.3 million, RMB35.8 million, RMB58.8 million and RMB53.2 million, respectively, representing 5.0%, 5.2%, 6.0% and 6.1% of our total purchases for the corresponding periods.

In 2021, 2022 and 2023, our revenue was primarily derived from the sales of pharmaceutical products, mainly to third-party distributors. In the nine months ended September 30, 2024, our revenue was primarily derived from the license fee income representing part of the upfront payment received from BMS in March 2024 under the global strategic license and collaboration agreement. Our revenue from our five largest customers, calculated on the group level with entities controlled by the same group combined together, were RMB314.1 million, RMB266.8 million, RMB199.1 million and RMB5,476.6 million in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively, representing 39.5%, 38.0%, 35.5% and 96.7% of our total revenue for the corresponding periods. Our revenue from our largest customer in 2021, 2022 and 2023 and the nine months ended September 30, 2024 were RMB150.2 million, RMB110.1 million, RMB83.6 million and RMB5,334.3 million, respectively, representing 18.9%, 15.7%, 14.9% and 94.2% of our total revenue for the corresponding periods. For details, see “Business — Suppliers” and “Business — Customers.”

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SUMMARY OF HISTORICAL FINANCIAL INFORMATION

The following tables set forth summary financial data from our consolidated financial information for the Track Record Period, extracted from the Accountants’ Report set out in Appendix I to this document.

Summary of Consolidated Statements of Profit or Loss

The following table sets forth selected consolidated statements of profit or loss with line items in absolute amounts and as percentages of our revenue for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	% of revenue	Amount	% of revenue	Amount	% of revenue	Amount	% of revenue	Amount	% of revenue
<i>(RMB in thousands, except for percentages)</i>										
<i>(Unaudited)</i>										
Revenue	794,955	100.0	701,833	100.0	560,416	100.0	376,599	100.0	5,661,227	100.0
Cost of sales	(212,735)	(26.8)	(246,844)	(35.2)	(253,401)	(45.2)	(161,031)	(42.8)	(190,920)	(3.4)
Gross profit	582,220	73.2	454,989	64.8	307,015	54.8	215,568	57.2	5,470,307	96.6
Other income	70,311	8.8	70,489	10.0	59,249	10.6	42,906	11.4	163,819	2.9
Other gains and losses, net	2,434	0.3	(563)	(0.1)	(1,248)	(0.2)	(733)	(0.2)	(46,296)	(0.8)
Impairment losses under expected credit loss (“ECL”) model, net of reversal	2,998	0.4	(7,686)	(1.1)	6,442	1.1	6,224	1.7	1,477	0.0
Research and development expenses	(278,603)	(35.0)	(375,020)	(53.4)	(746,232)	(133.2)	(509,799)	(135.4)	(931,701)	(16.5)
Distribution and selling expenses	(391,296)	(49.2)	(324,297)	(46.2)	(251,193)	(44.8)	(179,718)	(47.7)	(156,046)	(2.8)
Administrative expenses	(79,869)	(10.0)	(82,194)	(11.7)	(115,397)	(20.6)	(87,211)	(23.2)	(122,322)	(2.2)
Other expenses	(3,939)	(0.5)	(2,311)	(0.3)	(2,970)	(0.5)	(2,441)	(0.6)	(1,748)	(0.0)
Finance costs	(16,343)	(2.1)	(22,481)	(3.2)	(24,679)	(4.4)	(18,492)	(4.9)	(27,798)	(0.5)
(Loss) Profit before tax	(112,087)	(14.1)	(289,074)	(41.2)	(769,013)	(137.2)	(533,696)	(141.7)	4,349,692	76.8
Income tax credit/(expense)	4,445	0.6	6,695	1.0	(11,486)	(2.0)	18,590	4.9	(284,324)	(5.0)
(Loss) Profit for the year/period	(107,642)	(13.5)	(282,379)	(40.2)	(780,499)	(139.3)	(515,106)	(136.8)	4,065,368	71.8

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Revenue

Revenue by Nature

During the Track Record Period, we generated revenue primarily from the sale of pharmaceutical products in China and the license fee income in the United States. The following table sets forth a breakdown of our revenue by nature in both absolute amounts and as percentages of our revenue for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	% of		% of		% of		% of		% of	
	Amount	revenue	Amount	revenue	Amount	revenue	Amount	revenue	Amount	revenue
(RMB in thousands, except for percentages)										
(Unaudited)										
Sale of pharmaceutical products	794,955	100.0	701,833	100.0	560,416	100.0	376,599	100.0	326,936	5.8
License fee income	-	-	-	-	-	-	-	-	5,331,724	94.2
Others ⁽¹⁾	-	-	-	-	-	-	-	-	2,567	0.0
Total	794,955	100.0	701,833	100.0	560,416	100.0	376,599	100.0	5,661,227	100.0

Note:

- (1) Representing revenue generated from the sale of clinical trial supplies relating to BL-B01D1 to BMS pursuant to a clinical supply agreement entered between us and BMS. See “Business — License and Collaboration Agreement with Bristol-Myers Squibb Company” for more details.

Revenue from the sale of pharmaceutical products

In 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, our revenue from the sale of pharmaceutical products was RMB795.0 million, RMB701.8 million, RMB560.4 million, RMB376.6 million and RMB326.9 million, respectively. Sales of pharmaceutical products decreased over the Track Record Period as certain of our major marketed products are generic drugs that were impacted by the VBP schemes, which resulted in decreases in both prices and sales volumes of relevant products during the Track Record Period. See “Financial Information — Period to Period Comparison of Results of Operations” for more details.

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Revenue from the license fee income

In the nine months ended September 30, 2024, we also generated revenue from the license fee income, representing part of the upfront payment under the BMS Agreement. Pursuant to the BMS Agreement, in March 2024, we received a non-refundable and non-creditable upfront payment of US\$800 million (equivalent to approximately RMB5,679.7 million) from BMS. We recognized revenue of US\$751.0 million (equivalent to approximately RMB5,331.7 million) in relation to our performance of the grant of license to BMS in the nine months ended September 30, 2024.

Revenue from the Sale of Pharmaceutical Products by Product

The following table sets forth our revenue from the sale of our pharmaceutical products by product for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
(RMB in thousands, except for percentages)										
(Unaudited)										
Anesthesia										
Leweijing	258,356	32.5	313,652	44.7	212,429	37.9	149,888	39.8	96,801	29.6
Leweitai	116,805	14.7	28,414	4.0	19,636	3.5	14,464	3.8	18,549	5.7
Youmeining	26,729	3.4	23,272	3.3	11,400	2.0	8,655	2.3	12,240	3.7
Parenteral nutrition										
Tianze	115,555	14.5	61,554	8.8	39,864	7.1	30,874	8.2	19,159	5.9
Anti-infectives										
Xinbolin	34,500	4.3	58,724	8.4	33,492	6.0	13,336	3.5	10,461	3.2
Aobolin	10,408	1.3	8,427	1.2	1,988	0.4	1,516	0.4	1,632	0.5
Pediatric drugs										
Dulabao	14,058	1.8	8,590	1.2	13,877	2.5	11,346	3.0	6,819	2.1
Leyeping and Pujikang	15,593	2.0	19,623	2.8	31,407	5.6	23,071	6.1	14,907	4.6
Traditional Chinese medicine										
Astragalus granule	160,988	20.3	134,148	19.1	155,696	27.8	97,953	26.0	92,331	28.2
Chaihuang granule	24,303	3.1	28,870	4.1	21,317	3.8	15,251	4.0	9,685	3.0
Other chemical drugs and traditional Chinese medicines										
	17,660	2.1	16,559	2.4	19,310	3.4	10,246	2.7	44,352	13.6
Total	794,955	100.0	701,833	100.0	560,416	100.0	376,599	100.0	326,936	100.0

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Gross Profit and Gross Profit Margin

Our gross profit represents our revenue less cost of sales. Gross profit margin represents our gross profit as a percentage of our revenue. In 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, our gross profit was RMB582.2 million, RMB455.0 million, RMB307.0 million, RMB215.6 million and RMB5,470.3 million, representing a gross profit margin of 73.2%, 64.8%, 54.8%, 57.2% and 96.6%, respectively.

The following table sets forth a breakdown of our gross profit and gross profit margin by business for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Gross profit		Gross profit		Gross profit		Gross profit		Gross profit	
	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %
	(RMB in thousands, except for percentages)									
	(Unaudited)									
Sale of pharmaceutical products	582,220	73.2	454,989	64.8	307,015	54.8	215,568	57.2	136,016	41.6
License fee income	-	-	-	-	-	-	-	-	5,331,724	100.0
Others	-	-	-	-	-	-	-	-	2,567	100.0
Total	582,220	73.2	454,989	64.8	307,015	54.8	215,568	57.2	5,470,307	96.6

The following table sets forth a breakdown of our gross profit and gross profit margin of the sale of our major products by therapeutic area for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Gross profit		Gross profit		Gross profit		Gross profit		Gross profit	
	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %
	(RMB in thousands, except for percentages)									
	(Unaudited)									
Anesthesia										
Leweijing	215,412	83.4	240,778	76.8	151,057	71.1	107,336	71.6	35,172	36.3
Leweitai	111,118	95.1	24,810	87.3	14,103	71.8	10,651	73.6	12,655	68.2
Yuomeining	26,060	97.5	22,381	96.2	10,764	94.4	8,157	94.2	11,653	95.2

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	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Gross profit		Gross profit		Gross profit		Gross profit		Gross profit	
	Gross margin		Gross margin		Gross margin		Gross margin		Gross margin	
	profit	%	profit	%	profit	%	profit	%	profit	%
	(RMB in thousands, except for percentages)									
	(Unaudited)									
Parenteral nutrition										
Tianze	82,711	71.6	38,881	63.2	23,647	59.3	18,233	59.1	10,870	56.7
Anti-infectives										
Xinbolin	26,534	76.9	40,812	69.5	22,063	65.9	9,407	70.5	6,012	57.5
Aobolin	6,388	61.4	4,793	56.9	1,148	57.7	903	59.6	672	41.1
Pediatric drugs										
Dulabao	12,279	87.3	7,439	86.6	12,108	87.3	9,925	87.5	5,708	83.7
Leyeping and Pujikang	11,300	72.5	12,590	64.2	22,336	71.1	16,281	70.6	10,334	69.3
Traditional Chinese medicine										
Astragalus granule	84,397	52.4	53,485	39.9	56,774	36.5	38,375	39.2	30,564	33.1
Chaihuang granule	12,469	51.3	14,037	48.6	9,940	46.6	7,329	48.1	3,371	34.8
Other chemical drugs and traditional Chinese medicines	9,951	56.3	10,386	62.7	8,515	44.1	5,764	56.3	25,390	57.2
Add: Others⁽¹⁾	(16,399)	–	(15,403)	–	(25,440)	–	(16,793)	–	(16,385)	–
Total	582,220	73.2	454,989	64.8	307,015	54.8	215,568	57.2	136,016	41.6

Note:

- (1) Represent the add-back of other cost of sales primarily including impairment and write-off losses related to inventory.

In 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, our gross profit from the sale of pharmaceutical products was RMB582.2 million, RMB455.0 million, RMB307.0 million, RMB215.6 million and RMB136.0 million, representing a gross profit margin of 73.2%, 64.8%, 54.8%, 57.2% and 41.6%, respectively. The decreasing trend was mainly due to (i) a decrease in the respective average selling price of our major products including Lewejjing (propofol injectable emulsion) and Leweitai (propofol medium and long chain fat emulsion injection) following their inclusion in the VBP schemes at the national and/or provincial level; and (ii) an increase in the respective cost of sales per unit of our major products as a result of fixed production costs such as equipment depreciation and other expenses allocating to fewer units as the sales volume of relevant products decreased over the Track Record Period. See “Financial Information — Period to Period Comparison of Results of Operations” for more details.

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(Loss) Profit for the Year/Period

We recorded net losses of RMB107.6 million, RMB282.4 million and RMB780.5 million in 2021, 2022 and 2023, respectively. Our net losses recorded during the Track Record Period were primarily in relation to: (i) our substantial investment in R&D activities for the development of ADC, bispecific as well as multi-specific antibody drugs, and (ii) the reduction of revenue from the sale of pharmaceutical products mainly because certain of our major marketed products are generic drugs which were impacted by the VBP schemes, which resulted in decreases in both prices and sales volumes of relevant products during the Track Record Period. See “Financial Information — Business Sustainability” for more details. We recorded a net profit of RMB4,065.4 million in the nine months ended September 30, 2024, mainly attributable to the license fee we received as part of the Upfront Payment in connection with the licenses and other rights granted to BMS by us pursuant to the BMS Agreement. See “Financial Information — Description of Key Statements of Profit or Loss Items — Revenue” for more details.

Summary of Consolidated Statements of Financial Position

The table below sets forth our current assets and current liabilities as of the dates indicated:

	As of December 31,			As of September 30,
	2021	2022	2023	2024
	<i>(RMB in thousands)</i>			
Total current assets	423,812	1,426,345	775,820	6,141,533
Total non-current assets	527,644	565,088	649,279	818,630
Total current liabilities	487,696	752,059	1,066,620	2,080,028
Net current (liabilities)				
assets	(63,884)	674,286	(290,800)	4,061,505
Total non-current liabilities	132,000	305,480	206,606	638,236
Net Assets	331,760	933,894	151,873	4,241,899

We recorded net current assets of RMB674.3 million as of December 31, 2022, as compared to net current liabilities of RMB63.9 million as of December 31, 2021, primarily due to (i) an increase in cash and cash equivalents of RMB846.5 million as we received the proceeds raised from our A-share initial public offering in December 2022; and (ii) an increase in trade and other receivables of RMB119.6 million, which was partially offset by an increase in trade and other payables of RMB186.9 million.

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We recorded net current liabilities of RMB290.8 million as of December 31, 2023, as compared to net current assets of RMB674.3 million as of December 31, 2022, primarily due to (i) a decrease in cash and cash equivalents of RMB609.0 million as a result of the operating costs associated with our R&D activities; and (ii) an increase in borrowings of RMB263.9 million.

We recorded net current assets of RMB4,061.5 million as of September 30, 2024, as compared to net current liabilities of RMB290.8 million as of December 31, 2023, primarily due to an increase in cash and cash equivalents of RMB4,559.0 million as we received the Upfront Payment from BMS under the BMS Agreement, which was partially offset by (i) an increase in borrowings of RMB457.1 million; and (ii) an increase in contract liabilities of RMB341.7 million.

Our net assets increased from RMB331.8 million as of December 31, 2021 to RMB933.9 million as of December 31, 2022, primarily due to an issuance of A shares of RMB884.4 million in 2022 in relation to our A-share initial public offering, partially offset by total comprehensive expenses for the year of RMB282.3 million in the same year. Our net assets subsequently decreased to RMB151.9 million as of December 31, 2023, primarily due to total comprehensive expenses for the year of RMB782.2 million in 2023. Our net assets subsequently increased to RMB4,241.9 million as of September 30, 2024, primarily due to total comprehensive income for the period of RMB4,081.0 million in the nine months ended September 30, 2024. See Note 34 to the Accountants’ Report in Appendix I for details on the issuance of A shares.

Summary of Consolidated Statements of Cash Flows

The following table sets forth a summary of our consolidated statements of cash flows for the periods indicated:

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	<i>(RMB in thousands)</i>			<i>(Unaudited)</i>	
(Loss) profit before tax	(112,087)	(289,074)	(769,013)	(533,696)	4,349,692
Adjustment for cash flows from operating activities before movement of working capital	64,702	81,000	91,534	66,059	19,074
Changes in working capital	(67,992)	(41,288)	69,270	27,664	271,590
Income tax paid	(22,073)	(7,278)	(9,778)	(8,680)	(209,798)

SUMMARY

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	(RMB in thousands)			(Unaudited)	
Net cash flows (used in)/ from operating activities	(137,450)	(256,640)	(617,987)	(448,653)	4,430,558
Net cash flows from/ (used in) investing activities	158,345	(36,977)	(79,399)	(68,559)	(604,189)
Net cash flows from/ (used in) financing activities	88,876	1,139,833	91,003	(97,502)	794,684
Net increase (decrease) in cash and cash equivalents	109,771	846,216	(606,383)	(614,714)	4,621,053
Cash and cash equivalents at the beginning of the year/period	45,212	154,222	1,000,695	1,000,695	391,693
Effect of foreign exchange rate changes	(761)	257	(2,619)	(624)	(62,047)
Cash and cash equivalents at the end of the year/period	154,222	1,000,695	391,693	385,357	4,950,699

We had a net operating cash outflow of RMB137.5 million, RMB256.6 million and RMB618.0 million in 2021, 2022 and 2023, respectively, which was primarily due to our losses before tax. See “Financial Information — Liquidity and Capital Resources — Cash Flows” for more details. We monitor and maintain a level of cash and cash equivalents deemed adequate by our management to finance our operations and mitigate the effects of fluctuations in cash flows. We regularly review our major funding positions to ensure that we have adequate financial resources for meeting our financial obligations.

Taking into account the financial resources available to our Group, including our cash and cash equivalents and the [REDACTED] from the [REDACTED], our Directors are of the view that we have sufficient working capital to meet our present requirements and for the next 12 months from the date of this document. See “Financial Information — Liquidity and Capital Resources — Working Capital Sufficiency” for more details.

SUMMARY

Key Financial Ratios

The following table sets forth certain of our key financial ratios as of the dates and for the periods indicated:

	As of/For the year ended December 31,			As of/ For the nine months ended September 30,
	2021	2022	2023	2024
Gross profit margin ⁽¹⁾	73.2%	64.8%	54.8%	96.6%
Current ratio ⁽²⁾	0.87	1.90	0.73	2.95
Quick ratio ⁽³⁾	0.70	1.76	0.60	2.87

Notes:

- (1) Gross profit margin is calculated based on gross profit divided by revenue for the year/period.
- (2) Current ratio is calculated based on total current assets divided by total current liabilities as of year/period end.
- (3) Quick ratio is calculated based current assets less inventories divided by current liabilities as of year/period end.

SUMMARY OF MATERIAL RISK FACTORS

Our business and the [REDACTED] involve certain risks including those set out in the section headed “Risk Factors” in this document. 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 [REDACTED]. Some of the major risks that we face include:

- Our business and prospects depend substantially on the success of our drug candidates, including BL-B01D1. 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.
- The regulatory approval process for the NMPA, FDA, and other comparable regulatory agencies is lengthy, time-consuming, and unpredictable. If we fail to obtain timely regulatory approvals in the target markets for our drug candidates, our business may suffer material and substantial damage.

SUMMARY

- Adverse events caused by our drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved drug, or result in significant negative consequences following any regulatory approval.
- Before we start to generate revenue from the commercialization of our innovative drug candidates, if we are unable to maintain the sales volume, pricing levels and profit margins of our existing marketed products, our operations, revenue and profitability could be adversely affected.
- We had net losses during the Track Record Period except for the nine months ended September 30, 2024. The revenue generated from the BMS Agreement contributed to a substantial portion of our revenue in the nine months ended September 30, 2024. Such historical performance may not be indicative of our future performance.
- We have net cash outflows used in our operating activities in 2021, 2022 and 2023, and we may need to obtain additional financing to fund our operations. If we are unable to obtain sufficient financing on terms acceptable to us or at all, we may be unable to complete the development and commercialization of our drug candidates.
- If we or BMS do not achieve our product development or commercialization objectives in the time frames we expect, we may not receive milestone or royalty payments or make profits to support our future development plan.
- We face substantial competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do.
- Our products and future approved products may fail to achieve or maintain the degree of market acceptance by physicians, medical institutions, pharmacies, patients, third-party payers and others in the medical community necessary for commercial success, and the actual market size of our drug candidates might be smaller than expected, which could render some drug candidates less profitable than expected even if commercialized.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDER

As of the Latest Practicable Date, Dr. Zhu directly held approximately 74.35% of our total issued Shares. Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), Dr. Zhu will directly hold approximately [REDACTED]% of our total issued Shares. Accordingly, Dr. Zhu will remain as our Controlling Shareholder upon the completion of the [REDACTED]. For details, see “Relationship with our Controlling Shareholder.”

SUMMARY

CERTAIN WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

We have applied to the Hong Kong Stock Exchange, and the Hong Kong Stock Exchange [has] granted us, among others, the following waivers:

- (i) [REDACTED]; and
- (ii) [REDACTED].

For details, see “Waivers from Strict Compliance with the Listing Rules.”

RECENT DEVELOPMENT

Subsequent to the Track Record Period, there was no material adverse change with respect to our business operations in all material respects. In 2024, as compared to 2023, our total revenue increased mainly because we recognized revenue of US\$751.0 million (equivalent to approximately RMB5,331.7 million) in relation to the grant of license to BMS. In 2024, we experienced a decrease in revenue generated from the sale of pharmaceutical products compared to 2023, which was mainly attributable to a decrease of revenue from the sales of Lewejing (propofol injectable emulsion) and Xinbolin (ribavirin granule). Our gross profit and gross profit margin of the sale of pharmaceutical products decreased in 2024 compared to 2023. The average selling price of our major products in 2024 remained relatively stable compared to the nine months ended September 30, 2024. Among our ten major products, the sales volume of three, Leweitai, Youmeining and Aobolin, increased in 2024 compared to 2023, and the sales volume of our remaining major products decreased during this period. In addition, Lewejing, which contributed over 30% of our revenue from the sales of pharmaceutical products during most of the Track Record Period, only participated in the national VBP scheme in March 2024. In 2024, the average selling price of Lewejing remained stable compared to the nine months ended September 30, 2024, and the period-to-period decline in its sales revenue during this period remained stable compared to the decline experienced in the nine months ended September 30, 2024. As a result, the impact of this inclusion on its sales revenue has been gradually reflected in our financial results since March 2024, although such impact may not have been fully reflected so far. Once the impact of inclusion in the national VBP scheme is realized, we expect Lewejing’s sales to stabilize for the remainder of the national VBP scheme’s duration.

SUMMARY

NO MATERIAL ADVERSE CHANGE

After performing sufficient due diligence work which our Directors consider appropriate and after due and careful consideration, the Directors confirm that, up to the date of this document, there has been no material adverse change in our financial or [REDACTED] position or prospects since September 30, 2024, being the latest date of our consolidated financial statements as set out in Appendix I to this document, and there is no event since September 30, 2024 that would materially affect the information as set out in the Accountants’ Report included in Appendix I to this document.

LISTING ON THE SSE STAR MARKET

On January 6, 2023, our A Shares were listed on the SSE STAR Market with the stock code of 688506. For details, see “History, Development and Corporate Structure.”

APPLICATION FOR [REDACTED] ON THE STOCK EXCHANGE

We have applied to the [REDACTED] Committee of the Stock Exchange for the grant of the [REDACTED] of, and permission to [REDACTED], our H Shares to be [REDACTED] pursuant to the [REDACTED] (including any H Shares which may be [REDACTED] pursuant to the exercise of the [REDACTED]), on the basis that, among other things, we satisfy the market capitalization/revenue test under Rule 8.05(3) of the Listing Rules.

PROFIT ESTIMATE FOR [REDACTED]

The following profit estimate has been prepared based on (i) the audited consolidated results of our Group for the nine months ended September 30, 2024; and (ii) the unaudited consolidated results of our Group based on the management accounts of our Group for [REDACTED]. The profit estimate has been prepared on a basis consistent in all material respects with the accounting policies currently adopted by our Group as set out in the Accountants’ Report, the text of which is set forth in Appendix I to this document.

Estimated consolidated profit attributable to owners of our Company for [REDACTED]	Not less than RMB[REDACTED]
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See “Appendix IIB — Profit Estimate” in this document for further details.

SUMMARY

[REDACTED] STATISTICS⁽¹⁾

	Based on [REDACTED] of HK\$[REDACTED] per H Share	Based on [REDACTED] of HK\$[REDACTED] per H Share
[REDACTED] of the H Shares following the completion of the [REDACTED] ⁽²⁾	HK\$[REDACTED] million	HK\$[REDACTED] million
Total [REDACTED] of our A Shares and H Shares ⁽³⁾	HK\$[REDACTED] million	HK\$[REDACTED] million
Unaudited [REDACTED] adjusted consolidated net tangible assets of the Group attributable to the owners of the Company per Share ⁽⁴⁾	HK\$[REDACTED]	HK\$[REDACTED]

Notes:

- (1) All statistics in this table are based on the assumption that the [REDACTED] is not exercised.
- (2) The calculation of the [REDACTED] is based on the assumption that [REDACTED] H Shares will be in issue immediately after completion of the [REDACTED].
- (3) The calculation of the [REDACTED] is based on the assumption that [REDACTED] H Shares will be in issue immediately after completion of the [REDACTED] and [REDACTED] A Shares will be in issue immediately after completion of the [REDACTED] with the closing price of RMB[188.58] on the Latest Practicable Date.
- (4) The unaudited [REDACTED] adjusted consolidated net tangible assets of our Group attributable to owners of our Company as of September 30, 2024 were calculated after adjustments as specified in Note 4 in “Unaudited [REDACTED] Financial Information” as set out in Appendix IIA to this document. No adjustment has been made to the unaudited [REDACTED] adjusted consolidated net tangible assets of our Group attributable to owners of our Company as of September 30, 2024 to reflect any trading result or other transactions of the Group entered into subsequent to September 30, 2024.

[REDACTED] EXPENSES

Our [REDACTED] expenses mainly include [REDACTED], professional fees paid to legal advisors and the Reporting Accountants for their services rendered in relation to the [REDACTED] and the [REDACTED]. The estimated total [REDACTED] expenses (based on the mid-point of our indicative [REDACTED] range for the [REDACTED] and assuming that the [REDACTED] is not exercised) for the [REDACTED] are approximately RMB[REDACTED] (equivalent to HK\$[REDACTED]), representing [REDACTED]% of the gross [REDACTED]. The estimated total [REDACTED] expenses consist of (i) [REDACTED]-related expenses (including but not limited to [REDACTED] and fees) of approximately RMB[REDACTED] (approximately HK\$[REDACTED]), and (ii) non-[REDACTED] related expenses of approximately RMB[REDACTED] million (approximately HK\$[REDACTED]), which consist of fees and expenses of legal advisors and Reporting Accountants of approximately RMB[REDACTED] (approximately HK\$[REDACTED]), and other fees and expenses of approximately RMB[REDACTED] (approximately HK\$[REDACTED]). During the Track Record Period, we incurred

SUMMARY

[REDACTED] expenses of RMB[REDACTED], which is recognized as deferred issue costs included in trade and other receivables. Of our estimated [REDACTED] expenses of approximately RMB[REDACTED] (equivalent to HK\$[REDACTED]), RMB[REDACTED] (equivalent to HK\$[REDACTED]) is expected to be charged to our consolidated statements of profit and loss and RMB[REDACTED] million (equivalent to HK\$[REDACTED]) will be deducted from equity. The [REDACTED] expenses above are the best estimate as of the Latest Practicable Date and are for reference only and the actual amount may differ from such estimate.

DIVIDEND

We do not currently have a formal dividend policy or a fixed dividend payout ratio. After the completion of the [REDACTED], we may distribute dividends in the form of cash or by other means permitted by our Articles of Association. A decision to declare or to pay dividends in the future and the amount of dividends will be at the discretion of our Board and will depend on a number of factors, including our results of operations, cash flows, financial condition, payments by our subsidiaries of cash dividends to us, business prospects, statutory, regulatory restrictions on our declaration and payment of dividends and other factors that our Board may consider important. Any declaration and payment as well as the amount of dividends will be subject to our constitutional documents and the relevant laws. Our Shareholders in a general meeting may approve any declaration of dividends.

According to the applicable PRC laws and our Articles of Association, we will pay dividends out of our profit after tax only after we have made the following allocations: recovery of the losses incurred in the previous year; allocations to the statutory reserve equivalent to 10% of our profit after tax; and allocations to a discretionary common reserve of certain percentage of our profit after tax that are approved by a Shareholders’ meeting.

Any distributable profits that are not distributed in any given year will be retained and become available for distribution in subsequent years. Pursuant to our Articles of Association, the amount of the cash dividend distributed should be at least 10% of our profits available for distribution generated in each financial year.

In 2021, we distributed dividends of RMB20.0 million, representing a dividend of RMB0.06 per Share. Other than the foregoing, no dividend has been proposed, paid or declared by us during the Track Record Period. Our future declarations of dividends may or may not reflect our historical declarations of dividends and will be at the discretion of our Directors and subject to the approval of the Shareholders’ meeting.

SUMMARY

FUTURE PLANS AND USE OF [REDACTED]

We estimate that we will receive net [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED], after deducting [REDACTED], fees and estimated expenses payable by us in connection with the [REDACTED], based on an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range stated in this document, assuming the [REDACTED] is not exercised. We currently intend to apply these net [REDACTED] for the following purposes:

- Approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the research and development activities of our biologic drug candidates outside of mainland China;
- Approximately [REDACTED]%, or HK\$[REDACTED], will be used to establish our global supply chain, primarily to fund the construction or acquisition of new manufacturing facilities for our biologic drug candidates outside of mainland China; and
- Approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the working capital and other general corporate purposes for our operations outside of mainland China.

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

DEFINITIONS

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

“A Share(s)”	the domestic share(s) of our Company, with a nominal value of RMB1.00 each, which is/are listed on the SSE STAR Market and traded in Renminbi
“Accountants’ Report”	the accountants’ report from the reporting accountant of our Company, Deloitte Touche Tohmatsu, the text of which is set out in Appendix I to this document
“affiliate(s)”	with respect to any specified person, any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“AFRC”	the Accounting and Financial Reporting Council of Hong Kong
“Articles of Association” or “Articles”	the articles of association of our Company, as amended, which shall become effective on the [REDACTED], a summary of which is set out in “Appendix V — Summary of Articles of Association” to this Document
“associate(s)”	has the meaning ascribed to it under the Listing Rules
“Audit Committee”	the audit committee of our Board
“Baili Base”	our manufacturing facility in Wenjiang, Sichuan Province, PRC, which is operated by Baili Pharmaceutical
“Baili-Bio”	Baili-Bio (Chengdu) Pharmaceutical Co., Ltd. (成都百利多特生物藥業有限責任公司), a limited liability company established in the PRC on February 21, 2017 and formerly known as Chengdu Baili Duote Antibody Drug Co., Ltd. (成都多特抗體藥物有限責任公司), which is a wholly-owned subsidiary of our Company
“Baili-Bio Base”	our manufacturing facility in Chengdu, Sichuan Province, PRC, which is operated by Baili-Bio

DEFINITIONS

“Baili Pharm R&D Center”	our R&D facility located in Chengdu, Sichuan Province, PRC
“Baili Pharmaceutical”	Sichuan Baili Pharmaceutical Co., Ltd. (四川百利藥業有限責任公司), a limited liability company established in the PRC on August 23, 1996, which is a wholly-owned subsidiary of our Company
“BMS”	Bristol-Myers Squibb Company, a leading global pharmaceutical company headquartered in the U.S. and listed on the New York Stock Exchange under the ticker symbol BMJ
“BMS Agreement”	the global strategic license and collaboration agreement we entered into with BMS on December 11, 2023, which became effective on February 8, 2024, under which we and BMS will conduct a global strategic collaboration to co-develop and co-commercialize BL-B01D1
“Board” or “Board of Directors”	the board of Directors of our Company
“Business Day” or “business day”	a day on which banks in Hong Kong are generally open for normal business to the public and which is not a Saturday, Sunday or public holiday in Hong Kong
“BVI”	the British Virgin Islands

[REDACTED]

“CDE”	Center for Drug Evaluation of NMPA (國家藥品監督管理局藥品審評中心), a division of the NMPA mainly responsible for review and approval of IND and NDA
“Chief Scientific Officer”	the chief scientific officer of the Company

DEFINITIONS

“China” or “PRC”	the People’s Republic of China which, for the purpose of this Document and for geographical reference only, excluding Hong Kong Special Administrative Region of the People’s Republic of China, Macau Special Administrative Region of the People’s Republic of China, and Taiwan Region
“CIC”	China Insights Industry Consultancy Limited, an independent market research and consulting company
“CIC Report”	the industry report commissioned by our Company and independently prepared by CIC, a summary of which is set forth in “Industry Overview”
“close associate(s)”	has the meaning ascribed to it under the Listing Rules
“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
“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong) as amended, supplemented or otherwise modified from time to time
“Company,” “our Company” or “the Company”	Sichuan Biokin Pharmaceutical Co., Ltd. (四川百利天恒藥業股份有限公司), a joint stock company incorporated in the PRC with limited liability on November 29, 2011 and listed on the SSE STAR Market with the stock code of 688506 on January 6, 2023, or, where the context requires (as the case may be), its predecessor, Sichuan Tianheng Pharmaceutical Co., Ltd. (四川天恒藥業有限責任公司), a limited liability company established in the PRC on August 17, 2006
“Compliance Adviser”	Messis Capital Limited
“connected person(s)”	has the meaning ascribed to it under the Listing Rules
“connected transaction(s)”	has the meaning ascribed to it under the Listing Rules

DEFINITIONS

“Controlling Shareholder”	has the meaning ascribed to it under the Listing Rules and unless the context otherwise requires, refers to Dr. Zhu. For further details, see “Relationship with Our Controlling Shareholder”
“core connected person(s)”	has the meaning ascribed to it under the Listing Rules
“Corporate Governance Code”	the Corporate Governance Code set out in Appendix C1 to the Listing Rules
“CSDC”	China Securities Depository and Clearing Corporation Limited (中國證券登記結算有限責任公司)
“CSRC”	China Securities Regulatory Commission (中國證券監督管理委員會)
“Director(s)” or “our Director(s)”	the director(s) of our Company
“Dr. Zhu”	Dr. Zhu Yi (朱義), the founder, the chairman of the Board, the general manager, the Chief Scientific Officer and an executive Director of our Company, and our Controlling Shareholder
“EIT”	enterprise income tax
“EIT Law”	Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》), as amended, supplemented or otherwise modified from time to time

[REDACTED]

“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the Government of Hong Kong
“FDA”	the Food and Drug Administration of the United States

DEFINITIONS

[REDACTED]

“Group,” “our Group,” “we” or “us”	our Company and our subsidiaries (or our Company and any one or more of our subsidiaries, as the context may require)
“Guorui Base”	our manufacturing facility in Leshan, Sichuan Province, PRC, which is operated by Guorui Pharmaceutical
“Guorui Pharmaceutical”	Sichuan Guorui Pharmaceutical Co., Ltd. (四川國瑞藥業有限責任公司), a limited liability company established in the PRC on December 7, 2005, which is a wholly-owned subsidiary of our Company
“H Share(s)”	the ordinary share(s) in the share capital of our Company, with a nominal value of RMB1.00 per H Share, which is/are to be [REDACTED] for and [REDACTED] in HK dollars and to be [REDACTED] on the Stock Exchange

[REDACTED]

“Hiatt/Jingxi Base”	our manufacturing facility in Qionglai, Sichuan Province, PRC, which is operated by Jingxi Pharmaceutical and Hiatt Technology
“Hiatt Technology”	Chengdu Hiatt Technology Co., Ltd. (成都海亞特科技有限責任公司), a limited liability company established in the PRC on September 29, 2014, which is a wholly-owned subsidiary of our Company
“HK\$” or “HK dollar” or “Hong Kong dollar”	Hong Kong dollars, the lawful currency of Hong Kong

DEFINITIONS

[REDACTED]

“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the PRC
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[REDACTED]

“Hong Kong Stock Exchange” or “Stock Exchange”	The Stock Exchange of Hong Kong Limited, a wholly-owned subsidiary of Hong Kong Exchanges and Clearing Limited
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[REDACTED]

DEFINITIONS

[REDACTED]

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

[REDACTED]

DEFINITIONS

[REDACTED]

“Jingxi Pharmaceutical” Chengdu Jingxi Pharmaceutical Co., Ltd. (成都精西藥業有限責任公司), a limited liability company established in the PRC on September 29, 2014, which is a wholly-owned subsidiary of our Company

[REDACTED]

“Joint Sponsors” the joint sponsors as named in “Directors, Supervisors and Parties involved in the [REDACTED]”

“Latest Practicable Date” January 15, 2025, being the latest practicable date for the purpose of ascertaining certain information contained in this Document prior to its publication

“Lhasa Xinbo” Lhasa Xinbo Pharmaceutical Co., Ltd. (拉薩新博藥業有限責任公司), a limited liability company established in the PRC on August 22, 2013, which is a wholly-owned subsidiary of our Company

[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
“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
“Ministry of Finance” or “MOF”	the Ministry of Finance of the PRC (中華人民共和國財政部)
“MOFCOM”	the Ministry of Commerce of the PRC (中華人民共和國商務部)
“NDRC”	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會)
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局), successor to the China Food and Drug Administration or CFDA (國家食品藥品監督管理總局)
“Nomination Committee”	the nomination committee of our Board

[REDACTED]

DEFINITIONS

[REDACTED]

“Panku Capital”	Panku Capital Limited, a limited company incorporated under the laws of the British Virgin Islands on April 16, 2014, which is a wholly-owned subsidiary of our Company
“PBOC”	the People’s Bank of China (中國人民銀行), the central bank of the PRC
“PRC Company Law”	the Company Law of the PRC (《中華人民共和國公司法》), as amended, supplemented or otherwise modified from time to time
“PRC GAAP”	generally accepted accounting principles in the PRC
“PRC Government” or “State”	the central government of the PRC, including all governmental subdivisions (including principal, municipal and other regional or local government entities) and instrumentalities thereof or, where the context requires, any of them
“PRC Legal Advisor”	JunHe LLP, our legal advisor as to PRC laws

[REDACTED]

DEFINITIONS

[REDACTED]

“QIB”	a qualified institutional buyer within the meaning of Rule 144A
“Regulation S”	Regulation S under the U.S. Securities Act
“Remuneration and Appraisal Committee”	the remuneration and appraisal committee of our Board
“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 (中國國家外匯管理局)
“SAT”	the State Administration of Taxation of the PRC (中國國家稅務總局)
“Securities and Futures Ordinance” or “SFO”	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“SFC”	the Securities and Futures Commission of Hong Kong
“Share(s)”	ordinary share(s) in the share capital of our Company, with a nominal value of RMB1.00 each, comprising our A Share(s) and H Share(s)
“Shareholder(s)”	holder(s) of the Share(s)
“SSE STAR Market”	the Shanghai Stock Exchange Science and Technology Innovation Board (上海證券交易所科創板)
“SSE STAR Market Listing Rules”	the Rules Governing the Listing of Stock on the Science and Technology Innovation Board of Shanghai Stock Exchange (《上海證券交易所科創板股票上市規則》), as amended, supplemented or otherwise modified from time to time

DEFINITIONS

[REDACTED]

“State Council”	the State Council of the PRC (中華人民共和國國務院)
“Strategy and Development Committee”	the strategy and development committee of our Board
“subsidiary(ies)”	has the meaning ascribed to it under the Listing Rules
“substantial Shareholder(s)”	has the meaning ascribed to it under the Listing Rules
“Supervisor(s)”	member(s) of our Supervisory Committee
“Supervisory Committee”	the supervisory committee of our Company
“SystImmune”	SystImmune, INC., a company incorporated under the laws of the United States on April 21, 2014, which is a wholly-owned subsidiary of our Company
“SystImmune Incentive Plan I”	the incentive plan adopted in 2015 by SystImmune, the principal terms of which are set out in “Statutory and General Information — D. SystImmune Incentive Plans” in Appendix VI
“SystImmune Incentive Plan II”	the incentive plan adopted in 2022 by SystImmune (as amended and restated in 2024), the principal terms of which are set out in “Statutory and General Information — D. SystImmune Incentive Plans” in Appendix VI
“SystImmune Incentive Plan III”	the incentive plan adopted in 2023 by SystImmune, the principal terms of which are set out in “Statutory and General Information — D. SystImmune Incentive Plans” in Appendix VI
“SystImmune Incentive Plan IV”	the incentive plan adopted in 2024 by SystImmune, the principal terms of which are set out in “Statutory and General Information — D. SystImmune Incentive Plans” in Appendix VI
“SystImmune Incentive Plans”	SystImmune Incentive Plan I, SystImmune Incentive Plan II, SystImmune Incentive Plan III and SystImmune Incentive Plan IV
“SystImmune R&D Center”	our R&D facility located in Seattle, U.S.

DEFINITIONS

“Takeovers Code”	the Codes on Takeovers and Mergers and Share Buy-back issued by the SFC, as amended, supplemented or otherwise modified from time to time
“Tianze Pharmaceutical”	Lhasa Tianze Pharmaceutical Co., Ltd. (拉薩天澤藥業有限公司), a limited liability company established in the PRC on November 26, 2020, which is a wholly-owned subsidiary of our Company
“Track Record Period”	the period comprising the three financial years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2024
“Trial Measures for Overseas Listing”	Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》) issued by the CSRC on February 17, 2023 and effective from March 31, 2023
[REDACTED]	
“U.S.” or “United States”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“U.S. dollar”, “US\$” or “USD”	United States dollar, the lawful currency of the United States
“U.S. Securities Act”	the United States Securities Act of 1933, as amended and supplemented or otherwise modified from time to time, and the rules and regulations promulgated thereunder
“VAT”	value-added tax

[REDACTED]

DEFINITIONS

[REDACTED]

“%”

per cent

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

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

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

GLOSSARY OF TECHNICAL TERMS

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

“4-1BB”	a receptor expressed on activated T cells and NK cells which gives costimulatory signals to promote T cell division and survival, activate cytotoxic effects and help form memory T cells
“A431”	a human epidermoid carcinoma cell line utilized in biomedical research to study cancer biology, particularly in the context of EGFR signaling and related therapeutic interventions
“ADA”	anti-drug antibody, is an antibody produced by the human immune system to respond to exogenous drugs (such as antibody and protein drugs)
“ADC”	antibody-drug conjugates, a therapeutic modality in cancer therapies that comprise antibodies, linkers and cytotoxic drugs, binding to tumor antigens and delivering the payload directly to tumor cells
“ADCC”	antibody-dependent cell-mediated cytotoxicity, an immune mechanism through which Fc gamma receptor-bearing effector cells can kill target cells expressing tumor- or pathogen-derived antigens on their surface through antibody-binding effect
“adjuvant”	a substance or treatment added to a primary therapy to enhance its effectiveness
“AGA”	actionable genomic alterations
“AKT”	also known as protein kinase B (PKB), a serine/threonine-specific protein kinase that plays a key role in multiple cellular processes such as glucose metabolism, apoptosis, cell proliferation, transcription, and cell migration

GLOSSARY OF TECHNICAL TERMS

“ALL”	acute lymphocytic leukemia, a cancer of the blood and bone marrow that affects white blood cells, which progresses rapidly and creates immature lymphocytes (a type of white blood cell)
“ALK”	anaplastic lymphoma kinase, a receptor tyrosine kinase protein that is likely to play a role in the development and function of the nervous system
“AML”	acute myeloid leukemia, a cancer of the blood and bone marrow which progresses rapidly and creates abnormal myeloblasts (a type of white blood cell), red blood cells or platelets
“antibody”	a blood protein produced in response to and counteracting a specific antigen. Antibodies combine chemically with substances which the body recognizes as alien, such as bacteria, viruses, and foreign substances in the blood
“API”	active pharmaceutical ingredient, the biologically active component in a pharmaceutical drug that produces the intended therapeutic effects
“ARC”	antibody radionuclide conjugate, a targeted cancer therapy combining a monoclonal antibody with a radioactive isotope for precise tumor irradiation
“ASCO”	American Society of Clinical Oncology
“B cell”	B lymphocyte, a type of white blood cell that produces antibodies
“BC”	breast cancer, a malignant tumor that develops from the cells of the breast, often characterized by the uncontrolled growth of breast cells, which can invade surrounding tissues and metastasize to other parts of the body
“biliary cancer”	a type of cancer that originates in the bile ducts, which are the channels that transport bile from the liver and gallbladder to the small intestine
“biomarker”	a measurable indicator of a biological state or condition

GLOSSARY OF TECHNICAL TERMS

“biopharmaceutical”	therapeutic product derived from biological sources, such as proteins, nucleic acids, or living cells, used to treat or prevent diseases and medical conditions
“bispecific antibody”	antibody or antibody-constructs that have bispecific in their binding arms
“BLA”	biologics license application
“BTC”	biliary tract cancer, a group of cancers that occur in the bile ducts, gallbladder, and other parts of the biliary system
“bystander effect”	a phenomenon in which cells or tissues not directly targeted by a treatment or stimulus exhibit a response due to signaling from nearby affected cells
“CAGR”	compound annual growth rate
“carboplatin”	a platinum-based chemotherapy drug used to treat various cancers by interfering with DNA replication, thereby inhibiting cancer cell growth and proliferation
“cathepsin B cleavable linker”	a chemical linker used in targeted drug delivery systems that is cleaved by the enzyme cathepsin B, allowing for the controlled release of therapeutics within specific cellular environments
“CC”	cervical cancer, a type of cancer that occurs in the cells of the cervix
“CD3”	cluster of differentiation 3, a complex of proteins expressed on the surface of T lymphocytes, playing a crucial role in T cell activation, signal transduction, and immune response
“CD19”	cluster of differentiation 19, a surface protein expressed on B cells, serving as a biomarker for B cell development and function, and commonly used in the diagnosis and treatment of B cell-related diseases

GLOSSARY OF TECHNICAL TERMS

“CD33-”	a term refers to cells or populations that do not express the CD33 antigen, a surface protein commonly found on myeloid cells and often used as a marker in immunophenotyping and leukemia diagnostics
“CD33+”	a term refers to cells or populations that express the CD33 antigen, a surface protein typically found on myeloid cells, and frequently used as a biomarker in the diagnosis and treatment of certain leukemias
“CD33”	a transmembrane receptor expressed on cells of myeloid lineage
“CD34+”	a term refers to cells or populations that express the CD34 antigen, a surface glycoprotein commonly found on hematopoietic stem and progenitor cells, and used as a marker in stem cell research and transplantation
“CDMO”	contract development and manufacturing organization
“CDX”	cell line-derived xenograft, a preclinical cancer research model in which human cancer cell lines are implanted into immunocompromised mice to study tumor growth, drug efficacy, and therapeutic responses
“Claudin 18.2”	Claudin 18.2, a highly specific tissue junction protein for gastric tissue
“Claudin” or “CLDN”	a family of transmembrane proteins crucial for the formation and maintenance of tight junctions between cells, thereby regulating paracellular permeability and maintaining cellular barriers in epithelial and endothelial tissues
“CLL”	chronic lymphocytic leukemia, a type of cancer characterized by the accumulation of abnormal, mature lymphocytes in the blood, bone marrow, and lymphoid tissues
“CMO”	contract manufacturing organization
“CNS”	central nervous system

GLOSSARY OF TECHNICAL TERMS

“combination therapy” or “combo”	treatment in which a patient is given two or more drugs (or other therapeutic agents) for a single disease
“cORR”	confirmed objective response rate, the percentage of patients who achieve and maintain a predefined tumor size reduction for a specified duration, confirmed by follow-up assessments
“CR”	complete response, the disappearance of all signs of cancer in response to treatment
“CRC”	colorectal cancer, is the development of cancer from the colon or rectum (parts of the large intestine)
“CRO”	contract research organization
“CTLA-4”	cytotoxic T lymphocyte-associated antigen-4, an essential receptor involved in the negative regulation of T cell activation
“DAR”	drug-to-antibody ratio, the average number of drugs conjugated to the antibodies
“DCR”	disease control rate, the percentage of patients in a clinical trial who achieve complete response, partial response, or stable disease, indicating the overall effectiveness of a treatment in controlling cancer progression
“DLBCL”	diffuse large B cell lymphoma, a heterogeneous group of aggressive non-Hodgkin lymphomas characterized by large B lymphoid cells with varying degrees of differentiation, typically exhibiting a diffuse growth pattern
“DLT”	dose-limiting toxicity, a side effect or adverse reaction of a drug or treatment that is severe enough to prevent an increase in dose or continuation of therapy
“DNA synthesis”	the biological process by which cells replicate their DNA, involving the formation of a new strand of DNA based on the template provided by the original strand, essential for cell division and growth

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
“EC”	esophageal cancer, a malignancy that develops in the esophagus, the muscular tube connecting the throat to the stomach, often presenting with symptoms such as difficulty swallowing and weight loss
“ECOG”	Eastern Cooperative Oncology Group, one of the first publicly funded cooperative groups to perform multicenter clinical trials for cancer research
“EGFR”	epidermal growth factor receptor, a cell surface receptor that binds to epidermal growth factor, triggering intracellular signaling pathways that regulate cell proliferation, differentiation, and survival, often implicated in cancer development and progression
“EGFR homodimer”	a molecular complex formed by the pairing of two EGFR, which activates intracellular signaling pathways involved in cell growth, differentiation, and survival
“EGFRmut”	a term refers to cells or tissues harboring mutations in the EGFR gene, which can affect receptor function and are often associated with certain types of cancer
“EGFRvIII”	a mutant variant of the EGFR characterized by a deletion in the extracellular domain, commonly found in various cancers and associated with enhanced tumorigenic potential
“EGFRwt”	a term refers to the wild-type form of the EGFR, indicating the normal, non-mutated version of the receptor as found in healthy cells
“endometrial cancer”	a type of cancer that originates in the lining of the uterus (endometrium), often presenting with symptoms such as abnormal uterine bleeding and commonly diagnosed in postmenopausal women
“epidermal carcinoma”	a type of skin cancer that originates from the epidermis, the outermost layer of the skin

GLOSSARY OF TECHNICAL TERMS

“epithelial tumor”	a type of tumor arising from the epithelial cells that line the surfaces and cavities of organs and structures throughout the body, often classified based on the organ of origin and cellular characteristics
“ErbB1”	also known as the epidermal growth factor receptor (EGFR)
“ErbB2”	also known as human epidermal growth factor receptor 2 (HER2) or neu
“ErbB3”	also known as human epidermal growth factor receptor 3 (HER3), a member of the ErbB family of receptor tyrosine kinases, playing a role in cell growth and differentiation, and often involved in cancer signaling pathways
“ErbB4”	also known as human epidermal growth factor receptor 4 (HER4), a member of the ErbB family of receptor tyrosine kinases, involved in regulating cell growth, differentiation, and survival, with roles in both normal physiology and cancer
“ESCC”	esophageal squamous cell carcinoma
“exons 2-7”	a term refers to specific segments of a gene that are transcribed into RNA and translated into protein, often examined in genetic studies to identify mutations or variations affecting protein function
“exploratory endpoint”	an outcome measure in a clinical trial used to gather preliminary data on potential effects or mechanisms of action, which may inform future research but is not intended to provide definitive evidence of efficacy
“Fc”	the fragment crystallizable region of an antibody that interacts with cell surface receptors and complement proteins, playing a crucial role in mediating immune responses such as antibody-dependent cellular cytotoxicity and complement activation

GLOSSARY OF TECHNICAL TERMS

“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
“GC”	gastric cancer, a malignant condition originating in the stomach lining, often presenting with symptoms like indigestion, stomach pain, and weight loss, and commonly associated with risk factors such as <i>Helicobacter pylori</i> infection and dietary factors
“GCP”	good clinical practice
“GFA”	gross floor area
“GIC”	gastrointestinal cancer, a group of malignancies affecting the digestive system, including cancers of the esophagus, stomach, liver, pancreas, intestines, and rectum, often presenting with symptoms related to the affected organ
“Good Laboratory Practices” or “GLP”	a quality system of management controls for research laboratories and organizations to try to ensure the uniformity, consistency, reliability, reproducibility, quality and integrity of chemical and pharmaceuticals non-clinical safety tests
“GMP”	Good Manufacturing Practice
“GNC”	guidance, navigation, and control
“HER2-”	a term refers to cells or tissues that do not overexpress HER2, often used in the context of cancer diagnostics to guide treatment decisions
“HER2+”	a term refers to cells or tissues that overexpress HER2, commonly associated with more aggressive forms of cancer, particularly breast and gastric cancers, and often targeted by specific therapies
“HER2”	human epidermal growth factor receptor 2, also known as ErbB2 or neu, a protein that promotes cell growth and division, often overexpressed in certain cancers such as breast and gastric cancers, and serving as a target for specific therapeutic agents

GLOSSARY OF TECHNICAL TERMS

“HER3”	human epidermal growth factor receptor 3, a member of the ErbB family of receptor tyrosine kinases, involved in cell signaling pathways that regulate growth, differentiation, and survival, with implications in cancer development and progression
“HER4”	human epidermal growth factor receptor 4, a member of the ErbB family of receptor tyrosine kinases, involved in mediating cell signaling pathways that regulate cellular growth, differentiation, and survival, with roles in both normal physiology and cancer
“HIRE-ADC”	high internalizing receptor-targeted antibody-drug conjugate, a type of targeted cancer therapy that combines an antibody specific to a high internalizing receptor on tumor cells with a cytotoxic drug, enabling selective delivery and enhanced killing of cancer cells
“HNSCC”	head and neck squamous cell carcinoma, a type of cancer arising from the mucous membranes of the mouth, nose, and throat and can spread to other parts of the body
“HR+”	a term refers to cancer cells that express hormone receptors, such as estrogen receptors or progesterone receptors, which can influence the growth of the tumor and guide hormone-based treatment strategies
“ICF”	informed consent form, a document used in clinical research to ensure that participants are fully informed about the study, including its purpose, procedures, risks, benefits, and their rights, and provide their voluntary agreement to participate
“ICI(s)”	immune checkpoint inhibitor(s), a type of immunotherapy that blocks proteins called immune checkpoints that prevent that immune system from attacking the cancer cells
“IgG”	Immunoglobulin G, the most common type of antibody found in blood circulation, which plays an essential role in immune system
“IgG1”	Immunoglobulin G1

GLOSSARY OF TECHNICAL TERMS

“ILD”	interstitial lung disease, a group of disorders characterized by inflammation and scarring of the lung interstitium, leading to progressive lung function impairment and symptoms such as shortness of breath and cough
“immune cell”	a type of cell that plays a role in the body’s immune system, responsible for detecting, responding to, and eliminating pathogens, infected cells, and cancer cells, and includes various cell types such as T cells, B cells, NK cells, macrophages, dendritic cells, and neutrophils
“immunohistochemistry” or “IHC”	a laboratory technique used to visualize the presence and localization of specific antigens in tissue sections by using labeled antibodies, often employed in the diagnosis and research of diseases, including cancer
“IND”	investigational new drug
“KOL”	key opinion leaders
“LogP”	logarithm of the partition coefficient between n-octanol and water, a measure used to assess the hydrophobicity of a molecule
“lung cancer”	a type of cancer that begins in the lungs, characterized by uncontrolled cell growth in lung tissues, often associated with risk factors such as smoking, exposure to radon gas, and environmental pollutants, and presenting with symptoms like persistent cough, chest pain, and shortness of breath
“MAD”	maximum administered dose, the highest dose of a drug or treatment that is administered to subjects in a clinical trial, used to evaluate safety, tolerability, and potential toxicity
“MAPK”	mitogen-activated protein kinase, a key enzyme in a signaling pathway that transmits signals from the cell surface to the DNA in the nucleus, regulating various cellular activities such as gene expression, cell division, and survival, and often implicated in cancer and other diseases

GLOSSARY OF TECHNICAL TERMS

“mDOR”	median duration of response, the length of time that a tumor continues to respond to treatment without the cancer growing or spreading
“mPFS”	median progression-free survival, a measure used in clinical trials to indicate the median length of time during and after treatment that a patient lives with the disease without it worsening
“MTD”	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects, established through clinical trials to determine the optimal balance between efficacy and toxicity
“NDA”	new drug application
“NE”	not evaluable, which indicates the response that cannot be assessed
“NEDL”	National Essential Drug List of China, an official list of selected medications deemed essential for addressing the primary healthcare needs of the population, which are prioritized for availability, affordability, and accessibility across the national healthcare system
“neoadjuvant”	a therapy administered before the main treatment to reduce the size of a tumor and increase the effectiveness of the subsequent primary treatment
“NHL”	non-Hodgkin’s lymphoma
“NPC”	nasopharyngeal cancer, a type of cancer that originates in the nasopharynx, the upper part of the throat behind the nose, often associated with Epstein-Barr virus (EBV) infection, and presenting with symptoms such as nasal congestion, nosebleeds, and hearing loss
“NRDL”	National Reimbursement Drug List of China, a government-approved list of medications that are covered and reimbursed under the public health insurance system, ensuring affordable access to essential drugs for the population

GLOSSARY OF TECHNICAL TERMS

“NSCLC”	non-small cell lung cancer, the most common type of lung cancer, characterized by slower growth and spread compared to small cell lung cancer, and includes subtypes such as adenocarcinoma, squamous cell carcinoma, and large cell carcinoma
“OC”	ovarian cancer, a type of cancer that originates in the ovaries, the female reproductive glands, often presenting with non-specific symptoms such as abdominal bloating, pelvic pain, and changes in bowel habits, and frequently diagnosed at an advanced stage
“oncology”	the branch of medicine that specializes in the diagnosis, treatment, and research of cancer
“oral infection”	an infection occurring in the mouth, caused by bacteria, viruses, fungi, or other pathogens, and manifesting symptoms such as pain, swelling, redness, and sometimes pus, commonly including conditions like gingivitis, periodontitis, and oral thrush
“ORR”	objective response rate, the percentage of patients in a clinical trial who experience a measurable reduction in tumor size or cancer symptoms, encompassing both complete and partial responses to treatment
“OS”	overall survival, the duration of time from the start of treatment or diagnosis that patients are still alive, regardless of the cause of death, serving as a key endpoint in clinical trials
“OTC”	over-the-counter, referring to medications and health products that can be purchased without a prescription from a healthcare provider, typically used for the treatment of common ailments and conditions
“paclitaxel”	a chemotherapy drug derived from the Pacific yew tree, used to treat various cancers, including breast, ovarian, and lung cancers, by inhibiting cell division through stabilization of microtubules, thereby preventing cancer cell replication
“PC”	prostate cancer, a type of cancer that develops in the prostate gland

GLOSSARY OF TECHNICAL TERMS

“PD”	progressive disease, which refers to a at least 20% increase in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST
“PD-(L)1”	PD-1 and/or PD-L1
“PD-1”	programmed death-1, an immune checkpoint receptor expressed on T cells, B-cells and macrophages. The normal function of PD-1 is to turn off the T cell mediated immune response as part of the process that stops a healthy immune system from attacking other pathogenic cells in the body. When PD-1 on the surface of a T cell attaches to certain proteins on the surface of a normal cell or a cancer cell, the T cell turns off its ability to kill the cell
“PD-L1”	program death ligand 1, which is a protein on the surface of a normal cell or a cancer cell that attaches to certain proteins on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
“PFS”	progression-free survival, a measure in clinical trials that indicates the length of time during and after treatment that a patient lives with the disease without it worsening, used to evaluate the efficacy of a treatment
“Phase I clinical trial”	the initial stage of clinical study in humans, primarily focused on assessing the safety, tolerability, and pharmacokinetics of a new drug or treatment in a small group of participants
“Phase Ia clinical trial”	an early phase of clinical trials primarily focused on assessing the safety, tolerability, pharmacokinetics, and pharmacodynamics of a new drug in a small group of healthy volunteers or patients, often serving as the first-in-human study for the investigational drug
“Phase Ib clinical trial”	a subset of Phase I clinical trials that further explores the safety and preliminary efficacy of a new treatment, often in a slightly larger group of patients, and may include initial assessments of dosage and treatment effects

GLOSSARY OF TECHNICAL TERMS

“Phase II clinical trial”	a clinical study designed to evaluate the efficacy and further assess the safety of a new treatment in a larger group of patients, often focusing on specific types of diseases or conditions
“Phase III clinical trial”	a clinical 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 and to provide adequate information for the labeling of the product
“PI3K”	phosphoinositide 3-kinase, an enzyme involved in cellular functions such as growth, proliferation, differentiation, and survival, playing a crucial role in the PI3K/AKT/mTOR signaling pathway, which is often dysregulated in cancer
“pivotal trial”	a clinical trial designed to provide definitive evidence of a drug’s efficacy and safety, often serving as the basis for regulatory approval
“PK”	pharmacokinetic, a term refers to the study of how a drug is absorbed, distributed, metabolized, and eliminated by the body, providing crucial information on the drug’s behavior and dosing regimen
“PK/PD evaluation”	pharmacokinetic-pharmacodynamic evaluation, an alternative to conventional dose-effect analysis, relating drug effects to a measure of drug concentration in a body compartment rather than to drug dose
“PR”	partial response, which refers to an at least 30% but below 100% decrease in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST
“Platinum-based chemotherapy”	chemotherapy containing platinum complexes, which is used to treat multiple types of cancers

GLOSSARY OF TECHNICAL TERMS

“preclinical”	the stage of research that occurs before clinical trials, involving laboratory and animal studies to assess the safety, efficacy, and biological activity of a drug or treatment
“primary endpoint”	the main outcome measure used in a clinical trial to determine the effect of a treatment, reflecting the primary objective of the study, such as overall survival or disease progression
“QW”	once a week, a term indicating the frequency at which a treatment
“Q3W”	every three weeks, a term indicating the frequency at which a treatment or medication is administered
“Q4W”	every four weeks, a term indicating the frequency at which a treatment or medication is administered
“R&D”	research and development
“RAF”	rapidly accelerated fibrosarcoma, a family of proteins involved in the RAS-RAF-MEK-ERK signaling pathway, which regulates cell division and differentiation, and is often implicated in cancer when mutated or dysregulated
“RAS-MAPK”	RAS-mitogen-activated protein kinase, a signaling pathway that transmits signals from cell surface receptors to the DNA in the nucleus, regulating key cellular processes such as growth, division, and differentiation, and often implicated in cancer when dysregulated
“RAS”	a family of related proteins involved in transmitting signals within cells (cell signaling), playing a critical role in regulating cell growth, differentiation, and survival, with mutations in RAS genes frequently associated with various cancers
“RCC”	renal cell cancer, characterized by the uncontrolled growth of malignant cells in the renal cortex
“RDC”	radionuclide drug conjugates, the innovative cancer therapeutics developed by conjugating radionuclides with targeting ligands

GLOSSARY OF TECHNICAL TERMS

“RECIST v1.1”	response evaluation criteria in solid tumors version 1.1, a standardized set of guidelines used to assess the response of solid tumors to treatment in clinical trials, focusing on the measurement of tumor size and changes over time to evaluate the effectiveness of therapies
“ROR1”	receptor tyrosine kinase-like orphan receptor 1, a protein involved in embryonic development and cell signaling, which is typically expressed during fetal development but found to be re-expressed in certain cancers, making it a potential target for cancer therapy
“ROW”	rest of world
“RP2D”	recommended phase 2 dose, the dose of a drug determined during Phase 1 clinical trials to be the most appropriate for further testing in Phase 2 trials, based on safety, tolerability, and pharmacokinetic data
“SCLC”	small cell lung cancer, a highly aggressive form of lung cancer characterized by small, round cells that multiply rapidly and often spread early to other parts of the body
“SEBA”	specificity enhanced bi-specific antibody
“second-line” or “2L”	with respect to any disease, the therapy or therapies that are given when initial treatments (1L therapy) do not work, or stop working
“secondary endpoint”	an additional outcome measure in a clinical trial used to evaluate the effects of a treatment, providing supplementary information on efficacy and safety, such as quality of life or biomarker changes
“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
“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

“SW620”	a human colorectal adenocarcinoma cell line commonly used in cancer research to study the biology of colorectal cancer and to test the efficacy of potential therapeutic agents
“T cell”	a type of lymphocyte, a white blood cell that plays a central role in the immune response, particularly in identifying and destroying infected or cancerous cells and in coordinating other aspects of the immune system
“TEAE”	treatment-emergent adverse event, an adverse event that occurs after a patient starts receiving a treatment or medication and is either not present before the treatment or has worsened compared to the baseline condition
“third-line” or “3L”	with respect to any disease, the therapy or therapies that are given when both initial treatment (1L therapy) and subsequent treatment (2L 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
“TOP-1 inhibitor”	topoisomerase 1 inhibitor, a type of chemotherapeutic agent that interferes with topoisomerase 1 which is the enzyme essential for DNA replication and transcription, thereby inducing DNA damage and cell death, particularly in rapidly dividing cancer cells
“Treg”	regulatory t cells, a subset of T cells that play a critical role in maintaining immune tolerance and preventing autoimmune responses by suppressing the activity of other immune cells
“TRAE”	treatment related adverse event, which is an adverse event present after medical treatment
“TROP2”	a cell surface glycoprotein, also known as trophoblast cell surface antigen 2, involved in cell signaling and growth, often overexpressed in various cancers, making it a potential target for cancer therapy

GLOSSARY OF TECHNICAL TERMS

“UC”	urothelial carcinoma, a type of cancer that originates in the urothelial cells lining the urinary tract, including the bladder, ureters, and renal pelvis, often associated with risk factors like smoking and chemical exposure, and presenting with symptoms such as blood in the urine and urinary irritation
“VBP”	volume-based procurement, a set of drug procurement regulations implemented in China with the goal of promoting generic substitutes and lowering the price of medications that have outlived their exclusivity periods

FORWARD-LOOKING STATEMENTS

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

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

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

FORWARD-LOOKING STATEMENTS

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

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

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

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

RISK FACTORS

You should carefully consider all of the information set out in this document, including the risks and uncertainties described below, before making an [REDACTED] in our H Shares. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks and uncertainties. The [REDACTED] of our H Shares could decline due to any of these risks, and you may lose all or part of your [REDACTED]. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations.

KEY RISKS RELATING TO OUR BUSINESS AND INDUSTRY

Our business and prospects depend substantially on the success of our drug candidates, including BL-B01D1. 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.

We have systematically built a pipeline of drug candidates across multiple modalities that target major tumor types. As of the Latest Practicable Date, all of our innovative drug candidates remained in clinical and preclinical development. Our business will depend on our ability to successfully complete the development of our drug candidates, obtain necessary regulatory approvals, and manufacture and commercialize our drug candidates. We have invested a significant portion of our efforts and financial resources in the development of our existing drug candidates, and we expect to continue to incur substantial and increasing expenditures for the development and commercialization of our drug candidates. The success of our drug candidates will depend on several factors, including but not limited to:

- successful enrolment of patients in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals for our drug candidates;
- successfully launching commercial sales of our drug candidates, if and when approved;
- sufficient resources to discover additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- ensuring sufficient commercial manufacturing capabilities to facilitate a swift market entry;

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- the performance by CROs or other third parties we may retain to conduct clinical trials, and the fulfillment of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- ensuring we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successfully defending against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- obtaining and maintaining favorable governmental and private reimbursements for drugs, if and when approved;
- competition with other drug candidates and drugs; and
- continued acceptable safety profiles of our drug candidates following regulatory approval.

As of the Latest Practicable Date, our innovative drug pipeline featured 14 clinical-stage drug candidates, including BL-B01D1, an EGFR × HER3 bispecific ADC currently in Phase III clinical trials. Our pipeline also includes two other candidates in Phase III clinical trials: BL-M07D1, an innovative HER2-specific ADC, and SI-B001, a potential first-in-class EGFR × HER3 bispecific antibody. See “Business — Our Technology Platforms and Biologics Portfolio” for more details. However, we cannot guarantee that we will be able to obtain regulatory approvals for our drug candidates in a timely manner, or at all. In addition, none of our drug candidates in our innovative drug pipeline has been approved for marketing in any jurisdiction. Our pipeline products may require additional preclinical and/or clinical development, regulatory approvals, and substantial investment and significant marketing efforts, before we are able to generate any revenue from product sales.

The regulatory approval process for the NMPA, FDA, and other comparable regulatory agencies is lengthy, time-consuming, and unpredictable. If we fail to obtain timely regulatory approvals in the target markets for our drug candidates, our business may suffer material and substantial damage.

Significant time, efforts and expenses are required to bring our drug candidates to market in compliance with the regulatory process, and we cannot assure you that any of our drug candidates will be approved for sale. The time required to obtain approvals from the NMPA, the FDA and other comparable regulatory authorities is often unpredictable, and depends on numerous factors, including the substantial discretion of the regulatory authorities. Our drug candidates could fail to receive regulatory approval in a timely manner for many reasons, including but not limited to:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;

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- failure to demonstrate that a drug candidate is safe and effective or, it is safe, pure and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

In addition, the NMPA, the FDA or a comparable regulatory authority may require more information, including additional analyses, reports, data, non-clinical studies and clinical trials, or questions regarding interpretations of data and results, to support approval, which may prolong, delay or prevent approval and our commercialization plans, or we may decide to abandon the development programs. Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to competent regulatory authorities to reflect these changes. Resubmission may impact the costs, timing or successful completion of a clinical trial. The policies of the NMPA, the FDA and other comparable regulatory authorities may also change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may not obtain the regulatory approvals or may lose the approvals that we may have obtained and we may not achieve or sustain profitability.

Additionally, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. 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.

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If we experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates, the commercial prospects of that drug candidate will be harmed, and our ability to generate product sales revenues from any of those drug candidates will be compromised. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenues for that candidate. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates.

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

Undesirable adverse events caused by our drug candidates, or caused by our drug candidates when used in combination with other drugs, could cause significant negative consequences, including but not limited to the following:

- regulatory authorities could interrupt, delay or halt pending clinical trials;
- regulatory authorities may order us to cease further development of, or delay or even deny approval of, our drug candidates for any or all targeted indications if results of our trials reveal a high and unacceptable severity or prevalence of certain adverse events;
- regulatory authorities may withdraw approvals or revoke licenses of an approved drug candidate, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label of an approved drug, issue safety alerts or other communications containing warnings or other safety information of such approved drug, or impose other limitations on such approved drug;
- we may suspend, delay or alter development or marketing of our drug candidates;
- we may be required to develop a risk evaluation mitigation strategy, or REMS, for the drug candidate, or, if one is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a comparable regulatory authority;
- we may be required to change the way the drug candidate is administered or conduct post-market studies;

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- the patient enrollment may be insufficient or slower than we anticipate, or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated;
- we could be required to recall our drug candidates and subject to litigation proceedings and regulatory investigations and held liable for harm caused to patients exposed to or taking our drug candidates; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any particular drug candidate that is approved and could significantly harm our business, results of operations and prospects.

Before we start to generate revenue from the commercialization of our innovative drug candidates, if we are unable to maintain the sales volume, pricing levels and profit margins of our existing marketed products, our operations, revenue and profitability could be adversely affected.

In 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, our revenue generated from the sale of pharmaceutical products was RMB795.0 million, RMB701.8 million, RMB560.4 million, RMB376.6 million and RMB326.9 million, respectively. Sales of pharmaceutical products decreased over the Track Record Period as certain of our major marketed products are generic drugs that were impacted by the VBP schemes, which resulted in decreases in both prices and sales volumes of relevant products during the Track Record Period. Before we start to generate revenue from the commercialization of our innovative drug candidates, we expect that revenue from the sale of our existing marketed products will continue to contribute to our revenue in the near future. If the performance of our existing marketed products declines, we may experience substantial reductions in our revenue, which could hinder our ability to invest in and develop new products, thereby affecting our long-term growth prospects. Factors that could adversely affect the sales volumes, pricing levels and profitability of these products include: exclusion from, or reduced coverage under, the provincial or other government-sponsored medical insurance programs, the impact of government pricing regulations, competition and lack of success in the centralized procurement process necessary for sales to PRC public hospitals and other medical institutions, sales of substitute products by competitors, interruptions in the supply of raw materials, increases in the cost of raw materials, issues with product quality or side effects, intellectual property infringements, adverse changes in our sales and distribution network, and unfavorable policy, regulatory or enforcement changes. Many of these factors are outside of our control, and any factor adversely affecting the sales volumes, pricing levels and profit margins of our products could adversely affect our operations, revenue and profitability.

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We had net losses during the Track Record Period except for the nine months ended September 30, 2024. The revenue generated from the license fee income under the BMS Agreement contributed to a substantial portion of our revenue in the nine months ended September 30, 2024. Such historical performance may not be indicative of our future performance.

We entered into the BMS Agreement in respect of the co-development and co-commercialization of BL-B01D1, a bispecific ADC which targets both EGFR and HER3. We received a non-refundable and non-creditable upfront payment of US\$800 million from BMS in March 2024. As such, we recorded revenue of RMB5,661.2 million in the nine months ended September 30, 2024, as compared to that of RMB795.0 million, RMB701.8 million and RMB560.4 million in 2021, 2022 and 2023, respectively; we recorded net profit of RMB4,065.4 million in the nine months ended September 30, 2024, as compared to net loss of RMB107.6 million, RMB282.4 million and RMB780.5 million in 2021, 2022 and 2023, respectively. Our net losses recorded during the Track Record Period were primarily in relation to: (i) our substantial investment in R&D activities for the development of ADC, bispecific as well as multi-specific antibody drugs, and (ii) the reduction of revenue from the sale of pharmaceutical products mainly because certain of our major marketed products are generic drugs which were impacted by the VBP schemes, which resulted in decreases in both prices and sales volumes of relevant products during the Track Record Period.

Our historical growth rate and results in the nine months ended September 30, 2024 may not be indicative of our future growth or performance. Our revenue, expenses and operating results may vary from period to period due to a variety of factors beyond our control. As a result of these and other factors, there can be no assurance that our revenue will continue at similar levels or increase as it did or that we will continue to record profits as we did in the nine months ended September 30, 2024. Accordingly, [REDACTED] should not rely on our historical results as an indication of our future financial or operating performance.

We have net cash outflows used in our operating activities in 2021, 2022 and 2023, and we may need to obtain additional financing to fund our operations. If we are unable to obtain sufficient financing on terms acceptable to us or at all, we may be unable to complete the development and commercialization of our drug candidates.

We had net cash used in operating activities of RMB137.5 million, RMB256.6 million and RMB618.0 million in 2021, 2022 and 2023, respectively. The reasons of our cash flows used in operating activities in 2021, 2022 and 2023 primarily include our loss for the year, which is in turn primarily attributable to our cost of sales, R&D expenses, distribution and selling expenses, and administrative expenses. Our drug candidates require substantial investments for the completion of clinical development, regulatory review, drug manufacturing, marketing and launch before they can generate product sales revenue. We will need to expend substantial resources on the R&D and commercialization of our product pipelines. 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;

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- the outcome, timing and costs of regulatory approvals of our drug candidates;
- 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 construction progress of our production lines and facilities;
- our effective management of our CROs and other collaboration partners and associated costs;
- selling and marketing costs associated with any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the cost of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights;
- the amount and timing of any profit sharing, milestone and royalty payments we receive from our future collaborators;
- cash requirements of any future development of other pipeline drug candidates;
- our headcount growth and associated costs; and
- the costs of operating as a public company and our need to implement additional internal systems and infrastructure, including but not limited to financial and reporting systems.

We expect our cash operating costs will increase significantly in light of our expanding clinical trial programs. If the financial resources available to us are insufficient to satisfy our cash requirements, we may seek additional funding through equity offerings, debt financings, collaborations and licensing arrangements. It is uncertain whether financing will be available in the amounts or on terms acceptable to us, if at all. If we were not able to obtain additional capital to meet our cash requirements in the future, our business, financial condition, results of operations and prospects could be materially and adversely affected.

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If we or BMS do not achieve our product development or commercialization objectives in the time frames we expect, we may not receive milestone or royalty payments or make profits to support our future development plan.

Under the BMS Agreement, we and BMS will jointly develop and commercialize BL-B01D1 with BMS in the United States, we retained exclusive rights to develop and commercialize BL-B01D1 in mainland China, and we granted BMS an exclusive license to develop and commercialize BL-B01D1 in the rest of the world, subject to certain specified conditions and limitations. In addition to a non-refundable and non-creditable upfront payment of US\$800 million made from BMS to us in March 2024, BMS is required to pay up to US\$500 million in contingent near-term payments. We are also eligible to receive up to an aggregate of US\$7.1 billion contingent upon the achievement of certain specified regulatory and sales performance milestones for a total potential consideration of up to US\$8.4 billion. BMS is also required to pay us tiered royalties based on a percentage of aggregate annual net sales of BL-B01D1 in the world excluding the United States and the mainland China ranging from high single-digit to low double-digits, subject to certain customary reductions and a royalty floor. We are required to pay BMS a single-tier royalty of a mid-single-digit percentage of aggregate annual net sales of BL-B01D1 in mainland China. Further, under the BMS Agreement, we and BMS will share the relevant development costs of and the net profits/losses related to the sales of BL-B01D1 in the U.S. according to certain agreed-upon percentages. See “Business — License and Collaboration Agreement with Bristol-Myers Squibb Company” for more details. BMS may not execute its obligations as planned or may refuse to honor their commitments under the BMS Agreement. The non-performance of BMS, early termination of the BMS Agreement, or our inability to find new or replacement partners may negatively impact our revenue and research and development activities and funding therefor. Should any of these risks materialize, this would have an adverse effect on our business, prospects, financial condition and results of operations. Further, the milestone payments in the BMS Agreement are generally dependent on the accomplishment of various clinical, regulatory, sales and other product development objectives. The successful or timely achievement of many of these milestones is outside of our control, in part because some of these activities are being or will be conducted by BMS. If we or BMS fail to achieve the applicable milestones, we will not receive such milestone payments. A failure to receive any such milestone payment may cause us to:

- delay, reduce or terminate certain research and development programs or otherwise find ways to reduce short-term expenses that may not be in our long-term best interest;
- raise funds through additional equity or convertible debt financings that could be dilutive to our Shareholders;
- obtain funds through collaboration agreements that may require us to assign rights to technologies or products that we would have otherwise retained;

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- sign new collaboration or license agreements that may be less favorable than those we would have obtained under different circumstances; and
- consider strategic transactions or engaging in a joint venture with a third party.

Any potential royalty payments and profits are also dependent on the successful product development and commercialization of our drug candidates, which may never occur. Our failure to receive milestone or royalty payments or make profits and the occurrence of any of the events above may have an adverse impact on our future development plan.

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

The development and commercialization of new drugs, especially biological products, is highly competitive. We face competition from other pharmaceutical and biopharmaceutical companies worldwide. There are a number of large pharmaceutical and biopharmaceutical companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of the same indications for which we are developing our drug candidates. In particular, we may face intense competition in the development of ADC drugs, an emerging class of therapeutics that has garnered substantial interest and activity from companies worldwide. Some of these competitors have better resources and expertise than us. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. The competitive landscape of our target market is constantly evolving with the introduction of next-generation treatments and advanced technologies, which could provide more effective or convenient treatment options. In light of the intense competition, we may not be able to compete effectively and obtain substantial market share even if we successfully complete the development and commercialization of our drug candidates. We anticipate that we will face increasing competition as new drugs enter the market and advanced technologies become available.

Our commercial opportunity could be significantly reduced or even eliminated if our competitors develop and commercialize drugs that are safer, more effective, more convenient, or less expensive than the drugs we may develop or commercialize. Our competitors also may obtain approval from the NMPA, FDA, or other comparable regulatory authorities for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. They may render our drug candidates obsolete or non-competitive before we can recover expenses of developing and commercializing any of our drug candidates.

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

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We may experience difficulties in our sales efforts as a result of pricing regulations or other policies that are intended to reduce healthcare costs, which could adversely affect our operations, revenue and profitability.

During the Track Record Period, a number of our products were subject to national or provincial VBP schemes. For example, propofol medium and long chain fat emulsion injection and dexmedetomidine hydrochloride injection were subject to the national VBP scheme; Lewejing (propofol injectable emulsion) participated in provincial VBP schemes and later the national VBP scheme; Tianze (medium and long chain fat emulsion injection) and Xinbolin (ribavirin granule) participated in provincial VBP schemes. The VBP mechanism operates on the principle of purchasing larger quantities of pharmaceutical products at lower prices. While this allows us to sell our products in larger volumes, it also exerts downward pressure on the prices at which we sell our products to our distributors, thus impacting our revenue, gross profits and gross profit margins and may even cause certain of our products or the business segment to be loss-making. There are uncertainties with respect to future drug coverage of centralized VBP schemes. As a result, there can be no assurance that we may have additional drugs added to such schemes in the future, which may result in increased pricing pressure on us and adversely affect our revenue and profitability. If our competitors win the bid in such schemes while we fail to do so for our products with the same generic names, demands for our products may decrease and our revenue, profitability and market share could be adversely affected. Moreover, even if we win the bid for our products, there may be discrepancies between the estimated procurement volumes set out in the tender documents and the actual procurement volumes. Consequently, there are uncertainties with respect to the impact of the implementation of centralized VBP schemes on the sales volume as well as the revenue of the winning products.

Any such or future changes of policies, which we may not be able to predict or control, could create uncertainties that materially and adversely affect our product pricing, and accordingly, revenue and profitability.

If the products we sell are excluded, removed, or limited from government-sponsored or commercial medical insurance programs, or are included in any national or provincial negative catalogs in China or assigned with black box warnings issued by the FDA, our sales, profitability and business prospects could be adversely affected.

Insurance coverage is a critical factor in a patient’s ability to afford treatments, and without it, the demand for our products could diminish significantly. If a pharmaceutical product is covered by medical insurance, whether provided by the government or a private entity, patients may be entitled to reimbursement for all or a portion of the cost. Consequently, the inclusion or exclusion of a pharmaceutical product in or from insurance program such as the NRDL or provincial medical insurance catalogues in the PRC, or Medicare and other commercial health insurance schemes in the United States, as well as any limitations imposed on the coverage, will significantly affect patient demand. The inclusion of pharmaceutical products within the scope of insurance coverage is based on a variety of factors, including efficacy, safety and price, which may be outside of our control. Moreover, insurance providers

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may also, from time to time, review and revise, or change the scope of reimbursement for, the products that were previously covered. There can be no assurance that any of our products currently covered by such insurance schemes will maintain coverage in the future, or that changes in the scope of reimbursement will not negatively affect our product sales. If any of our products or their indications are removed from coverage, or if the scope of reimbursement is reduced, demand for our products may decrease and our operations, revenue and profitability could be adversely affected.

In addition, inclusion in any national or provincial negative catalogs in China represents considerable risk. These catalogs require medical institutions to strictly monitor and control the clinical use of pharmaceuticals included therein, therefore significantly decreasing physicians’ capability as well as willingness to prescribe the relevant pharmaceuticals. As of the date of this document, none of our products is included in any national or provincial negative catalogs in China. There can be no assurance that similar catalogs will be issued at national or provincial level, nor can we predict future pharmaceutical coverage of such catalogs. If any of our products are included in such negative catalogs, demand for our products may decrease and our revenue and profitability could be adversely affected.

Further, considering that we may in the future commercialize our drug candidates in the United States, the assignment of a black box warning by the FDA for our drug candidates may impose significant risks. Such warnings, often based on late-stage clinical data or findings from animal toxicity studies, indicate that the drug carries a significant risk of serious or life-threatening adverse effects. The presence of a black box warning can lead to decreased physician prescribing, heightened liability concerns, and ultimately, a substantial reduction in sales. Moreover, it can negatively affect the perception of our commitment to safety, potentially harming our reputation and long-term business prospects.

Our products and future approved products may fail to achieve or maintain the degree of market acceptance by physicians, medical institutions, pharmacies, patients, third-party payers and others in the medical community necessary for commercial success, and the actual market size of our drug candidates might be smaller than expected, which could render some drug candidates less profitable than expected even if commercialized.

The commercial success of our products, including existing or future products, is highly dependent on their continued market acceptance among patients, healthcare practitioners, and others in the medical community. We believe that the market acceptance of our products and future approved drug candidates depends on many factors, including: (i) the perceived advantages of our products over competing products and the availability and success of competing products; (ii) the safety and efficacy of our products and the prevalence and severity of side effects, if any; (iii) the pricing and cost effectiveness of our products; (iv) the effectiveness of our sales and marketing efforts; (v) publicity concerning our products or competing products; (vi) our ability to respond to changes in needs and preferences of healthcare practitioners and patients; and (vii) the inclusion of our products in key insurance or reimbursement schemes.

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If our products fail to achieve or maintain widespread market acceptance, or if new products introduced by our competitors are more cost-effective or are received more favorably by physicians, medical institutions, pharmacies, patients, third-party payers and others in the medical community, our products may be rendered obsolete, and the demand for our products may decline and our business and profitability may be materially and adversely affected.

Furthermore, the actual market size of our drug candidates may not be as large as we anticipate, influenced by various factors such as market acceptance, pricing, and patient availability. The number of patients in the addressable markets may turn out to be lower than expected, or new patient identification and access may become more challenging. Any of the above unfavorable developments could adversely impact on our business, financial condition and results of operations.

If we fail to maintain and optimize an effective distribution network for our products or encounter problems with our distributors, our operations, revenue and profitability could be adversely affected.

Our ability to maintain and grow our sales depends on our ability to manage, expand and optimize distribution channels that ensure timely delivery of our products across China and/or in other jurisdictions in the future where market demand for our products is generated through our promotion and marketing activities, or otherwise. Consistent with the industry practice, as of the date of this document, we sell our products either by ourselves or through distributors in China. As of the Latest Practicable Date, we had a distribution network of more than 1,000 distributors in China, which we rely on to distribute a substantial portion of our products. In 2021, 2022 and 2023 and the nine months ended September 30, 2024, our sales to distributors accounted for 99.1%, 99.4%, 99.0% and 99.4%, respectively, of our revenue from the sale of pharmaceutical products during the respective period. However, all of our distributors are Independent Third Parties over whom we have limited control. We cannot assure you that our distributors will always distribute our products in an effective or compliant manner. For example, if our distributors distribute our products outside their designated distribution areas as provided under their distribution agreements with us, the effectiveness of our distribution network could be adversely affected. Non-compliance by any of our distributors under applicable regulations may adversely affect the sales and distribution of our products. Further, as we rely on our distributors to manage their sales practices, we have limited control over the ultimate sales by these distributors. We cannot assure you that they will at all times comply with our sales policies or that they will not compete with each other for market share in respect of our products. If any of our distributors fails to distribute our products to their customers in a timely manner, overstock, or carries out actions which are inconsistent with our business strategy, it may adversely affect our future sales. There may be instances when these distributors take actions which are not consistent with our business strategies, such as failure to follow our pricing and marketing policies and participate in our marketing and promotional activities. Any occurrence of aforementioned non-compliance may in turn materially and adversely affect our business, financial condition, and results of operations and prospects.

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We have incurred significant research and development expenses and expect to continue to enhance our research and development capabilities, which has been our growth strategy to advance our clinical-stage assets. If we fail to effectively execute on such growth strategy, our business, financial condition, results of operations and prospects could suffer.

The pharmaceutical and biopharmaceutical industries are constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. In 2021, 2022 and 2023 and the nine months ended September 30, 2024, our research and development expenses were RMB278.6 million, RMB375.0 million, RMB746.2 million and RMB931.7 million, respectively. We need to continue to invest in human resources and technologies that will allow us to enhance the scope and quality of our research and development. We intend to continue to enhance our technical capabilities in drug discovery, development and manufacturing, which are capital-and-time-intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or innovative drugs to market, obtain sufficient or any patent or other intellectual property protection for such new or innovative drugs, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such drugs are introduced to the market, that those drugs will achieve market acceptance. Any failure to do so may make our technologies obsolete, which could harm our business and prospects.

The investment in our research and development capabilities aligns with our growth strategy to advance the clinical development of BL-B01D1 and our other differentiated pipeline assets. For more details, see “Business — Our Journey.” Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on capital and other resources. In addition, managing our growth and executing our growth strategies will require, among other things, our ability to continue to innovate and develop advanced technology in the highly competitive pharmaceutical and biopharmaceutical industries, effective coordination and integration of our facilities and teams across different sites, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, increased marketing and customer support activities, effective quality control, management of our suppliers to leverage our purchasing power, and regulatory approvals and reviews by various authorities in relevant jurisdictions. Any failure to execute on our growth strategies or realize our anticipated growth could materially and adversely affect our business, financial condition, results of operations and prospects.

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If we are unable to conduct effective promotion or maintain a qualified sales force, the sales volume of our products and our operations, revenue, profitability and business prospects could be adversely affected.

Successful sales and marketing are crucial for us to increase the market penetration of our existing products, expand our coverage of hospitals and other medical institutions and promote new products in the future. If we are unable to increase or maintain the effectiveness and efficiency of our sales and marketing activities, or to successfully implement our experience and expertise on marketed product portfolio to our innovative biologics portfolio, our sales volumes and business prospects could be adversely affected.

In particular, our sales and marketing efforts consist of raising awareness and knowledge of our products and drug candidates among medical professionals, hospitals and other medical institutions. Therefore, our sales and marketing force must possess a relatively high level of technical knowledge, up-to-date understanding of industry trends, necessary expertise in the relevant therapeutic areas and products, as well as sufficient promotion and communication skills. If we are unable to effectively train our in-house sales representatives and evaluate their academic marketing performance, our sales and marketing may be less successful than desired. See “Business — Sales and Marketing.”

Moreover, our ability to attract, motivate and retain a sufficient number of qualified sales professionals is especially important because we primarily rely on our in-house sales force to market and sell our products. Competition for experienced marketing, promotion and sales personnel is intense. If we are unable to attract, motivate and retain a sufficient number of marketing, promotion and sales professionals, sales volume of our products may be adversely affected and we may be unable to expand our hospital coverage or increase our market penetration as contemplated.

RISKS RELATING TO THE DEVELOPMENT OF OUR DRUG CANDIDATES

If we encounter difficulties in recruiting clinical trial subjects, our clinical development activities may be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials as required by the NMPA, the FDA, or similar regulatory authorities, or if there are delays in the enrollment of eligible subjects as a result of the competitive clinical enrollment environment. Moreover, such difficulties could significantly increase our overall development costs. Overall, we may experience difficulties in subject enrollment in our clinical trials for a variety of reasons, including but not limited to:

- severity of the disease under investigation;
- the size and nature of the subject population;

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- 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 subjects’ perceptions of the potential advantages and side effects of the drug candidate under study compared to other available therapies;
- our ability to obtain and maintain subject consents;
- the risk that subjects enrolled in clinical trials will not complete a clinical trial;
- the availability of approved therapies that are similar in mechanism to our drug candidates; and
- force majeure events that may disrupt trial operations and subject participation.

Our clinical trials may compete with clinical trials for other drug candidates that are in the same therapeutic areas as our drug candidates. This competition will potentially reduce the number and types of subjects available to us, since some subjects who might have opted to enroll in our trials may instead opt for a trial being conducted by our competitors. 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 prevent completion of these trials and materially and adversely affect our ability to advance the development of our drug candidates.

We may be unable to identify, discover, in-license, acquire or develop new drug candidates, or to identify additional therapeutic opportunities for our drug candidates, in order to expand or maintain our product pipeline.

Although a substantial amount of our effort will focus on the continued clinical testing, potential regulatory approval, and commercialization of our existing drug candidates, the success of our business depends in part upon our ability to continue to discover, develop, license, or commercialize additional drug candidates. However, we may not be successful in discovering and developing new drug candidates. Although we have developed three proprietary technology platforms, HIRE-ADC, GNC and SEBA, which we believe will continue to help us develop new product candidates to enrich our pipeline, we cannot guarantee that we will be successful in this regard. Further, pursuant to the global license and collaboration agreement with BMS, we and BMS will conduct a global strategic collaboration to co-develop and co-commercialize BL-B01D1, a bispecific ADC which targets both EGFR and HER3, and we may also pursue collaboration with third parties in the discovery and development of potential drug candidates, but we cannot assure you that such collaboration will be able to deliver the intended results.

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Research programs to discover and develop new drug candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or drug candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to identify, discover or in-license new drug candidates for clinical development and commercialization for a number of reasons, including, without limitation, the following:

- the research methodology used may not be successful in identifying potential indications and/or new drug candidates;
- potential drug candidates may, after further study, be shown to have adverse effects or other characteristics that indicate they are unlikely to achieve desired efficacy; or
- it may take greater resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates, thereby limiting our ability to diversify and expand our drug portfolio.

Accordingly, there can be no assurance that we will be able to discover and develop new drug candidates or identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially adversely affect our future growth and prospects.

If safety, efficacy, manufacturing or supply issues arise with any drug product used in combination with or to facilitate the use of our drug candidates, we may be unable to market such drug candidates or may experience significant regulatory delays or supply shortages.

Our strategy to develop combination therapies depends on the safety and efficacy of each component drug within each combination therapy. For example, as of the Latest Practicable Date, we had conducted eight Phase II clinical trials evaluating the combination of BL-B01D1 with PD-(L)1 therapies for 1L treatment of nine cancer indications (*SCLC*, *NSCLC*, *NPC*, *HNSCC*, *EC*, *GC*, *CRC*, *BC*, and *UC*); and two Phase II clinical trial evaluating its combination with TKI for 1L treatment of lung cancer. If the NMPA, FDA or another comparable regulatory agency revokes or denies its approval of a component therapeutic, in either the clinical design, clinical administration, therapy approval or commercialization stage, we will be forced to terminate or redesign the clinical trials, experience significant regulatory delays or stop our commercialization efforts.

Generally, we do not enter into collaboration agreements on the supply of certain drugs we use in our combination trials to avoid time-consuming negotiation and potential restrictions under the collaboration, thus ensuring our full control over the clinical development process and intellectual property rights. However, the absence of collaboration arrangements with drug suppliers may subject us to unstable supply. If we cannot purchase a sufficient amount of those component drugs from their manufacturers or distributors, or we experience any supply shortage of such component drugs, the clinical development of our drug candidates may be

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disrupted. The supply shortage may also delay the regulatory approval of our drug candidates or our ability to timely meet market demand for our products upon receipt of marketing approval, which will adversely affect our business and prospects.

Although we have not used companion diagnostic tests in the development of our drug candidates, it is common practice in the industry to use companion diagnostic tests to detect a predictive biomarker, such as PD-L1, EGFR and HER2, in patients to evaluate their likely response to certain treatment. In the United States, the FDA has generally required *in vitro* companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a pre-market approval for that diagnostic, which can take up to several years, simultaneously with approval of the biologic product. The regulations in China on the companion diagnostic test used for patient identification are developing. It remains uncertain whether the future regulatory changes would provide additional restrictions or requirements. If we determine to develop companion diagnostic tests in the future for patient screening or our drug development entails the use of such tests, the developing regulations in China would present uncertainties to our drug development and commercialization and may have an adverse effect on our business and results of operations.

Results of early clinical trials may not be predictive of future trial results.

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 predict successful final results. Our 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. In some instances, there can be significant variability in safety and/or efficacy results among different trials of the same drug candidate due to numerous factors, including, but not limited to, changes in trial procedures set forth in protocols, differences in the size and demographics of the patient populations, including genetic differences, patient adherence to the dosing regimen, other trial protocol elements and the rate of dropout among clinical trial participants. As drug candidates are developed through preclinical and clinical trials towards approval and commercialization, it is customary that various aspects of the development programs, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Differences in the number of clinical trial sites and countries involved may also lead to variability between earlier and later-phase clinical trials. Constantly updated standard therapies may change patient resistance, which may affect the efficacy of our medicines. Such changes carry the inherent risks that they may not necessarily achieve the intended objectives. In addition, our future clinical trial results may differ from earlier trials and may not be favorable. Even if our future clinical trial results show favorable efficacy, not all patients may benefit. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different and other than as predicted, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates. If so, we would have expended a significant amount of capital to progress the relevant drug candidates to that stage, and would

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not realize any revenue on such drug candidate if it then ultimately failed to receive regulatory approval due to poor clinical trial results. Such an uncompensated expenditure could materially and adversely affect our business, financial condition, results of operations and prospects.

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

As we have limited financial and managerial resources, we focus our product pipeline on research programs and drug candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

Interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more participant data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then available data, whose results, related findings and conclusions are subject to changes following a more comprehensive review of such data. We also make assumptions, estimations, calculations and conclusions as part of our analyses progress, for which we may not necessarily receive or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results reported by us may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

We may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risks that one or more of the clinical outcomes may materially change along with participant enrolment where more participant data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or our competitors could result in volatile prices of our Shares after this [REDACTED].

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Moreover, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, or may interpret or weigh the importance of data differently, which could impact the value of our particular program, the approvability or commercialization of our particular drug candidate or product and us in general.

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

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

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

In addition, we rely on certain third parties to monitor and manage data for some of our ongoing preclinical and clinical programs and control only certain aspects of their activities. If any of our CROs or other third parties do not perform to our standards in terms of data accuracy or completeness, data from those preclinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For details, see “— Risks Relating to Our Reliance on Third Parties — We

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engage with third parties for certain aspects of our business, and the inability of any of these parties to reliably, timely or cost-effectively provide us with their obligated services could materially harm the timing of bringing our products to market and accordingly adversely affect our business.”

We may seek approvals from the NMPA, FDA or other comparable regulatory authorities to use data from registrational trials via accelerated approval pathways for our drug candidates. If we are not able to use such pathways, we may be required to conduct additional clinical trials beyond those that we contemplate, which would increase the expense of obtaining, and delay the receipt of, necessary marketing approvals, if we receive them at all.

The NMPA, FDA and comparable regulatory authorities in other jurisdictions may allow the use of data from a registrational trial and grant accelerated approval to a drug candidate that provides meaningful therapeutic benefit over available therapies, for treatment of a serious or life-threatening condition. The determination is made based on a finding that the drug candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. For example, the FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on irreversible morbidity or mortality. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. Prior to seeking such accelerated approval, we will continue to seek feedback from the NMPA, FDA and otherwise evaluate our ability to seek and receive such accelerated approval.

There can be no assurance that in the future regulatory authorities will agree with our surrogate endpoints or intermediate clinical endpoints, or that we will decide to pursue or submit any new drug applications, or NDAs, or other comparable applications, for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that, after feedback from the regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, for any submission of an application for accelerated approval or application under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted for filing or that any expedited development, review or approval will be granted on a timely basis, or at all. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our drug candidates, would result in a longer time period for commercialization of such drug candidate, could increase the cost of development of such drug

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candidate, and could harm our competitive position in the marketplace. Even if we obtain accelerated approval of a drug candidate based on a surrogate endpoint, we will likely be required to conduct a post-approval clinical outcomes trial to confirm the clinical benefit of the drug candidate and, if the post-approval trial is not successful, we may not be able to continue marketing the drug for the relevant indication.

If we participate in compassionate use programs, current regulatory discrepancies among competent authorities of different countries may lead to increased risk of adverse drug reactions and serious adverse events arising from the use of our products.

Compassionate use programs are regulatory programs that facilitate access to investigational drugs for the treatment of patients with serious or immediately life-threatening diseases or conditions that lack therapeutic alternatives. Currently, there is no unified approach or standard practice to regulate expanded access programs among competent authorities in different countries for access to investigational drugs. In China, currently there is no officially approved regulation to oversee expanded access programs. In the United States, compassionate use programs are limited to patients who have a life-threatening disease or serious disease or condition, who may gain access to an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

The regulatory discrepancy for compassionate use programs among competent authorities in different countries may lead to uneven patient entry criteria and protocols for compassionate use programs. This may create increased risk of serious adverse events because of enrolled patients’ advanced disease or comorbidities. In addition, because the products in compassionate use programs are investigational drugs, many of which are still in experimental stages and have not received marketing approval, patients in compassionate use programs may exhibit adverse drug reactions from using these products. If we participate in compassionate use programs, we may be subject to the risk of enrolled patients exhibiting adverse drug reactions or serious adverse events arising from the use of our products. These occurrences can potentially lead to clinical holds of our ongoing clinical trials or complicate the determination of the safety profile of a drug candidate under regulatory review for commercial marketing.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

Failure to adequately protect our intellectual property throughout the world, or if the scope of our intellectual property fails to sufficiently protect our proprietary rights, other pharmaceutical companies could compete against us directly or indirectly, which may have a material adverse impact on our business and results of operations.

Our success depends in large part on our ability to protect our proprietary technologies and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect our drug candidates and technologies that we consider commercially important by filing patent applications in China, the United States and other jurisdictions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. As of the Latest Practicable Date, we

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owned (i) 183 issued invention patents, including 80 in China, 13 in the U.S., and 90 in other jurisdictions, and (ii) 461 patent applications, including 65 in China, 39 in the U.S., 16 under the Patent Cooperation Treaty (PCT) and 341 in other jurisdictions. For details of the material patents and patent applications in connection with our drugs and drug candidates, see “Appendix VI — Statutory and General Information — B. Further Information about Our Business — 2. Our Material Intellectual Property Rights” to this document.

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

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

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The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. An adverse determination in any proceeding challenging our patent rights could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drug candidates without infringing third-party patent rights. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. In addition, the patent position of biopharmaceutical and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Furthermore, although various extensions may be available, the life of a patent and the protection it offers is limited. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, 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. Our issued patents for our drug candidates are expected to expire on various dates as described in “Business — Intellectual Property” of this document. Upon the expiration of these patents, we will not be able to assert such patent rights against potential competitors, and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. Additionally, patent rights we own currently or in the future or may license in the future may be subject to a reservation of rights by one or more third parties.

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.

Competitors or other third parties may challenge the validity and enforceability of our patents, infringe, misappropriate or otherwise violate our other intellectual property rights. To counter infringement, misappropriation or any other unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Litigation and other proceedings in connection with any of the foregoing claims can be expensive and time-consuming and, even if resolved in our favor, may

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cause us to incur significant expenses and could distract management and our scientific and technical personnel from their normal responsibilities. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any claims that we assert against perceived infringers and other violators could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and defend their intellectual property rights than we can.

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights. An adverse result in any such litigation proceeding could put our patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. 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. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. Moreover, we may not be able to detect infringement against our patents. Even if we detect infringement by a third party of any of our patents, we may choose not to pursue litigation against or settlement with such third party. If we later sue such third party for patent infringement, the third party may have certain legal defense available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defense may make it impossible for us to enforce our patents against such third party.

In addition, although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaboration partners or other third parties have an interest in our owned, out-licensed or in-licensed patents, patent applications, trade secrets or other intellectual property as an inventor or co-inventor. For instance, we may have inventorship disputes arising from conflicting obligations of employees, collaboration partners, consultants or others who are involved in developing our drug candidates or technologies. Litigation may be necessary to defend against these and other claims challenging inventorship of our owned, out-licensed or in-licensed patents, patent applications, trade secrets or other intellectual property. If we fail to defend any claim, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to our drug candidates. Even if we are successful in defending against such claims, litigation could lead to substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our drug candidates, our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office (“USPTO”), China National Intellectual Property Administration (“CNIPA”), or the applicable foreign counterpart, or made a misleading statement, during prosecution. 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.

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA, the USPTO and other patent agencies in other jurisdictions in several stages over the lifetime of a patent. The CNIPA, the USPTO and other governmental patent agencies also require compliance with a number of procedural, documentary, and other similar provisions during the patent application process. We work with our counsel and professionals to help us comply with these requirements with respect to our intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or

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patent application include the failure to respond to official actions within prescribed time limits, nonpayment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors or other third parties might be able to enter the market, which would have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Changes in patent and other intellectual property laws of China, the United States or other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates and future drugs.

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

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

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

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

In addition to our issued patents and pending patent applications, we rely on trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drugs and 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, consultants, advisors and other third parties that have access to them.

However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Any of the parties with whom we enter into confidentiality agreements may breach the terms of any such agreements and may disclose our proprietary information, and we may not be able to obtain adequate remedies for any such breach or violation. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our drugs, 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, our employees, consultants and advisors, including our senior management, may currently be, or were previously employed at other pharmaceutical or biopharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisors, including each member of our senior management, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and advisors 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 current or former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such

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claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our employees and management.

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

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

If our trademarks and trade names are not adequately protected, we may not be able to build brand awareness in our target markets and our business may be adversely affected.

We currently own issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. We cannot assure you that any currently pending trademark applications or any trademark applications we may file in the future will be approved. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the CNIPA, USPTO or

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comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

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

Claims that our drugs and drug candidates or the sale or use of our drugs and drugs candidates infringes, misappropriates or otherwise violates the patent, trademark, or other intellectual rights of third parties could result in costly litigation, the outcome of which would be uncertain, or could require substantial time and money to resolve, even if litigation is avoided.

Our commercial success depends upon our ability to develop, manufacture, market and sell our drugs and drug candidates without infringing, misappropriating or otherwise violating the intellectual property rights of others. The pharmaceutical and biopharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We cannot guarantee that our drugs and drug candidates or any uses of our drugs and drug candidates do not and will not in the future infringe third-party patents, trademarks, or other intellectual property rights. It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our drugs and drug candidates. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

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Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, use or manufacture of the compounds we have developed or are developing. Such third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

Parties making infringement, misappropriation, or other intellectual property claims against us may obtain injunctive or other equitable relief, which could block our ability to further develop and commercialize one or more of our drugs and drug candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. In addition, even if we believe any third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of validity, enforceability, priority, or non-infringement. A court of competent jurisdiction could hold that such third party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any of our products or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such third-party U.S. patents in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property, and it could require us to make substantial licensing and royalty payments. Ultimately, we could be prevented from commercializing future approved drugs, or be forced, by court order or otherwise, to cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement, including treble damages and attorneys’ fees if we are found to willfully infringe a third party’s patent.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could be costly and time-consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated adverse impacts on our business.

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

As intellectual property rights have limitations, they do not necessarily protect us from all potential threats in our competition with other pharmaceutical and biopharmaceutical companies. For example:

- others may be able to manufacture drugs that are similar to our drug candidates or apply similar technology that is not covered by the patents we own or license, now or in the future;
- others may independently develop similar drugs through methods or means that do not technically infringe, misappropriate or otherwise violate our intellectual property rights, particularly if the scope of protection afforded by our intellectual property rights is limited by the laws and regulations of certain jurisdictions or pursuant to court judgments or other legal proceedings;
- we might not have been the first to file patent applications covering certain of our inventions;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- we may not develop additional proprietary technologies that are patentable;
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property;
- our patents may be rendered invalid or unenforceable as a result of legal challenges by our competitors; and
- our competitors might conduct research and development activities in countries where we do not have patent rights and use the information learned to develop competitive drugs for sale in our major markets.

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

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RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

We engage with third parties for certain aspects of our business, and the inability of any of these parties to reliably, timely or cost-effectively provide us with their obligated services could materially harm the timing of bringing our products to market and accordingly adversely affect our business.

We rely on third parties, such as collaboration partners, medical institutions, clinical investigators, and contract laboratories, in the development of our drug candidates and in the conduct of clinical trials for our drug candidates. We are also dependent upon third parties for the commercialization or distribution of products or drug candidates. Our business will be harmed if business, economic conditions or future developments in laws and regulations in the PRC, U.S. or other jurisdictions result in deteriorations our service providers’ operations and consequently a reduction of their provision of services to us. If these parties, whom we do not control, do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if our collaboration partners do not have the ability or the resources to successfully complete their objectives, or choose not to continue their relationship with us, our development efforts could be delayed, suspended or terminated, or our commercialization efforts may be delayed, impaired or terminated. If the quality or accuracy of the data they obtain through third parties is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical or clinical activities could be delayed and we may not be able to obtain regulatory approval for our drug candidates.

Actions taken by our distributors in violation of the relevant agreements or taken by the distributors with whom we have not entered into distribution agreements could materially and adversely affect our business, prospects and reputation.

While we rely on the distribution agreements and the policies and measures we have in place to manage our distributors, we cannot guarantee that we will be able to effectively manage our distributors, or that our distributors will abide by our agreements and policies. Specifically, if our distributors take one or more of the following actions, our business, results of operations, prospects and reputation may be adversely affected: (i) failing to distribute our products in the manner we have agreed upon can impair the effectiveness of our distribution network; (ii) breaching the distribution agreements or our policies and measures; (iii) failing to maintain the requisite licenses, permits or approvals, or failure to comply with applicable regulatory requirements; and (iv) violating any applicable anti-corruption, anti-bribery, competition or other laws and regulations. Any such actual or alleged violation or noncompliance by our distributors of the distribution agreements, our policies or any applicable laws and regulations could result in the erosion of our goodwill, expose us to liabilities, disrupt our distribution network and create an unfavorable public perception about the quality of our products.

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Delivery delays and poor handling by third-party logistics service providers may adversely affect our business, financial condition and results of operations.

We have entered into logistic service agreements with third-party logistics service providers for the transportation of our products. Although pursuant to the arrangement, logistics service providers should provide delivery services in a safe and timely manner pursuant to our requirements, delivery delays may occur for various reasons beyond our control, including poor handling by our logistics service providers, labor disputes or strikes, acts of war or terrorism, health epidemics, earthquakes and other natural disasters, and could lead to delayed or lost deliveries. Any major interruptions to or failures in these third parties’ services could prevent the timely or successful delivery of our products, which may have an impact on our business. We have purchased cargo insurance policies for our products, however, we cannot guarantee you that the existing insurance coverage is sufficient to compensate for actual losses suffered or incurred. If products are not delivered on time or are delivered in a damaged state, our customers may refuse to accept products and claim refund from us, and may have less confidence in our services. Poor handling of our products could also result in product contamination or damage, which may in turn lead to product recalls, product returns or exchanges, product liability, increased costs and damage to our reputation, thereby adversely affect our business, financial condition and results of operations.

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 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 committed to enhancing our collaborations with KOLs, top hospitals and academic institutions to ensure our timely access to cutting-edge research and support our existing and future pipeline.

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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We have entered into collaborations with our partners and may pursue additional collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships or other investments or arrangements in the future. If such arrangements fail to achieve our set goals or produce anticipated benefits, our operations, revenue and profitability could be adversely affected.

We have in the past entered into collaboration arrangements with third parties, such as BMS, in relation to the development of our drug candidates. See “Business — License and Collaboration Agreement with Bristol-Myers Squibb Company” for more details. We may form or seek additional strategic partnerships, enter into licensing arrangements or establish other collaborative relationships with third parties that we believe will complement or augment our R&D and commercialization efforts with respect to our drug candidates. Any of these relationships may require us to incur nonrecurring and other charges, increase our near-and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business. Our strategic collaboration with partners involves various risks, including that we may not achieve the revenue and cost synergies expected from the transaction. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and beyond our control. Also, the synergies from our collaboration with partners may be offset by other costs incurred in the collaboration, increases in other expenses, operating losses or problems in the business unrelated to our collaboration. As a result, there can be no assurance that expected synergies will be achieved in due course, or at all.

We may face challenges in seeking appropriate strategic partners as the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for the development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical or biopharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits.

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Collaborations involving our product candidates are subject to specific risks, which include, but are not limited to, the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue the development and commercialization of our drug candidates or may elect to cease collaboration due to change in their strategic focus, potential acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, discontinue a clinical trial, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drug candidates or future drugs;
- collaborators 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 litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may not always be cooperative or responsive in providing their services in a clinical trial;
- disputes may arise between us and a collaborator that cause a delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborators may own or co-own intellectual property covering our drug candidates or future drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right over such intellectual property.

As a result, we cannot be certain that, following a strategic transaction or license, we will be able to achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product 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. Either would harm our business, financial condition, results of operations and prospects.

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RISKS RELATING TO MANUFACTURING OF OUR PRODUCTS

If we suffer substantial disruption to any of our production facilities or encounter problems in manufacturing our products, our business and results of operations could be adversely affected.

We currently have four manufacturing facilities, all of which are located in Sichuan Province, China. The continued operation of our production facilities and our production safety can be substantially interrupted and materially and adversely due to a number of factors, many of which are outside our control, including fire, flood, earthquakes, power outages, fuel shortages, mechanical breakdowns, terrorist attacks and wars or other natural disasters, as well as expiry of land use rights, loss of licenses, certifications and permits, changes in governmental planning for the land underlying these facilities or their vicinity and regulatory changes. If the operation of any of our production facilities is substantially disrupted, we may not be able to replace the equipment or inventories at such facility or secure a replacement facility or a third-party contractor to continue our production in a legal, timely and cost-effective manner or at all. Although we maintain property insurance for our production facilities and equipment, we do not maintain business interruption insurance, and the amount of our insurance coverage may not be sufficient to cover our losses in the event of a significant disruption to any of our production facilities. Problems may also arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays related to the construction of new facilities or the expansion of our existing production facilities, including changes in production facilities and limits to production capacity due to regulatory requirements, changes in the types of products produced, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. As a result, disruption to any of our production facilities or any problem in manufacturing our products may prevent us from fulfilling our contract obligations or meeting market demand for our products, and adversely affect our business, revenue and profitability.

The expansion of our production facilities may not be as successful as we have planned. If we fail to increase our production capacity in response to the increasing demand of our customers, our business prospects could be adversely affected.

We plan to engage in the expansion of our existing production facilities and production lines to meet the increasing demand for our products and prepare for the expected commercialization of our drug candidates, if approved. The financing and completion of such expansion of the production facilities and production lines involves regulatory approvals and reviews by various authorities in relevant jurisdictions, including, but not limited to, urban planning, construction and environmental protection authorities. For the expansion of production facilities and production lines, we cannot assure you that we will be able to obtain all of the required approvals, permits and licenses. Expansion of the production facilities also may not be completed on the anticipated timetable or within budget. We may also be unable to fully utilize the production capacity after the expansion of our production facilities. Any of the foregoing factors could materially and adversely affect our results of operations and prospects and result in loss of business opportunities.

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If we fail to perform proper quality control or assurance, or our products are not produced to the necessary quality standards, our business and reputation could be harmed, and our revenue and profitability could be adversely affected.

Our products and manufacturing processes are required to meet certain quality standards. We have established a quality control management system and standard operating procedures to help prevent quality issues in respect of our products. See “Business — Quality Control and Assurance” for further details of our quality control management system and standard operating procedures. Despite our quality control system and procedures, we cannot eliminate the risk of errors, defects or failure. We may fail to detect or cure quality defects as a result of a number of factors, many of which are outside our control, including but not limited to:

- manufacturing errors;
- technical or mechanical malfunctions in the manufacturing process;
- human error or malfeasance by our quality control personnel;
- tampering by third parties; and
- quality issues with the raw materials we purchase or produce.

In addition, when we expand our production capacity in the future, we may not be able to ensure consistent quality between products manufactured in the existing and new facilities, or need to incur substantial costs for doing so. Furthermore, if we acquire other pharmaceutical companies, we may not be able to immediately ensure that their production facilities and processes will meet our own quality standards. Failure to detect quality defects in our products or to prevent such defective products from being delivered to end-users could result in patient injury or death, product recalls or withdrawals, license revocation or regulatory fines, or other problems that could seriously harm our reputation and business, expose us to liability, and adversely affect our revenues and profitability.

Our operations are dependent on the supply of certain raw materials. If the supply of raw materials decreases or the cost increases, or there are disruptions in the supply chain, our ability to conduct our business could be materially impaired and our operations, revenue and profitability could be adversely affected.

Purchase of raw materials accounted for a significant portion of our total cost of sales during the Track Record Period. In order to manufacture our products, we must obtain sufficient quantities of high-quality raw materials at commercially acceptable prices and in a timely manner. During the Track Record Period, we sourced chemical raw materials, traditional Chinese medicinal materials, and specialized intermediates, ancillary materials and packaging materials for all of our pharmaceuticals from qualified suppliers. For more details, see “Business — Quality Control and Assurance — Supply Chain Quality Control.” We typically do not enter into long-term supply agreements with raw material suppliers and as a result are

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vulnerable to supply shortages and fluctuations in market prices. Should any of our suppliers fail to supply sufficient quantities of raw materials of an acceptable quality in the future, we may be unable to obtain substitute raw materials elsewhere in a timely manner, or at all. We may also be forced to obtain raw materials from different suppliers, who may require us to pay prices that are not commercially reasonable or may provide us with raw materials that are not of an acceptable quality. Although we have not experienced material interruptions in our supply chain or raw material supplies in the past, any potential interruption could delay the production and delivery schedules of the relevant products, which may result in the loss of customers and revenue. In addition, the market prices of raw materials may be subject to significant fluctuations due to various factors. We cannot assure you that we would be able to pass on any increase in raw material costs to our customers, and any substantial fluctuation in market prices of raw materials may materially increase our costs and impact our profitability. Potential disruptions to the supply chain, such as natural disasters, geopolitical tensions, transportation issues, or other unforeseen events, could further exacerbate these challenges and result in delays, increased costs, or interruptions in our production processes.

Failure to manage our inventory effectively would materially and adversely affect our results of operations, financial condition and cash flows.

Our inventory consists of raw materials, and work-in-progress and finished goods. To operate our business successfully and meet our customers’ demands and expectations, we must manage our inventory effectively to ensure immediate delivery when required. We regularly monitor our inventory to ensure timely supply and reduce the risk of overstocking. We maintain our inventory levels based on our internal forecasts which are inherently uncertain. We are exposed to inventory risk as a result of rapid changes in product life cycles, changing clinical demands, uncertainty of product developments and launches as well as the volatile economic environment in jurisdictions where we operate. There can be no assurance that we can accurately predict these trends and events and avoid over-stocking or under-stocking our products. Further, demand for products could change significantly between the time when the products are ordered and the time they are ready for delivery. When we begin to sell a new product, it is particularly difficult to forecast product demand accurately. As of December 31, 2021, 2022 and 2023 and September 30, 2024, we had inventories of RMB82.3 million, RMB101.3 million, RMB140.9 million and RMB164.9 million, respectively. In 2021, 2022 and 2023 and the nine months ended September 30, 2024, our inventory turnover days were 127 days, 136 days, 175 days and 216 days, respectively. For more details, see “Financial Information — Discussion of Selected Items from the Consolidated Statements of Financial Position — Inventories.” We may be exposed to increased inventory risks due to accumulated excess inventory of our products or raw materials, some of which are subject to expiration. Excess inventory levels may increase our inventory holding costs, obsolescence risks or potential impairment loss. On the other hand, if our forecasted demand is lower than actual level, we may not be able to maintain an adequate inventory level of our products or manufacture our products in a timely manner, and may lose sales and market share to our competitors.

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Furthermore, as we will not be able to recoup our cash paid for raw materials during the production process until the finished products are sold to customers and the purchase price is settled, our business is subject to significant working capital requirements given the high inventory level and inventory turnover days. If our inventory level increases substantially in the future, our financial condition and cash flows could be materially and adversely affected.

Our therapeutic biological products, like any other biological product, may involve risks of contamination.

The manufacturing of therapeutic biological products usually requires cultivation steps, including growth of the appropriate organism and the use of substances of animal origin, which makes it easy to introduce a contaminant and to amplify low levels of contamination. In addition, cross-contamination could result from manufacturing activities at shared equipment and facilities, which are common. Other activities such as diagnosis and research are frequently linked to manufacturing, which may create opportunities for cross-contamination. Furthermore, improper actions during the long-distance transportation, storage and delivery services may also result in contamination.

In the event of contamination or injury resulting from such contamination, we could be subject to liabilities for any resulting damages to patients, product recalls, confiscation and/or destroy. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with laws and regulations. In addition, contamination of our products could cause customers or other third parties with whom we conduct business to lose confidence in our products’ quality and the reliability of our manufacturing procedures, which could adversely affect our sales and profits. In addition, contaminated products that are unknowingly distributed could result in harm on patients, threaten the reputation of our products and expose us to product liability claims, criminal charges and administrative sanctions.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We are uncertain about the recoverability of our deferred tax assets, which may affect our financial position in the future.

As of December 31, 2021, 2022 and 2023 and September 30, 2024, our deferred tax assets amounted to RMB65.8 million, RMB83.2 million, RMB76.2 million and RMB222.1 million, respectively, which primarily consist of losses available for offsetting against future taxable profits. For details of the movement of our deferred tax assets during the Track Record Period, see Note 20 to the Accountants’ Report in Appendix I to this document.

Deferred tax assets are generally recognized for all deductible temporary differences to the extent that it is probable that taxable profits will be available against which those deductible temporary differences can be utilized. Such deferred tax assets are not recognized if the temporary difference arises from the initial recognition (other than in a business combination) of assets and liabilities in a transaction that affects neither the taxable profit nor

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the accounting profit. As such, this requires significant judgment on the tax treatments of certain transactions and also assessment on the probability that adequate future taxable profits will be available for the deferred tax assets to be recovered. In this context, we cannot guarantee the recoverability or predict the movement of our deferred tax assets, and to what extent they may affect our financial position in the future.

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

During the Track Record Period, we have incurred indebtedness, including bank borrowings, lease liabilities and sale and leaseback payable. As of December 31, 2021, 2022 and 2023 and September 30, 2024, our indebtedness amounted to RMB286.9 million, RMB547.3 million, RMB688.2 million and RMB1,550.5 million, respectively. See “Financial Information — Indebtedness” for more details. Our indebtedness could, among other consequences: (i) increase the level of financial risk to us, which would negatively affect our ability to operate as a going concern; (ii) require us to dedicate a substantial portion of our cash flows from operations to interest and principal payments on our indebtedness, reducing the availability of our cash flows for other purposes, such as capital expenditures, acquisitions and working capital; (iii) limit our flexibility in planning for, or reacting to, changes in our business and the industries in which we operate; (iv) increase our vulnerability to general adverse economic and industry conditions; (v) place us at a disadvantage compared to our competitors that have less debt; (vi) increase our cost of borrowing; (vii) limit our ability to borrow additional funds to compete effectively or to take advantage of new business opportunities; and (viii) require us to sell assets to raise funds, if needed, for working capital, capital expenditures, acquisitions or other purposes.

Our ability to generate sufficient cash to satisfy our outstanding and future debt obligations will depend upon our future operating performance, which will be affected by, among other things, prevailing economic conditions, the governmental regulation, the demand of the markets where we operate and other factors, many of which are beyond our control. We may not generate sufficient cash flow to pay our anticipated operating expenses and to service our debt, in which case we will be forced to adopt an alternative strategy that may include actions such as reducing or delaying capital expenditures, disposing of our assets, restructuring or refinancing our indebtedness or seeking equity capital. If we are unable to fulfill our repayment obligations under our borrowings or are otherwise unable to comply with the restrictions and covenants in our current or future loan agreements and other agreements, there could be a default under the terms of these agreements. In the event of a default under these agreements, the lenders may accelerate the repayment of outstanding debt or, with respect to secured borrowings, enforce the security interest securing the loan. Any acceleration clause may also be triggered as a result. If any of these events occur, we cannot assure you that our assets and cash flow would be sufficient to repay all of our indebtedness, or that we would be able to obtain alternative financing on terms that are favorable or acceptable to us. As a result, our cash flow, financial condition and results of operations may be materially and adversely affected.

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We are exposed to credit risk in relation to our trade and other receivables.

Our trade receivables consisted of amounts due from our customers which include distributors who on-sell our products to hospitals and, to a lesser extent, pharmaceutical retail chains. We generally grant credit terms of 30 to 120 days to our customers. As of December 31, 2021, 2022 and 2023 and September 30, 2024, we had trade receivables of RMB118.8 million, RMB247.2 million, RMB109.4 million and RMB79.1 million, respectively. In 2021, 2022 and 2023 and the nine months ended September 30, 2024, trade receivables turnover days were 62 days, 87 days, 107 days and 69 days, respectively. See “Financial Information — Discussion of Selected Items from the Consolidated Statements of Financial Position — Trade and Other Receivables.”

We are exposed to the risks that our customers or other business partners may delay or even be unable to pay us in accordance with the payment terms included in our agreements in a timely manner, or at all. Although we closely monitor our outstanding trade and other receivables, we cannot assure you that we will be able to fully recover the outstanding amounts in a timely manner, or at all. In addition, as our business continues to scale up, our trade and other receivables may continue to grow, which may increase our credit risk. Any substantial delay in or default of payments from our customers and other business partners could materially and adversely affect our cash flows. Moreover, we could be required to terminate our relationship with distributors in a manner that will impair the effective distribution of our products. Any of the foregoing could materially and adversely affect our business, results of operations and financial condition.

The discontinuation of any of the financial incentives, such as preferential tax treatment or government grants, currently available to us could adversely affect our operations, revenue and profitability.

During the Track Record Period, we have benefited from government grants and subsidies. During the Track Record Period, our other income related to the government grants amounted to RMB67.9 million, RMB68.2 million, RMB52.0 million and RMB31.8 million in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively. We also enjoyed preferential tax treatment during the Track Record Period. See “Financial Information — Description of Key Statements of Profit or Loss Items — Other Income” and “— Income Tax (Credit) Expense” for more details. The incentives to some extent are subject to the discretion of the relevant government authorities, which could determine at any time to eliminate or reduce these financial incentives or preferential treatments, generally with prospective effect. Since our receipt of the financial incentives or preferential treatments is subject to periodic time lags and inconsistent government practice, as long as we continue to receive these financial incentives or preferential treatments, our net income in a particular period may be higher or lower relative to other periods depending on the potential changes in these financial incentives in addition to any business or operational factors that we may otherwise experience. Therefore, the discontinuation of financial incentives currently available to us could have a material adverse effect on our financial condition, results of operations, cash flows and prospects.

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We have incurred net current liabilities in the past and may not be able to achieve or maintain net current assets in the foreseeable future.

We had net current liabilities of RMB63.9 million and RMB290.8 million as of December 31, 2021 and 2023, respectively. There can be no assurance that we will not experience liquidity problems in the future. If we fail to generate sufficient revenue from our operations, or if we fail to maintain sufficient cash and financing, we may not have sufficient cash flows to fund our business, operations and capital expenditure and our business and financial position will be adversely affected.

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

During the Track Record Period, our financial assets at FVTPL comprised wealth management products that were purchased via a financial institution. We purchased wealth management products in the nine months ended September 30, 2024 for cash management purpose and disposed them during the same period. As of September 30, 2024, our financial assets at FVTPL were nil. We may continue to make such investment as part of our cash management and treasury measures and therefore may face exposure to fair value change for the financial assets at FVTPL. 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 the results of our operations for future periods. In addition, the valuation of fair value changes of financial assets at FVTPL is subject to uncertainties in estimations. Such estimated changes in 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 financial assets at FVTPL valuation 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 significant fluctuations in profit or loss from period to period.

We may be affected by exchange rate fluctuations.

The value of the Renminbi against the Hong Kong dollar, U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in global political and economic conditions. Any significant appreciation or depreciation of Renminbi against Hong Kong dollars and US dollars may affect our revenues, earnings and financial position, and the value of, and any dividends payable on, our Shares. To the extent that we need to convert Hong Kong dollars we receive from this [REDACTED] into Renminbi for our operations, appreciation of the Renminbi against the Hong Kong dollars would have an adverse effect on the Renminbi amount we would receive. Conversely, if we decide to convert our Renminbi into Hong Kong dollars for making payments for dividends on our ordinary shares or for other business purposes, appreciation of the Hong Kong dollars against the Renminbi would have a negative effect on the Hong Kong dollar amount. With the development of the foreign exchange market, there might be further changes to the exchange rate system. Any significant fluctuation of relevant currencies could adversely affect our business, results of operations and financial condition, and the value of any dividends payable in Hong Kong dollars. As of the Latest

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Practicable Date, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited, and we may not be able to adequately hedge our exposure or at all.

Share-based payments may impact our financial performance and cause shareholding dilution to our existing Shareholders.

Since 2014, SystImmune, a wholly-owned subsidiary of our Company in the United States, entered into share option arrangements with certain eligible employees to recognize their contributions and to strive for the future development of the Group’s overseas operations. For more details, see Note 41 to the Accountants’ Report in Appendix I to this document. Expenses incurred with respect to such share-based payment may increase our operating expenses and therefore have an adverse effect on our financial performance. Issuance of additional shares by SystImmune with respect to such share-based payment may also dilute the shareholding interest of our Company in SystImmune.

RISKS RELATING TO GOVERNMENT REGULATIONS

The pharmaceutical and biopharmaceutical industries are subject to change of regulations, which may affect our operations, revenue and profitability or impose additional compliance burden on us.

We operate in the pharmaceutical and biopharmaceutical industries in China and the U.S. The industries we operate in are subject to comprehensive government regulation and supervision, including but not limited to comprehensive governance around the approval, registration, manufacturing, packaging, licensing, marketing, sales and distribution of drugs. Ensuring that we remain compliant with the various rules and regulations can be time- and cost-consuming, particularly for a company like us that operates in various jurisdictions with different policies. For example, the process of obtaining regulatory approvals and maintaining compliance with applicable laws and regulations requires the expenditure of substantial time and financial resources. Any recently enacted and future legislations may increase the difficulty and cost for us to obtain regulatory approval of, and commercialize, our drug candidates, and affect the prices we may obtain.

Changes in government regulations or in practices relating to the pharmaceutical and biopharmaceutical industries, such as a relaxation in regulatory requirements or the introduction of simplified approval procedures which would lower the entry barrier for potential competitors, or an increase in regulatory requirements which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations, and prospects.

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In addition, we are subject to scheduled or unscheduled periodic inspections of our facilities to monitor our regulatory compliance. During the Track Record Period, we passed all the inspections and obtained clearance in relation to the manufacturing of our drug candidates and drugs from the regulatory authorities in all relevant jurisdictions in all material respects. However, we cannot assure you that we will be able to do so going forward.

Failure to comply with the applicable regulatory requirements in any of the jurisdictions where we operate 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 business, financial condition, results of operations and prospects.

If we or our business partners fail to maintain the necessary licenses for the development, production, promotion, sales and distribution of our products, our ability to conduct our business could be materially impaired and our revenue and profitability could be adversely affected.

We are required to obtain, maintain and renew various permits, licenses, approvals and certificates in order to develop, produce, promote and sell our products, and the third parties on whom we may rely on to develop, produce, promote, sell and distribute our products may be subject to similar requirements. For more details, see “Business — Licenses, Permits and Approvals.” We and the parties on whom we rely, such as distributors and suppliers, may be subject to regular inspections, examinations, inquiries and audits by the regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries and audits may result in the loss or non-renewal of the relevant permits, licenses, approvals and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses, approvals and certificates may change from time to time, and there can be no assurance we or the parties on whom we rely on will be able to meet new criteria that may be imposed in order to obtain or renew the necessary permits, licenses, approvals and certificates. Many of such permits, licenses, approvals and certificates are material to the operation of our business, and if we or parties on whom we rely on fail to maintain or renew material permits, licenses, approvals and certificates, it could materially impair our ability to conduct our business. While we have been able to maintain and renew our material permits, licenses, approvals and certificates, there is no assurance that we will be able to continue doing so in the future.

Any changes in the standards used by governmental authorities in considering whether to renew or reassess our licenses, permits, approvals and certificates, as well as any enactment of new regulations that may restrict the conduct of our business, may also decrease our revenue and increase our costs, which in turn could materially and adversely affect our profitability and prospects. Furthermore, if the interpretation or implementation of existing laws and regulations changes, or new regulations come into effect, so as to require us or parties upon whom we rely

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to obtain any additional permits, licenses, approvals or certificates that were previously not required to operate our business, there can be no assurances that we or parties upon whom we rely will successfully obtain such permits, licenses, approvals or certificates.

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

If any of our drug candidates is approved in the future, it will be subject to ongoing or additional regulatory requirements for manufacturing, labelling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy and other post-market information, including requirements of regulatory authorities in China, the United States and other jurisdictions. These requirements also include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacture Practices, or the cGMP, and Good Clinical Practice, or the GCP, for any clinical trials that we conduct post-approval.

Any approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, which could adversely affect the drug’s commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the drug candidates. The NMPA, FDA or a comparable regulatory authority may also require a risk evaluation mitigation strategy program as a condition of approval of our drug candidates or following approval.

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

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

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In addition, we are subject to ongoing regulatory requirements for our day-to-day business operations. Accordingly, we and third parties we work with must continue to expend time, money and efforts in all areas of regulatory compliance, including manufacturing, production and quality control. We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China, the United States or other jurisdictions, where the regulatory environment is constantly evolving. If we are unable to maintain regulatory compliance, or if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, we may lose any regulatory approval that we have obtained, and we may not achieve or sustain profitability.

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

Our business operations and current and future arrangements with clinical site investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we market, sell, and distribute our products and drug candidates, if approved. Such laws include the PRC Anti-Unfair Competition Law (中華人民共和國反不正當競爭法), the PRC Criminal Law (中華人民共和國刑法), the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act, the Health Insurance Portability and Accountability Act of 1996, and the U.S. Physician Payments Sunshine Act.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Government authorities could conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which may also adversely affect our business. Furthermore, defending against any such actions can be costly, time-consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

RISK FACTORS

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

We receive, collect, generate, store, process, transmit and maintain de-identified codes of subjects enrolled in our clinical trials and the corresponding clinical trial data. As such, we are subject to the relevant local, state (the U.S.), 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. As of the Latest Practicable Date, we are primarily subject to PRC laws and U.S. federal and state laws governing data protection and privacy.

In recent years, the PRC authorities have promulgated certain laws and regulations in respect of information security, data collection and privacy protection regulations in the PRC. For more information regarding the PRC laws and regulations governing data protection and privacy, see “Regulatory Overview — Overview of Laws and Regulations in the PRC” in this document. Numerous U.S. federal and state laws and regulations relate to the privacy and security of personal information, such as regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 and the Health Information Technology for Economic and Clinical Health Act.

Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security, and transfers may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, our clinical trials frequently also involve professionals from third-party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. We also cooperate with third parties including principal investigators, hospitals, CROs and other third-party contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as our fault, negligence or a result of our failure. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted

RISK FACTORS

purposes. 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 become subject to fines or penalties or incur costs that could materially and adversely affect the success of our business.

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

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

In terms of the construction of our manufacturing facilities, they can be put into operation after the relevant administrative authorities in charge of environmental protection and health and safety examine and approve such facilities. 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 construction projects may affect our abilities to develop, manufacture and commercialize our drug candidates as we plan.

RISK FACTORS

Restrictions on foreign currency conversion and currency remittance may limit our ability to utilize our revenue effectively and adversely affect the value of your [REDACTED].

The convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency into or out of the PRC are required to comply with applicable PRC laws and regulations. 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 our future uses as well as 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 current PRC foreign exchange regulations, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from SAFE, but we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. Approval from appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses.

Our operations are subject to and may be affected by changes in tax rates, the adoption of new tax legislation in the jurisdictions in which we operate, or exposure to additional tax liabilities.

The nature of our operations subjects us to local, state, regional and national tax laws in jurisdictions including China and the United States. Our subsidiary Lhasa Xinbo was subject to an enterprise income tax rate of 15% pursuant to the tax-related “Encouraged Industries in the Western Region” policy during the Track Record Period and Baili Pharmaceutical was subject to an enterprise income tax rate of 15% pursuant to the tax-related “Encouraged Industries in the Western Region” policy in 2022, and since 2024, Baili-Bio was subject to an enterprise income tax rate of 15% pursuant to the tax-related “Encouraged Industries in the Western Region” policy. As a “New Hi-tech Enterprise”, our subsidiary Guorui Pharmaceutical is subject to an enterprise income tax rate of 15% pursuant to the tax-related regulations during the Track Record Period, and Baili Pharmaceutical is subject to an enterprise income tax rate of 15% pursuant to the tax-related regulations in 2021 and 2023 and the nine months ended September 30, 2024. Since 2023, two subsidiaries of our Company, Hiatt Technology and Tianze Pharmaceutical, are qualified as small and micro enterprises and are eligible for the preferential EIT rate at 20%. Our subsidiary, SystImmune, is subject to U.S. enterprise income tax representing 21% of the applicable U.S. Federal Income Tax rate and blended average rate of 3.52% of the State Income Tax arising from applicable State in the United States. Further adjustments or changes to tax laws and regulations that we are subject to, together with any uncertainty resulting therefrom, could have an adverse effect on our business, financial condition and results of operations. Although we believe that in the past we had acted in compliance with the requirements under the relevant tax laws and regulations in all material respects and had established effective internal control measures in relation to accounting regularities, we cannot assure you that future examinations by relevant tax authorities would not result in fines, other penalties or actions that could adversely affect our business, financial condition and results of operations, as well as our reputation.

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Dividends received by foreign holders of our H Shares and gains derived from the disposition of our H Shares by such holders may be subject to PRC taxation.

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

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

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

Considering the above, non-PRC resident holders of our H Shares should be aware that they may be obligated to pay PRC income tax on the dividends and gains realized through sales or transfers by other means of the H Shares.

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We may be restricted from transferring our scientific data abroad or using human genetic resources collected in China.

To the extent our R&D of our drug candidates are subject to the relevant scientific data measures and any subsequent laws as required by the relevant government authorities, if we are unable to obtain necessary approvals in a timely manner, or at all, our R&D of drug candidates may be hindered, which may materially and adversely affect our business, operations, financial conditions and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the scientific data measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

Cross-border data transfer from other jurisdictions may also be limited if we fail to comply with relevant requirements, such as obtaining authorization from subjects regarding the use, transfer and retrieval of their personal information or data and adopting measures to ensure the safety of personal information or data in the transfer. Also, cross-border transfer of personal data by its nature is subject to general data privacy regulations in various jurisdictions, and thus any failure to comply with data privacy protection may lead to a restriction of transferring our data across different jurisdictions.

Any uncertainties embedded in the legal systems of certain geographic markets where we operate could affect our business, financial condition and results of operations.

We are subject to certain uncertainties embedded in the legal systems of some geographic markets where we operate. Some jurisdictions have a civil law system based on written statutes and others are based on common law. Prior court decisions under the civil law system may be cited for reference but have limited precedential value. Laws and regulations that are recently enacted may not sufficiently cover all aspects of economic activities in such markets. In particular, the interpretation and enforcement of these laws and regulations are subject to future implementations, and the application of some of these laws and regulations to our businesses is not settled. Since local administrative and court authorities are authorized to interpret and implement statutory provisions and contractual terms, it may be difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we have in many of the geographic markets where we operate. Local courts where we operate may have discretion to reject enforcement of foreign awards or arbitration awards. These uncertainties may affect our judgment on the relevance of legal requirements and our ability to enforce our contractual rights or claims. In addition, the regulatory uncertainties in different jurisdictions may be exploited through unmerited or frivolous legal actions, claims concerning the conduct of third parties, or threats in attempt to extract payments or benefits from us.

Furthermore, many of the legal systems in the geographic markets where we operate are based in part on their respective government policies and internal rules, some of which are not published on a timely basis or at all and may have retroactive effects. There are other circumstances where key regulatory definitions are unclear or not published. As a result, we may not be aware of our violation of certain policies or rules until sometime after the violation. In addition, administrative and court proceedings in certain of our geographic markets may be protracted, resulting in substantial costs and diversion of resources and management attention.

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It is possible that a number of laws and regulations may be adopted or construed to be applicable to us in our geographic markets and elsewhere that could affect our businesses and operations. Scrutiny and regulations of the industries in which we operate may further increase, and we may be required to devote additional legal and other resources to addressing these regulations. Evolvement in current laws or regulations or the imposition of new laws and regulations in our geographic markets may affect the growth of our industry and our business, financial condition and results of operations.

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

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

Failure to comply with relevant regulations relating to social insurance and housing provident fund may subject us to penalties and adversely affect our business, financial condition, results of operations and prospects.

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), we are required to make contributions to social insurance and housing provident funds for our employees. During the Track Record Period, we did not make full contributions to the social insurance and housing provident funds for certain employees in accordance with the relevant PRC laws and regulations. According to relevant PRC laws and regulations, (i) we may be requested by relevant PRC authorities to pay the outstanding social insurance contributions within a prescribed period and pay an overdue charge equal to 0.05% of the outstanding amount for each day of delay. If we fail to pay the outstanding social insurance contributions within the prescribed period, we may be liable to a fine of one to three times the amount of the overdue payment; and (ii) if we fail to pay the full amount of housing provident funds as required, the relevant PRC authorities may order us to make the outstanding payment within a prescribed time limit, failing which, the relevant PRC authorities may apply to the PRC courts for compulsory enforcement.

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As of the Latest Practicable Date, (i) to our knowledge and based on the written confirmations issued by the competent government authorities of our Company, we had complied with national and local laws, regulations and practices related to the social insurance, and/or had not been subject to any administrative penalties in relation to the shortfall in such contributions; (ii) according to the Emergency Circular of the General Office of the Ministry of Human Resources and Social Security on Applying the Spirit of the Executive Meetings of the State Council to Practically and Effectively Stabilize the Collection of Social Insurance Contributions (人力資源社會保障部辦公廳關於貫徹落實國務院常務會議精神切實做好穩定社保費徵收工作的緊急通知) issued on September 21, 2018, it is prohibited for relevant authorities to organize a centralized collection of enterprises’ historical social insurance arrears; (iii) we were neither aware of any material pending employee complaints filed against us nor involved in any material pending labor disputes with our employees with respect to social insurance and housing provident funds; (iv) we had not received any notification from the relevant PRC authorities requiring us to collectively pay for the shortfalls or any overdue charges with respect to social insurance and housing provident funds; (v) we have conducted, and will regularly conduct in the future, internal training for our Directors and senior management on the relevant laws and regulations to ensure due compliance; (vi) we undertake to make timely payments for the outstanding amount and late charges, as soon as requested by the competent government authorities; (vii) our Company had completed necessary adjustments of the contribution base of social insurance and housing provident funds for our employees from December 2023 and January 2024, respectively, to fully comply with the relevant PRC laws and regulations; (viii) consultation with Chengdu Housing Provident Fund Management Center (“Chengdu Center”) confirms that, in general, Chengdu Center will verify the housing provident fund contributions and require the enterprise to settle outstanding amount if employees complain; and currently no housing provident funds inspection has been conducted on enterprises within the jurisdiction of Chengdu Center without employee complaints. Based on the foregoing and the confirmations from relevant government authorities, our PRC Legal Advisor is of the view that, the likelihood that we will be subject to material administrative penalties and required by relevant authorities actively to pay the shortfall for social insurance and housing provident fund contributions entirely and collectively is remote. As such, our Directors believe that our failure to fully contribute to social insurance and housing provident funds during the Track Record Period would not have any material adverse effect on our business operations or results of operations, and as a result we did not make any provisions in connection with these non-compliances during the Track Record Period.

As the laws and policies related to social insurance and housing provident funds may continue to evolve, we cannot assure you that our employment policies and practices will always be regarded as fully complying with the relevant laws and regulations in China, and we may face labor disputes or government investigations. The PRC government may strengthen its measures and requirements on social insurance and housing provident funds collection, which may lead to stricter law enforcement. Compliance with stricter regulatory requirements may increase our operating expenses, especially our staff costs. We cannot guarantee that the amount of social insurance contributions we would be required to pay will not increase, nor that we would not be required to pay any shortfall or be subject to any penalties or fines, any of which may have a material and adverse effect on our business and results of operations.

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OTHER RISKS RELATING TO OUR OPERATIONS

If we, our employees, agencies, distributors or other business partners engage, or are perceived to engage, in misconduct or breaches, including corrupt or bribery practices, leakage of confidential information, unfair competition, or insider trading, or if we, our employees, agencies, distributors, or other business partners are involved in negative publicity or allegations, our operations and reputation could be adversely affected, and we could be exposed to regulatory investigations, costs and liabilities.

We are subject to risks in relation to actions taken by us, our employees, agencies, distributors or other business partners that may constitute violations of applicable anti-corruption and other related laws. We are subject to the anti-bribery and corruption laws of China. The anti-bribery laws in China generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are also subject to the U.S. Foreign Corrupt Practices Act (the “FCPA”). The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. As our business has expanded, the applicability of the FCPA and other anti-bribery and corruption laws to our operations has increased. Further, there have been instances of corrupt practices in the pharmaceutical industry in recent years, including, among other things, provision of kickbacks, bribes or other illegal gains or benefits to pharmacies, hospitals and medical practitioners from manufacturers, distributors and pharmacies in connection with the prescription of pharmaceutical products. Any allegations of such behavior against us, our employees, agencies, distributors, other business partners or the pharmaceutical industry in general could generate negative publicity and materially and adversely affect our reputation and business prospects.

We do not and cannot fully control the conducts of our employees, agencies, distributors or other business partners. Our employees, agencies, distributors or other business partners may, in their interactions with hospitals, medical institutions and medical professionals, attempt to increase the sales volume of our products through means that constitute violations of applicable anti-corruption and other related laws. If our employees, agencies, distributors or other business partners engage in corrupt or other improper conduct that results in violation of applicable anti-corruption laws in the PRC, the United States or other jurisdictions, our reputation could be harmed. While we have implemented specific measures against corruption and bribery, there can be no assurance that we were or are able to entirely prevent our employees, agencies, distributors or other business partners from engaging in such activities in the past or in the future. We may be held liable for actions taken by our employees, agencies, distributors or other business partners, which could expose us to regulatory investigations and penalties. Actions taken by relevant regulatory authorities or the courts that provide an interpretation of the laws and regulations that differs from our interpretation or that adopt additional anti-bribery, anti-corruption laws and regulations could also require us to make changes to our operations. Our reputation, corporate image, and business operations may be materially and adversely affected if we, our employees, agencies, distributors or other business partners fail to comply with these measures or become the target of any negative publicity as a result of actions taken by us, our employees, agencies, distributors or other business partners, which may in turn have a material adverse effect on our results of operations and prospects.

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For example, pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》), which was promulgated by the NHFPC and came into effect on March 1, 2014, if we are involved in criminal, investigational or administrative procedures for commercial bribery, we will be listed in the adverse records of commercial briberies by the relevant government authorities, as a result of which, for two years from the date the list of adverse records of commercial briberies is published, (i) our products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies within the relevant provinces, and (ii) the scores of our products in the centralized tender processes of public medical institutions or medical and health institutions receiving financial subsidies in other provinces will be reduced. Furthermore, if we are listed in the adverse records of commercial briberies twice within five years, our products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies throughout China for two years from the date the list of adverse records of commercial briberies is published. See “Regulatory Overview — Laws and Regulations in Relation to Anti-Bribery” for more details.

In addition, we are required to comply with anti-corruption and confidentiality requirements in our agreements with our business partners. Any breach of such anti-corruption or confidentiality requirements by us may result in negative consequences, including payment of penalties and termination of agreements, which could have a material adverse effect on our business, financial condition, results of operations and profitability. Moreover, our business may be materially and adversely affected if our business partners breach confidentiality requirements, or if our employees breach the non-disclosure, non-compete and non-solicitation clauses in their employment agreements.

Our business depends on our key senior management members, development personnel and marketing and sales personnel. If we are unable to retain our key employees or to attract and retain skilled and experienced personnel, our ability to conduct our business could be materially impaired and our business prospects could be adversely affected.

We depend on the continued contributions of our senior management, especially the executive officers listed in the section headed “Directors, Supervisors and Senior Management” in this document, and other key employees, many of whom are difficult to replace. The loss of the services of any of our executive officers or other key employees could materially harm our business.

Our future success is dependent on our ability to attract a significant number of qualified employees and retain existing key employees, especially our product development and technology professionals. We believe that there is, and will continue to be, intense competition for highly skilled management, technical, sales and other personnel with experience in our industry in the cities where our offices are located. Our need to significantly increase the number of our qualified employees and retain key employees may cause us to materially increase compensation-related costs, including share-based compensation. We must provide competitive compensation packages and a high-quality work environment to hire, retain and

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motivate employees. In addition, our senior management team has limited experience in running [REDACTED], which will require us to expend additional resources in hiring additional support staff and incur additional costs and expenses. To the extent we hire personnel from competitors, we also may be subject to allegations that they have been improperly solicited or divulged proprietary or other confidential information. If we are unable to retain and motivate our existing employees and attract qualified personnel for important positions, we may be unable to manage our business effectively, including the development, marketing and sale, which could adversely affect our business, operating results and financial condition, and the price of our [REDACTED] could suffer.

If we are unable to succeed in tender processes to sell our products to PRC public hospitals and other medical institutions, we may lose market share and our revenue and profitability could be adversely affected.

During the Track Record Period, we sold our products to distributors who then sold to end-customers which include public hospitals and other medical institutions owned or controlled by government authorities in China. Each of these institutions must generally procure pharmaceuticals through a centralized pharmaceutical procurement platform organized by local government authorities, and source substantially all of their pharmaceuticals through a centralized tender process. We and our competitors submit bids in such tender process to supply pharmaceutical products to these institutions at specified prices. The relevant government authorities evaluate these bids based on a number of criteria, such as bidding price, product quality, clinical effectiveness and reputation and after-sales service of the manufacturers. If we succeed in the tender process, the relevant products will be sold to the public hospitals and other medical institutions at the bid prices through our distributors, which is the primary determinant of the prices at which we sell these products to our distributors.

We may fail to win bids in a tender process due to various factors, including reduced demand for the relevant product, uncompetitive bidding price, failure to meet certain quality requirements, insufficient service quality to meet tender requirements, perception that our product is less clinically effective than competing products or our service or other aspects of our operations are less competitive. If our products are not selected in the tender processes in one or more regions, we will be unable to sell these products to the public hospitals and other medical institutions in those regions, and our market share, revenue and profitability could be adversely affected.

The tender processes can also create pricing pressure among substitute products or products that are perceived to be substitute products. Our sales volumes and profitability depend on our ability to successfully differentiate our products and price our bids in a manner that enables us to succeed in the centralized tender processes without compromising our profitability. If we are unable to differentiate our products or are otherwise not successful in winning bids in the centralized tender processes at profitable levels, our market share, results of operations and profitability could be adversely affected.

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Furthermore, there are uncertainties as to when a province will commence its centralized tender process, and when the new prices will come into effect pursuant to the completion of a centralized tender process. The uncertain timeline in relation to the centralized tender process could adversely affect our business, results of operations and prospects.

We may incur unexpected charges relating to our operations.

Certain post-production processes, including transportation, storage, warehousing and usage, may adversely affect the quality of our products. We generally rely on transport operators for delivery of our products. Delivery disruptions for reasons beyond our control, including weather conditions, political turmoil, social unrest and strikes, could lead to delayed deliveries. The nature of pharmaceutical products may also mean that poor handling or storage by pharmacies, hospitals, patients or transport operators could result in damage to our products, including contamination or degeneration. For example, prolonged exposure to heat or sunlight may damage certain pharmaceutical products. Some of these processes are managed by third parties, over which we have limited control. In particular, once we have sold our products to distributors, we have limited control over how our distributors store and transport our products.

If, as a result of such post-production processes, our products are deemed or proven to be unsafe, ineffective, defective or contaminated, this may result in product liability or product recalls. Even if a situation does not necessitate a product recall, we cannot assure you that product liability claims will not be asserted against us as a result. Any claims relating to the quality of our products, regardless of their merit, could adversely affect our reputation, divert the time, resources and attention of our management, and result in material and adverse impact on our operations, revenue and profitability.

We may incur future charges relating to inventory that expires or as a result of customer failures to pay invoiced amounts timely or in full. We may have significant bad debt expenses or write-offs in the future. We could also experience additional charges for potential inventory obsolescence related to other products if we are unable to sell units that are nearing their expiration dates, or for bad debt if other distributors do not pay outstanding receivables in full. Those or similar future events would have an adverse impact upon our operating results.

If counterfeit of our products become available in the market, it could negatively affect our sales, damage our reputation and the brand names for the relevant products and expose us to liability claims.

Certain products distributed or sold in the pharmaceutical markets may be manufactured without proper licenses or approvals or fraudulently mislabeled with respect to their content or manufacturer. These products are generally referred to as counterfeit products. The counterfeit product control and enforcement system may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit products, including those imitating the products we sell. Since counterfeit products are generally sold at lower prices than authentic products, and are in some cases very similar in appearance to authentic products, counterfeit products imitating our own products can quickly erode our sales volume of the relevant product. Moreover,

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counterfeit products may or may not have the same chemical composition as our products, which may make them less effective than our products, entirely ineffective or more likely to cause severe adverse side effects. This could expose us to negative publicity, reputational damage, fines and other administrative penalties, and may even result in litigation against us. As a result of these factors, the continued proliferation of counterfeit products in the market could affect our sales, damage our reputation and the brand names for the relevant products and expose us to liability claims. There can be no assurances that instances of counterfeit version of our products in the future will not have a material adverse effect on us or we will be able to prevent future occurrences. In addition, any negative publicity relating to counterfeit products concerning us, any other company in the pharmaceutical industry or in general, even if untrue, could adversely affect our reputation and business prospects. We cannot assure you that negative publicity about us would not damage our brand image or have a material adverse effect on our operations, revenue and profitability.

If we or our brand names fail to maintain a positive reputation, many aspects of our business and our business prospects could be adversely affected.

We depend on our reputation and the brand names of our products in many aspects of our business, including but not limited to:

- gain access to, and for our products to be perceived favorably by, medical institutions and healthcare professionals that drive and affect patient demand for products;
- to effectively work with the relevant authorities that regulate various aspects of our business;
- to gain the trust of patients and consumers of our products;
- to competitively position ourselves in the centralized tender process required for our products to be sold to public hospitals and medical institutions;
- to successfully attract employees, distributors, and other business partners to work with us; and
- to increase market share of our products through brand recognition.

However, there can be no assurance that we will be able to maintain a positive reputation or brand name for all our products in the future. Our reputation and the brand names of our products may be adversely affected by a number of factors, many of which are outside our control, including but not limited to:

- adverse associations with our products, including with respect to their efficacy or side effects;

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- the effects of counterfeit products purporting to be our products;
- lawsuits and regulatory investigations against us or otherwise relating to our products or industry;
- improper or illegal conduct by our employees, distributors, suppliers and third-party promoters, whether or not authorized by us; and
- adverse publicity that is associated with us, our products or our industry, whether founded or unfounded.

If we or the brand names of our products fail to maintain a positive reputation as a result of these or other factors, our products may be perceived unfavourably by hospitals, medical professionals, regulators and patients, and our operations and business prospects could be adversely affected.

In addition, despite our internal guidelines and supervision efforts, our employees or distributors may fail to follow such guidelines, which may adversely affect our sales and reputation. For example, our employees or distributors may fail to provide accurate and complete information about our products, as a result of which hospitals, medical institutions, doctors and patients may misunderstand or misuse our products. During the Track Record Period and as of the Latest Practicable Date, there had been no such incident to the best of our knowledge. Such misunderstanding or misuse, if occurred, could result in our products being less effective or cause severe adverse effects that could otherwise be avoided. As a result, the sales volume and reputation of our products could be adversely affected and we could be exposed to product liability lawsuits or regulatory investigations, resulting in penalties, fines or other disruptions to our operations.

Our business could be adversely affected by natural disasters, public health crises, political relationships and crises, economic downturns or other unexpected events.

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 the world could materially disrupt our business and operations. These uncertain and unpredictable factors include adverse effects of the pandemic on the economy, potential delays of our ongoing and

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future clinical trials, and disruptions to the operations of our business partners and CROs. Our business operations and financial results may be adversely affected in the future by COVID-19 resurgence, and 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.

With international footprint, our business is subject to constantly changing international economic, regulatory, social, and political conditions, and local conditions in those countries and regions where we operate and we may be subject to various risks relating to legal compliance in different jurisdictions, exposure to potential disputes and litigations, geopolitical actions, trade restrictions or prohibitions, foreign exchange rates, local market conditions, cultural and language difficulties, geopolitical risks, competitions, and taxes. As a result, international political relationships among jurisdictions where we operate and conduct business may affect our cost structure, the demand for our products and our collaboration with business partners. Any such relationship tensions and political concerns may adversely affect our business, results of operations and prospects. In addition, any economic downturn, decrease in economic growth rates and other uncertain economic outlook in the market that we operate in could also affect our business, financial condition and results of operations.

Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of 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.

If we, our management or directors become party to litigation, legal disputes, claims or administrative proceedings, our management or directors’ attention may be diverted and our operations, reputation, revenue and profitability could be adversely affected.

We, our management or directors may from time to time become party to litigation, legal disputes, claims or administrative proceedings arising in the ordinary course of our business. Involvement in litigation, legal disputes, claims or administrative proceedings may distract our management’s or directors’ attention and consume our time and other resources. Furthermore, any litigation, legal disputes, claims or administrative proceedings which are initially not of material importance may escalate due to the various factors involved, such as the facts and circumstances of the cases, the likelihood of winning or losing, the monetary amount at stake and the parties concerned, and such factors may result in these cases becoming of material importance to us.

In addition, negative publicity arising from litigation, legal disputes, claims or administrative proceedings may damage our reputation and adversely affect the image of our brands and products. In addition, if any verdict or award is rendered against us, we could be required to pay significant monetary damages, assume other liabilities, and suspend or terminate the related business ventures or projects. Consequently, our business, financial condition and results of operations may be materially and adversely affected.

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Product liability claims or lawsuits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.

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

- decreased demand for our drug candidates;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulatory authorities;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labelling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any approved product candidate; and
- a decline in the market price of our H Shares.

To cover such liability claims arising from clinical studies, we purchase clinical trial insurance to cover adverse events in our clinical trials. It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that

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may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute the value of your [REDACTED] in our H Shares, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including, but not limited to:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- dilution to our existing Shareholders from our issuance of additional equity securities;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the assimilation of operations, corporate culture intellectual property, products and personnel of the acquired company or business;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and its existing products or drug candidates and regulatory approvals;
- inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and
- changes in accounting principles relating to recognition and measurement of our investments that may have a significant impact on our financial results.

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Additionally, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large onetime expenses and acquire intangible assets that could result in significant future amortization expenses. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Further, according to the Anti-Monopoly Law of PRC (《反壟斷法》) and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings (《關於經營者集中申報標準的規定》) issued by the State Council, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the MOFCOM when the threshold is crossed and such concentration shall not be implemented without the clearance of prior notification.

We may also be subject to similar review and regulations in other jurisdictions, such as the laws and regulations on foreign investment in the United States under the jurisdiction of the Committee on Foreign Investment in the United States (“CFIUS”) and other agencies, including the Foreign Investment Risk Review Modernization Act.

In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time consuming, and any required approval or filing processes, including obtaining approval from or filing with CFIUS, the SAMR, the MOFCOM, the CSRC, the SAFE or other agencies may delay or inhibit our ability to complete such transactions. Furthermore, CFIUS, SAMR, MOFCOM, CSRC, SAFE or other government agencies may make further determinations that increase the scrutiny of our future acquisitions in the United States or the PRC or prohibits such acquisitions. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

If we fail to maintain effective internal controls, we may not be able to accurately report our financial results or prevent fraud, and our business, financial condition, results of operations and reputation could be materially and adversely affected.

We will become a H share [REDACTED] company upon completion of the [REDACTED], and our internal controls will be essential to the integrity of our business and financial results. Our public reporting obligations are expected to place a strain on our managerial, operational and financial resources and systems in the foreseeable future. To address our internal controls issues and to generally enhance our internal controls and compliance environment, we have taken various measures to improve our internal controls and procedures including establishing a compliance program, adopting new policies, and providing extensive and ongoing training on our controls, procedures and policies to our employees. The violation of or deviation from these internal controls and procedures by any of our employees could adversely affect our reputation, financial position and current and future business relationships. If one or more of our employees or former employees were to engage in

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misconduct or were to be accused of such misconduct, our businesses and our reputation could be adversely affected. In addition, in preparation for the [REDACTED], we have implemented other measures to further enhance our internal controls, and plan to take steps to further improve our internal controls. If we encounter difficulties in improving our internal controls and management information systems, we may incur additional costs and management time in meeting our improvement goals. We cannot assure you that the measures taken to improve our internal controls will be effective. If we fail to maintain effective internal controls in the future, our business, financial condition, results of operation and reputation may be materially and adversely affected.

Our internal information technology systems, or those used by our CROs, partners, other independent contractors or consultants, may fail or suffer security breaches, which may require us to expend additional resources to protect our information technology systems and could materially and adversely affect our business, financial condition, results of operations and prospects.

Our internal computer systems and those of our current and any future third-party vendors, collaborators, consultants, and third parties performing services for us, as well as our clinical sites and regulatory authorities, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, and telecommunication and electrical failures. Although we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our drug candidate development and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from our current or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in the theft or destruction of intellectual property, data, or other misappropriation of assets, financial loss, or otherwise compromise our confidential or proprietary information and disrupt our operations, our competitive position could be harmed, and the further development and commercialization of our drug candidates could be delayed.

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

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

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

Increased labor costs could result in exceeding expenses, slow our growth and affect our profitability. In the event of labor shortages, labor disputes or striking, our business operation and financial performance may be materially adversely affected.

Our success depends in part upon our ability to attract, motivate and retain a sufficient number of qualified employees, including management, technical, research and development, sales and marketing, production, quality control and other personnel. We face intense competition in recruiting and retaining qualified personnel, as competitors are competing for the same pool of qualified personnel and our remuneration packages may not be as competitive as those of our competitors. Increasing market competition may cause market demand and competition for qualified employees to intensify.

As our production process requires skilled technical workers in design, operating and quality control, we cannot guarantee that we can retain and attract sufficient qualified employees on reasonable employment terms. In the event that we cannot keep the existing skilled workers or recruit sufficient skilled workers to replace the departing skilled workers, or to cope with our expansion plan on a timely basis at reasonable costs, or that the turnover rate of our workers is high and we do not have time to train up the workers to cope with our standards, our production process can be severely affected or interrupted. If we face labor shortages or significant increases in labor costs, higher employee turnover rates or changes to labor laws and regulations, our operating costs could increase significantly, which could materially adversely affect our results of operations. In addition, we could face labor disputes with our employees, which could lead to fines by governmental authorities and settlement costs to resolve the disputes. Labor disputes could also make it more difficult to recruit new employees due to the reputational damage caused by labor disputes.

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

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

We are exposed to risks associated with the potential [REDACTED].

[REDACTED]

Our legal right to certain properties may be challenged.

Pursuant to the applicable PRC laws and regulations, property lease contracts must be registered with the local branches of the Ministry of Housing and Urban Development. As of the Latest Practicable Date, six lease agreements of our leased properties which are leased from third parties and used for production or office had not been registered and filed with relevant land and real estate management departments in China. Under the relevant PRC laws and regulations, the parties to a lease agreement have the obligation to register and file the executed lease agreement. As advised by our PRC Legal Advisor, the validity of the lease agreements are not affected by the failure to register or file the lease agreements with the relevant

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government authorities. According to the relevant PRC regulations, we may be ordered by the relevant government authorities to register the relevant lease agreements within a prescribed period, failing which we may be subject to a fine ranging from RMB1,000 to RMB10,000 for each unregistered lease. As of the Latest Practicable Date, we have not received any order from the relevant government authorities requiring us to register these lease agreements. We undertake to cooperate fully to facilitate the registration of lease agreements once we are notified of any requirements by the relevant government authorities.

In addition, as of the Latest Practicable Date, we had not obtained the real estate ownership certificates for two properties occupied by us used for dormitories and warehouses, with an aggregate GFA of approximately 279.52 sq.m., representing around 0.2% of the total GFAs of our owned properties. These properties are primarily used for dormitories and warehouses and are not directly related to our production and operations. Our Controlling Shareholder has committed to compensating us for any losses incurred in connection with these properties. Based on the above, we believe that the title defect will not have a material adverse impact on production and business operations.

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

A substantial part of our assets, and a majority of our Directors, Supervisors and senior management, are located in China. As a result, it may not be possible for [REDACTED] to effect services of process upon us, or our Directors, Supervisors or senior management who reside in China. China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions.

On July 14, 2006, the Supreme People’s Court of the PRC and Hong Kong entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》), or the 2006 Arrangement. Pursuant to the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a mainland court is expressly selected as the court having sole jurisdiction for the dispute.

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On January 18, 2019, the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》), or the New Arrangement, was signed between the Supreme People’s Court of the PRC and Hong Kong and effective on January 29, 2024, and the 2006 Arrangement has been superseded. The New Arrangement establishes a bilateral legal mechanism with greater clarity and certainty for reciprocal recognition and enforcement of judgments between Hong Kong and the PRC in civil and commercial matters under both Hong Kong and PRC law. The New Arrangement sets forth, among others, the scope, specific types of matters to be covered or excluded, jurisdictional grounds for the purpose of recognition and enforcement as well as grounds for refusal of recognition and enforcement. However, the 2006 Arrangement will remain applicable to a “choice of court agreement in writing” within the meaning of 2006 Arrangement which is made before the effective date of New Arrangement. As the New Arrangement went effective relatively recently and its implementation and interpretation are still evolving, as a result, [REDACTED] may have limited resources when they seek recognition and enforcement of judgments obtained from non-PRC courts against us or our Directors or officers who live in the PRC.

RISKS RELATING TO THE [REDACTED]

Our A Shares were listed in China in January 2023, and the characteristics of the A share and H share markets may differ.

Our A Shares were listed on the SSE STAR Market in January 2023. Following the [REDACTED], our A Shares will continue to be traded on the SSE STAR Market and our H Shares will be [REDACTED] on the Stock Exchange. Under current PRC laws and regulations, our H Shares and A Shares are neither interchangeable nor fungible, and there is no [REDACTED] or settlement between the H Share and A Share markets. With different trading characteristics, the H Share and A Share markets have divergent trading volumes, liquidity and investor bases, as well as different levels of retail and institutional investor participation. As a result, the [REDACTED] performance of our H Shares and A Shares may not be comparable. Nonetheless, fluctuations in the price of our A Shares may adversely affect the price of our H Shares, and vice versa. The fluctuations in the price of our A Shares may also affect our [REDACTED] in Hong Kong. Due to the different characteristics of the H Share and A Share markets, the historical prices of our A Shares may not be indicative of the performance of our H Shares. You should therefore not place undue reliance on the trading history of our A Shares when evaluating the [REDACTED] decision in our H Shares.

An active [REDACTED] market for our H Shares may not develop or be sustained.

Prior to the [REDACTED], there has been no public market for our H Shares. We cannot assure you that a public market for our H Shares with adequate liquidity will develop and be sustained following the completion of [REDACTED]. In addition, the [REDACTED] of our H Shares may not be indicative of the market price of our H Shares following the completion of the [REDACTED]. If an active public market for our H Shares does not develop following the completion of the [REDACTED], the market price and liquidity of our H Shares could be materially and adversely affected.

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

The price and [REDACTED] volume of our H Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the price and [REDACTED] volume of our Shares. In addition to market and industry factors, the price and [REDACTED] volume of our Shares may be highly volatile for specific business reasons, such as fluctuations in our revenue, earnings, cash flows, investments, expenditures, regulatory developments, the developments of our drugs and drug candidates, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies [REDACTED] on the Hong Kong Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our H Shares may be subject to changes in price not directly related to our performance.

You will experience immediate and substantial dilution and may experience further dilution if we issue additional Shares in the future.

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

Future sales or perceived sales of significant amounts of our H Shares in the [REDACTED] following the [REDACTED] could materially and adversely affect the price of our H Shares.

The market price of our H Shares could decline as a result of substantial future sales of our H Shares or other securities relating to our Shares in the [REDACTED]. Such a decline could also occur with the issuance of new Shares or other securities relating to our Shares, or the perception that such sales or issuances may occur. Future sales, or perceived sales, of substantial amounts of our Shares could materially and adversely affect the price of our H Shares.

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Our Controlling Shareholder has significant influence over our Company and his interests may not be aligned with the interest of our other Shareholders.

Immediately following the completion of the [REDACTED], assuming the [REDACTED] is not exercised, our Controlling Shareholder will directly hold approximately [REDACTED]% of our total issued Shares. Our Controlling Shareholder will, through his voting power at the Shareholders meetings and his delegates or positions on the Board, have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional shares or other equity securities, timing and amount of dividend payments, and our management. Our Controlling Shareholder may not act in the best interests of our minority Shareholders. In addition, without the consent of our Controlling Shareholder, we could be prevented from entering into transactions that could be beneficial to us. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for the Shares as part of a sale of our Company and may significantly reduce the price of our H Shares.

Our historical dividends may not be indicative of our future dividend policy, and there can be no assurance that we will declare and distribute any amount of dividends in the future and you may have to rely on price appreciation of our H Shares for return on your [REDACTED].

In 2021, 2022 and 2023 and the nine months ended September 30, 2024, we distributed dividends of RMB20.0 million, nil, nil and nil, respectively. Our historical dividends may not be indicative of our future dividend policy. There can be no assurance that future dividends will be declared or paid. The declaration, payment and amount of any future dividends are subject to the discretion of our Directors depending on, among other considerations, our business and financial performance, cash requirements and availability, capital and regulatory requirements and general business conditions. We may not have sufficient or any profits to enable us to make dividend distributions to our Shareholders in the future, even if our financial statements indicate that our operations have been profitable. Accordingly, the return on your [REDACTED] in our Shares will likely depend entirely upon any future price appreciation of our H Shares. There is no guarantee that our H Shares will appreciate in value after the [REDACTED] or even maintain the price at which you purchased the H Shares. You may not realize a return on your [REDACTED] in our H Shares and you may even lose your entire [REDACTED] in our H Shares.

Facts, forecasts and statistics in this document derived from third-party reports or publicly available sources may not be fully reliable.

This document, particularly the “Industry Overview” section, contains information and statistics, including, but not limited to, information and statistics relating to the PRC, the PRC economy and the healthcare industry in the PRC that have been derived from various official government publications, third-party reports or publicly available sources. We believe that the sources of such information are appropriate sources for such information and have taken reasonable care in extracting and reproducing such information. We have no reason to believe

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that such information is false or misleading in any material respect or that any fact has been omitted that would render such information false or misleading in any material respect. Neither we or the [REDACTED] nor our or their respective affiliates or advisors have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources, and no representation is given as to its accuracy. We cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy, as the case may be, as that in other jurisdictions.

If securities or industry analysts do not publish research or reports about our business, or if they adversely change their recommendations, the market price and [REDACTED] volume may decline.

If research analysts do not establish and maintain adequate research coverage or if one or more of the analysts who covers us downgrades our Shares or publishes inaccurate or unfavorable research about our business, the market price for our Shares would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or [REDACTED] volume for our Shares to decline.

You should not place any reliance on any information released by us in connection with the listing of our A Shares on the SSE STAR Market.

Following the listing of our A Shares on the SSE STAR Market, we have been subject to periodic reporting and other information disclosure requirements in the PRC. As a result, from time to time we publicly release information, including financial statements and financial data, relating to us on the SSE STAR Market or other media outlets designated by the SSE STAR Market or the CSRC or other regulatory bodies. However, the information announced by us in connection with our A Shares is based on regulatory requirements of the securities authorities and market practices in the PRC which are different from those applicable to the [REDACTED]. Such information does not and will not form a part of this document. As a result, prospective [REDACTED] in our H Shares are reminded that, in making their [REDACTED] decisions as to whether to purchase our H Shares, they should rely only on the financial, operating and other information included in this document. By applying to purchase our H Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong with respect to the [REDACTED].

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

Subsequent to the date of this document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other

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forward-looking information about us and the [REDACTED]. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective [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.

You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong when making your [REDACTED] decision regarding our Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective [REDACTED] should not rely on any such information, reports or publications in making their decisions as to whether to [REDACTED] in our [REDACTED]. By applying to purchase our Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document.

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

In preparation of the [REDACTED], the Company has sought the following waivers from strict compliance with the relevant provisions of the Listing Rules:

MANAGEMENT PRESENCE IN HONG KONG

Rule 8.12 of the Listing Rules provides that a new applicant for listing on the Hong Kong Stock Exchange must have a sufficient management presence in Hong Kong and, under normal circumstances, at least two of the new applicant’s executive directors must be ordinarily resident in Hong Kong. Rule 19A.15 of the Listing Rules further provides that the requirement in Rule 8.12 may be waived by having regard to, among other considerations, the new applicant’s arrangements for maintaining regular communication with the Hong Kong Stock Exchange.

The Company’s business operations and assets are mostly located outside Hong Kong. The Company’s executive Directors are based in the PRC as the Board believes it would be more effective and efficient for its executive Directors to be based where the Company’s operations are located. The Directors consider that relocation of the executive Directors to Hong Kong will be burdensome and costly for our Company, and it may not be in the best interests of the Company and Shareholders as a whole to appoint two additional executive Directors who ordinarily reside in Hong Kong. Therefore, no executive Directors will, in the foreseeable future be ordinarily resident in Hong Kong.

Accordingly, pursuant to Rule 19A.15 of the Listing Rules, the Company has applied to the Hong Kong Stock Exchange for, and the Hong Kong Stock Exchange [has] granted the Company, a waiver from strict compliance with the requirements under Rule 8.12 and Rule 19A.15 of the Listing Rules, provided that the Company implements the following arrangements:

- (i) the Company has appointed Ms. Zhang Suyu and Mr. Lee Chung Shing as the authorized representatives of the Company (the “**Authorized Representatives**”) for the purpose of Rule 3.05 of the Listing Rules. The Authorized Representatives will serve as the Company’s principal channel of communication with the Hong Kong Stock Exchange. They can be readily contactable by phone, fax and email to deal promptly with enquiries from the Hong Kong Stock Exchange and will also be available to meet with the Hong Kong Stock Exchange to discuss any matters on short notice. The contact details of our Authorized Representatives have been provided to the Hong Kong Stock Exchange.
- (ii) all the Directors who are not ordinarily resident in Hong Kong possess or can apply for valid travel documents to visit Hong Kong and can meet with the Hong Kong Stock Exchange within a reasonable period. In addition, each Director has provided his/her contact details, including mobile phone numbers, office phone numbers and email addresses, to the Authorized Representatives and to the Hong Kong Stock Exchange. The Directors have also provided the contact information of their emergency contacts to the Authorized Representatives, so that each of the Authorized Representatives would be able to contact all the Directors (including the independent non-executive Directors) promptly at all times if and when the Hong Kong Stock Exchange wishes to contact the Directors on any matter.

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

- (iii) the Company has appointed Messis Capital Limited as its compliance adviser for the period commencing on the [REDACTED] and ending on the date on which the Company complies with Rule 13.46 of the Listing Rules in respect of the Company’s financial results for the first full financial year commencing after the [REDACTED]. The Company’s compliance adviser will act as the Company’s additional and alternative channel of communication with the Hong Kong Stock Exchange, and its representatives will be readily available to answer enquiries from the Hong Kong Stock Exchange.

WAIVER IN RELATION TO RULE 4.04(1) OF THE LISTING RULES AND EXEMPTION FROM STRICT COMPLIANCE WITH SECTION 342(1)(B) 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

Rule 4.04(1) of the Listing Rules requires our Company to include in the document an accountants’ report covering the consolidated results of our Group in respect of each of the three financial years immediately preceding the issue of the document or such shorter period as may be acceptable to the Stock Exchange.

Section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires all prospectuses to include an accountants’ report which contains the matters specified in Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

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

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

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

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

Chapter 1.1A of the Guide for New Listing Applicants issued by the Stock Exchange has provided the conditions for granting a waiver from strict compliance with Rule 4.04(1) of the Listing Rules as follows:

- (i) the applicant must list on the Stock Exchange within three months after the latest year end;
- (ii) the applicant must obtain a certificate of exemption from the SFC on compliance with the requirements of Section 342(1) in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance;
- (iii) a profit estimate for the latest financial year (which must comply with Rules 11.17 to 11.19 of the Listing Rules) must be included in the document or the applicant must provide justification why a profit estimate cannot be included in the document; and
- (iv) there must be a directors’ statement in the document that there is no material adverse change to our Company’s financial and trading positions or prospect with specific reference to the trading results from the end of the stub period to the latest financial year end.

The Accountants’ Report for each of the three years ended December 31, 2021, 2022, 2023 and the nine months ended September 30, 2024 has been prepared and set out in Appendix I to this document.

Pursuant to the relevant requirements set out above, our Company is required to produce three full years of audited accounts for the years ended December 31, 2022, 2023 and 2024. However, an application has been made to the Stock Exchange for a waiver from strict compliance with Rule 4.04(1) of the Listing Rules, and such waiver [has] been granted by the Stock Exchange on the conditions that:

- (a) this document will be issued on or before [REDACTED] and our H Shares will be [REDACTED] on the Stock Exchange on or before [REDACTED] (i.e. within three months after the latest financial year end of our Company);
- (b) our Company will obtain from the SFC a certificate of exemption on strict compliance with the requirements under section 342(1) 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;
- (c) this document contains the profit estimate for [REDACTED] (which complies with Rules 11.17 to 11.19 of the Listing Rules);

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

- (d) this document contains the statement of our Directors that there is no material adverse change to our Group’s financial and trading positions or prospect with specific reference to the trading results from October 1, 2024 to December 31, 2024; and
- (e) the Company will publish the preliminary results announcement for the financial year ended December 31, 2024 by not later than [REDACTED] and the annual report for the financial year ended December 31, 2024 by not later than [REDACTED], respectively, in compliance with Rules 13.49 and 13.46 of the Listing Rules.

An application has also been made to the SFC for a certificate of exemption from strict compliance with the requirements under section 342(1)(b) in respect of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance 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:

- (a) the particulars of the exemption be set out in this document;
- (b) this document to be issued on or before [REDACTED]; and
- (c) the Company’s H Shares will be [REDACTED] on the Stock Exchange on or before [REDACTED] (i.e. three months after the latest financial year end of our Company).

The applications to Stock Exchange for a waiver from strict compliance with Rule 4.04(1) of the Listing Rules and to the SFC for a certificate of exemption from strict compliance with the requirements under section 342(1)(b) in respect of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance have been made on the grounds, among others, that strict compliance with the above requirements would be unduly burdensome and the exemption would not prejudice the interests of the [REDACTED] public as:

- (a) there would not be sufficient time for our Company and the Reporting Accountants to finalize the audited financial statements for the full financial year ended December 31, 2024 for inclusion in this document. If the financial information for the year ended December 31, 2024 is required to be audited, our Company and the Reporting Accountants would have to carry out substantial work to prepare, update and finalize the Accountants’ Report and this document, and the relevant sections of this document will need to be updated to cover such additional period. This would involve additional time and costs since substantial work is required to be carried out for audit purposes. It would be unduly burdensome for the audited results for the year ended December 31, 2024 to be finalized in such short period of time. Our Directors consider that the benefits of such work to the existing and prospective shareholders of our Company may not justify the additional work and expenses involved and a delay in the [REDACTED] timetable;

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

- (b) our Directors are of the view that, after performing all reasonable due diligence work which they consider appropriate, up to the date of this document, except to the extent disclosed in the paragraph headed “Summary – Recent Development” in this document, there has been no material adverse change to the financial or trading positions or prospects since October 1, 2024 (immediately following the date of the latest audited statement of financial position in the Accountants’ Report set out in Appendix I to this document) to the date of this document; and there has been no event since October 1, 2024 which would materially affect the information shown in the Accountants’ Report as set out in Appendix I to this document, the profit estimate for [REDACTED] as set out in Appendix IIB to this document and the section headed “Financial Information” in this document and other parts of this document;
- (c) our Company is of the view that the Accountants’ Report covering the each of the years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2024, together with the profit estimate for [REDACTED] (in compliance with Rules 11.17 to 11.19 of the Listing Rules) included in this document have already provided the potential [REDACTED] with adequate and reasonably up-to-date information in the circumstances to form a view on the track record and earnings trend of our Company; and our Directors confirm that all information which is reasonably necessary to enable the [REDACTED] public to make an informed assessment of the business, assets and liabilities, financial position, management and prospects of our Group has been included in this document, and the exemption from strict compliance would not prejudice the interests of the [REDACTED] public; and
- (d) we will publish our annual results and annual report for the year ended December 31, 2024 within the time prescribed under the Rules 13.46(2) and 13.49(1) of the Listing Rules, respectively. In this regard, we consider that our Shareholders, the [REDACTED] public as well as potential [REDACTED] of our Company will be kept informed of the financial results of our Group for the financial year ended December 31, 2024.

[REDACTED]

[REDACTED]

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

[REDACTED]

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

[REDACTED]

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

[REDACTED]

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

[REDACTED]

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

[REDACTED]

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

[REDACTED]

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

[REDACTED]

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

[REDACTED]

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

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[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]

DIRECTORS

Name	Address	Nationality
Executive Directors		
Dr. Zhu Yi (朱義)	No. 24, 8th Floor, Block 6 No. 6 Lidu Road Wuhou District Chengdu Sichuan Province PRC	Chinese
Ms. Zhang Suyu (張蘇婭)	No. 8, 4th Floor, Unit 2 Building 2, No. 1 Shexue Lane Liucheng Wenjiang District Chengdu Sichuan Province PRC	Chinese
Mr. Kang Jian (康健)	No. 6, Unit 2, Building 14 No. 11 Construction Lane Chenghua District Chengdu Sichuan Province PRC	Chinese
Mr. Zhuo Shi (卓識)	No. 403, 4/F, Unit 2, Building 14 No. 55 Jinlv San Road Wuhou District Chengdu Sichuan Province PRC	Chinese
Dr. Zhu Hai (朱海)	17476 NE 122ND ST REDMOND WA 98052-3093 United States	Chinese

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
Non-executive Director		
Dr. David Guowei Wang	45 DOGWOOD DR #106 NASHUA NH 03062 United States	American
Independent Non-executive Directors		
Mr. Li Mingyuan (李明遠)	No. 1, Floor 17, New Building 6 No. 16 Section 3 of Renmin South Road Chengdu Sichuan Province PRC	Chinese
Mr. Yu Xiong (俞雄)	Room 303, No. 3, Lane 665 Miyun Huayuan Miyun Road Hongkou District Shanghai PRC	Chinese
Mr. Yang Min (楊敏)	No. 401, Unit 2, Building 2 No. 199 Jiaozi Avenue Hi-Tech Zone Chengdu Sichuan Province PRC	Chinese
Dr. Xiao Geng (肖耿)	Flat H, 21/F, Double Cove Starview Prime Tower 16 8 Wu Kai Sha Road Ma On Shan New Territories Hong Kong	Chinese (Hong Kong)

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

SUPERVISORS

Name	Address	Nationality
Ms. Wang Jie (汪捷)	No. 1, Floor 15, Unit 2, Building 1 No. 109 South Cujin Road Wuhou District Chengdu Sichuan Province PRC	Chinese
Mr. Liu Liang (劉亮)	No. 3, Unit 3, Building 3 No. 29 Baihui Road Qingyang District Chengdu Sichuan Province PRC	Chinese
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For more details in respect of our Directors and Supervisors, see “Directors, Supervisors and Senior Management.”

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PARTIES INVOLVED IN THE [REDACTED]

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Company’s Websites

www.baili-pharm.com
*(The information contained in this website
does not form part of this document)*

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Mr. Li Mingyuan (李明遠)
Mr. Yu Xiong (俞雄)

Remuneration and Appraisal Committee

Mr. Yu Xiong (俞雄) (*Chairperson*)
Ms. Zhang Suyu (張蘇婭)
Mr. Yang Min (楊敏)

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Dr. Zhu Yi (朱義)
Mr. Yu Xiong (俞雄)

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INDUSTRY OVERVIEW

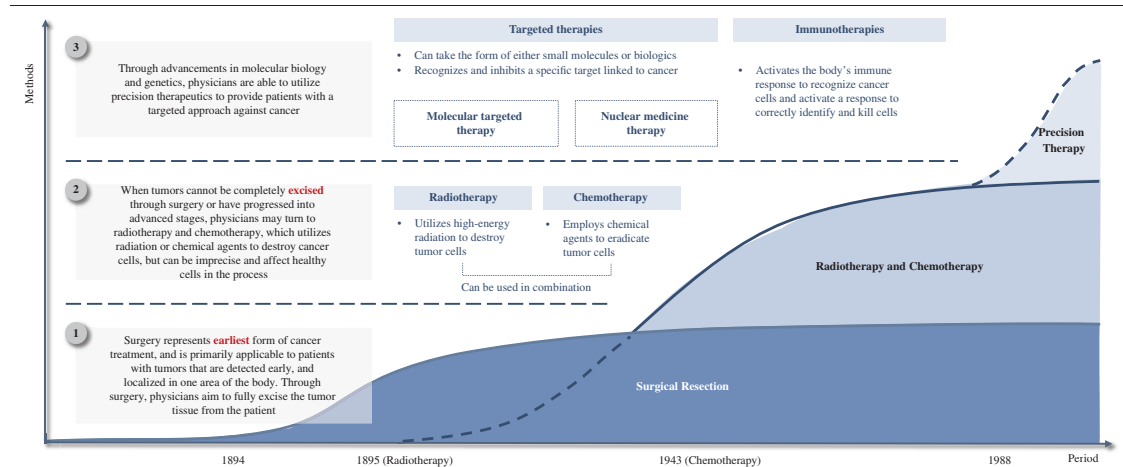
The information and statistics set forth in this section were extracted from official government publications, public market research and independent research. In particular, we engaged CIC, an independent market research and consulting company, to prepare an industry report, or the CIC Report, for the [REDACTED]. Except as otherwise noted, all of the information contained in this section is derived from the CIC Report. We believe that the sources of the information set forth in this section are appropriate sources for such information and have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading or that any material fact has been omitted that would render such information false or misleading. The information from official government sources has not been independently verified by us, the Joint Sponsors, [REDACTED], [REDACTED], [REDACTED], [REDACTED], any of their respective directors, officers and advisors, or any other persons or parties involved in the [REDACTED], except for CIC, and no representation is given as to its accuracy. Accordingly, the information from official governmental sources contained herein may not be accurate and should not be unduly relied upon.

OVERVIEW OF THE CANCER TREATMENT LANDSCAPE

Overview

Over the past century, cancer treatments have experienced significant evolution, first with the development of surgical techniques to remove a tumor from a patient’s body; then with the advent of radiotherapy and chemotherapy to kill or halt the growth of cancer cells; and today, with precision oncology to deliver safer and more selective approaches and harness a patient’s own immune system to fight cancer.

The following diagram illustrates the evolution of cancer treatment to date:



Source: CA-A CANCER JOURNAL FOR CLINICIANS; Nature Reviews Disease Primers; Cancer Discovery; CIC

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In the era of precision oncology, targeted therapies and immunotherapies represent two of the most exciting innovations in cancer treatments in recent decades:

- **Targeted therapies:** Unlike radiotherapy and chemotherapy which are potent in tumor-killing but affect both healthy and cancerous cells, targeted therapies are designed to recognize and interact with specific targets associated with a particular cancer, and minimize damage to normal cells. The precision of these treatments can not only improve therapeutic efficacy, but also significantly reduce adverse events.
- **Immunotherapies:** While most targeted therapies act by inhibiting the proliferation of cancer cells, immunotherapies actively engage the body’s immune system to attack cancer cells. The core principle of immunotherapy is to activate an immune response to accurately kill these cancer cells.

Despite these advancements, today’s cancer treatment methods remain imperfect, as the genesis of cancer remains highly complex. Certain treatment methods that have shown to be effective for certain types of cancers may be less effective for others. Cancers can also emerge through various pathways, or build resistance to the treatment being administered due to downregulation of tumor-associated antigens or activation of a signaling pathway granting resistance to apoptosis. The tumor microenvironment itself can also significantly impact the efficacy of cancer treatments, by suppressing the body’s immune system or inhibiting the drug’s mechanism as it approaches the tumor.

As such, despite the maturation of multiple approaches for cancer treatment today, there continues to be a significant unmet medical need for differentiated therapeutics to improve duration of response and overall survival in oncology patients, which has only grown larger in number over the years as populations continue to age, screening and detection methods become more prevalent, and lifestyle choices drive increased incidences of cancer.

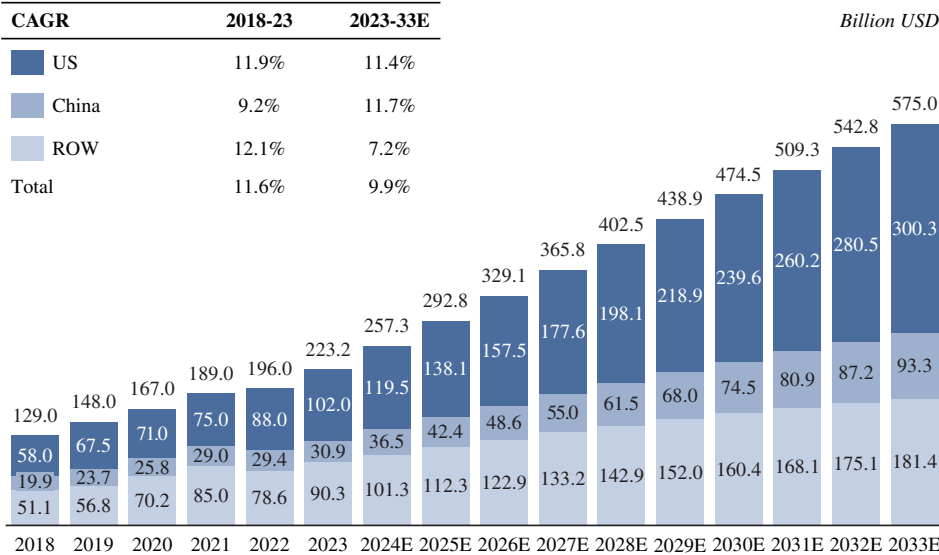
Market Size of the Oncology Drug Market

Cancer, a broad group of diseases in which abnormal cells grow in an uncontrolled manner, is a leading cause of death globally. New incidences have been on the rise, totaling 5.0 million, 2.4 million and 20.4 million in China, the U.S. and globally in 2023, driving the continued growth of the oncology drug market.

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The oncology drug markets globally, in China and in the U.S. have expanded rapidly in recent years. The global oncology drug market rose from US\$129.0 billion in 2018 to US\$223.2 billion in 2023, representing a CAGR of 11.6% and is projected to reach US\$575.0 billion in 2033 at a CAGR of 9.9% from 2023. The following diagram sets forth the size of the oncology drug market globally, in China, the U.S. and the rest of the world for the periods indicated:

Global Oncology Drug Market Size, 2018-2033E



Source: International Agency for Research on Cancer (IARC); NCCR; Chinese Society of Clinical Oncology (CSCO); CIC

Top 10 Cancer Drugs by Sales Globally

In 2023, the top 10 cancer drugs each generated revenues of over US\$4.0 billion, showcasing that there is significant demand for effective cancer drugs. Notably, the top 10 best selling oncology drugs all belong to the field of precision therapeutics.

INDUSTRY OVERVIEW

Global Top 10 Best Selling Oncology Drugs, 2023

Brand name	Target	Modality	Generic name	Company	Indications	First FDA approval date	Global revenue in 2023 (million USD)
Keytruda	PD-1	mAb	pembrolizumab	Merck	NSCLC, TNBC, CRC, GC, etc.	2014/09/04	25,011
Opdivo	PD-1	mAb	nivolumab	BMS	NSCLC, RCC, etc.	2014/12/22	10,031
Darzalex	CD38	mAb	daratumumab	J&J	MM, Amyloidosis	2015/11/16	9,744
Imbruvica	BTkI	Small molecule	ibrutinib	Abbvie, J&J	WM, CLL/SLL, MCL, GVHD	2013/11/13	6,860
Revlimid	CRBN	Small molecule	lenalidomide	BMS	MM, MDS, MCL, FL	2005/12/27	6,097
Tagrisso	EGFR	Small molecule	osimertinib	AstraZeneca	NSCLC	2015/11/13	5,799
Xtandi	AR	Small molecule	enzalutamide	Astellas	PC	2012/08/31	5,067
Ibrance	CDK 4/6	Small molecule	palbociclib	Pfizer	HR+/HER2- BC	2015/02/03	4,753
Imfinzi	PD-L1	mAb	durvalumab	AstraZeneca	UC, NSCLC, SCLC	2017/05/01	4,237
Perjeta	HER2	mAb	pertuzumab	Roche	HER2+ BC	2012/06/08	4,211

Source: FDA, annual reports, CIC

Next-Generation Cancer Therapeutics

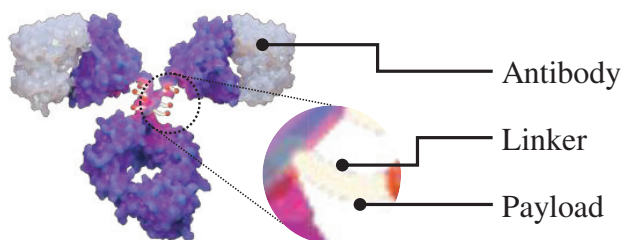
While new approaches to cancer are becoming increasingly diverse, the underlying goals for cancer treatments remain similar to make cancer killing more potent and more specific. Existing targeted therapies and immunotherapies face several limitations that impede their effectiveness in cancer treatment. The emergence of drug resistance, both primary and secondary, poses a significant challenge, and diminishes the long-term efficacy of these therapies. Additionally, cold tumors, characterized by a low level of T cell infiltration, exhibit poor response rates to immunotherapy. Furthermore, the duration of responses to treatment is limited for some patients, translating into a lack of substantial survival benefits. Overcoming these challenges is crucial for the development of more robust and durable cancer therapies.

Antibody drug conjugates (“ADCs”)

ADCs have become a key therapeutic modality in cancer therapies that combine an antibody specific to cancer cells with a potent cytotoxic drug, delivering the payload directly to tumor cancer cells while minimizing impact on healthy tissues. Dubbed as a “magic bullet” due to its targeting properties, ADCs operate by first identifying and attaching themselves to specific antigens on the surface of cancer cells through its embedded antibody. Upon attachment, a biochemical reaction is then initiated in which the ADC is internalized by the cancer cell, the active cytotoxic payload detaches and is released within the cancer cell, and the cancer cell is killed by the cytotoxic agent and undergoes apoptosis. When the cytotoxic drug is released, certain drugs can also diffuse into surrounding cells that may not express the ADC target antigen, resulting in bystander killing. By bringing together specificity and potent cancer-killing properties, ADCs have shown to be able to provide patients with a more effective and safer treatment option than chemotherapies and the previous generation of targeted therapies.

INDUSTRY OVERVIEW

Despite their significant therapeutic potential, developing ADCs is challenging. Progress in early iterations of ADCs were stymied by toxicities and suboptimal efficacy. The following diagram illustrates a typical structure of an ADC:



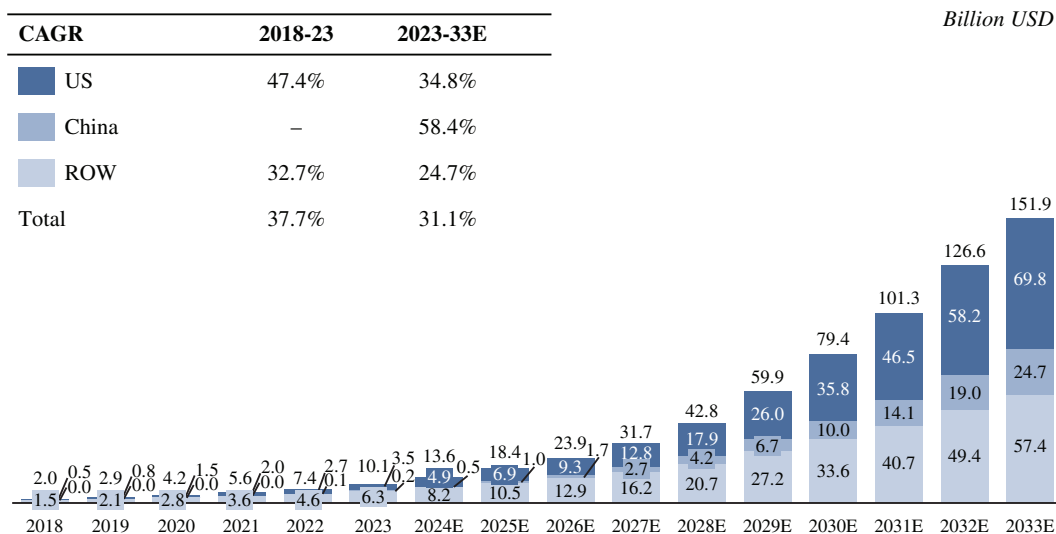
- **Antibody and target selection:** The antibody determines the specificity of the ADC. Target selection involves identifying targets overexpressed on cancer cells with favorable internalization efficiency to enhance ADC efficacy while sparing healthy tissues.
- **Payloads:** Payloads are potent cytotoxic agents that are released upon internalization. Selecting the right payload is essential for inducing targeted cell death while minimizing toxicity to normal cells. Effective payloads disrupt crucial cellular processes, such as DNA replication or microtubule assembly, which leads to cancer cell death.
- **Linker:** ADC development is more complex than other targeted therapies due to the critical role of the linker, which connects the antibody to the cytotoxic drug. The linker is crucial for the efficacy and safety of ADC, as it enables controlled release of the drug within cancer cells through precise cleavage. Inaccurate cleavage of the linker, which leads to premature release of payload into the blood circulation, can decrease efficacy and increase toxicity. Further, cleavable linkers may enhance the bystander effect due to their ability to release the cytotoxic drug into the surrounding environment.
- **DAR and conjugation technology:** The drug-to-antibody ratio (DAR) indicates the number of drug molecules attached to each antibody, which impacts drug loading capability and efficacy. Advanced conjugation technologies enable precise control of DAR, which improves an ADC's therapeutic window, stability in circulation, and manufacturing efficiency. Optimizing DAR and conjugation strategies is crucial for enhancing the effectiveness of ADCs.

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Going forward, innovation in the ADC field is expected to be driven by continued development in each of the four key elements of ADC construction. In antibody and target selection, innovation is occurring in the discovery of novel targets, as well as the development of multi-targeting technology to produce multi-specific drug conjugates; in payloads, innovation is occurring in developing new substance to kill cancer cells; in linker and conjugation technology, innovation is occurring in developing site-specific conjugation and cleavable linkers, which will be able to provide higher safety levels given the more uniform DAR distribution and increased payload capacity, respectively.

As ADCs continue to demonstrate effectiveness in pan-tumor treatment and as front-line therapies, the market size of ADCs is expected to grow significantly. In 2023, the size of the global ADC market reached US\$10.1 billion and is expected to reach US\$151.9 billion by 2033, and its share of the overall oncology market is expected to increase from 4.5% to 26.4% during the same period. The ADC markets in China and U.S. reached US\$0.2 billion and US\$3.5 billion in 2023, respectively, and are expected to grow to reach US\$24.7 billion and US\$69.8 billion in 2033, respectively. Certain ADC drugs have demonstrated significant commercial success, with Enhertu® recording US\$2.4 billion in annual sales in 2023. The following diagram sets forth the size of the ADC market globally, in China, the U.S. and the rest of the world for the periods indicated:

Global ADC Market Size, 2018-2033E



Source: Global Cancer Observatory (GLOBOCAN), NCCR, NCCN, CSCO, Annual reports, CIC

The significant potential of the ADC market has attracted substantial investments by pharmaceutical companies in this field. In 2023 alone, the sector witnessed 62 collaboration transactions for ADC assets, cumulatively valued at over US\$57.5 billion. Notably, our global strategic license and collaboration agreement for BL-B01D1 with BMS, with a total deal value

INDUSTRY OVERVIEW

worth up to US\$8.4 billion, is the largest single-asset collaboration transaction ever in the ADC space in terms of total deal value. The following diagram sets forth the top 10 collaboration transactions within the ADC space, ranked by the deal value for single transaction amount for a single asset:

Top 10 ADC Drug Collaboration Transactions by Global Pharmaceutical Companies (Sorted by Single Transaction Amount for a Single Asset, USD)

Rank	Date	Transferor	Transferee	Transaction Details	Target	Initial upfront payment, Mn USD	Transaction Amount, Mn USD
1	2023/12/12	Biokin/SystImmune	BMS	BL-B01D1	EGFR/HER3	800	8,400
2	2023/10/19	Daiichi Sankyo	Merck	DS-7300a	B7H3	1,500*	7,500
3	2023/10/19	Daiichi Sankyo	Merck	U3-1402	HER3	750*	7,500
4	2023/10/19	Daiichi Sankyo	Merck	DS-6000	CDH6	750*	7,000
5	2019/03/28	Daiichi Sankyo	AstraZeneca	DS-8201	HER2	1,350	6,900
6	2020/07/27	Daiichi Sankyo	AstraZeneca	DS-1062a	TROP2	1,000	6,000
7	2020/09/14	Seagen	Merck	SGN-LIV1A	LIV-1	600	3,200
8	2021/06/17	Eisai**	BMS	MORAb-202	FR α	650	3,100
9	2021/08/09	Remegen	Seagen	RC48	HER2	200	2,600
10	2017/02/10	Immunomedics	Seagen	IMMU-132	TROP2	250	2,000

* From the Daiichi Sankyo official website, not including payments due 12/24 months after contract execution.

** BMS has returned the rights to the FR α ADC to Eisai.




Source: Official websites, news releases, annual reports, CIC

Bispecific and multi-specific antibodies

Bispecific and multi-specific antibodies represent another potentially leading segment in next generation cancer therapeutics, and build upon the science behind monoclonal antibodies, or mAbs, which has been a staple in targeted therapies and immunotherapies in recent years. While mAbs have been effective for many cancers, certain healthy cells can also express the same target that is often overexpressed in cancer cells, leading to on-target, off-tumor toxicity. Moreover, mAbs can experience reduced effectiveness over time, as cancer cells that do not express the specific target continue to proliferate and thereby resulting in drug resistance. As bispecific and multi-specific antibodies have two or more binding sites directed at different antigens or different epitope of one antigen simultaneously, there are several mechanisms of action through which this modality can be exploited. Some bispecific and multi-specific antibodies target two or more complementary tumor-specific/associated antigens to block dual or multiple signaling pathways, thereby increasing its specificity and reduce drug resistance. Another major class of bispecific and multi-specific antibodies are designed to simultaneously bind with antigens on tumor cells and effector T cells, thereby activating and redirecting the T cells to exert tumor killing effect. Some other bispecific and multi-specific antibodies target multiple immune checkpoints, further improving the overall immunomodulatory effect. Compared to monoclonal antibodies, bispecific and multi-specific antibodies add additional antigen-binding sites, thereby increasing specificity, improving tumor cell targeting accuracy, and reducing off-target toxicity.

INDUSTRY OVERVIEW

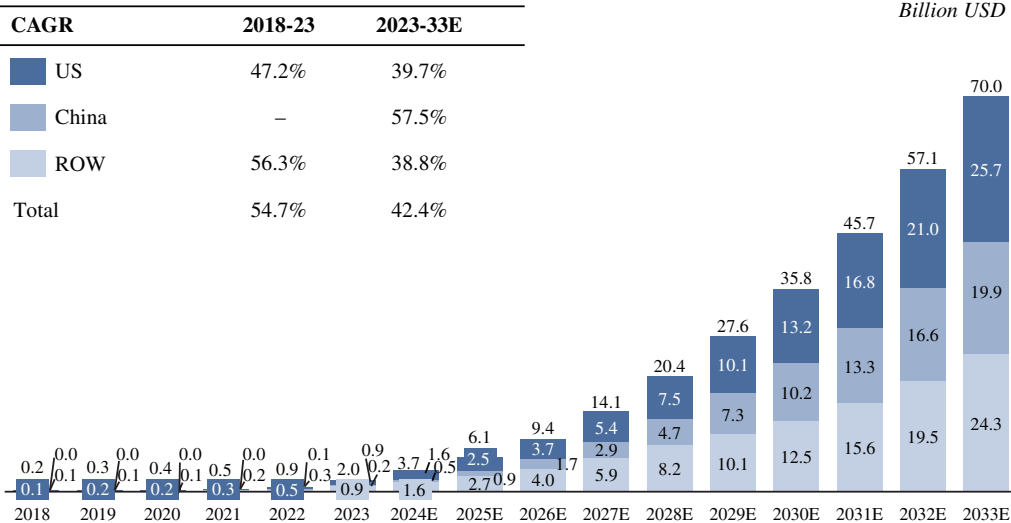
The following table sets forth a comparison between bispecific antibodies with different structure designs and multi-specific antibodies.

Classification	Bispecific antibody drug (BsAb)		Multi-specific antibody drug (MsAb) 
	IgG-like with an Fc region 	Non-IgG-like without an Fc region 	
Representative platform	KiH; CrossMAb; Orthogonal Fab IgG; SEBA	BiTE; Nanobody; DART	GNC; Contorsbody; ProTECT; CODV-Ig
Advantages	CMC: <ul style="list-style-type: none">• Good solubility• High stability Efficacy: <ul style="list-style-type: none">• Longer half-life• Greater therapeutic potential through Fc-mediated ADCC, CDC, and ADCC effects	CMC: <ul style="list-style-type: none">• Lower cost• Higher yield Efficacy: <ul style="list-style-type: none">• Lack of Fc fragment, therapeutic effect solely through antigen binding, lower immunogenicity• High penetration, great potential for solid tumor treatment	<ul style="list-style-type: none">• Synergistic effect of targeted immunotherapy and escape inhibition• Simultaneous blockade/activation of two distinct immune signaling pathways downstream, enhances cell-killing toxicity• Reducing off-target toxicity
Disadvantages	<ul style="list-style-type: none">• Poor permeability• Complex production• Higher immunogenicity	<ul style="list-style-type: none">• Short half-life• Frequent dosing requirement• Poor patient compliance	<ul style="list-style-type: none">• Complex production• Higher cost• Lower yield
Representative Drug	Catumaxomab®	Blinicyto®	No approved drugs currently

Source: Signal Transduction And Targeted Therapy, CIC

The bispecific and multi-specific oncology drugs market is expected to grow significantly in the coming years due to its therapeutic potential. In 2023, the size of the bispecific and multi-specific oncology drugs market was US\$2.0 billion, and is expected to reach US\$70.0 billion by 2033. The bispecific and multi-specifics markets of China and U.S. reached US\$0.2 billion and US\$0.9 billion in 2023, respectively, and are expected to reach US\$19.9 billion and US\$25.7 billion in 2033, respectively. The following diagram sets forth the size of the global oncology drug market for bispecific and multi-specific drugs:

Global Bispecific and Multi-Specific Oncology Drugs Market Size, 2018-2033E



Source: GLOBOCAN, NCCR, NCCN, CSCO, Annual reports, CIC

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“X” drug conjugates (“XDCs”)

While many innovations around ADCs today revolve around modifying the antibody component of ADCs, another area that is rapidly emerging focuses on modifying the payload components. Instead of a typical antibody and cytotoxic payload, alternative formats under the broader conjugate technology umbrella can include radionuclides, peptides, nucleotides and others to achieve targeted and effective cancer-killing. Through different types of conjugate technologies, XDCs have the potential to provide physicians with a variety of weapons to tackle difficult-to-treat cancers.

Taking RDCs as an example, these therapies utilize similar tumor antigen-specific targeting molecules to identify cancer cells, but attack cancer cells with a radioisotope payload instead of a cytotoxic payload, which can be seen as targeted radiotherapy. ARCs are a specialized type of RDCs where the targeting molecule is an antibody. Selecting appropriate nuclides is critical in shaping the efficacy of RDCs. Nuclides with suitable decay characteristics and emission profiles can significantly influence the therapeutic and imaging capabilities of the conjugates. Due to these dual capabilities, RDCs can be used for both diagnosis and treatment. Understanding the mechanism of action concerning how nuclides diffuse and become enriched within target tissues is essential for optimizing radiation delivery. Additionally, aligning logistics systems with the half-life of chosen nuclides is crucial. Proper coordination ensures stability during transportation and timely arrival at target tissues, maximizing therapeutic outcomes. In 2023, the size of the global RDC market was US\$1.5 billion and is expected to reach US\$6.1 billion by 2033 with a CAGR of 15.1%.

TOP 10 CANCER TYPES GLOBALLY

The most prevalent types of cancer globally include lung, breast and colorectal cancers. In China, thyroid, liver and stomach cancers are also major tumor types, while in the U.S., prostate cancer has also been among the most prevalent types of cancer. The following diagram sets forth the top 10 cancer types globally, in China, and in the U.S. in 2023 by incidence rate:

Top 10 Cancer Types Globally, in China, and in the United States in 2023



Source: GLOBOCAN, NCC, IARC, CIC

INDUSTRY OVERVIEW

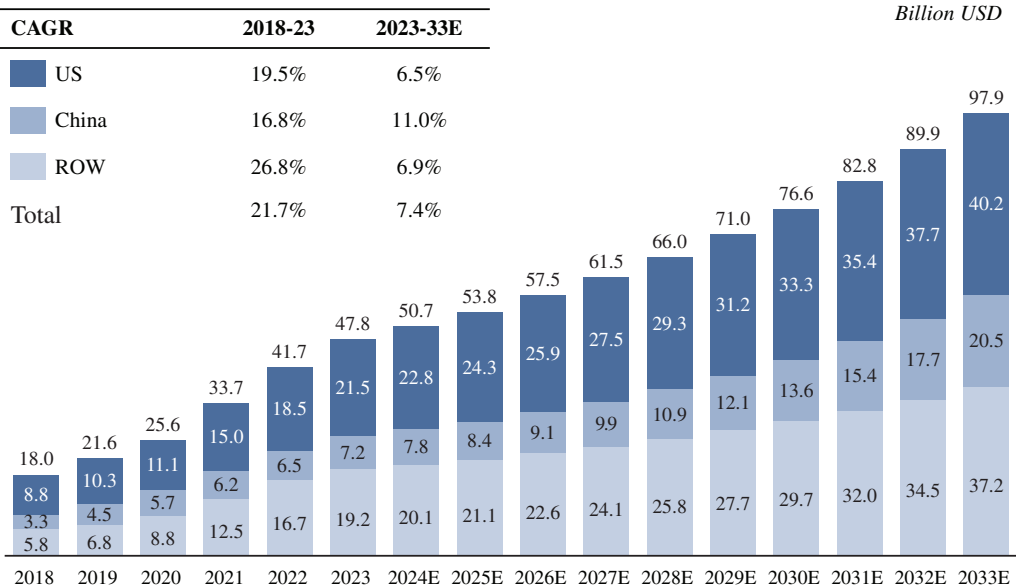
LUNG CANCER

Overview

Lung cancer represents the most common type of cancer and the leading cause of cancer death globally. While causes of lung cancers can vary greatly, cigarette smoking and inhaling hazardous substances are two key causes. In 2023, there were approximately 2.5 million new incidences of lung cancer across the globe, including approximately 1.1 million new incidences of lung cancer in China and approximately 231 thousand in the U.S. The five-year survival rate is approximately 19.7% in China and 20.5% in the U.S.

As the most prevalent cancer indication globally, the size of the lung cancer drug market is significant. In 2023, the size of the global lung cancer drug market was US\$47.8 billion, including US\$7.2 billion in China and US\$21.5 billion in the U.S., respectively, and is expected to reach US\$97.9 billion globally by 2033, including US\$20.5 billion in China and US\$40.2 billion in the U.S., respectively. The following diagram sets forth the size of the global lung cancer drug market:

Global Lung Cancer Drug Market Size, 2018-2033E



Source: GLOBOCAN, NCCR, NCCN, CSCO, annual reports, CIC

NSCLC

There are two primary types of lung cancer: non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC). Of the two, NSCLC represents the more common subtype of lung cancer, accounting for approximately 85% of lung cancer cases.

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In NSCLC, subtypes can be categorized based on the presence or absence of driver gene mutations. Among the common driver genes identified in NSCLC, EGFR mutations (EGFRmut) are the most prevalent in Chinese patients diagnosed with NSCLC, taking up about 40% of cases, and the second most prevalent in U.S. and European patients, comprising approximately 15% of cases.

Unlike their mutated counterparts, EGFR wild-type (EGFRwt) NSCLC refers to tumors that do not possess activating EGFR mutations. EGFRwt NSCLC is further divided into actionable genomic alterations (AGA) positive and AGA negative types, depending on whether the patient exhibits any known driver gene variations. AGA negative NSCLC occurs in around 30% of Chinese patients and around 40% of patients in the U.S. and Europe.

Treatment Paradigm for NSCLC and Their Limitations

NSCLC with EGFR mutations

EGFR-TKIs are the preferred 1L therapy for EGFRmut NSCLC, given their higher efficacy and reduced adverse events compared to conventional platinum-based chemotherapy. However, resistance to EGFR-TKIs inevitably develops in nearly all cases, typically within 8-19 months of treatment.

For patients who have acquired resistance to EGFR-TKIs, chemotherapy remains a standard treatment. However, its effectiveness is constrained, with an ORR of approximately 30%, and an mPFS of 4-5 months, and it is associated with severe and systemic adverse events. Immunotherapy, particularly immune checkpoint inhibitors (ICIs), in combination with chemotherapy and/or anti-angiogenesis therapy, have emerged as promising therapeutic approaches for 2L treatment of EGFRmut NSCLC. Nonetheless, the efficacy of ICI-based combination therapies is limited.

NSCLC with EGFR wild-type

For EGFRwt AGA positive NSCLC, targeted therapies are typically the initial treatment modality. As resistance to targeted therapies is inevitable, chemotherapy is the primary option for 2L treatment.

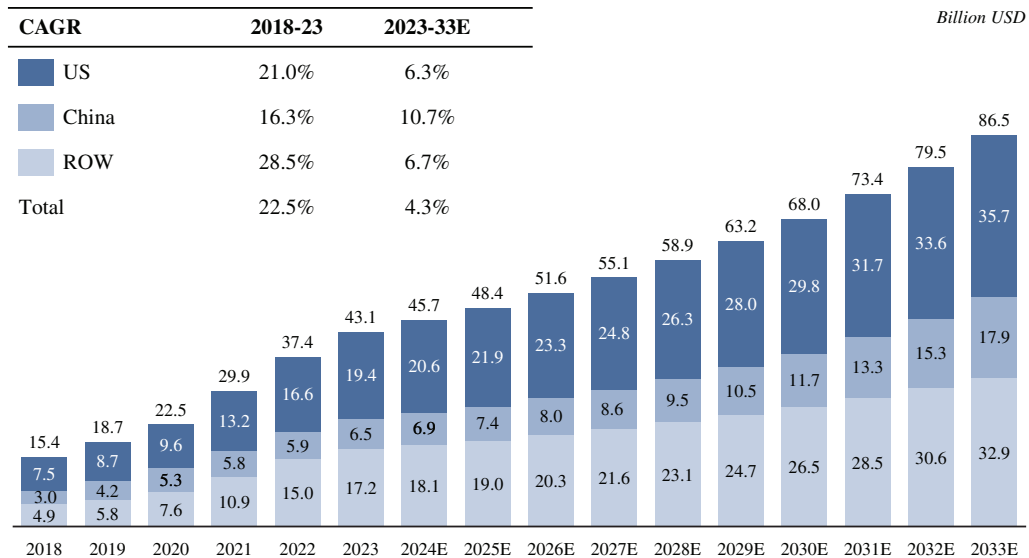
For AGA negative NSCLC, depending on the PD-L1 expression levels, ICI-based mono or combination therapies are recommended as 1L treatment. However, only approximately 20% of patients respond to PD-(L)1 inhibitors, and many eventually develop resistance. Consequently, chemotherapy is typically used as 2L treatment. Despite these efforts, improvements in mPFS remain limited, highlighting the urgent need for new drugs and combination therapies.

INDUSTRY OVERVIEW

Market Opportunity and Competitive Landscape for NSCLC

In 2023, the size of the global NSCLC drug market was US\$43.1 billion, including US\$6.5 billion in China and US\$19.4 billion in the U.S., and is expected to reach US\$86.5 billion globally by 2033, including US\$17.9 billion and US\$35.7 billion in China and in the U.S. The following diagram sets forth the size of the global NSCLC drug market:

Global NSCLC Drug Market Size, 2018-2033E



Source: GLOBOCAN, NCCR, NCCN, CSCO, annual reports, CIC

Although targeted therapy and immunotherapy have made significant strides in the treatment of NSCLC, persistent challenges such as drug resistance and limited efficacy underscore the need for continued research in this area. In recent years, ADCs have emerged as a promising cancer therapeutic approach due to their targeted delivery mechanism and strong tumor-killing activity, presenting substantial clinical potentials for the treatment of NSCLC.

Several potential ADC targets have been identified for NSCLC, such as EGFR, HER3, HER2, TROP2, and c-MET. Enhertu[®] has been approved for HER2 mutant NSCLC in the U.S. and EU. As of the Latest Practicable Date, over 20 ADC candidates were under clinical development for this cancer type. Notably, our BL-B01D1 is the first and only bispecific ADC to enter Phase III clinical development globally. BL-B01D1 has so far generated one of the most promising clinical data profiles for late-line NSCLC.

INDUSTRY OVERVIEW

The following diagram sets forth a pipeline of ADC drug candidates targeting NSCLC which are being evaluated in clinical trials conducted in China and/or the U.S., with the most advanced stage in Phase III:

Target	Candidate	Company	Most advanced stage ¹	Trial number ²	Indication ^{2,4}	First posted date ²	Location ²
HER3xEGFR	BL-B01D1	Biokin	III	• NCT06382129 • NCT06382116	• EGFRwt NSCLC • EGFRmut a/mNSCLC	• 2024-04-24 • 2024-04-24	• China • China
	Dato-DXd	Daiichi Sankyo/AstraZeneca	III	• NCT04656652	• EGFRmut a/mNSCLC • EGFRwt a/mNSCLC	• 2020-12-07	• Global
TROP2	Trodelvy ³	Merck/Gilead	III	• NCT05609968	• mNSCLC	• 2022-11-08	• Global
	SKB264	Merck/Kelun	III	• NCT06074588 • NCT06170788	• EGFRmut a/mNSCLC • mNSCLC	• 2023-10-10 • 2023-12-14	• Global • Global
	Enhertu ³	Daiichi Sankyo/AstraZeneca	III	• NCT05048797	• HER2mut a/mNSCLC	• 2021-09-17	• Global
HER2	SHR-A1811	HengRui	III	• NCT06430437	• HER2mut a/mNSCLC	• 2024-05-28	• China

Source: *ClinicalTrials.gov, CDE, CIC*

Notes:

1. Represent the most advanced stage of candidates in China and the U.S.
2. Represent the trial numbers, indications, first posted dates and locations of the clinical trials at the most advanced stage evaluating corresponding drug candidates across China and the U.S.
3. Represent marketed drugs which are being explored for indication expansion.
4. a/m NSCLC refers to advanced/metastatic non-small cell lung cancer.

BREAST CANCER (BC)

Overview

BC is the most commonly diagnosed malignant tumor in women worldwide and one of the leading causes of death from malignant tumors. Like many other cancers, causes of BC can vary, but genetic mutations, estrogen and progesterone exposure and lifestyle factors and others have been attributed to the heightened risk of BC. In 2023, there were approximately 2.3 million new incidences of BC, including approximately 366 thousand incidences in China and 279 thousand incidences in the U.S.

Types of BC and Treatment Paradigm

BC can be classified into three subtypes based on hormone receptor status and HER2 status, each with different characteristics and treatment approaches.

INDUSTRY OVERVIEW

HR+/HER2- BC

HR+/HER2- BC is characterized by positive hormone receptor (HR) level without overexpression of HER2 protein, representing approximately 75% of BC cases. The HR+/HER2- subtype has been associated with improved survival compared with other subtypes in the metastatic setting.

1L treatment for HR+/HER2- BC includes hormone therapies, such as aromatase inhibitors (AIs), and targeted therapies, such as CDK4/6 inhibitors. In 2L settings, primary treatment options include fulvestrant coupled with CDK4/6 inhibitors in CDK4/6 inhibitor naive patients, and other CDK4/6 inhibitors coupled with hormone therapy if previously treated with CDK4/6 inhibitor. Despite initial treatment efficacy, existing therapies are less effective in managing recurrent or metastatic HR+/HER2- cases, necessitating innovative treatments to delay disease progression and improve survival rates.

HER2+ BC

HER2+ BC, characterized by the overexpression of HER2 protein, accounts for approximately 15% of BC cases. Progression of HER2+ subtype is typically more aggressive than HR+/HER2- subtype.

1L treatment for HER2+ BC includes HER2-targeted monoclonal antibody and HER2 TKI, often used in combination with chemotherapy. For patients who fail to respond to HER2-targeted monoclonal antibody, 2L treatments include targeted therapy, such as pyrotinib, combined with chemotherapy, and HER2-targeted ADC, such as T-DM1 and T-DXd. Despite the substantial improvements in prognosis due to HER2-targeted therapies, patients often develop primary or acquired resistance, resulting in disease recurrence or progression.

Triple-negative Breast Cancer (TNBC)

TNBC is characterized by the absence of estrogen receptors, progesterone receptors, and HER2 protein, comprising approximately 10% of BC cases. Compared to other forms, it is a particularly aggressive subtype known for its extremely high drug resistance, progression, and poor prognosis.

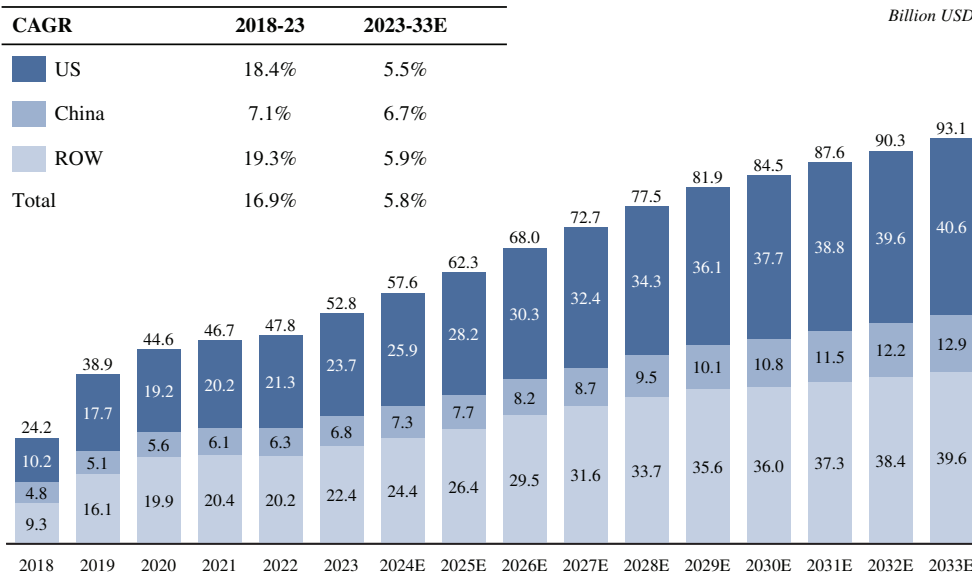
Due to the lack of hormone receptors and HER2 expression, TNBC is not responsive to conventional hormone therapy or HER2-targeted therapy. Patients with TNBC often rely on chemotherapy as the primary treatment, which has limited efficacy and poor prognosis. There is an urgent need for effective treatment options specifically for TNBC to improve survival rates and quality of life for this patient group.

INDUSTRY OVERVIEW

Market Opportunity and Competitive Landscape in BC

As one of the most prevalent cancer indications globally, the size of the BC drug market is significant. In 2023, the size of the BC drug market was US\$52.8 billion, including US\$6.8 billion in China and US\$23.7 billion in the U.S., respectively, and is expected to reach US\$93.1 billion globally by 2033, including US\$12.9 billion in China and US\$40.6 billion in the U.S., respectively. The following diagram sets forth the global market size of BC drugs.

Global BC Drugs Market Size, 2018-2033E



Source: GLOBOCAN, NCCR, NCCN, CSCO, annual reports, CIC

In recent years, efforts and investments in ADC research has led to numerous breakthroughs and approvals for cancer treatment, which has significantly impacted the management of BC. ADCs such as Enhertu[®] for HER2-low disease and Trodelvy[®] for TNBC have provided valuable options for challenging subtypes of BC. However, essential questions still need to be addressed, including the strategies to improve effectiveness and safety, and overcome resistance mechanisms.

INDUSTRY OVERVIEW

As of the Latest Practicable Date, over 20 ADC candidates were under clinical development for BC. Our BL-B01D1 is under Phase III clinical trials for both HR+/HER2- BC and TNBC, and our BL-M07D1 is under a Phase III clinical trial for HER2+ BC. The following diagram sets forth a pipeline of ADC drug candidates targeting BC which are being evaluated in clinical trials conducted in China and/or the U.S., with the most advanced stage in Phase III:

Target	Candidates	Company	Highest stage ¹	Trial number ²	Indication ^{2,4}	First posted date ²	Location ²
HER3/EGFR	BL-B01D1	Biokin	III	• NCT06382142 • NCT06343948	• a/mTNBC • HER2-/HR+ a/m/BC	• 2024-04-24 • 2024-04-03	• China • China
	FDA018	Shanghai Fudan-Zhangjiang Bio-Pharmaceutical	III	• NCT06519370	• a/m/TNBC	• 2024-07-25	• China
TROP2	ESG401	Shanghai Escugen Biotechnology	III	• NCT06383767	• HER2-/HR+ a/m/BC	• 2024-04-25	• China
	SKB264	Merck Sharp & Dohme/ Klus Pharma	III	• NCT06081959	• HER2-/HR+ a/m/BC	• 2023-10-13	• China
	Trodelvy ³	Gilead Sciences	III	• NCT05382299 • NCT05840211	• a/mTNBC • HER2-/HR+ a/m/BC	• 2022-05-19 • 2023-05-03	• Global • Global
	Dato-DXd	AstraZeneca	III	• NCT05629585 • NCT05104866	• early/a/mTNBC • HR+/HER2-mBC	• 2022-11-29 • 2021-11-03	• Global • Global
	Kadcyla ³	Hoffmann-La Roche	III	• NCT04873362	• HER2+ BC	• 2021-05-05	• Global
	Enhertu ³	AstraZeneca/ Daiichi Sankyo	III	• NCT05113251 • NCT04784715 • NCT04949423	• HER2+ earlyBC • HER2+ mBC • HER2-/HR+ a/m/BC	• 2021-11-09 • 2021-03-05 • 2020-07-31	• Global • Global • Global
	DB-1303	DualityBio	III	• NCT06365428 • NCT06018337	• HER2+ mBC • HR+/HER2-a/mBC	• 2024-02-20 • 2023-08-30	• China • Global
	SHR-A1811	HengRui	III	• NCT05814354	• HER2-low m/BC	• 2023-04-14	• China
	TQB2102	Chia Tai Tianqing	III	• NCT06561607	• HER2-low m/BC	• 2024-08-20	• China
	DP303c	CSPC ZhongQi	III	• NCT06313086	• HER2+ aBC	• 2024-03-15	• China
HER2	BL-M07D1	Biokin	III	• NCT06316531	• HER2+ a/mBC	• 2024-03-18	• China
	FS-1502	Shanghai Fosun	III	• NCT05755048	• HER2+ a/mBC	• 2023-03-06	• China
	JSKN003	Jiangsu Alphamab	III	• NCT06079983	• HER2-low m/BC	• 2023-10-12	• China
	MRC002	Shanghai Miracogen	III	• NCT04924699	• HER2+ a/mBC	• 2021-06-14	• China
	RC48	RemeGen	III	• NCT04400695	• HER2-low a/BC	• 2020-05-22	• China

Source: ClinicalTrials.gov, CDE, CIC

Notes:

1. Represent the most advanced stage of candidates in China and the U.S.
2. Represent the trial numbers, indications, first posted dates and locations of the clinical trials at the most advanced stage evaluating corresponding drug candidates across China and the U.S.
3. Represent marketed drugs which are being explored for indication expansion.
4. a/m/r BC refers to advanced/metastatic/recurrent breast cancer.

Source: ClinicalTrials.gov, CDE, CIC

Notes:

1. Represent the indications being evaluated in Phase III clinical trials across China and the U.S.
2. Represent marketed drugs which are being explored for indication expansion.

INDUSTRY OVERVIEW

OTHER CANCER TYPES

In addition to NSCLC and BC, we have observed robust anti-tumor activity and a manageable safety profile from BL-B01D1 consistently across a variety of other solid tumor types, including but not limited to CRC, PC, GC, HNSCC, liver cancer, CC, UC, EC, endometrial cancer, RCC, OC, SCLC, BTC and NPC. These clinical results have demonstrated BL-B01D1’s potential to become the next backbone cancer therapy and to even replace conventional chemotherapy as the pan-tumor standard of care. In addition, other assets in our pipeline have demonstrated anti-tumor activity in a wide variety of tumor types, including blood cancers.

The following chart summarizes the incidences and prevalence of selected cancer indications targeted by BL-B01D1 and our other pipeline assets.

Epidemiology of the Selected Cancers

Cancer type	Global			The U.S.			China		
	2023	2028E	2033E	2023	2028E	2033E	2023	2028E	2033E
Solid tumor	Incidence (thousand people)								
CRC	1,969	2,224	2,511	163	175	190	537	631	716
PC	1,498	1,713	1,941	235	256	270	146	212	282
GC	916	1,040	1,291	26	29	31	353	330	313
HNSCC	865	1,050	1,065	52	56	59	134	146	156
Liver Cancer	846	953	1,127	44	48	51	365	351	341
CC	675	742	804	14	15	15	156	183	208
UC	501	570	653	66	75	84	80	87	93
EC	473	534	675	19	21	23	220	203	190
Endometrial cancer	431	485	547	67	71	75	79	85	91
RCC	381	427	465	62	67	71	62	61	60
OC	332	365	398	22	23	25	62	65	67
SCLC	313	352	399	35	39	42	166	196	223
BTC	256	294	333	14	15	16	101	89	82
NPC	119	135	146	2	2	2	51	50	50
Blood cancer	Prevalence (thousand people)								
NHL	3,032	3,297	3,536	460	473	486	676	827	962
ALL	380	368	361	22	19	17	187	184	180
AML	207	213	219	27	28	29	25	26	26

Source: GLOBOCAN; NCC; IARC; GHDx; CIC

INDUSTRY OVERVIEW

GENERICS AND TRADITIONAL CHINESE MEDICINES

Anesthesia

Overview

Anesthesia drugs induce a temporary loss of sensation or awareness, and are essential in medical practice to facilitate the performance of surgical procedures and other interventions that would otherwise cause significant pain or distress to patients. These drugs can be administered through various modalities, including inhalation, intravenous injection, and regional nerve block techniques. Anesthesia drugs are broadly categorized into general anesthetics, which induce a reversible state of unconsciousness, and local anesthetics, which cause localized numbness. The administration and choice of anesthesia depend on factors such as the type of surgery, patient health status, and expected duration of the procedure. Advances in anesthesia drugs and techniques continue to improve patient safety, recovery times, and overall outcomes in surgical care.

Market Opportunities and Entry barriers

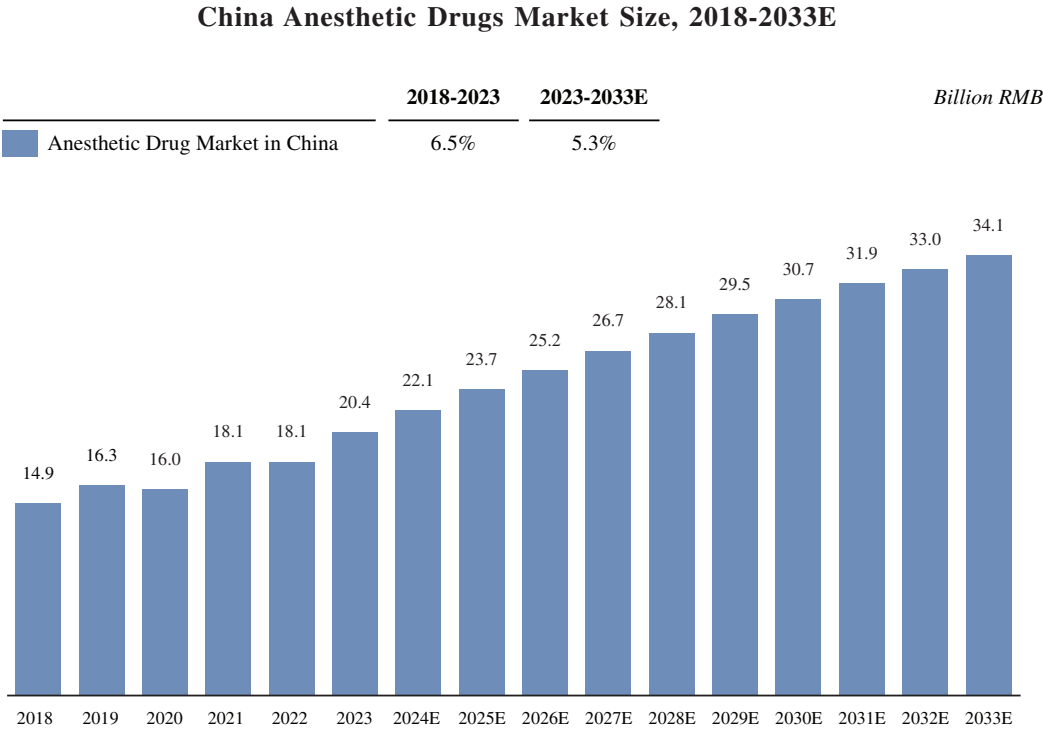
The anesthesia drug market in China is primarily driven by an increasing prevalence of chronic diseases, advances in R&D and funding and emphasis on patient safety and regional anesthesia. While anesthesia as a drug class has been established for many years, the market continues to grow as incidences of chronic conditions such as cancer and cardiovascular diseases continue to increase, many of which require surgical intervention, which in turn leads to greater demand for general anesthesia. In addition, sustained R&D expenditure from pharmaceutical companies has been funding the pursuit for more effective drugs with better safety profile in the anesthesia drug treatment landscape, driving market growth. The anesthesia market is also characterized by certain entry barriers, such as regulation. Anesthesia drugs are highly regulated and as such, bringing a new product to market requires significant costs and time. Physicians also tend to favor familiar brands, which in turn favors current market incumbents.

The forecasted growth of the anesthesia market in China is driven by increasing demand for anesthesia in both surgical and procedural settings. According to CIC, the number of inpatient surgeries in China is expected to increase from 83.0 million in 2023 to 102.6 million in 2032, driving the adoption of anesthesia drugs in perioperative treatments to ensure patient preparation and safety during surgery. Additionally, procedures conducted outside the operating room, such as diagnostic endoscopies, are also boosting demand. The number of diagnostic endoscopic procedures under general anesthesia in China is expected to grow from 17.5 million in 2023 to 26.9 million in 2032, driven by an aging population and growing health awareness, with anesthesia drugs playing a crucial role in stabilizing patients to enhance diagnostic accuracy.

INDUSTRY OVERVIEW

Market Size and Competitive Landscape of Anesthesia Drugs in China

The anesthesia drug market in China rose from RMB14.9 billion in 2018 to RMB20.4 billion in 2023 at a CAGR of 6.5% and is projected to reach RMB34.1 billion in 2033 at a CAGR of 5.3% from 2023. The market experienced contractions in 2020 and 2022 due to the combined impact of the COVID-19 pandemic and VBP policies, which resulted in a reduction in drug prices and usage of anesthesia drugs. The following diagram sets forth the size of the anesthesia drug market in China:



Source: Annual reports, National Bureau of Statistics of China, Chin J Crit Care Intensive Care Med., CIC

Our three major products in this therapeutic area are Lewejing 乐维静® (propofol emulsion injection), Leweitai 乐维泰® (propofol medium and long chain fat emulsion injection), and Youmeining 右美宁® (dexmedetomidine hydrochloride injection). As of the Latest Practicable Date, there were 29 propofol emulsion injection, 50 propofol medium and long chain fat emulsion injection products, and over 30 dexmedetomidine hydrochloride injection products in China. According to CIC, in the China market, Lewejing ranked the fourth with a market share of 12.1%; Leweitai ranked the third with a market share of 20.1%; and Youmeining ranked eighth with a market share of 1.2% in each product’s respective market in 2023. In terms of drug price, propofol emulsion injection was covered in the ninth national VBP scheme and experienced a price cut of around 70%; propofol medium and long chain fat emulsion injection was covered in the fourth national VBP scheme and experienced price cut of around 80%; dexmedetomidine hydrochloride injection was included in the first “4+7” national VBP scheme in December 2018 and the expanded “4+7” national VBP scheme in September 2019 with nearly no price cut, and experienced an over 80% price cut on average in the subsequent bidding price for regional VBP varies.

INDUSTRY OVERVIEW

The following tables set forth the top five players in the propofol emulsion injection, propofol medium and long chain emulsion injection and the top ten players in the dexmedetomidine hydrochloride injection markets in China, in terms of revenue in 2023:

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2023
Propofol Injectable Emulsion	20ml:0.2g 50ml:0.5g 50ml:1.0g	ASPEN PHARMA	2017	–	45.2%
Propofol Injectable Emulsion	20ml:0.2g 50ml:0.5g 50ml:1.0g	Fresenius Kabi Austria GmbH	2017	–	21.4%
Propofol Injectable Emulsion	10ml:0.1g 10ml:0.2g 20ml:0.2g 50ml:0.5g 50ml:1.0g	西安力邦製藥 Xi'an Libang Pharmaceutical	1999	2023.11 (20ml:0.2g)	16.6%
Propofol Injectable Emulsion	10ml:0.1g 20ml:0.2g 50ml:0.5g	四川國瑞藥業 Sichuan Guorui Pharmaceutical	2003	2023.11 (50ml:0.5g)	12.1%
Propofol Injectable Emulsion	10ml:0.2g 20ml:0.2g 20ml:0.4g 50ml:0.5g 50ml:1.0g	廣東嘉博製藥 Jiabo Pharmaceutical	2005	2023.11 (20ml:0.2g)	2.5%

Source: NMPA; CIC

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2023
Propofol Medium and Long Chain Fat Emulsion Injection	10ml:0.1g 20ml:0.2g 50ml:0.5g 50ml:1.0g 100ml:1.0g	Fresenius Kabi Austria GmbH	2015	2021.01 (20ml:0.2g)	32.6%
Propofol Medium and Long Chain Fat Emulsion Injection	10ml:0.1g 20ml:0.2g 50ml:0.5g 50ml:1.0g 100ml:1.0g	廣東嘉博製藥 Jiabo Pharmaceutical	2013	–	20.5%
Propofol Medium and Long Chain Fat Emulsion Injection	10ml:0.1g 20ml:0.1g 20ml:0.2g 50ml:0.5g 100ml:1.0g	四川國瑞藥業 Sichuan Guorui Pharmaceutical	2014	–	20.1%
Propofol Medium and Long Chain Fat Emulsion Injection	20ml:0.2g	江蘇盈科生物製藥 Jiangsu Yingke Biopharmaceutical	2020	2021.01 (20ml:0.2g)	9.4%
Propofol Medium and Long Chain Fat Emulsion Injection	20ml:0.2g 50ml:0.5g 50ml:1.0g	揚子江藥業集團 Yangtze River Pharmaceutical	2021	2021.01 (20ml:0.2g)	8.8%

Source: NMPA; CIC

INDUSTRY OVERVIEW

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2023
Dexmedetomidine Hydrochloride Injection	2ml:0.2mg 50ml:0.2mg	揚子江藥業集團 Yangtze River Pharmaceutical	2021	2019.10 (2ml:0.2mg)	74.7%
Dexmedetomidine Hydrochloride Injection	1ml:0.1mg 2ml:0.2mg 50ml:0.2mg	江蘇恒瑞醫藥 Jiangsu Hengrui Pharmaceutical	2009	–	12.4%
Dexmedetomidine Hydrochloride Injection	2ml:0.2mg	南京正大天晴製藥 Nanjing Chia-Tai Tianqing Pharmaceutical	2021	–	2.6%
Dexmedetomidine Hydrochloride Injection	1ml:0.1mg 2ml:0.2mg	辰欣藥業 Cisen Pharmaceutical	2016	–	2.4%
Dexmedetomidine Hydrochloride Injection	2ml:0.2mg	江蘇恩華藥業 Jiangsu Nhwa Pharmaceutical	2011	–	1.8%
Dexmedetomidine Hydrochloride Injection	2ml:0.2mg	四川美大康華康藥業 Sichuan Meidakang Huakang Pharmaceutical	2021	–	1.5%
Dexmedetomidine Hydrochloride Injection	2ml:0.2mg	國藥集團工業 China National Pharmaceutical Industry	2020	–	1.3%
Dexmedetomidine Hydrochloride Injection	1ml:0.1mg 2ml:0.2mg 4ml:0.4mg 10ml:1.0mg 20ml:0.08mg 50ml:0.2mg 100ml:0.4mg	四川國瑞藥業 Sichuan Guorui Pharmaceutical	2011	–	1.3%
Dexmedetomidine Hydrochloride Injection	1ml:0.1mg 2ml:0.2mg	石家莊第四製藥 Shijiazhuang No. 4 Pharmaceutical	2021	–	0.5%
Dexmedetomidine Hydrochloride Injection	1ml:0.1mg 2ml:0.2mg	湖南科倫製藥 Hunan Kelun Pharmaceutical	2018	–	0.5%

Source: NMPA; CIC

Parenteral Nutrition

Overview

Parenteral nutrition is a life-sustaining therapy that offers nutritional support to patients who are unable to meet their nutritional needs through oral or enteral routes. Medium and long chain fat emulsion injections are a critical component of parenteral nutrition, supplying essential fatty acids and calories that help maintain energy balance, support cellular functions, and modulate immune responses. These emulsions are composed of triglycerides derived from medium-chain fatty acids (MCFAs) and long-chain fatty acids (LCFAs), offering a balanced and efficient energy source. The integration of both MCFAs and LCFAs enhances the metabolic profile and tolerance of the fat emulsion, making it suitable for a wide range of patients, including those with impaired fat metabolism. The market size for medium and long chain fat emulsion in China was RMB0.7 billion in 2023, according to CIC.

Market Opportunities and Entry barriers

The parenteral nutrition market in China is primarily driven by continuous advancements in formulation. These formulations are becoming more precise and personalized, with researchers optimizing amino acid compositions to better meet the needs of various patient groups. The diversification of product specifications presents significant opportunities. Traditional single-chamber bags require a complex mixing process before use, increasing the risk of contamination and operational errors. In contrast, multi-chamber bags store different ingredients separately and allow for simple mixing before use, greatly simplifying the process and enhancing safety and convenience.

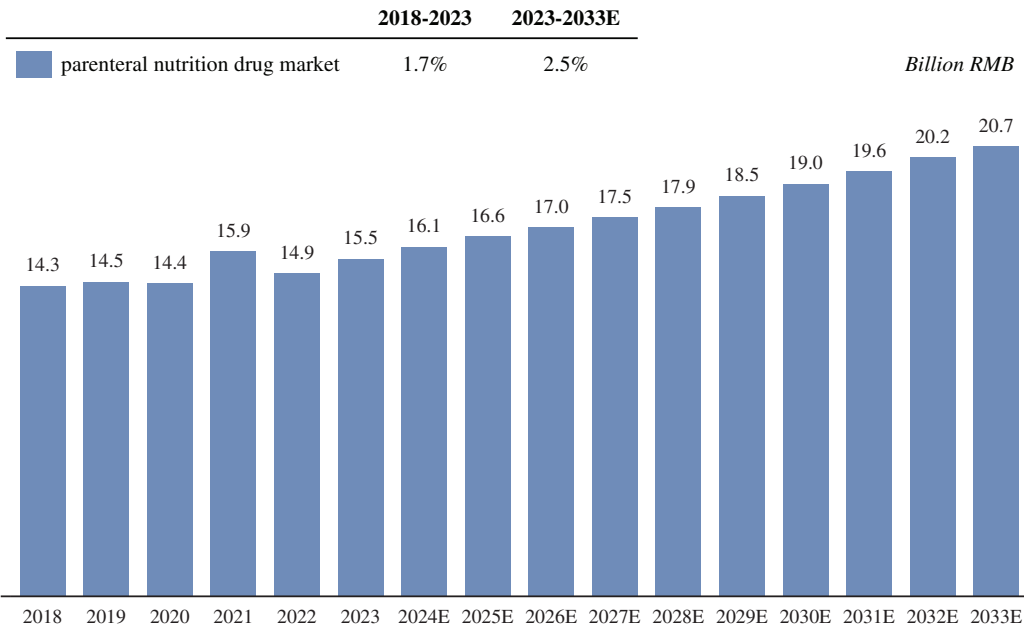
INDUSTRY OVERVIEW

The parenteral nutrition market also faces significant technical and investment entry barriers. Developing parenteral nutrition preparations involves complex formula design, sophisticated production processes, and stringent quality control, requiring extensive experience. Furthermore, the R&D cycle is lengthy and demands substantial investment, covering activities from formula research to clinical trials and market approval.

Market Size

The parenteral nutrition drug market in China rose from RMB14.3 billion in 2018 to RMB15.5 billion in 2023 at a CAGR of 1.7% and is projected to reach RMB20.7 billion in 2033 at a CAGR of 2.5% from 2023. The market experienced a contraction in 2022 due to the impact of the VBP policies, which resulted in a reduction in drug prices. The following diagram sets forth the size of the parenteral nutrition drug market in China:

China Parental Nutrition Drug Market Size, 2018-2033E



Source: Annual reports, Expert interviews, CIC

INDUSTRY OVERVIEW

Competitive Landscape of Parenteral Nutrition in China

Our major product in this therapeutic area is Tianze 天泽® (medium and long chain fat emulsion injection). As of the Latest Practicable Date, there were over 50 medium and long chain fat emulsion injection products in China. According to CIC, Tianze was ranked sixth in China’s medium and long chain fat emulsion injection market, with a market share of approximately 5.1% in 2023, and medium and long chain fat emulsion injection was covered in the fifth national VBP and experienced price cut of around 20% in historical price. The following table sets forth the top ten market players of medium and long chain fat emulsion injection in China in terms of revenue in 2023:

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2023
Medium and Long-chain Fat Emulsion Injection	100ml 250ml	B. Braun	2014	2021.06 (250ml)	37.5%
Medium and Long-chain Fat Emulsion Injection	100ml 250ml	四川科倫藥業 Sichuan Kelun Pharmaceutical	2017	2021.06 (250ml)	24.8%
Medium and Long-chain Fat Emulsion Injection	250ml	廣東嘉博製藥 Jiabo Pharmaceutical	2021	2021.06 (250ml)	13.6%
Medium and Long-chain Fat Emulsion Injection	100ml 250ml 500ml	Baxter	2001	–	8.1%
Medium and Long-chain Fat Emulsion Injection	100ml 250ml	西安力邦製藥 Xi'an Libang Pharmaceutical	2012	–	6.8%
Medium and Long-chain Fat Emulsion Injection	100ml 250ml 500ml	四川國瑞藥業 Sichuan Guorui Pharmaceutical	2012	–	5.1%
Medium and Long-chain Fat Emulsion Injection	250ml 500ml	安徽豐原藥業 Anhui BBKA Pharmaceuticals	2011	–	2.1%
Medium and Long-chain Fat Emulsion Injection	250ml	石家庄第四製藥 Shijiazhuang No. 4 Pharmaceutical	2017	–	1.3%
Medium and Long-chain Fat Emulsion Injection	500ml	辰欣藥業 Cisen Pharmaceutical	2010	–	0.8%
Medium and Long-chain Fat Emulsion Injection	100ml	重慶樂友製藥 Chongqing YaoPharma CO., Ltd.	2011	–	–

Source: NMPA; CIC

Anti-Infective Drugs

Overview

Anti-infective drugs play a critical role in combating infections caused by bacteria, viruses, fungi, and parasites, thus safeguarding public health. They are indispensable in preventing and treating infectious diseases, which, if left unchecked, can lead to significant morbidity and mortality. Anti-infective drugs encompass a wide range of categories, including antibiotics, antivirals, antifungals, and antiparasitics. These medications work through various mechanisms, such as inhibiting the growth of pathogens, disrupting their cellular structures, or interfering with their metabolic pathways. The global demand for anti-infective drugs is driven by factors such as the prevalence of infectious diseases, the emergence of drug-resistant strains, and the continuous need for new and more effective treatments.

INDUSTRY OVERVIEW

Market Opportunities and Entry barriers

The anti-infective drugs market in China is driven by the continued occurrence of infectious diseases such as influenza, and the COVID-19 pandemic, which in turn have continued to increase demand for effective antiviral therapies. Additionally, R&D efforts dedicated by pharmaceutical companies to overcome anti-infective drug resistance and improve drug safety profile are driving market growth. The anti-infective drugs market is also characterized by several entry barriers, including the need to invest amounts of funding into R&D, accumulate high levels of technical expertise to develop effective anti-infective drugs with stringent pharmaceutical regulations and safety standards in China.

Market Size

The anti-infective drug market in China declined from RMB212.8 billion in 2018 to RMB178.9 billion in 2023 at a CAGR of -3.4% and is projected to reach RMB244.4 billion in 2033 at a CAGR of 3.2% from 2023. The market experienced contractions in 2020 and 2022, and 2021 to 2022 due to the combined impact of the COVID-19 pandemic and VBP policies, which resulted in a reduction in drug prices. The following diagram sets forth the size of the anti-infective drugs market in China:

China Anti-infective Drugs Market Size, 2018-2033E



Source: Annual reports, National Bureau of Statistics of China, Chin J Tuberc Respir Dis., CIC

INDUSTRY OVERVIEW

Competitive Landscape of Anti-Infective Drugs in China

Our major products in this therapeutic area are Xinbolin 新博林® (ribavirin granule) and Aobolin 奧博林® (ornidazole capsule). As of the Latest Practicable Date, there were over 700 ribavirin products and over 100 ornidazole products in China, according to CIC. Xinbolin was ranked sixth in China’s ribavirin market, with a market share of approximately 3.4% in 2023 and the historical price of ribavirin granule remained stable; Aobolin was ranked 17th in China’s ornidazole market, with a market share of approximately 0.5% in 2023 and historical price of ornidazole drugs dropped owing to the coverage of ornidazole tablets in the seventh national VBP scheme leading to a price cut of around 80% and ornidazole injection in the eighth national VBP scheme which resulted in a price cut of around 90%, according to the same source. The following tables set forth the top ten players in the Ribavirin and Ornidazole markets in China, in terms of revenue in 2023:

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2023
Ribavirin/Ribavirin Spray	0.02g; 0.05g; 0.1g (oral) 0.075g (spray)	上海信誼藥廠 Shanghai Sine Pharmaceutical	1995	N/A	13.9%
Ribavirin Injection	1ml:0.1g 5ml:0.5g 10ml:1.0g	中嘉生物科技(湖北) Zhongjia Biopharm (Hubei)	1999	N/A	13.2%
Ribavirin Injection	1ml:0.1g 2ml:0.25g	陝西頓斯製藥 Shaanxi Dunsui Pharmaceutical	1999	N/A	4.1%
Ribavirin Injection	1ml:0.1g 2ml:0.1g 5ml:0.5g	辰欣藥業 Cisen Pharmaceutical	1999	N/A	4.1%
Ribavirin Injection	1ml:0.05g 1ml:0.1g	重慶迪康長江製藥 Chongqing Dikang Changjiang Pharmaceutical	2002	N/A	3.7%
Ribavirin Granules/Ribavirin Effervescent Granules	0.05g; 0.1g; 0.15g (granules) 0.15g (effervescent granules)	四川百利藥業 Sichuan Baili Pharmaceuticals	2010	N/A	3.4%
Ribavirin	0.05g 0.1g	廣東華南藥業集團 Guangdong Huanan Pharmaceutical	1995	N/A	3.3%
Ribavirin Injection	1ml:0.1g	青島金峰製藥 Qingdao Jinfeng Pharmaceutical	1999	N/A	2.9%
Ribavirin Injection	1ml:0.1g 2ml:0.1g	山東益康藥業 Shandong Yikang Pharmaceutical	1999	N/A	2.8%
Ribavirin and Glucose Injection/Ribavirin Injection	250ml:0.5g; 100ml:0.2g (ribavirin and glucose injection) 2ml:0.25g; 1ml:100mg (ribavirin injection)	湖北津藥藥業 Hubei TianYao Pharmaceutical	1999	N/A	2.3%

Source: NMPA; CIC

INDUSTRY OVERVIEW

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2023
Ornidazole Tablet/Ornidazole Injection/Ornidazole and Sodium Chloride Injection	3ml:0.5g; etc. (injection) 100ml:0.25g; etc. (ornidazole and sodium chloride injection)	四川科倫製藥 Sichuan Kelun Pharmaceutical	2005	2023.03 (3ml:0.5g, injection) 2022.07 (0.25g, tablet)	33.7%
Ornidazole Injection/Ornidazole Vaginal Effervescent Tablets/Ornidazole Capsules	3ml:0.5g; etc. (injection) 0.5g (vaginal effervescent tablets) 0.25g (capsules)	西安萬隆製藥 Xi'an Wanlong Pharmaceutical	2003	2023.03 (3ml:0.5g, injection)	19.9%
Ornidazole Capsules	0.25g	揚子江南京海陵藥業 Yangtze River Nanjing Hailing Pharmaceutical	2003	—	7.8%
Ornidazole and Sodium Chloride Injection	100ml:0.25g 100ml:0.5g	陝西金裕製藥 Shaanxi Jinyu Pharmaceutical	2004	—	6.3%
Ornidazole Injection	3ml:0.5g 6ml:1.0g	北京雙鷺藥業 Beijing Shuanglu Pharmaceutical	2018	2023.03 (3ml:0.5g, injection)	5.2%
Ornidazole Tablets/Ornidazole Dispersible Tablets	0.25g; 0.5g (tablets) 0.25g (dispersible tablets)	湖南九典製藥* Hunan Jiudian Pharmaceuticals	2004	2022.07 (0.25g, tablet) 2022.07 (0.5g, tablet)	5.9%
Ornidazole Tablets/Ornidazole Vaginal Suppositories	0.25g; 0.5g (tablets) 0.5g (vaginal suppositories)	華東醫藥（西安）博華製藥 Huadong Medicine (Xi'an) Bodyguard Pharmaceutical	2001	2022.07 (0.5g, tablet)	4.5%
Ornidazole Dispersible Tablets	0.25g	天方藥業 Topfond Pharmaceutical		—	2.6%
Ornidazole Injection	0.25g	湖北長聯杜勒製藥 Hubei Changlian Dulle Pharmaceutical	2003	—	2.4%
Ornidazole Injection/Ornidazole Tablets/Ornidazole Vaginal Effervescent Tablets	3ml:0.5g; etc. (injection) 0.5g (tablets) 0.5g (vaginal effervescent tablets)	南京聖和藥業 Nanjing Sanhome Pharmaceutical	2002	—	2.1%

Note: Jiudian Pharmaceutical is the contract manufacturer of national VBP included ornidazole tablet products of Taiyangsheng (Bozhou) (太阳升(亳州)生物) and Hangzhou Muyuan (杭州沐源)

Source: NMPA; CIC

Pediatric Drugs

Overview

Pediatric drugs, including racecadotril and glucose electrolyte solutions, play a vital role in managing common childhood conditions such as acute diarrhea and dehydration. Racecadotril, an enkephalinase inhibitor, effectively reduces fluid secretion in the intestines without altering gut motility, making it ideal for pediatric patients by minimizing adverse effects like constipation. Its use improves clinical outcomes and reduces hospitalization duration, thereby enhancing recovery times. Similarly, glucose electrolyte solutions are fundamental in treating dehydration caused by diarrhea or vomiting. These solutions replenish essential fluids and electrolytes, ensuring proper hydration and electrolyte balance, and are a cornerstone of oral rehydration therapy recommended globally. The inclusion of glucose in these solutions facilitates the efficient absorption of sodium and water in the intestine, boosting rehydration effectiveness. As pediatric dehydration and diarrhea remain prevalent issues worldwide, the demand for these drugs is expected to grow, driven by their proven safety, efficacy, and ease of use, particularly in both developed and emerging markets. The market size for racecadotril granule in China was RMB28.5 million in 2023. The market size for glucose electrolyte effervescent tablet in China rose from RMB8.1 million in 2018 to RMB18.5 million in 2023 at a CAGR of 18.0%, and is projected to reach RMB47.1 million in 2033 at a CAGR of 9.8% from 2023.

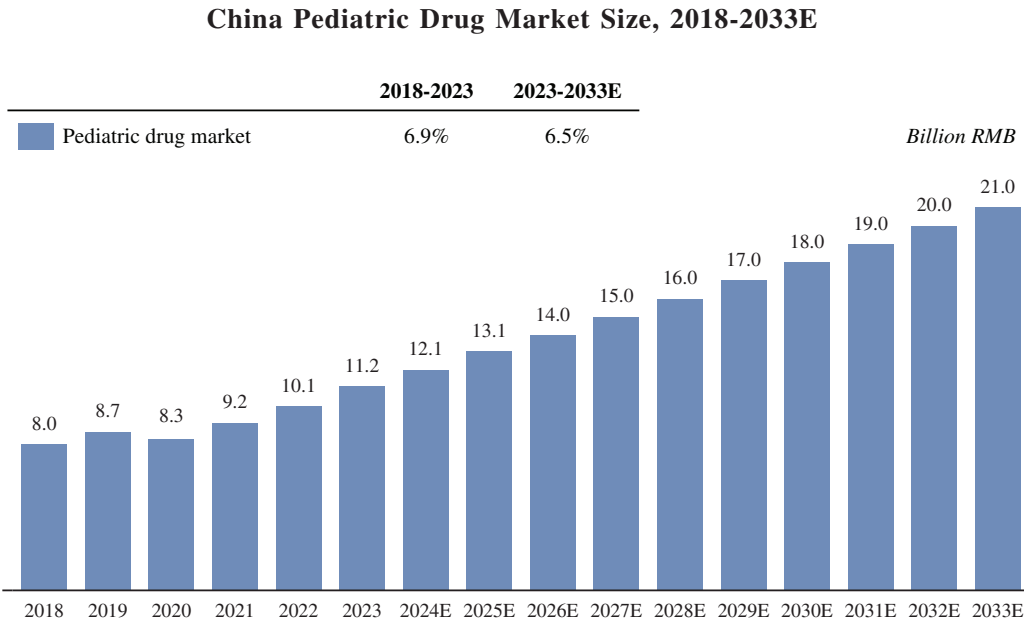
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Market Opportunities and Entry barriers

The pediatric drug market in China is driven by supportive policies that encourage the development of pediatric medications. The PRC government has boosted R&D by releasing multiple policies, such as the fourth batch of the encouraged pediatric drugs list issued in August 2023 by the National Health Commission. However, the pediatric drug market also faces significant entry barriers, primarily due to the complexities of R&D. The unique indications for pediatric drugs present challenges, as there are substantial differences between children and adults in metabolism, renal clearance, and other drug disposition mechanisms. Additionally, there are strong variations among children of different ages in their ability to metabolize, absorb, excrete, and transform medications, imposing higher R&D requirements.

Market Size

The pediatric drug market in China rose from RMB8.0 billion in 2018 to RMB11.2 billion in 2023 at a CAGR of 6.9% and is projected to reach RMB21.0 billion in 2033 at a CAGR of 6.5% from 2023. The market experienced contraction in 2020 due to the impact of the COVID-19 pandemic. The following diagram sets forth the size of the pediatric drug market in China:



Source: CIC

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Competitive Landscape of Pediatric Drugs in China

Our major products in this therapeutic area are Dulabao 杜拉宝® (racecadotril granule), Leyeping 乐液平® and Pujikang 朴吉康® (glucose electrolyte effervescent tablets under two different brand names). As of the Latest Practicable Date, there were 12 racecadotril products and only two glucose electrolyte products in China, according to CIC. Dulabao was ranked first in China’s racecadotril market, with a market share of approximately 66.6% in 2023, and we are the only manufacturer of glucose electrolyte products in China, and the historical prices of both racecadotril and glucose electrolyte product remained stable, according to the same source. The following tables set forth the top five players in the racecadotril product and the competitive landscape of glucose electrolyte in China, in terms of revenue in 2023:

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2023
Racecadotril granules	10mg	四川百利藥業 Sichuan Baili Pharmaceutical	2005	–	66.6%
Racecadotril granules/capsules	10mg; 30mg; 0.1g	江蘇正大豐海製藥 Jiangsu CTFH Pharmaceutical	2005	–	33.3%
Racecadotril powder/capsules	30mg; 0.1g	Bioprojet Pharma	2013	–	0.1%
Racecadotril orally disintegrating tablets	6mg	亞寶藥業四川製藥 Yabao Pharmaceutical	2005	–	0.1%
Racecadotril tablets	30mg	揚子江北京海燕藥業 Beijing Haiyan Pharmaceutical	2005	–	–

Source: NMPA; CIC

Drug Name	Specification	Company	First approval year	VBP inclusion	Market share in 2023
Glucose electrolyte effervescent tablets	0.138g sodium 0.098g potassium 0.16g chloride 1.62g anhydrous glucose 0.384g anhydrous citric acid	四川百利藥業 Sichuan Baili Pharmaceutical	2013	–	100.0%

Source: NMPA; CIC

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Challenges of the Generic Drug Market

The generic drug market faces several significant challenges. One major issue is the price pressure from the VBP policy. As of the Latest Practicable Date, a number of anesthetic and parenteral nutrition drugs had already been included in VBP schemes, experiencing deep price cuts, according to CIC. A broader range of drugs may be affected in the future, leading to market volatility as prices drop to improve accessibility and reduce medical expenses. Additionally, the regulatory framework for anesthetics and other drugs is becoming increasingly stringent, covering aspects from manufacturing to distribution and consumption, complicating market entry for new drugs. Furthermore, the strict supervision of anti-infective drug use in hospitals, driven by concerns over drug abuse, poses a challenge to market growth. In the pediatric sector, high requirements for flavor and drug form are necessary to address poor compliance in children, necessitating additional R&D efforts and significant investment in capital and talent. These factors together create a complex landscape for the generic drug market, demanding strategic adaptation to navigate these hurdles effectively.

Traditional Chinese Medicine

Overview

Huangqi (黄芪), also known as astragalus, and chaihuang (柴黄), a formulation combining Bupleurum (Chaihu) and astragalus, are integral components of traditional Chinese medicine with a long history of use. Astragalus is renowned for its immunomodulatory and anti-inflammatory properties, and is traditionally used to enhance immune function. It is prescribed for chronic fatigue, respiratory infections, and as an adjunct therapy in cancer treatment. The growing interest in natural and holistic health solutions has increased the demand for astragalus-based products. Meanwhile, chaihuang is valued for its heat-clearing and detoxifying properties, and is effective in treating fever, inflammation, and liver disorders. It is commonly used for upper respiratory tract infections, hepatitis, and digestive issues, working by modulating the immune response and exerting anti-inflammatory effects. Supported by modern pharmacological studies and a long history of safe usage, the acceptance for traditional Chinese medicine, particularly astragalus and chaihuang have significantly risen, which bolstered the market potential for both astragalus and chaihuang, positioning them as valuable assets in preventive and therapeutic healthcare.

The traditional Chinese medicine market where we operate is driven by the continued government support, where the Chinese government has continued to actively promote traditional Chinese medicine in its national health policies. Additionally, traditional Chinese medicine is being increasingly integrated with modern healthcare practices as consumers are increasingly focusing on holistic, natural health solutions, resulting in increased demand for products in this industry. The traditional Chinese medicine market where we operate in is also characterized by several entry barriers such as brand loyalty. Most users of traditional Chinese medicine favor familiar, established brands. Additionally, new entrants to the traditional Chinese medicine must also establish a reliable supply chain to be able to source the required raw medicinal materials for production of traditional Chinese medicines.

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The following table set forth the key policies of the PRC government in promoting traditional Chinese medicine in recent years:

Date	Policy	Main Content
February 2023	<i>Implementation Plan for Major Projects on the Revitalization and Development of Traditional Chinese Medicine</i> (《中醫藥振興發展重大工程實施方案》)	By 2025, the goal is to accelerate the development of a high-quality and efficient traditional Chinese medicine service system. This involves significantly enhancing the capacity of traditional Chinese medicine for disease prevention and treatment, as well as improving the integration of traditional Chinese medicine with Western medicine services. Additionally, efforts will focus on boosting scientific and technological innovation within traditional Chinese medicine. There will be a gradual expansion of the pool of high-quality traditional Chinese medicine professionals, alongside continuous improvements in the quality of Chinese medicinal products. The promotion of traditional Chinese medicine culture will also be prioritized to enhance its international influence. Furthermore, policies and mechanisms will be refined to align with the unique characteristics of traditional Chinese medicine.
December 2022	<i>Outline of the Strategic Plan for Expanding Domestic Demand (2022-2035)</i> (《擴大內需戰略規劃綱要(2022-2035年)》)	To vigorously develop traditional Chinese medicine, the focus will be on increasing high-quality services in areas such as medical care, health preservation, rehabilitation, health tourism, and other related services.

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Date	Policy	Main Content
March 2022	<i>14th Five-Year Plan for the Development of Traditional Chinese Medicine</i> (《“十四五”中醫藥發展規劃》)	To enhance the field of traditional Chinese medicine, several key initiatives will be undertaken. (1) The plan includes expanding the number of traditional Chinese medicine hospitals, institutions, and beds in public hospitals. (2) It also encourages qualified traditional Chinese medicine professionals to establish their own clinics. (3) Equal emphasis will be placed on integrating traditional Chinese medicine with Western medicine, strengthening its capacity for emergency response and treatment, and enhancing its role in the prevention and control of emerging infectious diseases. (4) Efforts will focus on protecting and utilizing Chinese medicinal resources while improving the management of authentic medicinal material production. (5) Additionally, there will be a focus on preserving traditional Chinese medicine heritage, promoting key research areas, and facilitating the transformation of scientific and technological achievements. (6) Pricing for traditional Chinese medicine decoction pieces and preparations used in medical institutions will be self-determined, and these items will be included in the basic medical insurance payment system if they meet the necessary conditions.
December 2021	<i>Development Plan for High-Quality Integration of Traditional Chinese Medicine into the “Belt and Road” Initiative (2021-2025)</i> (《推進中醫藥高質量融入共建“一帶一路”發展規劃(2021-2025年)》)	To deepen cooperation in global health governance, efforts will focus on enhancing medical and health services, scientific and technological innovation, international trade, the health industry, regional and international exchanges, education, and cultural exchange. Establishing partnerships in traditional medicine will be key to increasing the supply of high-quality traditional Chinese medicine services. This approach aims to shape new advantages for traditional Chinese medicine development, expand its scale, strengthen the international talent pool, and enhance its global influence.

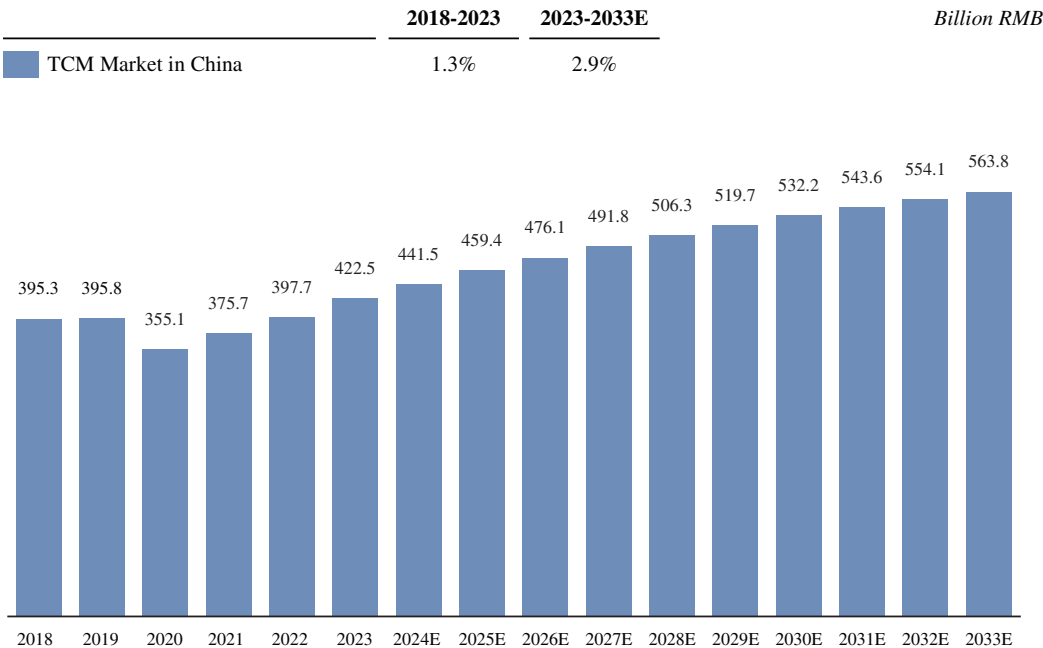
INDUSTRY OVERVIEW

Date	Policy	Main Content
January 2021	<i>Several Policy Measures for Accelerating the Development of Unique Characteristics of Traditional Chinese Medicine</i> (《關於加快中醫藥特色發展的若干政策措施》)	To further implement the <i>Opinions on Promoting the Inheritance and Innovation of Traditional Chinese Medicine</i> and the strategies from the National Traditional Chinese Medicine Conference, efforts will focus on following the development rules of traditional Chinese medicine. This includes summarizing traditional Chinese medicine’s experience in treating COVID-19 and promoting the coordinated development of traditional Chinese medicine and Western medicine as complementary approaches.

Market Size and Competitive Landscape of Traditional Chinese Medicine in China

The traditional Chinese medicine market in China rose from RMB395.3 billion in 2018 to RMB422.5 billion in 2023 at a CAGR of 1.3%, and is projected to reach RMB563.8 billion in 2033 at a CAGR of 2.9% from 2023. The market experienced contraction in 2020 due to the impact of the COVID-19 pandemic. The following diagram sets forth the size of the traditional Chinese medicine market in China:

China Traditional Chinese Medicine Market Size, 2018-2033E



Source: Annual reports, National Bureau of Statistics of China; CIC

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Our major products in this therapeutic area are astragalus granule (黃芪顆粒) and chaihuang granule (柴黃顆粒). As of the Latest Practicable Date, there were 19 types of medicines containing astragalus, with 58 approved drug products in China, and seven types of medicines containing chaihuang, with 35 approved drug products in China, according to CIC. Our astragalus product was ranked second in China’s astragalus market, with a market share of approximately 30.0% in 2022, and our chaihuang product was ranked first in China’s chaihuang market, with a market share of approximately 92.4% in 2022, and the historical prices of both astragalus granule and chaihuang granule remained stable with minor fluctuations, according to the same source. The following tables set forth the top players in the astragalus and chaihuang markets in China, in terms of revenue in 2022:

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2022
Astragalus slices	0.41g	四川奇力製藥 Sichuan Qili Pharmaceutical	2009	–	40.6%
Astragalus granules	4g; 10g; 15g	四川百利藥業 Sichuan Baili Pharmaceutical	1999	–	30.0%
Astragalus slices	0.55g	四川國康藥業 Sichuan Guokang Pharmaceutical	2009	–	17.3%
Astragalus granules	15g	南京同仁堂藥業 Nanjing Tongrentang Pharmaceutical	2002	–	5.9%
Astragalus injection	10ml	神威藥業集團 Shineway Pharmaceutical	2002	–	1.2%

Source: NMPA; CIC

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2022
Chaihuang granules	3g; 4g; 5g	四川百利藥業 Sichuan Baili Pharmaceutical	1999	–	92.4%
Chaihuang granules	4g	河南靈佑藥業 Henan Livu Pharmaceutical	2002	–	4.4%
Chaihuang granules	4g	江西京通美聯藥業 Jiangxi JTML Pharmaceutical	2000	–	2.3%
Chaihuang capsules	0.5g	江蘇頤海藥業 Jiangsu Yihai Pharmaceutical	2016	–	1.0%

Source: NMPA; CIC

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Challenges of Traditional Chinese Medicine Market

The market for traditional Chinese medicine faces significant challenges, primarily due to difficulties in quality control and standardization. Since traditional Chinese medicines are made from herbs and are not standardized products, maintaining consistent quality requires considerable effort. This lack of standardization can hinder the ability to meet market demand reliably. Additionally, there is a shortage of valid clinical evidence supporting the efficacy of some traditional Chinese medicines, as many do not have sufficient data from well-designed clinical trials. Conducting such trials demands substantial capital and talent, which can impact market growth. These challenges underscore the need for increased R&D investment to ensure quality and build a stronger evidence base for traditional Chinese medicine.

SOURCE OF INFORMATION

CIC was commissioned to conduct an analysis of, and to report on, the global pharmaceutical industry at a fee of approximately RMB380,000. The commissioned report has been prepared by CIC independent of the influence of the Company and other interested parties. CIC’s services include industry consulting, commercial due diligence, strategic consulting, etc. Its consulting team has been tracking the latest market trends across various industries, where it has relevant and insightful market intelligence.

CIC conducted both primary and secondary research using a variety of resources. Primary research involved interviewing key industry experts and leading industry participants. Secondary research involved analyzing data from various publicly available data sources, such as the WHO, National Bureau of Statistics of China, and other databases. The market projections in the commissioned report are based on the following key assumptions: (i) the overall social, economic, and political environment in China and globally is expected to remain stable during the forecast period; (ii) government policies on the pharmaceutical industry in China and globally will remain consistent during the forecast period; and (iii) there is no extreme force majeure or unforeseen set of industry regulations in which the market may be affected in either a dramatic or fundamental way.

Unless otherwise specified, all data and forecasts contained in this section are derived from the CIC report. The report has also incorporated actual and potential impact of the COVID-19 outbreak on our industry. The Directors have confirmed that there has been no occurrence of adverse change in the overall market information that would subject the data to significant restrictions, contradiction or negative effects since the date of the consultancy report.

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 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 the 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 of the PRC (中華人民共和國國務院) (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 of 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.

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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 on 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. 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 on January 22, 2020 and came into effect on 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 reregistration, 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 State Food and Drug Administration (the “SFDA”) in August 2003 and latest amended by the China Food and Drug Administration (the “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 Practices (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 came 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 Administrative Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) jointly promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision in December 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試

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行)》) promulgated by the Ministry of Science and Technology and other regulatory authorities in December 2001 and came into effect in January 2002, using experimental animals and related products requires a Certificate for Utilization of Laboratory Animals. A Certificate for Utilization 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. A Certificate for Utilization of Laboratory Animals shall be inspected annually by the local Science and Technology Bureau.

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 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 relevant data, files and 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 sixty (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)》), which came into effect in July 2020, 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 of the 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 preclinical 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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According to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), applicants may communicate with CDE on major issues at critical stages such as prior to application for clinical trial of a drug, during the process of clinical trial of a drug, and prior to application for marketing authorization of a drug. According to the Measures for the Administration of Communication and Exchange in Drug Development and Technology Review (《藥物研發與技術審評溝通交流管理辦法》) promulgated by the CDE on December 10, 2020, an applicant may propose to convene a communication meeting with the CDE during the process of drug research and development and registration application. There are three types of communication and exchange meetings: Type I meetings are held to resolve major safety issues encountered in the course of clinical trials of drugs and major technical issues in the course of R&D of breakthrough therapeutic drugs; Type II meetings are held for drugs at critical stages of R&D, which mainly include pre-application meetings for new drugs, meetings after the conclusion of Phase II clinical trials and before the commencement of Phase III clinical trials, meetings before application for marketing authorization of new drugs, and meetings for risk assessment and evaluation of new drugs. Type III meetings shall refer to meetings other than Type I and Type II meetings.

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.

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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 factors such as variety, process, facility, and previous acceptance of inspection for which an application is filed for registration. For innovative drugs, new modified drugs and biological products, production site inspection for drug registration and pre-marketing examination for management standards for drug production quality shall be conducted. For generic drugs, production site inspection for drug registration and pre-marketing examination for management standards for drug production quality shall be conducted based on the risks, according to whether a drug production license for the corresponding production scope has been obtained and whether a variety of the same dosage form has been marketed.

After an application for drug registration is accepted, the CDE shall conduct preliminary examination within forty (40) business days of acceptance, notify the Center for Food and Drug Inspection of NMPA (the “Center for Inspection”) 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 forty (40) business 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.

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The review period for an application for drug marketing authorization shall be 200 business days. Within this two hundred (200) business days period, the review period for the procedures for prioritized review and approval shall be one hundred and thirty (130) business 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 seventy (70) business days.

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

Reform of Evaluation and Approval System for Drugs

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

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

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

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

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Regulations on International Multi-Center Clinical Trials and Acceptance of Overseas Clinical Trial Data

According to the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) (《關於發佈國際多中心藥物臨床試驗指南(試行)的通告》), (“the Multi-Center Clinical Trial Guidelines”), promulgated by the NMPA on January 30, 2015 and came into effect from March 1, 2015, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicants plan to implement the international multi-center clinical trials in the PRC, the applicants shall comply with relevant laws and regulations, such as the PRC Drug Administration Law, the Implementing Regulations of the PRC Drug Administration Law and the Administrative Measures for Drug Registration, execute the Good Clinical Practice, make reference to universal international principles such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), and comply with the laws and regulations of the countries involved in the international multi-center clinical trials. Where the applicants plan to use the data derived from the international multi-center clinical trials for approval of a drug registration in the PRC, it shall involve at least two countries, including China, and shall satisfy the requirements for clinical trials set forth in the Multi-Center Clinical Trial Guidelines and other related laws and regulations.

According to the Opinions on Deepening the Reform of the Evaluation and Approval System and Inspiring Innovation of Drugs and Medical Devices, clinical trial data obtained in an international multi-center that conforms to China’s requirements for registration of drugs and medical devices can be used for the application for registration in China.

According to the Technical Guiding Principles for the Acceptance of Overseas Clinical Trial Data of Drugs (《接受藥品境外臨床試驗數據的技術指導原則》) promulgated by the NMPA on July 6, 2018, the basic principles for accepting overseas clinical trial data include: (i) applicants shall ensure the authenticity, integrity, accuracy and trace-ability of overseas clinical trial data; (ii) the process of generating overseas clinical trial data shall comply with the relevant requirements of the ICH-GCP; (iii) applicants shall ensure the scientific design of overseas clinical trials, the compliance of clinical trial quality management system with the requirements, and the accuracy and integrity of statistical analysis of data; and (iv) to ensure that the clinical trial design and statistical analysis of the data are scientific and reasonable, for the drugs with simultaneous R&D at home and abroad and forthcoming clinical trials in China, the applicants may, prior to implementing registrational clinical trials, contact the CDE to ensure the compliance of registrational clinical trial’s design with the essential technical requirements for drug registration in China.

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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 Authorization

Pursuant to the 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 authorization holder may transfer its drug marketing authorization. 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 authorization 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.

NRDL

Participants in the National Health Insurance Scheme and their employers (if any) have to pay a monthly premium. Participants may be reimbursed for all or part of the cost of medicines included in the medical insurance catalogue. The Notice on Provisional Measures for the Administration of the Scope of Medicines in the Basic Medical Insurance for Urban Workers (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》) (or the Medical Insurance Notice), jointly issued by the Ministry of Labor and Social Security of the PRC and the NDRC and other governmental organizations on May 12, 1999, stipulates that the medicines included in the medical insurance catalogue must be clinically necessary, safe and effective, reasonably priced, convenient to use and the supply of which can be guaranteed by the market.

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The NRDL for Basic Medical Insurance, Work 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》) sets out the standards for payment of medicines by the basic medical insurance, work injury insurance and maternity insurance funds. The National Healthcare Security Administration of the PRC and other governmental organizations have the authority to determine the drugs to be included in the NRDL. Drugs listed in the NRDL are divided into two parts: Class A and Class B. Class A drugs are widely used for clinical treatment, with favourable efficacy and lower prices than their counterparts, while Class B drugs are used for clinical treatment, with favourable efficacy and slightly higher prices than Class A drugs.

On December 7, 2023, the NHSA and the Ministry of Human Resources and Social Security of the PRC released the latest NRDL (effective from January 1, 2024), which has been expanded to cover a total of 3,088 drugs. Inclusion in the NRDL will generally result in increased sales volume and lower drug prices (which are determined on a case-by-case basis and negotiated based on factors such as the initial drug price).

On July 30, 2020, the NHSA issued the Provisional Measures for the Administration of Medicines for Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) (“Measures for the Administration of the NRDL”), which came into effect on September 1, 2020. The Measures for the Administration of the NRDL provides guidance on the inclusion and adjustment of the NRDL and the payment, management and supervision of basic medical insurance. According to the Measures for the Administration of the NRDL, a dynamic adjustment mechanism shall be established for the NRDL, which shall be adjusted annually in principle.

NEDL

On August 18, 2009, the MOH and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the NEDL (《國家基本藥物目錄管理辦法(暫行)》), which was revised on February 13, 2015 by the Notice on Issuing the Measures on the Administration of the NEDL (《關於印發國家基本藥物目錄管理辦法的通知》), and the Guidelines on the Implementation of the NEDL System (《關於建立國家基本藥物制度的實施意見》), which aims to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the NEDL. On September 13, 2018, the General Office of the State Council issued the Opinions of the General Office of the State Council on Improving the National Essential Drug System (《國務院辦公廳關於完善國家基本藥物制度的意見》). The NHC and the National Administration of Traditional Chinese Medicine promulgated the NEDL (2018 version) (《國家基本藥物目錄(2018年版)》) on September 30, 2018, replacing the NEDL (2012) (《國家基本藥物目錄(2012年版)》) which was promulgated on March 13, 2013. According to these regulations, basic healthcare institutions funded by the government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in the NEDL. The drugs listed in NEDL shall be purchased by centralized tender process and shall be subject to the price control by the NDRC. Remedial drugs in the NEDL are all listed in the Medical Insurance Catalog and the entire amount of the purchase price of such drugs is entitled to reimbursement.

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The Drug Centralized Procurement in “4+7 Cities” and Nationwide

On November 15, 2018, the Joint Procurement Office published the Papers on Drug Centralised Procurement in “4+7 Cities” (《4+7城市藥品集中採購文件》, the “Paper”), which launched the national pilot scheme for drugs centralised tendering with volume-based procurement quantities. The pilot scheme will be carried out in 11 cities, including Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi’an (the “4+7 cities”).

On January 1, 2019, the General Office of the State Council also published the Notice of Issuing Pilot Program of the Centralised Procurement and Use of Drugs Organized by the State (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》), which provides the detailed measures in the implementation of the national pilot scheme for drugs centralised tendering with minimum procurement quantities in the 4+7 cities.

In principle, the various types of pilot drugs covered by the Pilot Program of the Centralized Procurement and Use of Drugs should be selected from the generic names of drugs that have passed the consistency assessment on quality and efficacy.

The procurement process should be based on the number of pharmaceutical enterprises selected: if three or more pharmaceutical enterprises are selected, the procurement should be conducted through an open tender process; if two enterprises are selected, the procurement should be conducted through a bargaining process; and if only one enterprise is selected, the terms of the procurement should be determined through negotiation.

According to the Implementing Opinions on Expanding the Pilot Program for Conducting Centralised Procurement and Use of Drugs by the State to Wider Areas (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》) promulgated and came into effect on September 25, 2019, together with the Documents on National Centralised Drug Procurement (GY-YD2021-1) (《全國藥品集中採購文件(GY-YD2021-1)》) issued by the Joint Procurement Office on January 15, 2021, the centralised procurement program of drugs has been extended to nationwide. The centralised VBP program of drugs will be implemented on a nationwide basis. Eligible participants include all pharmaceutical manufacturers, sole agents of imported drugs and holders of marketing authorisations for drugs, provided that they own the drugs covered by the centralised purchasing program.

The NHSA, the NHC, the NMPA, the MIIT and the Ministry of Logistics and Security of the Central Military Commission jointly issued the Circular on Conducting the Second Batch of Centralised Procurement and Use of Drugs Organised by the State (《關於開展第二批國家組織藥品集中採購和使用工作的通知》) (the “Circular”), which became effective on January 13, 2020, and stipulated a number of principles for the implementation of the centralised procurement of drugs by the State in order to comprehensively deepen the reforms and to establish a standardised and regularized centralised purchasing program of drugs nationwide.

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The Joint Purchasing Office issued the Documents on National Centralised Drug Procurement (GY-YD2020-1) (《全國藥品集中採購文件(GY-YD2020-1)》) on July 29, 2020 to launch a new batch of centralized procurement of drugs that meet the conditions for centralised procurement.

On January 22, 2021, the General Office of the State Council issued the Opinions on Promoting the Normalisation and Institutionalisation of the Centralised VBP of Drugs (《關於推動藥品集中帶量採購工作常態化制度化開展的意見》), stating that various measures will be taken to promote the normalisation and institutionalization of the centralised VBP of drugs nationwide. All public medical institutions are required to participate in the centralised drug procurement program. The future procurement catalogue will include drugs with high market demand or high procurement prices that are included in the NRDL, and is expected to cover, as far as possible, domestically marketed drugs with clinical utility and reliable quality.

The Joint Purchasing Office issued the Documents on National Centralised Drug Procurement (GY-YD2021-2) (《全國藥品集中採購文件(GY-YD2021-2)》) on June 2, 2021, the Documents on National Centralised Drug Procurement (Insulin Specific) (GY-YD2021-3) (《全國藥品集中採購文件(胰島素專項)(GY-YD2021-3)》) on November 5, 2021, the Documents on National Centralised Drug Procurement (GY-YD2022-1) (《全國藥品集中採購文件(GY-YD2022-1)》) on June 20, 2022, the Documents on National Centralised Drug Procurement (GY-YD2023-1) (《全國藥品集中採購文件(GY-YD2023-1)》) on March 2, 2023, the Documents on National Centralised Drug Procurement (GY-YD2023-2) (《全國藥品集中採購文件(GY-YD2023-2)》) on October 13, 2023 and the Documents on National Centralised Drug Procurement (Insulin Specific Continuation) (GY-YD2024-1) (《全國藥品集中採購文件(胰島素專項接續)(GY-YD2024-1)》) on March 29, 2024, to launch multiple batches of centralised drug procurement.

Drug Distribution and Two-Invoice System

According to the Implementing Opinions on Promoting the “Two-Invoice System” for Drug Procurement By Public Medical Institutions (For Trial Implementation) (《關於在公立醫療機構藥品採購中推行[兩票制]的實施意見(試行)》) which was issued on December 26, 2016, the Two-Invoice System is a system under which invoices are issued by drug manufacturers to drug distributors on a once-off basis while invoices are issued by drug distributors to medical institutions on a once-off basis. Wholly-owned or holding commerce companies (there shall be only one commerce company throughout the country) and domestic general agents of overseas drugs (there shall be only one domestic general agent throughout the country) that are established by drug manufacturers or group enterprises integrating scientific research, manufacture, and trade to sell the drugs of these enterprise (groups) can be regarded as manufacturers. Within an enterprise that is a drug circulation group, the allocation of drugs between the group and wholly-owned (holding) subsidiaries or between wholly-owned (holding) subsidiaries should not be regarded as invoicing, but invoicing is allowed once at most.

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According to the Several Opinions of the General Office of the State Council on Further Reform and Improvement in Policies of Drug Production, Circulation and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》), which was issued on January 24, 2017, on a priority basis, the Two-Invoice System would be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) and pilot cities for public hospital reform, with the goal of having it implemented nationwide by 2018. Pharmaceutical companies must comply with the Two-Invoice System in order to engage in procurement processes with public hospitals.

Drug Recall

According to the Measures on Drug Recall (《藥品召回管理辦法》) promulgated on December 10, 2007, latest amended in October 2022 and came into effect on November 1, 2022, a drug manufacturer should establish and improve its recall system by collecting relevant information about drug safety and making an investigation and evaluation with respect to any drugs with potential safety hazards. If there are any potential safety hazards that endanger human health and life safety in respect of any drugs sold in the PRC, such manufacturer must start the drug recall procedures. Where a drug is recalled, the drug operating units and users should assist such manufacturer to satisfy its recall obligations by communicating the drug recall information and any feedback, controlling and recovering such drugs according to the recall plan.

Gathering, Collection and Filing of Human Genetic Resources

The Interim Measures for the Management of Human Genetic Resources (《人類遺傳資源管理暫行辦法》) 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、出境審批行政許可的通知》) promulgated by the Ministry of Science and Technology in August 2015, foreign investment sponsors who gather and collect human genetic resources through clinical trials should file a record with the China Human Genetic Resources Management Office through an online system. The Ministry of Science and Technology promulgated the Notice on Optimizing the Administrative Examination and Approval Process of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》) in October 2017 and came into effect in December 2017, which has simplified the approval process for the gathering and collection of human genetic resources for the listing of drugs in the PRC. The Ministry of Science and Technology promulgated the Notice on Updating the Scope and Procedures for Administrative Licensing, Filing, and Prior Reporting of Human Genetic Resource Services Guidelines (《關於更新人類遺傳資源行政許可事項服務指南、備案以及事先報告範圍和程序的通知》) on July 14, 2023 and came into effect since July 1, 2023, which has further refined the approval process for the gathering and collection of human genetic resources for the listing of drugs in the PRC.

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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》) (the “HGR Regulations”) promulgated by the State Council in May 2019, newly amended in March 2024 and came into effect on May 1, 2024, 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 within the territory of the PRC, or provide Chinese genetic resources to foreign countries. In addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall (i) conform to ethical principles and conduct ethical review in accordance with relevant regulations; (ii) respect the privacy of the human genetic resource providers, obtain their prior consents, and protect their lawful rights and interests; (iii) comply with technical specification promulgated by the healthcare department of the State Council.

On October 17, 2020, SCNPC promulgated Biosecurity Law of the PRC (《中華人民共和國生物安全法》), and latest amended and came into effect on April 26, 2024. 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 microorganism 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 healthcare department 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 healthcare department.

The Ministry of Science and Technology promulgated the Implementation Rules for the Administrative Regulation on Human Genetic Resources (《人類遺傳資源管理條例實施細則》) (the “Implementation Rules”) on May 26, 2023 and came into effect on July 1, 2023. The Implementation Rules has further provided detailed implementation regulations for the administration of human genetic resources of the PRC, including but not limited to the following:

- (a) clarifying the scope of human genetic resource information, which shall include information resources generated from human genetic resource materials (such as human genes and genome data) and exclude clinical data, image data, protein data and metabolic data;

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- (b) clarifying the criteria to constitute a foreign entity, which shall include (i) any foreign organization or individual that holds directly or indirectly more than 50% of the shares, equity interests, voting rights, property shares or other interests in the institution, (ii) any foreign organization or individual that is able to dominate or have material effect on the decision-making or management of the institution through its voting right or other interests, although the shares, equity interests, voting rights, property share or other interests it directly or indirectly holds in the institution is less than 50%, (iii) any foreign organization or individual that is able to dominate or have material effect on the decision-making or management of the institution through investment relationship, contract or other arrangement; and (iv) other situations stipulated by laws, regulations and rules;
- (c) listing the situations where security review may be required, which shall include: (i) human genetic resource information of important genetic families; (ii) human genetic resources information of specific regions, (iii) exome sequencing and genome sequencing information resources with a population greater than 500 cases; and (iv) other situation that may affect the public health, national security and social public interest of the PRC.

According to Articles 27 and 28 of the HGR Regulations, where human genetic resources materials of the PRC are transported, mailed or carried abroad, it shall be approved by the healthcare department of the State Council; where only human genetic resources information are transferred to foreign individuals or entities, a filing is required with the healthcare department of the State Council. Under our strategic collaboration with BMS, we provide human genetic resources information via online transmission, without involving the transportation, mailing or carrying of human genetic resources materials across borders. Therefore, according to the HGR Regulations, we are obligated to make a filing for record-keeping and submit information backups for providing such genetic information to our overseas subsidiary. We have reported and completed filing for the clinical trial data transmitted as well as submitted information backup in connection with the BMS Agreement. Additionally, Article 28 of the HGR Regulations stipulates that if the supply or use of human genetic resources information to foreign individuals or entities is likely to affect the public health, national security or public interests in the PRC, it shall pass a security review by the healthcare department of the State Council. To our best knowledge, the transmission of the clinical trial data in connection with the BMS Agreement is in line with typical practices for R&D collaborations in the pharmaceutical industry and does not pose a risk to public health, national security or public interests in the PRC. As of the Latest Practicable Date, we had not received any written notice from regulatory authorities requesting a security review in this regard. Based on the above, our PRC Legal Advisor is of the view that the transmission of human genetic resources information as described above is in compliance with the HGR Regulations and the Biosecurity Law of the PRC.

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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.

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,

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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 (2023) (《國家基本醫療保險、工傷保險和生育保險藥品目錄(2023年)》) came into effect since January 1, 2024.

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 and came into effect on June 1, 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.

Pricing Regulations and Policies relating to Traditional Chinese Medicine

According to the Notice on Issuing Opinions on Current Drug Price Management Work (《關於印發<關於做好當前藥品價格管理工作的意見>的通知》) promulgated by the NHSA on November 26, 2019, the scope of drugs managed by the department of healthcare security includes traditional Chinese medicine, chemical medicines, biochemical drugs, and hospital preparations, among which narcotic drugs and first-class psychotropic drugs implement government-guided prices, while other drugs implement market-adjusted prices. Pursuant to the Opinions on Promoting the Normalization and Institutionalization of the Centralized Volume-based Procurement of Drugs (《關於推動藥品集中帶量採購工作常態化制度化開展的意見》) issued by the General Office of the State Council on January 22, 2021, the highest effective declared price for purchasing drugs and other shortlisting conditions are determined based on the existing market prices. The number of eligible enterprises is determined according to the market competition pattern and supply capacity. Enterprises shall participate voluntarily and make independent offers. The eligible enterprises and drug prices are generated through competition in both quality and price. In November 2024, the National Joint Purchasing Office

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of Traditional Chinese Medicine issued the National Joint Purchasing Office of Traditional Chinese Medicine Centralized Procurement Document (ZYYPLM-2024-1) (《全國中藥飲片採購聯盟集中採購文件(ZYYPLM-2024-1)》) to launch the centralized procurement of 45 species of traditional Chinese medicines that meet the conditions for centralized procurement. During the Track Record Period, none of our major marketed traditional Chinese medicine products were included in the VBP schemes, and the relevant pricing regulations and policies pertaining to traditional Chinese medicines had limited impact on our operations and financial performance.

Advertising 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 in December 2019 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 business 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.

Insert Sheet, Labels and Packaging of Pharmaceutical Products

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

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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).

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 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.

Our PRC Legal Advisor has advised us that drug technology transfer as defined under the foregoing regulations pertains only to drugs that have passed clinical trials and received a registration certificate. Currently, our strategic collaboration with BMS does not involve any products that have obtained such certification. Therefore, the required procedures set out in the foregoing regulations do not apply to the technology transfer required under the BMS Agreement. For details of such technology transfer, see “Business — License and Collaboration Agreement with Bristol-Myers Squibb Company.”

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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.

Laws and 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 December 11, 2023 and came into effect on January 20, 2024. The Patent Law and the Implementation Rules provide for three types of patents, namely “invention,” “utility model” and “design.” “Invention” refers to any new technical solution relating to a product, a process or improvement thereof; “utility model” refers to any new technical solution relating to the shape, structure, or their combination, of a product, which is suitable for practical use; and “design” refers to any new design of the shape, pattern, color or the combination of any two of them, of a product, which creates an aesthetic feeling and is suitable for industrial application. The duration of a patent right for “invention” is twenty (20) years; the duration of a patent right for “utility model” is ten (10) years; and the duration of a patent right for “design” is fifteen (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.

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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 (5) years, and the total valid patent term after the new drug is approved for the market shall not exceed fourteen (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 (10) years to registered trademarks. When it is necessary to continue using the registered trademark upon expiration of period of validity, a trademark registrant shall make an application for renewal within twelve (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 (10) years as of the next day of the previous period of validity. If the formalities for renewal have not been handled upon expiration of period of validity, the registered trademarks will be deregistered.

Domain Names

Domain names are regulated under the Administrative Measures on the Internet Domain Names (《互聯網域名管理辦法》) issued by the Ministry of Industry and Information Technology (the “MIIT”), on August 24, 2017 and effective from November 1, 2017. The MIIT is the main regulatory authority responsible for the administration of the 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.

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Trade Secret

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by SCNPC, as amended and effective as of April 23, 2019, the term “trade secrets” refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the Anti-Unfair Competition Law of the PRC, business persons are prohibited from infringing others’ trade secrets by: (i) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other means; (ii) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (i) above; (iii) disclosing, using, or allowing another person use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (iv) abetting a person, or tempting another person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others’ trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and impose fine on the infringing parties.

Regulations in Relation to Foreign Direct Investment

Since January 1, 2020, the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “Foreign Investment Law”) promulgated by the National People’s Congress (the “NPC”) has come into effect. The Law of the PRC on Sino-Foreign Equity Joint Ventures and the Law of the PRC on Wholly Foreign-Owned and Law of the PRC on Sino-Foreign Cooperative Joint Ventures abolished at the same time. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. While the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law of the PRC and other laws. The PRC government will implement the management system of pre-entry national treatment and the Negative List for foreign investment abolished the original approval and filing administration system for the establishment and change of foreign-invested enterprises. Pre-entry national treatment refers to the treatment accorded to foreign investors and their investments at the stage of investment entry which is no less favorable than the treatment accorded to domestic investors and their investments. Negative List refers to a special administrative measure for the entry of foreign investment in specific sectors as imposed by the PRC. The PRC accords national treatment to foreign investment outside of the Negative List. The current Negative List is the Special Management Measures (Negative List) for the Access of Foreign Investment (2024 Revision) (《外商投資准入特別管理措施(負面清單)(2024年版)》) issued by the NDRC and the MOFCOM on September 6, 2024 and came into effect on November 1, 2024, which lists the special management measures for foreign investment access for industries regulated by the Negative List, such as equity requirements

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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 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 twenty (20) business days after the change. Foreign-invested listed companies may report information on changes in investors and their shareholdings only when the cumulative change in the foreign investors’ shareholding ratio exceeds 5% or the foreign parties’ shareholding or relative holding status have changed.

Regulations in Relation to Overseas Direct 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.

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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.

Pursuant to the Regulations on the Administration of Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) promulgated by the State Council on January 29, 1996, and last amended and effective on August 5, 2008, any domestic organization or individual that seeks to make a direct investment overseas or engage in the issuance or trading of negotiable securities or derivatives overseas shall make the appropriate registrations in accordance with State Council foreign exchange administrative department provisions. Any such organization or individual that is required to obtain approval from or make a filing with the relevant competent authority in accordance with state provisions shall undergo the approval or filing formalities before making said registrations.

The Circular of the State Administration of Foreign Exchange on Further Improving and Adjusting Foreign Exchange Administration Policies on Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》) (hereinafter referred to as the “Circular 59”), which was promulgated by the State Administration of Foreign Exchange (the “SAFE”) on November 19, 2012, and last amended on October 10, 2018, part of which was abolished on December 30, 2019, substantially amends and simplifies the foreign exchange procedures. Pursuant to Circular 59, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts, and deposits accounts, the reinvestment of RMB proceeds derived by foreign investors within the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of the SAFE, and multiple capital accounts for the same entity may be opened in different provinces. In February 2015, the SAFE promulgated the Notice on Further Simplifying and Improving Foreign Exchange Administration Policies on Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》), part of which was abolished in December 2019. It stipulates that banks shall, on behalf of the SAFE, directly examine and handle foreign exchange registration under domestic direct investment and overseas direct investment, and the SAFE and its branches shall exercise indirect supervision over foreign exchange registration of direct investment through banks. On April 3, 2024, the SAFE promulgated the Guidelines of Capital Account Foreign Exchange Business (2024 Version) (《資本項目外匯業務指引(2024年版)》), which came into effective on May 6, 2024, and stipulates guidelines for the capital account foreign exchange business.

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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 programs 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 and Fire Safety

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 Discharge Permit issued by the Ministry of Ecology and Environment on April 1, 2024 and came into effect on July 1, 2024, enterprises, public institutions and other producers and operators that are subject to the administration of pollutant discharge permits shall apply for pollutant discharge permit and discharge pollutants in accordance with the requirements of the pollutant discharge permit; and those who have not obtained the pollutant discharge permits shall not discharge pollutants. 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.

According to the Fire Safety Law of the PRC (《中華人民共和國消防法》) promulgated by the SCNPC in April 1998, last amended and effective on April 29, 2021, and the Interim Provisions on Administration of Fire Protection Design Review and Acceptance of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) (the “Interim Provisions”) promulgated by the Ministry of Housing and Urban-Rural Development on April 1, 2020, and last amended on August 21, 2023, the fire protection design or construction of a construction project must conform to the national fire protection technical standards for project construction and construction projects shall undergo the fire protection design review and acceptance system. The special construction projects as defined in the Interim Provisions must apply to the fire control department for fire protection design review, and complete the fire protection acceptance procedures after the completion of the construction project. The construction unit of other construction projects must complete the fire protection filing of the fire protection design and the completion acceptance within five (5) business days after the

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completion acceptance of the construction project. If a construction project fails to pass the fire safety inspection before it is put into use, or does not meet the fire safety requirements after the inspection, it will be ordered to suspend the construction and use of such project, or suspend production and business, and be imposed a fine.

Regulations in Relation to Prevention and Control of Occupational Diseases

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

Regulations in Relation to 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 Social Security Law of the PRC (《中華人民共和國社會保險法》), which was promulgated on 28 October 2010 and amended on 29 December 2018, an employer is required to make contributions to social insurance schemes for its employees, including basic pension insurance, basic medical insurance, unemployment insurance, maternity insurance and work-related injury insurance. If the employer fails to make social insurance contributions in full and on time, the social insurance authorities may demand the employer to make payments or supplementary payments for the unpaid social insurance premium within a prescribed time limit together with a 0.05% surcharge of the unpaid social insurance premium from the due date. If the payment is not made within such time limit, the relevant administrative authorities will impose a fine ranging from one to three times the total outstanding amount.

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According to the Reform Plan of the State Tax and Local Tax Collection Administration System (《國稅地稅徵管體制改革方案》), which was promulgated on 20 July 2018, commencing from 1 January 2019, all the social insurance premiums including the premiums of the basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and basic medical insurance shall be collected by the tax authorities. According to the Notice on Conducting the Relevant Work Concerning the Administration of Collection of Social Insurance Premiums in a Steady, Orderly and Effective Manner (《關於穩妥有序做好社會保險費徵管有關工作的通知》) promulgated by the General Office of the State Administration of Taxation on 13 September 2018 and the Urgent Notice on Implementing the Spirit of the Executive Meeting of the State Council in Stabilizing the Collection of Social Security Contributions (《關於貫徹落實國務院常務會議精神切實做好穩定社保費徵收工作的緊急通知》) promulgated by the General Office of the Ministry of Human Resources and Social Security on 21 September 2018, all the local authorities responsible for the collection of social insurance are strictly forbidden to conduct self-collection of historical unpaid social insurance contributions from enterprises. The Notice on Implementing Measures to Further Support and Serve the Development of Private Economy (《關於實施進一步支持和服務民營經濟發展若干措施的通知》), promulgated by the State Taxation Administration on 16 November 2018, repeats that tax authorities at all levels may not organize self-collection of arrears of taxpayers including private enterprises from the previous years. The Notice of General Office of the State Council on Promulgation of the Comprehensive Plan for the Reduction of Social Insurance Premium Rate (《國務院辦公廳關於印發降低社會保險費率綜合方案的通知》), promulgated on 1 April 2019, requires steady advancement of the reform of the system of social security collection. In principle, the basic pension insurance for enterprise employees and other insurance types for enterprise employees shall be collected temporarily according to the existing collection system to stabilize the payment method. It also emphasizes that the historical unpaid arrears of the enterprise shall be properly treated. In the process of reformation of the collection system, it is not allowed to conduct self-collection of historical unpaid arrears from enterprises, and it is not allowed to adopt any method of increasing the actual payment burden of small and micro enterprises to avoid causing difficulties in the production and operation of the enterprises.

According to the Administrative Regulations on Housing Provident Funds (《住房公積金管理條例》), which was promulgated on 3 April 1999 and latest amended on 24 March 2019, employers are required to make contribution to housing provident funds for their employees. Where an employer fails to pay up housing provident funds, the housing provident fund administration center may order it to make payment within a prescribed time limit. If the employer still fails to do so, the housing provident fund administration center may apply to the court for compulsory enforcement of the unpaid amount.

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Regulations in Relation to Information Security and Data Privacy

Data Security and Export

The NPCSC promulgated the Data Security Law of the People’s Republic of China (《中華人民共和國數據安全法》), on June 10, 2021 (effective from September 1, 2021), for the establishment of a data classification and grading protection system to conduct classified and hierarchical protection of data. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a sound full-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security.

According to the Measures for Security Assessment of Data Export (《數據出境安全評估辦法》) issued by the Cyberspace Administration of China on July 7, 2022 and came into effect on September 1, 2022, a data processor that provides data overseas under any of the following circumstances shall apply to the national cyberspace administration for the security assessment of the outbound data transfer through local provincial cyberspace administration: (i) a data processor provides important data abroad; (ii) the critical information infrastructure operator or the data processor that has processed the personal information of more than 1 million people provides personal information abroad; (iii) the data processor that has provided the personal information of over 100,000 people or the sensitive personal information of over 10,000 people cumulatively since January 1 of the previous year provides personal information abroad.; and (iv) any other circumstance where an application for the security assessment of outbound data transfer is required by the national cyberspace administration.

According to the Measures for Standard Contract for Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》) issued by the Cyberspace Administration of China on February 22, 2023 and effective from June 1, 2023, to provide personal information to an overseas recipient through the conclusion of the standard contract, a personal information processor shall meet all of the following circumstances: (i) it is not a critical information infrastructure operator; (ii) it has processed the personal information of less than one million individuals; (iii) it has cumulatively provided the personal information of less than 100,000 individuals to overseas recipients since January 1 of the previous year; and (iv) it has cumulatively provided the sensitive personal information of less than 10,000 individuals since January 1 of the previous year.

According to the Provisions on Facilitating and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》), a data handler that is not a critical information infrastructure operator, will be exempted from declaring for security assessment for outbound data transfer, signing a standard contract with overseas recipient or passing the personal protection certification, if such data handler accumulatively transfers overseas ordinary personal information of less than 100,000 individuals since the January 1 of the current year.

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Personal Information Protection

According to the Civil Code (《民法典》), personal information of natural persons is protected by law. If any organization or individual needs to obtain other people’s personal information, they should obtain it in accordance with the law and ensure the security of the information. They must not illegally collect, use, process, or transmit other people’s personal information, and must not illegally buy, sell, provide, or disclose the information. The Personal Information Protection Law of the People’s Republic of China (《中華人民共和國個人信息保護法》) promulgated by the NPCSC on August 20, 2021 and implemented on November 1, 2021, further emphasizes the obligations and responsibilities of processors for the protection of personal information, and requests higher level of protective measures on the processing of sensitive personal information.

According to the Cybersecurity Law of the People’s Republic of China (《中華人民共和國網絡安全法》) promulgated by the NPCSC on November 7, 2016 and effective on June 1, 2017, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, and publicly disclose the rules for collection and use, clearly state the purpose, method and scope of collecting and using information, and obtain the consent of the person whose data is being collected. Network operators shall not collect personal information unrelated to the services they provide. Network operators are not allowed to leak, tamper with, or damage the personal information they collect; they are not allowed to provide personal information to others without the consent of the person whose data is being collected. However, this does not apply to cases where a specific individual cannot be identified and the identity cannot be recovered after processing. Network operators should take technical measures and other necessary measures to ensure the security of the personal information they collect and prevent leakage, damage and loss of information.

Laws and Regulations in Relation to Anti-Bribery

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by SCNPC, as amended and effective as of April 23, 2019, and the Interim Provisions on the Prohibition of Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》) promulgated by the SAIC on November 15, 1996, any business operator shall not provide or promise to provide economic benefits (including cash, other property or by other means) to a counter-party in a transaction or a third party that may be able to influence the transaction, in order to entice such party to secure a transactional opportunity or competitive advantages for the business operator. Any business operator breaching the relevant anti-bribery rules above-mentioned may be subject to administrative punishment or criminal liability depending on the seriousness of the cases.

Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》), which was promulgated by the National Health and Family Planning Commission (currently the NHC) and came into effect on March 1, 2014, any medicine production and operation enterprises or agents that are involved in criminal, investigational or administrative procedures for commercial bribery will be listed in the adverse records of commercial bribes by the relevant government authorities, as a result of which, for two years

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from the date the list of adverse records of commercial briberies is published, (i) their products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies within the relevant provinces, and (ii) the scores of their products in the centralized tender processes of public medical institutions or medical and health institutions receiving financial subsidies in other provinces will be reduced. As for those enterprises or agents listed in adverse records twice within five years, their products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies throughout China for two years from the date the list of adverse records of commercial briberies is published.

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

According to the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》) issued by the China Securities Regulatory Commission (the “CSRC”) on February 17, 2023 and effective from March 31, 2023 (hereinafter referred to as the “Trial Measures”), where a domestic company seeks overseas securities issuance and listing, the issuer shall file with the CSRC in accordance with the Trial Measures. If an issuer procures an overseas initial public offering or listing, it shall file with the CSRC within three (3) business days after submitting application documents for overseas securities issuance and listing.

According to the Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) jointly issued by the CSRC and other departments on February 24, 2023 and effective on March 31, 2023, in the overseas offering and listing activities of domestic enterprises, domestic enterprises, and securities companies and securities service institutions that provide corresponding services shall strictly comply with the applicable laws and regulations of the People’s Republic of China and satisfy the requirements of these Provisions, enhance the legal awareness of safeguarding state secrets and strengthening archives administration, establish and improve the confidentiality and archives work system, and take necessary measures to fulfill the confidentiality and archives administration obligations, and shall not divulge state secrets or work secrets of state organs, or harm the interests of the state or the public. A domestic enterprise that, either directly or through its overseas listed entity, publicly discloses or provides to relevant securities companies, securities service institutions, overseas regulators, and other entities and individuals, any documents and materials that involve state secrets or work secrets of state organs, shall obtain approval from the competent department with the power of examination and approval according to the law, and report to the administrative department of confidentiality at the same level for filing. A domestic enterprise that, either directly or through its overseas listed entity, publicly discloses or provides to relevant securities companies, securities service institutions, overseas regulators, and other entities and individuals, other documents and materials whose divulgence will have adverse impact on national security or public interest, shall strictly undergo the relevant procedures in accordance with the relevant regulations of the state.

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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.

U.S. Government Regulation of Drug and Biological Products

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

Once a product candidate is identified for development, it enters 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 re-approve the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB’s requirements or if the product has been associated with unexpected serious harm to subjects.

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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 pharmacokinetics and pharmacodynamics information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase III clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify 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 current Good Manufacturing Practice (“cGMP”) requirements. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions.

U.S. Review and Approval Processes

The results of product development, 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 a BLA. Unless deferred or waived, BLAs, or supplements must contain data adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations

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and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The submission of a BLA is subject to the payment of a substantial user fee and an annual prescription drug program fee.

Within 60 days of its receipt, the FDA reviews the BLA to ensure that it is sufficiently complete for substantive review before it accepts the BLA for filing. After accepting the BLA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product’s manufacturing is cGMP-compliant to assure the product’s identity, strength, quality and purity. Before approving the BLA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the BLA to an advisory committee, a panel of experts, for review whether the application should be approved and under what conditions and considers such recommendations when making decisions.

The FDA may refuse to approve the BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response letter describing all of the specific deficiencies that the FDA identified in the BLA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase IV clinical trials, to further assess a product’s safety and effectiveness after BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited Development and Review Programs

The FDA has various programs that are intended to expedite or streamline the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

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Fast-track Designation

To be eligible for a fast-track designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and demonstrates the potential to address an unmet medical need for the disease or condition. Under the fast-track program, the sponsor of a drug candidate may request FDA to designate the product for a specific indication as a fast-track product concurrent with or after the filing of the IND for the drug candidate. The FDA must make a fast-track designation determination within 60 days after receipt of the sponsor’s request.

In addition to other benefits, such as the ability to use surrogate endpoints and have greater interactions with FDA, FDA may initiate review of sections of a fast-track product’s NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA’s time period goal for reviewing a fast-track application does not begin until the last section of the NDA is submitted. In addition, the fast-track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority Review

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under the Prescription Drug User Fee Act (the “PDUFA”) guidelines. These six- and ten-month review periods are measured from the “filing” date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast-track designation are also likely to be considered appropriate to receive a priority review.

Accelerated Approval

Under FDA’s accelerated approval regulations, the FDA may approve a drug or biologic candidate for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (“IMM”), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trial to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

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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.

Orphan Drugs

Under The Orphan Drug Act of 1983, the FDA may grant orphan drug designation to drugs or biologic candidates intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the U.S. or for which a manufacturer has no reasonable expectation of recovering drug treatment research and development costs. The first applicant to receive FDA approval for the disease or indication for which it has orphan drug designation is entitled to a seven-year exclusive marketing period. During the exclusivity period, the FDA may not approve any other applications to market the same product for the same disease or condition except in limited circumstance.

Post-Marketing Requirements

Following the approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations, known as “off-label use,” and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

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The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy (the “REMS”), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for noncompliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP.

Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including recall.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals; drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

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Patient Protection and Affordable Health Care Act

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the “ACA”), became law in the United States in March 2010, and have driven healthcare reform in the United States by extending health insurance coverage and substantially changing the way healthcare financed by both governmental and private insurers in the United States. With regard to pharmaceutical products specifically, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. Among other things, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies’ share of sales to federal health care programs.

Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA, and there may be additional challenges and amendments to the ACA in the future. Since January 2017, former President Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed, for example, the Tax Act enacted by the Congress in 2017 which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. There may be other efforts to challenge, repeal or replace the ACA.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of a BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product’s testing phase, which is the time between IND and BLA submission, and all of the review phase, which is the time between BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration, only those claims covering the approved product, a method for using

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it, or a method for manufacturing it may be extended, and the patent holder must apply for restoration within 60 days of approval. The United States Patent and Trademark Office (the “USPTO”), in consultation with the FDA, reviews and approves the application for patent term restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and the patent owner may apply for no more than four subsequent interim extensions. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which a BLA has not been submitted.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OVERVIEW

Our history can be traced back to 1996, when Dr. Zhu Yi, our chairman of the Board, general manager and Chief Scientific Officer, established Baili Pharmaceutical, which is the predecessor of our Company and currently one of our key subsidiaries. In August 2006, our Company, under the name of its predecessor, Tianheng Pharmaceutical, was established. In November 2011, our Company was converted into a joint stock company under the name of Sichuan Biokin Pharmaceutical Co., Ltd. (四川百利天恒藥業股份有限公司). In January 2023, our Company was listed on the SSE STAR Market (stock code: 688506). See “— Major Shareholding Changes of Our Company” for more details.

Through years of dedicated effort, we have cultivated expertise in complex generics and traditional Chinese medicine. More importantly, we have grown into an integrated pharmaceutical corporate group with capabilities spanning early-stage research, clinical development, manufacturing, and commercialization.

In 2010, we made the strategic move into the innovative drug business. To support this shift, we reinvested most of our revenue from our generic drug and traditional Chinese medicine business into innovative drug research and development. In 2014, we established SystImmune in Seattle, the U.S., to lead the 0-to-1 innovation of therapeutics modalities and discovery of novel drug pipelines. SystImmune also spearheads our global clinical development and future commercialization in global markets.

Our endeavors over the past decade have led to the creation of (i) an innovative ADC drug development platform, from which we have successfully advanced eight clinical-stage, innovative ADC candidates, including BL-B01D1, into approximately 50 clinical studies, including eight Phase III clinical trials for late-line cancer treatment and 12 Phase II clinical trials for 1L cancer treatment; and (ii) a multi-specific T cell engager platform, from which we have successfully advanced four innovative GNC multi-specific antibodies, including GNC-077, to clinical stage, which have been evaluated in 13 clinical studies.

OUR KEY MILESTONES

The following table sets out a summary of the key milestones in our corporate and business development:

Year	Milestone
1996	• Baili Pharmaceutical was established to produce traditional Chinese medicine and other drugs.
2005	• Guorui Pharmaceutical was established to produce anesthesia drugs.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Milestone
2006	<ul style="list-style-type: none"> Tianheng Pharmaceutical, our Company’s predecessor, was established.
2010	<ul style="list-style-type: none"> We made the strategic pivot to enter the innovative drug business.
2011	<ul style="list-style-type: none"> Our Company was converted into a joint stock limited company under the name of Sichuan Biokin Pharmaceutical Co., Ltd.
2014	<ul style="list-style-type: none"> Jingxi Pharmaceutical was established to produce active pharmaceutical ingredients. Hiatt Technology was established to produce pharmaceutical intermediates. We established SystImmune, a wholly-owned subsidiary, in Seattle, the U.S. to lead our innovation of therapeutics modalities and discovery of novel drug pipelines. We established our innovative HIRE-ADC platform and bispecific antibody SEBA platform.
2015	<ul style="list-style-type: none"> We established our innovative multi specific antibody GNC platform.
2017	<ul style="list-style-type: none"> Baili-Bio was established to produce antibody drugs.
2019	<ul style="list-style-type: none"> We brought SI-B001, a potentially first-in-class EGFR × HER3 bispecific antibody to the clinical stage.
2020	<ul style="list-style-type: none"> Our multi-specific T cell engagers, GNC-038 and GNC-039, were the first tetra-specific antibodies globally to reach the clinical stage.
2021	<ul style="list-style-type: none"> Our key asset BL-B01D1 entered the clinical stage, making it the world’s first and only clinical-stage EGFR × HER3 bispecific ADC.
2022	<ul style="list-style-type: none"> BL-M07D1, our HER2 ADC with a novel cleavable linker and a TOP-1 inhibitor payload, entered clinical development.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Milestone
2023	<ul style="list-style-type: none">• Our Company was listed on the SSE STAR Market (stock code: 688506) in January.• We announced data from our first-in-human, Phase I clinical trial of BL-B01D1 during the 2023 ASCO annual meeting.• We initiated our first U.S.-based clinical trial for BL-B01D1.• SI-B001 advanced to Phase III clinical development, marking our first Phase III clinical trial.• We advanced BL-B01D1 to Phase III clinical trial, making it the first and only bispecific ADC to enter Phase III clinical development globally.• We entered into the global strategic license and collaboration agreement with BMS, under which we and BMS will conduct a global strategic collaboration to co-develop and co-commercialize BL-B01D1.
2024	<ul style="list-style-type: none">• We advanced BL-B16D1 and BL-M17D1, our two novel ADCs with the same proprietary new-generation payload developed on our platform to Phase I clinical trials.• We advanced GNC-077, an innovative multi-specific antibody molecule to Phase I clinical trial.• We initiated a total of six Phase III clinical trials for BL-B01D1 this year.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

MAJOR SHAREHOLDING CHANGES OF OUR COMPANY

1. Incorporation and Early Development

On August 17, 2006, our predecessor, Tianheng Pharmaceutical, was established in PRC with a registered capital of RMB1,000,000, among which Baili Pharmaceutical and Chengdu Xinbo Technology Co., Ltd.* (成都新博科技有限責任公司) (“**Chengdu Xinbo**”), each of which was ultimately controlled by Dr. Zhu, contributed RMB950,000 and RMB50,000, representing 95% and 5% of the total registered capital, respectively.

On October 22, 2007, Chengdu Xinbo entered into a share transfer agreement with Baili Pharmaceutical, pursuant to which Chengdu Xinbo transferred its 5% equity interest to Baili Pharmaceutical at a consideration of RMB50,000, which equaled to the value of registered capital in Tianheng Pharmaceutical held by Chengdu Xinbo. Upon completion of such transfer, Tianheng Pharmaceutical became wholly owned by Baili Pharmaceutical.

On December 24, 2010, Baili Pharmaceutical entered into a share transfer agreement with its then shareholders, namely, Dr. Zhu, Ms. Zhang Suyu and Ms. Zhu Ying (being the sister of Dr. Zhu), pursuant to which Baili Pharmaceutical transferred 96.81%, 3.00% and 0.19% equity interest in Tianheng Pharmaceutical to Dr. Zhu, Ms. Zhang Suyu and Ms. Zhu Ying at a consideration of RMB968,100, RMB30,000 and RMB1,900, respectively, which were determined with reference to the then registered capital of Tianheng Pharmaceutical. Upon completion of the transfer, Dr. Zhu, Ms. Zhang Suyu and Ms. Zhu Ying held approximately 96.81%, 3.00% and 0.19% of the equity interest in Tianheng Pharmaceutical, respectively.

On July 15, 2011, Xinjiang Xinxu Equity Investment Limited Partnership* (新疆新璽股權投資有限合夥企業) (“**Xinjiang Xinxu**”) and Hangzhou Ronggao Equity Investment Co., Ltd.* (杭州融高股權投資有限公司) (“**Hangzhou Ronggao**”), each an Independent Third Party, agreed to subscribe approximately 2.75% and 1.93% equity interest in Tianheng Pharmaceutical at a consideration of RMB1,599,828 and RMB1,122,686, respectively, which was determined on an arm’s length basis between the Company and the investors, taking into account the development status of the Company at the time. Upon the completion of the capital injection, Dr. Zhu, Ms. Zhang Suyu, Xinjiang Xinxu, Hangzhou Ronggao and Ms. Zhu Ying held approximately 92.28%, 2.86%, 2.75%, 1.93% and 0.18% of the equity interest in Tianheng Pharmaceutical, respectively.

2. Conversion into a joint-stock company in November 2011

On November 29, 2011, Tianheng Pharmaceutical was converted into a joint stock company with a registered capital of RMB103,720,000 under the name of Sichuan Biokin Pharmaceutical Co., Ltd. Upon completion of the conversion, Dr. Zhu, Ms. Zhang Suyu, Xinjiang Xinxu, Hangzhou Ronggao and Ms. Zhu Ying continued to hold approximately 92.28%, 2.86%, 2.75%, 1.93% and 0.18% of the equity interest in our Company, respectively.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

3. Capital injection in December 2011

On December 19, 2011, Ms. Zhang Suyu and 45 other individuals agreed to subscribe for additional shares in the Company at a total consideration of RMB3,328,000, which was determined with reference to the net asset value of approximately RMB269.4 million of the Company as of July 31, 2011, as set out in the valuation report prepared by a third-party valuer. Our share capital increased to RMB105,000,000 after the capital injection. The shareholding structure of our Company immediately after the completion of the capital injection was as follows:

No.	Name of Shareholder	Number of shares	Approximate percentage of shareholding (%)
1.	Dr. Zhu	95,716,136	91.16
2.	Ms. Zhang Suyu	3,076,100	2.93
3.	Xinjiang Xinxi	2,850,000	2.71
4.	Hangzhou Ronggao	2,000,000	1.90
5.	Ms. Zhu Ying ⁽¹⁾	187,764	0.18
6.	Mr. Zhu Mingdong ⁽²⁾	100,000	0.095
7.	Mr. Zhu Xi ⁽³⁾	100,000	0.095
8.	Mr. Kang Jian ⁽⁴⁾	80,000	0.076
9.	Mr. Wang Yajun ⁽⁵⁾	80,000	0.076
10.	Mr. Zhong Shaoquan ⁽⁶⁾	80,000	0.076
11.	Mr. Li Jian ⁽⁷⁾	50,000	0.048
12.	Ms. Jiang Ling ⁽⁸⁾	40,000	0.038
13.	Ms. Liu Xin ⁽⁹⁾	40,000	0.038
14.	Ms. Wang Xiaoxiao ⁽¹⁰⁾	40,000	0.038
15.	Mr. Zhang Yong ⁽¹¹⁾	40,000	0.038
16.	Mr. Liu Liang ⁽¹²⁾	10,000	0.0095
17.	Mr. Wang Gang ⁽¹³⁾	10,000	0.0095
18.	Other Shareholders ⁽¹⁴⁾	500,000	0.48
Total		105,000,000	100

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Notes:

- (1) Ms. Zhu Ying is a supervisor of Baili Pharmaceutical and the sister of Dr. Zhu.
- (2) Mr. Zhu Mingdong is a former director and a former deputy general manager of our Company.
- (3) Mr. Zhu Xi is a former director of our Company and the brother of Dr. Zhu.
- (4) Mr. Kang Jian is an executive Director and a deputy general manager of our Company. See “Directors, Supervisors and Senior Management” for details.
- (5) Mr. Wang Yajun is a former employee of our Group and an Independent Third Party.
- (6) Mr. Zhong Shaoquan is a former employee of our Group and an Independent Third Party.
- (7) Mr. Li Jian is a former employee of our Group and an Independent Third Party.
- (8) Ms. Jiang Ling is a former supervisor of our Company.
- (9) Ms. Liu Xin is a former supervisor of our Company.
- (10) Ms. Wang Xiaoxiao is the vice president of the Group and the assistant to our chairman of the Board. She is the daughter (aged above 18) of Ms. Zhang Suyu.
- (11) Mr. Zhang Yong is a supervisor of Lhasa Xinbo and the brother of Ms. Zhang Suyu.
- (12) Mr. Liu Liang is a supervisor of our Company. See “Directors, Supervisors and Senior Management” for details.
- (13) Mr. Wang Gang is a supervisor of Tianze Pharmaceutical.
- (14) Other Shareholders included 33 individuals who are employees or ex-employees of our Company, each of whom is an Independent Third Party holding less than 0.03% equity interest in our Company immediately after the completion of such capital injection.

4. Capital injection by OAP III in September 2017

On August 16, 2017, OAP III (HK) Limited (“**OAP III**”) entered into a capital injection agreement with Dr. Zhu and our Company, pursuant to which OAP III agreed to subscribe for approximately 9.43% of the enlarged equity interest in our Company at a consideration of USD38,226,300, which is equivalent to RMB250,000,000, which was determined based on an arm’s length negotiation among the parties. The investment was duly settled on September 15, 2017. Our share capital increased to RMB115,937,500 after the capital injection.

OAP III is wholly owned by OrbiMed Asia Partners III, L.P. OrbiMed Asia GP III, L.P. is the general partner of OrbiMed Asia Partners III, L.P. OrbiMed Asia Partners III, L.P. has 102 limited partners and none of such limited partners individually hold more than 20% partnership interest in OrbiMed Asia Partners III, L.P. OrbiMed Advisors III Limited is the general partner of OrbiMed Asia GP III, L.P. OrbiMed Advisors III Limited has 12 shareholders, each of whom holds equal ownership. To the best of our knowledge, save for Mr. David Guowei Wang who is our non-executive Director, the other 11 shareholders of OrbiMed Advisors III Limited are all Independent Third Parties.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

5. Share transfer in March 2018

On January 25, 2018, Guangzhou Defu Phase II Equity Investment Fund (Limited Partnership) (廣州德福二期股權投資基金(有限合夥)) (“**Guangzhou Defu**”) entered into a share transfer agreement with Xinjiang Xinxi and Hangzhou Ronggao, pursuant to which Xinjiang Xinxi and Hangzhou Ronggao transferred approximately 2.46% and 1.73% of the equity interest in our Company to Guangzhou Defu at a total consideration of RMB65,142,300 and RMB45,715,200, respectively, which was determined based on an arm’s length negotiation between the parties.

6. A Shares offering and listing on the SSE STAR Market in January 2023

As approved by the CSRC, our A Shares were listed on the SSE STAR Market with the stock code of 688506 on January 6, 2023 (the “**A Share Offering**”). Upon completion of the A Share offering, our share capital increased to RMB401,000,000.

The shareholding structure of our Company immediately after the A Share Offering was as follows:

Name of Shareholder		Number of shares	Approximate percentage of shareholding (%)
1.	Dr. Zhu	298,108,880	74.34
2.	OAP III	34,047,171	8.49
3.	Guangzhou Defu	15,097,488	3.77
4.	Ms. Zhang Suyu	9,575,543	2.39
5.	Mr. Zhu Xi	902,737	0.23
6.	Ms. Zhu Ying	584,487	0.15
7.	Mr. Zhu Mingdong	311,289	0.08
8.	Mr. Kang Jian	249,030	0.06
9.	Mr. Wang Yajun	249,030	0.06
10.	Mr. Zhong Shaoquan	249,030	0.06
11.	Ms. Jiang Ling	124,514	0.03
12.	Ms. Liu Xin	124,514	0.03
13.	Ms. Wang Xiaoxiao	124,514	0.03
14.	Mr. Zhang Yong	124,514	0.03
15.	Mr. Liu Liang	31,129	0.0077
16.	Mr. Wang Gang	31,129	0.0077
17.	Other A Shareholders	41,065,001	10.23
Total		401,000,000	100

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

7. Non-public share transfer in March 2024

On March 27, 2024, OAP III transferred a total of 5,520,000 Shares of our Company to 21 institutional investors, by way of a non-public transfer at a price of RMB109.25 per A Share for a total consideration of RMB603.1 million, which was duly settled on March 26, 2024. Following the share transfer, OAP III held approximately 7.11% of equity interest in the Company. The following table sets out the details of the non-public share transfer:

Name of Shareholder	Number of A Shares acquired	Approximate percentage of shareholding immediately after the non-public share transfer (%)
Guotai Junan Financial Holdings Limited.	1,350,000	0.337
GF Fund Management Co., Ltd.	1,110,000	0.277
Fullgoal Fund Management Co., Ltd	940,000	0.234
Lord Abbett China Asset Management Co., Ltd.	510,000	0.127
UBS AG	410,000	0.102
Morgan Stanley & Co. International Plc.	250,000	0.062
Xingquan Organic Growth Flexible Allocation Hybrid Securities Investment Fund* (興全有機增長靈活配置混合型證券 投資基金)	180,000	0.045
Shanghai Ailixiang Private Equity Fund Management Partnership (Limited Partnership)* (上海艾禮象私募基金管理合 夥企業(有限合夥))	180,000	0.045
J.P. Morgan Securities plc	130,000	0.032
CITIC Securities Company Limited	60,000	0.015
Zhejiang Longhang Asset Management Co., Ltd.* (浙江龍航資產管理有限公司)	50,000	0.012
Qingdao Luxiu Investment Management Co., Ltd.* (青島鹿秀投資管理有限公司)	50,000	0.012
Panhou Weiran (Shanghai) Private Fund Management Limited	40,000	0.010
Abama Asset Management Co., Ltd	40,000	0.010
Ningbo Meishan Bonded Port Area Lingding Investment Management Co., Ltd.* (寧波 梅山保稅港區凌頂投資管理有限公司)	40,000	0.010

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Name of Shareholder	Number of A Shares acquired	Approximate percentage of shareholding immediately after the non-public share transfer (%)
Beijing Fanfan Private Fund Management Co., Ltd.* (北京平凡私募基金管理有限公司)	30,000	0.007
Minsheng Securities Co., Ltd.	30,000	0.007
Zhuhai Juyi Fund Management Co., Ltd.	30,000	0.007
Shanghai Mu Xin Asset Management Limited	30,000	0.007
Shanghai Fengyi Investment Management Co., Ltd.* (上海豐誼投資管理有限公司)	30,000	0.007
Beijing Renaissance Era Investment Management Co., Ltd	30,000	0.007
Total	5,520,000	1.38

[REDACTED]

To the best knowledge of the Company, the A Shares held by (i) Dr. Zhu, Ms. Zhang Suyu and Mr. Kang Jian, each a Director of the Company; (ii) Mr. Liu Liang, a Supervisor of the Company; (iii) Ms. Zhu Ying, Mr. Zhang Yong and Mr. Wang Gang, each a supervisor of the subsidiaries of the Company, will not be counted towards the [REDACTED] (as defined in the Listing Rules) upon the [REDACTED].

Except as stated above, to the best knowledge of the Company and based on its shareholding structure as of the Latest Practicable Date, none of the other Shareholders is expected to be our core connected person, and the Shares held by them, amounting to approximately [REDACTED]% of our total issued share capital immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised), are expected to be counted towards the [REDACTED] upon the [REDACTED].

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

[REDACTED]

MAJOR ACQUISITIONS AND DISPOSALS

During the Track Record Period and as of the Latest Practicable Date, we did not conduct any acquisitions, disposals or mergers that we consider to be material to us.

OUR SUBSIDIARIES

The following chart sets out the detailed information of our subsidiaries as of the Latest Practicable Date:

<u>Name of subsidiaries</u>	<u>Place of incorporation</u>	<u>Date of incorporation</u>	<u>Equity interest attributable to our Group</u>	<u>Principal activities</u>
Baili Pharmaceutical	PRC	August 23, 1996	100%	Production, research and development of pharmaceutical products
Guorui Pharmaceutical	PRC	December 7, 2005	100%	Production, research and development of pharmaceutical products
Lhasa Xinbo	PRC	August 22, 2013	100%	Sales and distribution of pharmaceutical products
Panku Capital	BVI	April 16, 2014	100%	Investment holding
SystImmune	US	April 21, 2014	100%	Research and development of pharmaceutical products
Hiatt Technology	PRC	September 29, 2014	100%	Production, research and development of pharmaceutical products

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Name of subsidiaries	Place of incorporation	Date of incorporation	Equity interest attributable to our Group	Principal activities
Jingxi Pharmaceutical	PRC	September 29, 2014	100%	Production, research and development of pharmaceutical products
Baili-Bio	PRC	February 21, 2017	100%	Production, research and development of pharmaceutical products
Tianze Pharmaceutical	PRC	November 26, 2020	100%	Production of pharmaceutical products

OUR LISTING ON THE SSE STAR MARKET AND THE REASONS FOR THE [REDACTED] ON THE STOCK EXCHANGE

Since the date of our listing on the SSE STAR Market up to the Latest Practicable Date, we had not received any notice from the SSE STAR Market alleging any non-compliance incidents on the part of our Company or our subsidiaries, and our Directors confirm that we had no instances of non-compliance with the rules of the SSE STAR Market in all material respects, and to the best knowledge of our Directors after having made all reasonable enquiries, there is no matter that should be brought to the attention of our potential [REDACTED] or the Stock Exchange in relation to our compliance record on the SSE STAR Market. Based on the independent due diligence conducted by the Joint Sponsors, nothing has come to the Joint Sponsors’ attention that would cause them to disagree with our Directors’ confirmation with regard to the compliance records of the Company on the SSE STAR Market.

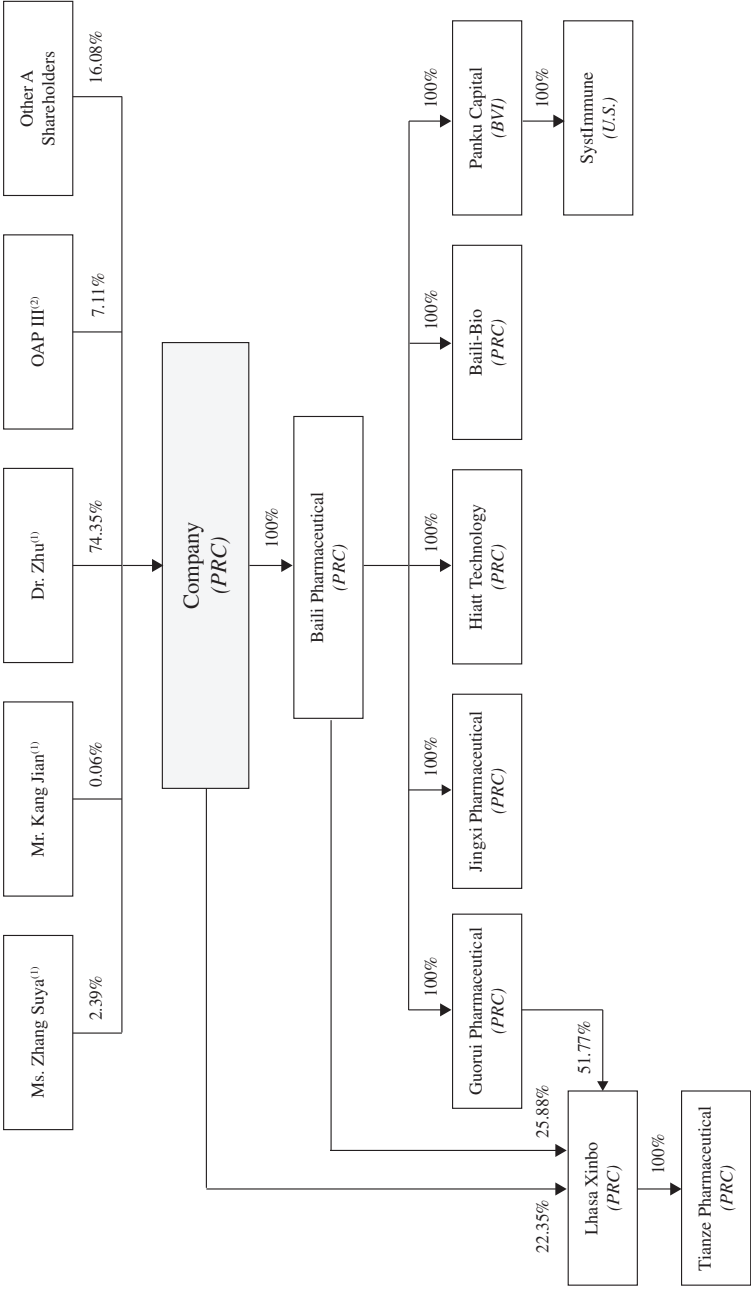
Immediately upon the listing of our A Shares on the SSE STAR Market, the market valuation of our Company was approximately RMB9,904.7 million. We had received approximately RMB884.4 million net proceeds after deducting the listing expenses from the initial public offering of our A Shares on the SSE STAR Market. As of the Latest Practicable Date, approximately 88.42% of such net proceeds had been utilized.

Our Company is seeking a [REDACTED] of its H shares on the Hong Kong Stock Exchange in order to raise further capital to enhance the development of our Company’s international business, better utilize domestic and oversea fundraising platform, strengthen the working capital of our Company, support our global clinical development and strategic growth towards a multinational pharmaceutical company with global leadership in the field of oncology drugs. See “Future Plans and Use of [REDACTED]” in this Document for further details.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

CORPORATE AND SHAREHOLDING STRUCTURE IMMEDIATELY PRIOR TO THE [REDACTED]

The following chart sets forth our corporate and shareholding structure immediately prior to the [REDACTED]:



HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Notes:

- (1) Dr. Zhu is our executive Director, chairman of the Board, general manager and Chief Scientific Officer.

Ms. Zhang Suyu is our executive Director, executive deputy general manager and chief financial officer.

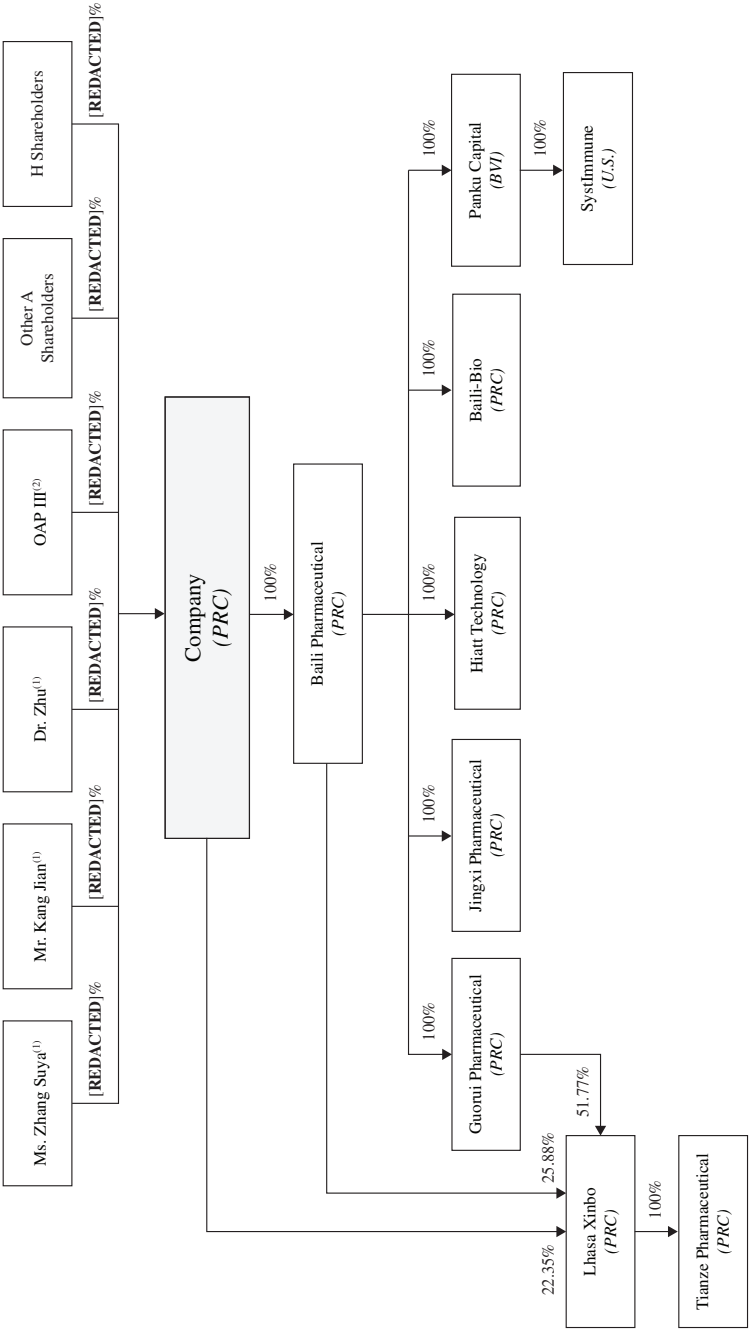
Mr. Kang Jian is our executive Director and deputy general manager.

See “Directors, Supervisors and Senior Management” for further details.
- (2) OAP III is wholly owned by OrbiMed Asia Partners III, L.P. OrbiMed Asia GP III, L.P. is the general partner of OrbiMed Asia Partners III, L.P. OrbiMed Advisors III Limited is the general partner of OrbiMed Asia GP III, L.P. OrbiMed Advisors III Limited is owned by 12 individuals, each of whom holds an equal ownership. To the best of our knowledge, save for Mr. David Guowei Wang who is our non-executive Director, the other 11 individuals are all Independent Third Parties. For more details, see “— 4. Capital injection by OAP III in September 2017” for more details.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

CORPORATE AND SHAREHOLDING STRUCTURE IMMEDIATELY FOLLOWING THE COMPLETION OF THE [REDACTED]

The following chart sets forth our corporate shareholding structure immediately following the completion of [REDACTED], assuming the [REDACTED] is not exercised:



Notes:

See notes (1) to (2) of the subsection headed “— Corporate and Shareholding Structure Immediately Prior to the [REDACTED]” above for details.

BUSINESS

OVERVIEW

We are an integrated pharmaceutical group with capabilities spanning early-stage research and development, clinical development, manufacturing and commercialization. We operate two major businesses: innovative biologics business, and generics and traditional Chinese medicine business.

Ten years ago, in 2014, we established SystImmune in Seattle, U.S., embarking on the development of BL-B01D1, the world’s first and only clinical-stage EGFR × HER3 bispecific ADC to date. A decade later, we entered into a global strategic license and collaboration agreement for BL-B01D1 with BMS, with a US\$800 million upfront payment and a total deal value worth up to US\$8.4 billion — being the largest ever for a single-asset collaboration transaction in the ADC space in terms of total deal value. Our endeavors in the U.S. over the past decade have led to the creation of (i) an innovative ADC drug development platform, from which we have successfully advanced eight clinical-stage, innovative ADC candidates, including BL-B01D1, into approximately 50 clinical studies, including eight Phase III clinical trials for late-line cancer treatment and 12 Phase II clinical trials for first-line cancer treatment; and (ii) a multi-specific T cell engager platform, from which we have successfully advanced four innovative Guidance Navigation & Control (GNC) multi-specific antibodies, including GNC-077, to clinical stage, which have been evaluated in 13 clinical studies.

Through years of dedicated effort since 1996, we have cultivated expertise in generics and traditional Chinese medicine. Our generics and traditional Chinese medicine business has a product portfolio in anesthesia, parenteral nutrition, anti-infection, pediatrics and other therapeutic areas. We have accumulated rich experience in R&D, production and marketing of special preparations such as emulsion injections and effervescent preparations, and have formed a competitive product portfolio. During the Track Record Period, we generated revenue from the sales of 29 approved drug products with over 100 specifications, which includes 25 generics products and four traditional Chinese medicine products. Revenue from these products has played a crucial role in funding our innovative drug development.

As of the Latest Practicable Date, all of our innovative drug candidates remained in clinical and preclinical development. In the nine months ended September 30, 2024, we recorded revenue of RMB5,661.2 million, among which 94.2% represented the license fee income generated under our license and collaboration agreement with BMS, and 5.8% represented sales of generics and traditional Chinese medicines. In 2021, 2022 and 2023, we generated a revenue of RMB795.0 million, RMB701.8 million, and RMB560.4 million, respectively, from sales of generics and traditional Chinese medicines. We incurred net losses of RMB107.6 million, RMB282.4 million, RMB780.5 million in 2021, 2022 and 2023, respectively, and achieved a profit of RMB4,065.4 million in the nine months ended September 30, 2024.

BUSINESS

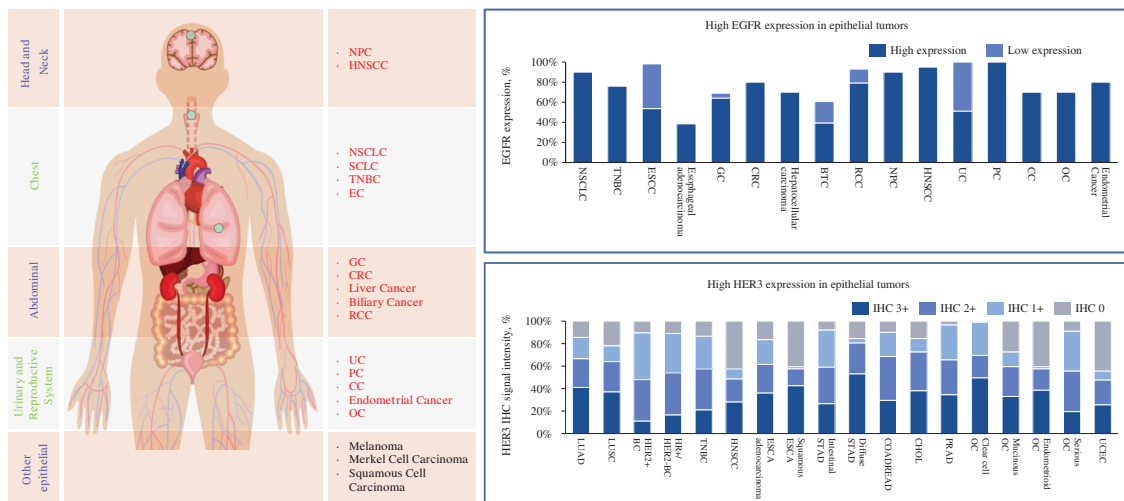
OUR INNOVATIVE BIOLOGICS BUSINESS

First-in-class EGFR × HER3 Bispecific ADC: BL-B01D1

BL-B01D1 is the world’s first and only clinical-stage EGFR × HER3 bispecific ADC. EGFR and HER3 are broadly overexpressed in numerous types of epithelial tumors. The bispecific structure of BL-B01D1 is designed to target a wide range of solid tumors and achieve greater enrichment within tumor tissues, thereby enhancing tumor killing activity and reducing on-target off-tumor toxicity.

We initiated the first-in-human Phase I clinical study for BL-B01D1 in November 2021 and have since enrolled over 2,000 patients across multiple clinical trials, covering over ten tumor types, including lung cancer, breast cancer (BC), head and neck squamous cell carcinoma (HNSCC), nasopharyngeal cancer (NPC), esophageal cancer (EC), gastric cancer (GC), colorectal cancer (CRC), biliary cancer, urothelial carcinoma (UC), prostate cancer (PC), ovarian cancer (OC), endometrial cancer, and cervical cancer (CC). BL-B01D1 has demonstrated promising efficacy and manageable safety in these tumor types, including one of the most promising clinical data profiles for late-line non-small cell lung cancer (NSCLC) to date.

The figures below illustrate major tumor types studied in clinical trials with BL-B01D1 (highlighted in red in the left panel), and various epithelial tumors that exhibit high expression of EGFR and HER3 (shown in the right panel):



Source: Company data; CIC; PLoS One; Frontiers in Oncology; Expert Review of Anticancer Therapy; British Journal of Cancer; Cancer Res Clinic; Radiation Oncology; Oncology Letters; OncoTargets and Therapy; Nature Cell Biology; World Journal of Gastroenterology; Journal of Pathology, Microbiology and Immunology

As of the Latest Practicable Date, we had conducted approximately 30 clinical trials for BL-B01D1, including, (i) seven Phase III clinical trials evaluating BL-B01D1 as monotherapy for late-line treatment of various cancers, including two NSCLC indications, SCLC, two BC indications, ESCC, and NPC, (ii) eight Phase II clinical trials evaluating its combination with

BUSINESS

On December 11, 2023, we reached a global strategic license and collaboration agreement with BMS to co-develop and co-commercialize BL-B01D1. Under the agreement, both parties will jointly develop and commercialize BL-B01D1 in the U.S. We are exclusively responsible for the development, commercialization, and manufacturing of BL-B01D1 in mainland China, and will be responsible for manufacturing certain drug supplies for use outside of mainland China. BMS has an exclusive license for BL-B01D1 in the rest of the world. This collaboration is expected to generate substantial global revenues for the Company, while also allowing us to extend our biopharmaceutical capabilities beyond early-stage drug discovery and development to include global clinical development and commercialization.

Innovative ADC Drug Development Platform

In the course of developing BL-B01D1 (EGFR × HER3 bispecific ADC), we have also made significant advancements in our technology platforms:

- (1) We have established the SEBA (Specificity Enhancement Bispecific Antibody) platform for iterative innovations in antibody discovery and engineering, safeguarded by a global patent portfolio. This platform has successfully identified and advanced a number of antibodies that specifically target and enrich in tumor cells, such as the EGFR × HER3 bispecific antibody. These antibodies are also used in our portfolio of ADC drug candidates, such as BL-B01D1.
- (2) We have established a technology platform for developing payloads with different mechanistic approaches that effectively overcome tumor heterogeneity and enable extensive and efficient tumor cell killing. This platform, protected by a global patent portfolio, has brought forth the TOP-1 inhibitor payload, Ed-04, utilized in four of our clinical-stage ADC drug candidates, including BL-B01D1 and BL-M07D1 (HER2 ADC). Additionally, we have developed another novel payload with a unique mechanism, currently incorporated in BL-B16D1 and BL-M17D1, both of which are in Phase I stage. We are actively developing other novel payloads with differentiated mechanisms as well.
- (3) We have developed a linker and conjugation technology platform that enables stable conjugation of varying numbers of payloads to antibodies, achieving drug-to-antibody ratios (DARs) of 2, 4, 6, 8, or 10. This platform is protected by a global patent portfolio. Among our eight clinical-stage ADC drug candidates, BL-M11D1 employs site-specific conjugation at a DAR of 10, while the others use a DAR of 8.
- (4) Our innovative ADC drug development platform possesses fully in-house, end-to-end capabilities, encompassing (a) target research and evaluation, (b) discovery, screening, and engineering, pilot to mid-scale process development, and large-scale manufacturing of antibodies, (c) design, screening, pilot to mid-scale process development, and large-scale manufacturing of linkers and payloads (small molecule drugs), (d) design and development of conjugation technologies and processes, (e) design, *in vitro/in vivo* efficacy and PK/PD evaluation, and large-scale

BUSINESS

manufacturing of entire ADC drug molecules. This platform has accrued a large volume of foundational research data, enabling continuous iteration of our innovative ADC technologies and development of innovative drug portfolio, thereby ensuring our capacity for sustained innovation.

GNC-077 and Innovative Multi-specific Antibody Development Platform

GNC-077 is an innovative multi-specific antibody molecule, representing a novel class of “targeted immunotherapy” for cancer treatment. We have initiated Phase I clinical trials for GNC-077 for the treatment of BC, NSCLC, GIC and other solid tumors as of the Latest Practicable Date. Its molecular structure features antibody domains targeting T cell CD3 and T cell immune checkpoints, as well as antibody domains targeting tumor antigens. GNC-077 can effectively induce activation, differentiation, and proliferation of naive T cells and guide these activated T cells to specifically target and kill antigen-bearing cancer cells. In our *in vivo* studies, GNC-077 has demonstrated robust “targeted immune” tumor-killing activity in multiple solid tumors.

GNC (Guidance Navigation & Control) is our proprietary multi-specific antibody development platform. It is designed to develop multi-specific antibody with symmetrical/asymmetrical structures that can simultaneously target multiple different antigens. Multi-specific GNC molecules developed on this platform coordinate interactions among several tumor/immune-related protein domains to synergistically and comprehensively activate several mechanisms of the immune system of cancer patients. These GNC compounds guide, navigate, and control T cells, ultimately leading to a stimulatory “targeted immune” attack against the tumors.

In addition to GNC-077, we are developing three other GNC drug candidates at Phase Ib stage, GNC-038 (CD3 × 4-1BB × PD-L1 × CD19), GNC-035 (CD3 × 4-1BB × PD-L1 × ROR1), and GNC-039 (CD3 × 4-1BB × PD-L1 × EGFRvIII). These three GNC molecules are the world’s first and only tetra-specific antibodies in clinical development.

OUR GENERICS AND TRADITIONAL CHINESE MEDICINE BUSINESS

All of our revenues in 2021, 2022 and 2023 and a portion of our revenue in the nine months ended September 30, 2024 were generated from the sale of generics and traditional Chinese medicine drug products. During the Track Record Period, we generated revenue from the sales of 29 approved drug products with over 100 specifications, which includes both generics (covering a wide range of therapeutic areas such as anesthesia, parenteral nutrition, anti-infective and pediatrics) and traditional Chinese medicine products. Revenue from these products has played a crucial role in funding our innovative drug development. We expect new products to be approved for commercialization in the future. As of the Latest Practicable Date, we had submitted nine generic drug applications for production registration with the NMPA.

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The following table summarizes our major marketed products as of the Latest Practicable Date:

Therapeutic Areas	Name of Products
Generic Drugs	
Anesthesia Drugs	Leweijing 乐维静® (Propofol Injectable Emulsion (丙泊酚乳狀注射液)) Leweitai 乐维泰® (Propofol Medium and Long Chain Fat Emulsion Injection (丙泊酚中/長鏈脂肪乳注射液)) Youmeining 右美宁® (Dexmedetomidine Hydrochloride Injection (鹽酸右美托咪定注射液))
Parenteral Nutrition Drugs	Tianze 天泽® (Medium and Long Chain Fat Emulsion Injection (中/長鏈脂肪乳注射液))
Anti-Infective Drugs	Xinbolin 新博林® (Ribavirin Granule (利巴韋林顆粒)) Aobolin 奥博林® (Ornidazole Capsule (奥硝唑膠囊))
Pediatric Drugs	Dulabao 杜拉宝® (Racecadotril Granule (消旋卡多曲顆粒)) Leyeping 乐液平® and Pujikang 朴吉康® (Glucose Electrolyte Effervescent Tablet (葡萄糖電解質泡騰片))
Traditional Chinese Medicine	
	Astragalus Granule (黃芪顆粒) Chaihuang Granule (柴黃顆粒)

OUR JOURNEY

Inception and Growth (1996-2010)

Our history can be traced back to 1996, when Dr. Zhu Yi, our chairman of the Board, general manager and Chief Scientific Officer, established Baili Pharmaceutical, which is the predecessor of our Company and currently one of our key subsidiaries. Through years of dedicated effort, we have cultivated expertise in complex generics and traditional Chinese medicine. Our generics and traditional Chinese medicine business has a product portfolio in anesthesia, parenteral nutrition, anti-infection, pediatrics and other therapeutic areas. We have accumulated rich experience in R&D, production and marketing of special preparations such as emulsion injections and effervescent preparations, and have formed a competitive product portfolio. As of the Latest Practicable Date, our portfolio of marketed products comprised 19 generics products and three traditional Chinese medicine products.

More importantly, we have grown into an integrated pharmaceutical corporate group with capabilities spanning early-stage research, clinical development, manufacturing, and commercialization.

BUSINESS

Strategic Pivot (2010-Present)

To realize long-term growth and enhance patient outcomes, we made the strategic move into the innovative drug business in 2010 and commenced the independent development of innovative drugs. To support this shift, we reinvested most of our revenue from our generic drug and traditional Chinese medicine business into innovative drug research and development. In 2014, we established SystImmune in Seattle, the U.S., to lead the 0-to-1 innovation of therapeutics modalities and discovery of novel drug pipelines. In the same year, we commenced the independent development of bispecific antibodies and ADCs. SystImmune also spearheads our global clinical development and future commercialization in global markets. Our presence in the U.S. has given us access to a highly skilled talent pool with expertise in drug discovery, development and clinical research. Immersion in the global biotech innovation epicenter also offers valuable networking opportunities and insights into emerging trends. At the same time, we have built a team of scientists and specialists in innovative drug development in China over the years.

Substantial Investments in Discovering and Developing Innovative Oncology Drugs (2014-2024)

Since 2014, discovering and developing innovative drugs has been our business focus. We have dedicated substantial resources to the development of ADC, bispecific as well as multi-specific antibody drugs: including establishing the SEBA and HIRE-ADC technology platforms in 2014, followed by the GNC multi-specific platform in 2015. These initiatives have enabled us to achieve a number of “firsts” in the industry, including the world’s first and only clinical-stage EGFR × HER3 bispecific ADC, and the first and only three tetra-specific antibodies to enter into clinical development to date. In 2021, 2022 and 2023 and the nine months ended September 30, 2024, our research and development expenses for innovative drug candidates accounted for 71.5%, 85.9%, 92.9% and 96.3% of our total research and development expenses, respectively.

Our dual R&D centers in the U.S. and China consist of highly experienced professionals specializing in drug discovery, preclinical development, CMC, clinical development, and regulatory affairs. These teams cover the entire R&D cycle for innovative drugs, comprising both exceptional scientists who have grown within our Company and top-tier professionals recruited from the industry. As of September 30, 2024, our R&D teams in the U.S. and China comprised 1,006 members, representing approximately 41.9% of our total workforce. Many of these individuals have extensive experience leading drug discovery and development projects at renowned multinational and domestic biopharmaceutical companies, as well as research institutions such as MD Anderson Cancer Center and Fred Hutchinson Cancer Center, and/or have worked with the FDA. This combination of talent and expertise has equipped us with the requisite R&D capabilities to advance our innovative drug development efforts.

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While as a private company, we received investment from leading healthcare investors such as OrbiMed. We successfully completed a listing of our Company on the SSE STAR Market in January 2023 and commenced a new chapter in our corporate development as a publicly traded company.

In December 2023, we entered into a global strategic license and collaboration agreement with BMS to co-develop and co-commercialize BL-B01D1, in which BMS agreed to pay to the Group a US\$800 million upfront payment and a total consideration of up to US\$8.4 billion. This collaboration is the culmination of years of dedication to innovative drug development and marks our first step toward generating revenue from our innovative oncology drug portfolio.

Insights and Strategies

Focused on oncology, we are committed to continuously innovating and developing new breakthrough cancer drugs, aiding cancer patients to gain an upper hand in the ceaseless fight against cancers.

In the realm of innovative drug development, North America’s innovation ecosystem excels at pioneering 0-to-1 breakthroughs, while China’s ecosystem is notably efficient at 1-to-100 innovative scale-ups. Through SystImmune, we embed ourselves in North America’s vibrant innovation ecosystem. Meanwhile, our R&D team fully leverages the China-efficiency to scale up and accelerate translational research, preclinical development, and proof-of-concept clinical development. Operating dual R&D centers in the U.S. and China allows us to advance innovations rapidly, efficiently and economically. This strategy has been instrumental in our development of innovative ADCs and multi-specific antibodies.

The ideal oncology therapies selectively target tumors without harming normal tissues. We believe ADCs, as “targeted chemotherapy,” and GNCs, as “targeted immunotherapy,” will become two of the most crucial types of weapons in our arsenal against cancer. Leveraging our proprietary ADC, GNC and other technology platforms, we have systematically built a pipeline of innovative drug candidates across multiple modalities that target major tumor types. Going forward, we aim to continue to make substantial investments in discovering and developing innovative drugs with blockbuster potential while realizing the commercial value of our pipeline assets. As many pipeline assets in our innovative drug portfolio are expected to rapidly advance into late-stage development and commercialization in the coming years, we expect that revenue from this business to be the primary driver of our top-line growth in the future.

Our near-term priority is to further accelerate the clinical development for BL-B01D1 both in China and around the globe by leveraging our global strategic collaboration with BMS. We will (i) proactively advance BL-B01D1’s development in combination with PD-(L)1 therapies, aiming to replace the chemotherapy component in 1L treatment for solid tumors where PD-(L)1 combo therapies are the current standard of care; (ii) proactively advance BL-B01D1’s development in combination with TKIs as the new standard of care for cancer indications currently treated with TKI monotherapy in 1L settings; and (iii) continue to develop

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BL-B01D1 in late-line settings, as well as in neoadjuvant and adjuvant settings across over ten epithelial cancers where BL-B01D1 has shown promising efficacy and manageable safety. We expect NDA submission to the NMPA for BL-B01D1 in its first indication by 2026, and the first BLA submission to the FDA in as early as 2028. Over the next three to five years, BL-B01D1 is anticipated to have multiple regulatory approval applications submitted for various indications in China, the U.S., Europe and other regulatory regions.

We reasonably anticipate near-term revenue from our strategic collaboration with BMS. In addition to the US\$800 million upfront payment we have already received in March 2024, we are eligible to receive a nonrefundable milestone payment of US\$250 million upon the initiation of the first Phase II or Phase III trial of the Licensed Product as 1L or 2L treatment in the U.S. on or before December 31, 2025, and another nonrefundable milestone payment of US\$250 million upon the initiation of the first Phase III trial of the Licensed Product as 1L treatment in the U.S. on or before December 31, 2026. Such milestones were established through mutual agreement. In the U.S., we initiated a Phase I clinical trial for BL-B01D1 in August 2023 for various solid tumors including NSCLC, BC, SCLC, EC, and NPC, and a Phase I/IIa clinical trial for BL-B01D1 in combination with osimertinib/pembrolizumab in December 2024 for advanced solid tumors. Based on the current pace of clinical progress, we reasonably anticipate that we will be eligible to receive the contingent near-term payments. We and BMS have conducted a Type B end-of-Phase I meeting with the FDA to discuss the clinical development strategy for a registration-enabling study of BL-B01D1 as a 2L treatment of a certain solid tumor, which we and BMS plan to initiate in 2025. Furthermore, we and BMS have conducted a Type B pre-IND meeting with the FDA to discuss the clinical development strategy for a registration-enabling study of BL-B01D1 as a 1L treatment of a certain solid tumor, which we and BMS also plan to initiate in 2025. The initiation of these registration-enabling studies will potentially qualify as the milestone events that will trigger the foregoing two contingent near-term payments by BMS. According to CIC, Type B meetings are typically held at critical junctures in the development process to align development strategies with regulatory expectations, reduce the risk of delays, and ensure readiness for transitioning to the next clinical phase.

In addition to BL-B01D1, we are committed to advancing the global clinical development of our other ADCs and GNC multi-specific antibodies, aiming to establish a robust and diverse pipeline of ADCs and GNC molecules.

As many of our pipeline assets are rapidly advancing into late-stage development and commercialization, in the medium to long term, we expect our revenue to come primarily from two sources: (i) sales of innovative drugs and (ii) out-licensing deals, partnerships, and co-development and co-commercialization agreements. As our lead asset, BL-B01D1, and other key candidates receive marketing approvals, sales of innovative drugs are expected to be an increasingly significant source of revenue for the Group. We believe our co-development and co-commercialization arrangement with BMS will contribute to fully realizing the global commercial potential of BL-B01D1. Under our global strategic collaboration with BMS, (i) we expect to generate revenue from the sales of BL-B01D1 in mainland China, where we have the exclusive right to commercialize BL-B01D1, while paying BMS a royalty of a mid-single-digit

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percentage of aggregate annual net sales; (ii) we and BMS will share the net profits/losses related to BL-B01D1 sales in the U.S. according to certain agreed-upon percentages; (iii) BMS is required to pay us tiered royalties based on a percentage of aggregate annual net sales of BL-B01D1 in the rest of the world, excluding the U.S. and mainland China, subject to certain customary reductions and a royalty floor; and (iv) for commercialization in the U.S. and the rest of the world, we will take on certain manufacturing responsibilities, which provides an additional source of revenue.

In addition, we will strategically explore out-licensing deals, partnerships, and co-development and co-commercialization agreements based on the unique circumstances surrounding each asset. Under the BMS Agreement, we are eligible to receive up to an aggregate of US\$7.1 billion contingent payments upon the achievement of certain specified regulatory and sales performance milestones. In addition, we believe our pipeline of innovative drug candidates across multiple modalities that target major tumor types are attractive targets for additional collaborations. Building on the BMS deal, we aim to establish out-licensing, partnerships, and co-development and co-commercialization arrangements as a sustainable source of revenue.

To meet our future business needs, we plan to further expand our global operating footprint in manufacturing and commercialization. We are confident that enhancement of our manufacturing, commercialization and operational capabilities will facilitate our integration with global quality systems, expedite market entry, and fully realize the commercial potential of our pipeline. This transition will require greater investments in clinical development, expanded manufacturing capabilities, and increased sales and marketing efforts. Successfully launching and marketing our innovative drug products could result in substantial revenue growth, contingent on market acceptance and adequate demand. Our risk profile will also evolve, with heightened regulatory, market, and operational risks during the commercialization phase. In addition to the inherent risks in discovering and developing innovative drugs, we will face uncertainties in obtaining regulatory approvals, achieving consumer acceptance, and competing with other treatments. Effective management of these factors will be crucial for sustaining growth and achieving long-term success.

OUR PORTFOLIO ASSETS

Our Biologics Pipeline

Leveraging our proprietary technology platforms, we have systematically built a pipeline of innovative drug candidates across multiple modalities that target major tumor types. As of the Latest Practicable Date, our innovative drug pipeline featured 14 clinical-stage drug candidates, led by our BL-B01D1, an EGFR × HER3 bispecific ADC currently in Phase III clinical trials, which we believe has the potential to become a backbone pan-tumor treatment. Our pipeline also includes two other candidates in Phase III clinical trials: BL-M07D1, an innovative HER2-specific ADC, and SI-B001, a potential first-in-class EGFR × HER3 bispecific antibody. All assets in our innovative drug pipeline as of the Latest Practicable Date are self-developed.

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BL-B01D1

The following chart summarizes the development status of BL-B01D1 as of the Latest Practicable Date:

	Indication	Mono/Combo	Treatment Line	Preclinical	IND	Phase Ia	Phase Ib	Phase II	Phase III	Expected Completion Year	Regulatory Authority	Clinical Trial Number
Lung Cancer	EGFRwt NSCLC	Mono	2L	★ Has been included in the list of breakthrough therapies by CDE of NMPA						2026	NMPA	NCT06382129
	EGFRmut NSCLC	Mono	2L	★ Has been included in the list of breakthrough therapies by CDE of NMPA						2026	NMPA	NCT06382116
	SCLC	Mono	2L	★ Has been included in the list of breakthrough therapies by CDE of NMPA						2026	NMPA	NCT06500026
	EGFRmut NSCLC	+ Osimertinib	1L							2025 2026	NMPA	NCT05880706 NCT06498986
	NSCLC	+ SI-B003	1L and 2L+							2025	NMPA	NCT05956587 ¹
	NSCLC	+ PD-(L)1	1L and 2L+							2026	NMPA	NCT06475300 ⁴
	SCLC	Mono/+ SI-B003	2L+							2025	NMPA	NCT05924841
	SCLC	+ PD-(L)1	1L and 2L+							2026	NMPA	NCT06437509
BC	HR+/HER2- BC	Mono	3L+							2026	NMPA	NCT06343948
	TNBC	Mono	2L+							2026	NMPA	NCT06382142
	TNBC	+ PD-(L)1	1L							2026	NMPA	NCT06471205
	HER2-BC	+ SI-B003	2L+							2025	NMPA	NCT06042894
	BC and other solid tumors	Mono	2L+							2025	NMPA	NCT05470348
GIC	ESCC	Mono	2L	★ Has been included in the list of breakthrough therapies by CDE of NMPA						2026	NMPA	NCT06304974
	EC, GC, CRC	+ SI-B003/ PD-(L)1	1L and 2L+							2025	NMPA	NCT06008054
	GIC	Mono	2L+							2025	NMPA	NCT05262491
Other Tumors	NPC	Mono	End-line	★ Has been included in the list of breakthrough therapies by CDE of NMPA						2025	NMPA	NCT06118333
	NPC	+ SI-B003	1L and 2L+							2025	NMPA	NCT05956587 ¹
	NPC	+ PD-(L)1	1L and 2L+							2026	NMPA	NCT06475300 ⁴
	HNSCC	Mono	2L+							2025	NMPA	NCT06006169 ⁵
	HNSCC	+ SI-B003	1L and 2L+							2025	NMPA	NCT06006169 ⁵
	HNSCC	+ PD-(L)1	1L and 2L+							2026	NMPA	NCT06437522
	Gynecological tumors and other solid tumors	Mono	2L+							2025	NMPA	NCT05803018
	CC	Mono/+ SI-B003	2L+							2025	NMPA	NCT05990803
	Glioblastoma	Mono	2L+							2026	NMPA	NCT06598787
	Urinary system tumors	Mono	2L+							2025	NMPA	NCT05785039
	UC and other solid tumors	+ SI-B003	2L+							2025	NMPA	NCT05965856
	UC	+ PD-(L)1	1L							2026	NMPA	NCT06405425
	Solid tumors ¹	+ Osimertinib/ Pembrolizumab	1L							2026 ⁶	FDA	NCT06618287
	Urological tumors and other solid tumors	Mono	2L+							2025	NMPA	NCT05393427
	Solid tumors	Mono	2L+							2025	NMPA	NCT05194982
	NSCLC, SCLC, BC, EC, NPC, etc. ¹	Mono	2L+							2025 ⁶	FDA	NCT05983432

Notes:

- denotes U.S. clinical trials.
- We have entered into a global strategic license and collaboration agreement with BMS to co-develop and co-commercialize BL-B01D1. Under this agreement, we and BMS will jointly develop and commercialize BL-B01D1 in the U.S., we have retained exclusive rights to develop and commercialize BL-B01D1 in mainland China, and we have granted BMS an exclusive license to develop and commercialize BL-B01D1 in the rest of the world, subject to certain specified conditions and limitations. For details of this agreement, see “— License and Collaboration Agreement with Bristol-Myers Squibb Company.”

BUSINESS

- NCT05956587 is a Phase II clinical trial for BL-B01D1 in combination with SI-B003 for the treatment of locally advanced or metastatic NSCLC and NPC.
- NCT06475300 is a Phase II clinical trial for BL-B01D1 in combination with a PD-(L)1 inhibitor for the treatment of locally advanced or metastatic NSCLC and NPC.
- BL-B01D1 is being investigated as both monotherapy and a combination therapy with SI-B003 for 1L and 2L+ HNSCC under NCT06006169.
- denotes estimated primary completion year.

Other Pipeline Assets

The following chart summarizes the development status of our other pipeline drugs as of the Latest Practicable Date:

	Product	Target	Type	Indication	Mono/Combo	Preclinical	IND	Ph Ia	Ph Ib	Ph II	Ph III	Expected Completion Year	Regulatory Authority	Commercial Rights
HIRE-ADC	BL-M07D1	HER2	Monospecific ADC	HER2+BC	Mono	<div><div></div></div>						2026	NMPA	Global
				HER2+BC	+ Pertuzumab ± Chemo	<div><div></div></div>					2026	NMPA		
				Solid tumors	+ PD-(L)1 ± Chemo	<div><div></div></div>					2026	NMPA		
				HER2-Low BC, GC, NSCLC, UC, gynecological malignancies, and other solid tumors	Mono	<div><div></div></div>					2025-2026	NMPA		
				CC, OC, endometrial cancer, UC, BTC, etc. ¹	Mono	<div><div></div></div>					2027	FDA		
	BL-M11D1	CD33		AML	Mono	<div><div></div></div>						2025	NMPA	
				AML ¹	Mono	<div><div></div></div>						2027	FDA	
	BL-B16D1	Undisclosed	Bispecific ADC	Solid tumors	Mono	<div><div></div></div>						2026	NMPA	
	BL-M17D1	Undisclosed		Solid tumors	Mono	<div><div></div></div>						2026	NMPA	
				Solid tumors ¹	Mono	<div><div></div></div>					2027	FDA		
	BL-M05D1	Claudin18.2	Monospecific ADC	Solid tumors	Mono	<div><div></div></div>						2026	NMPA	
	Solid tumors ¹			Mono	<div><div></div></div>					2026	FDA			
	BL-M14D1	DLL3		Solid tumors	Mono	<div><div></div></div>						2026	NMPA	
BL-M08D1	Undisclosed		Solid tumors and hematologic malignancies	Mono	<div><div></div></div>						2026	NMPA		
GNC	GNC-077	CD3 × other antigens	Multi-specific Antibody	Solid tumors	Mono	<div><div></div></div>						2026	NMPA	
	GNC-038	CD3 × 4-1BB × PD-L1 × CD19	Tetra-specific Antibody	ALL, NHL, SLE, RA and other hematologic malignancies	Mono	<div><div></div></div>						2025	NMPA	
	GNC-035	CD3 × 4-1BB × PD-L1 × ROR1		CLL, NHL and other hematologic malignancies	Mono	<div><div></div></div>					2025	NMPA		
				BC, lung cancer and other <i>r/r</i> solid tumors	Mono	<div><div></div></div>					2025	NMPA		
	GNC-039	CD3 × 4-1BB × PD-L1 × EGFRvIII	Glioma	Mono	<div><div></div></div>						2025	NMPA		
SEBA	SI-B001	EGFR × HER3	Bispecific Antibody	EGFRwt NSCLC	+ Chemo	<div><div></div></div>						2026	NMPA	
				EGFRmut NSCLC	+ Osimertinib	<div><div></div></div>					2025	NMPA		
				HNSCC	Mono	<div><div></div></div>					2025	NMPA		
				HNSCC	+ Chemo	<div><div></div></div>					2025	NMPA		
				ESCC	+ Chemo	<div><div></div></div>					2025	NMPA		
				HNSCC, NSCLC	+ SI-B003 ± Chemo	<div><div></div></div>					2025-2026	NMPA		
	SI-B003	CTLA-4 × PD-1		Solid tumors	Mono/combo	<div><div></div></div>					2025	NMPA		

Note:

- denotes U.S. clinical trials.

Abbreviation: NSCLC refers to non-small cell lung cancer, SCLC refers to small cell lung cancer, BC refers to breast cancer, TNBC refers to triple-negative breast cancer, ESCC refers to esophageal squamous cell carcinoma, EC refers to esophageal cancer, GC refers to gastric cancer, CRC refers to colorectal cancer, GIC refers to gastrointestinal cancer, NPC refers to nasopharyngeal carcinoma, HNSCC refers to head and neck squamous cell carcinoma, CC refers to cervical cancer, UC refers to urothelial carcinoma, BTC refers to biliary tract cancer, AML refers to acute myeloid leukemia, ALL refers to acute lymphocytic leukemia, CLL refers to chronic lymphocytic leukemia, NHL refers to non-Hodgkin's lymphoma, SLE refers to systemic lupus erythematosus, RA refers to rheumatoid arthritis, *r/r* refers to relapsed or refractory.






BUSINESS

Our Marketed Products

The following table summarizes our major marketed products as of the Latest Practicable Date:

Therapeutic Area	Product	Sample Picture	Type	Indication	Inclusion in NRDL ⁽¹⁾	Participation in VBP	Retail Price Range ⁽³⁾ (RMB)
Generic Drugs							
Anesthesia	Lewejing 乐维静®		Prescription only	Short-acting intravenous general anaesthetic for the induction and maintenance of general anaesthesia in adult and pediatric patients over the age of one month	Yes, Part A	Yes ⁽²⁾	1.8-75.0
Drugs	(Propofol Injectable Emulsion (丙泊酚乳状注射液))						
	Leweitai 乐维泰®		Prescription only	Short-acting general anaesthetic for the induction and maintenance of general anaesthesia in adult and pediatric patients over the age of one month, and for sedation in patients over 16 years of age undergoing mechanical ventilation in intensive care	Yes, Part B	Yes ⁽²⁾	5.7-286.0
	(Propofol Medium and Long Chain Fat Emulsion Injection (丙泊酚中/长链脂肪乳注射液))						
	Youmeining 右美宁®		Prescription only	Short-acting general anaesthetic for the induction and maintenance of general anaesthesia in adult and pediatric patients over the age of one month, and for sedation in patients over 16 years of age undergoing mechanical ventilation in intensive care	Yes, Part B	Yes ⁽²⁾	40.4-115.0
	(Dexmedetomidine Hydrochloride Injection (盐酸右美托咪定注射液))						

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Therapeutic Area	Product	Sample Picture	Type	Indication	Inclusion in NRDL ⁽¹⁾	Participation in VBP	Retail Price Range ⁽³⁾ (RMB)
Parenteral Nutrition Drugs	Tianze® (Medium and Long Chain Fat Emulsion Injection (中/長鏈脂肪乳注射液))		Prescription only	For the supplementation of energy and essential fatty acids when oral or enteral nutrition is not possible or sufficient	Yes, Part B	Yes ⁽²⁾	25.3-83.1
	Xinbolin 新博林® (Ribavirin Granule (利巴韋林顆粒))		Prescription only	Viral pneumonia and bronchitis caused by respiratory syncytial virus, herpes virus infection of the skin	No	Yes ⁽²⁾	4.7-10.6
Anti-Infective Drugs	Aobolin 奧博林® (Omidazole Capsule (奧硝唑膠囊))		Prescription only	Gynaecological infections caused by anaerobic bacteria and protozoa, oral infections caused by anaerobic bacteria, digestive system infections and surgical infections	Yes, Part B	No	19.4-24.0
	Dulabao 杜拉宝® (Racecadotril Granule (消旋卡多曲顆粒))		Prescription only	Acute diarrhea in infants and children over the age of one month, in combination with oral rehydration solution or intravenous rehydration solution, if necessary	Yes, Part B	No	17.2-37.3
Pediatric Drugs	Leyeping 乐液平® and Pujikang 朴吉康® (Glucose Electrolyte Effervescent Tablet (葡萄糖電解質泡騰片))		Prescription only	Prevention and treatment of mild to moderate dehydration due to diarrhea and vomiting, as well as due to prolonged and strenuous physical activity	No	No	44.9-540.0

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Therapeutic Area	Product	Sample Picture	Type	Indication	Inclusion in NRDL ⁽¹⁾	Participation in VBP	Retail Price Range ⁽³⁾ (RMB)
Traditional Chinese Medicine	葡萄糖电解质片		Prescription	Prescription: Qi-deficiency, diuretic, toxin-drainage and pus discharge, and muscle growth. Used in treating shortness of breath, palpitation, defecation, spontaneous sweating, swelling, prolonged diarrhea, prolapse of anus, prolapse of uterus, carbuncle and gangrene, sores that do not heal for an extended period of time	Yes, Part B	No	20.2-498.0
	Astragalus Granule (黄芪颗粒)		OTC	OTC: Qi-deficiency. For shortness of breath, palpitation, spontaneous sweating	Yes, Part B	No	17.1-60.0
	柴胡颗粒		OTC	For upper respiratory tract infections, colds and fever	Yes, Part B	No	17.1-60.0

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Notes:

- (1) The NRDL comprises Part A and Part B. Patients purchasing pharmaceuticals included in Part A of the NRDL are entitled to reimbursement of the entire amount of the purchase price, while patients purchasing pharmaceuticals included in Part B of the NRDL are required to pay a deductible amount and obtain reimbursement for the remainder of the purchase price. The amount of the deductible differs from region to region in the PRC. In principle, the NRDL was subject to a dynamic adjustment entitled to once a year.
- (2) See “— Generic Drugs” for details of the relevant products’ participation in the VBP schemes.
- (3) Retail price range represents the lowest retail price and highest retail price of the relevant product during the Track Record Period, covering respective specifications.

BUSINESS

OUR TECHNOLOGY PLATFORMS AND BIOLOGICS PORTFOLIO

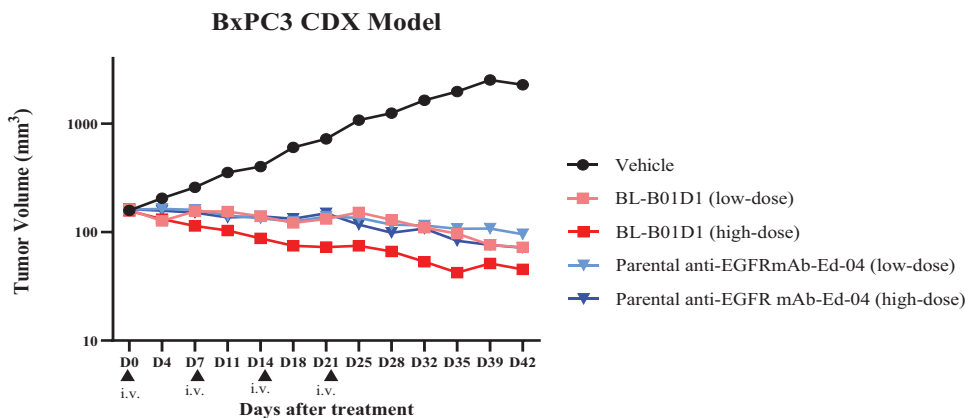
HIRE-ADC Platform

Our HIRE-ADC platform, short for “Heterogeneity overcoming — Immunogenic death inducing — Resistance antagonizing — Enhanced specificity,” is our proprietary, self-developed ADC platform. HIRE-ADC possesses fully in-house, end-to-end capabilities. It has accrued a large volume of foundational research data, enabling continuous iteration of our innovative ADC technologies and development of innovative drug portfolio, thereby ensuring our capacity for sustained innovation.

Antibody

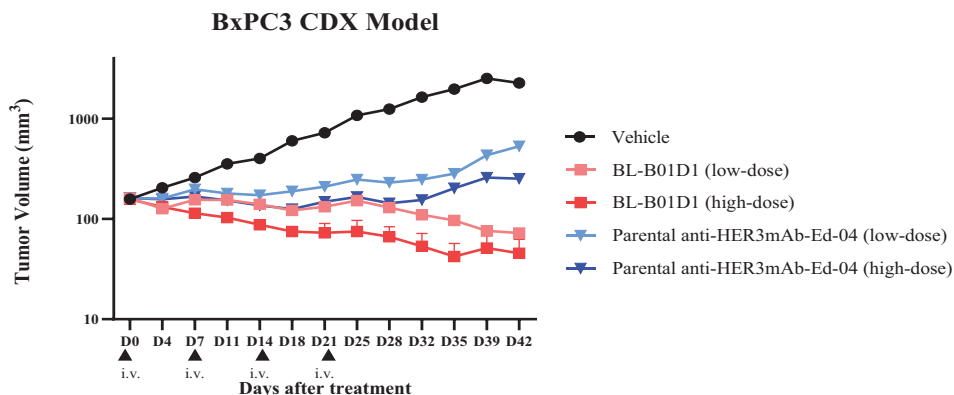
Our HIRE-ADC platform allows us to discover and develop proprietary mono/bispecific antibodies that are designed to achieve enhanced specificity and anti-tumor activity. For example, we have developed in-house the EGFR × HER3 bispecific antibody that is the antibody component of BL-B01D1. With this antibody, BL-B01D1 has demonstrated stronger *in vivo* anti-tumor efficacy, compared to ADCs using the parental monoclonal antibodies targeting either EGFR or HER3 alone (*Figures 1 and 2*).

Figure 1: Comparison of *in vivo* efficacy of BL-B01D1 vs. parental EGFR-ADC



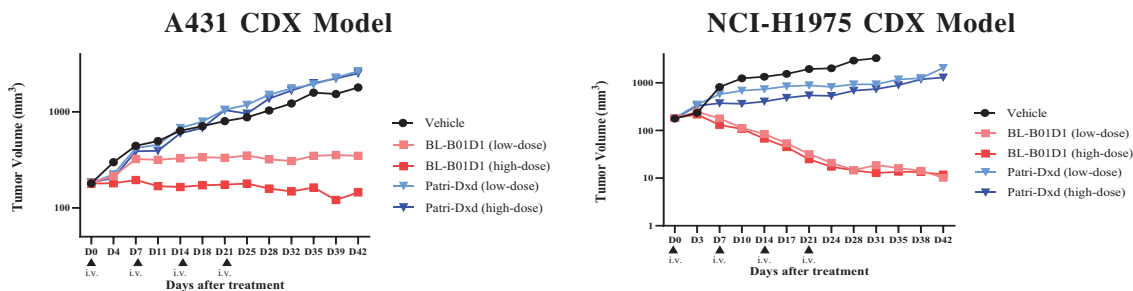
BUSINESS

Figure 2: Comparison of *in vivo* efficacy of BL-B01D1 vs. parental HER3-ADC



Moreover, in two xenograft mouse models using A431 (human squamous carcinoma) and NCI-H1975 (human lung cancer) cell lines, BL-B01D1 has exhibited significantly enhanced tumor inhibition, compared to an in-house generated analogue patritumab-Dxd (a HER3 ADC) at the same dosage levels (*Figure 3*). Notably, in our Phase I clinical study, unlike HER3 ADC whose efficacy depends on HER3 expression, BL-B01D1 showed anti-tumor activity in BC patients who had some level of expression of either EGFR or HER3 in tumor.

Figure 3: Comparison of *in vivo* efficacy of BL-B01D1 vs. Patritumab-Dxd



Linker

Our in-house developed cleavable linkers are characterized by high stability. As shown in our preclinical studies, the DAR of BL-M07D1 in plasma remained consistently above 7 after 21 days, in contrast to that of Enhertu (DS-8201, T-Dxd) which declined from 7 to below 5 in the same timeframe, suggesting the superior stability of our linker in circulation.

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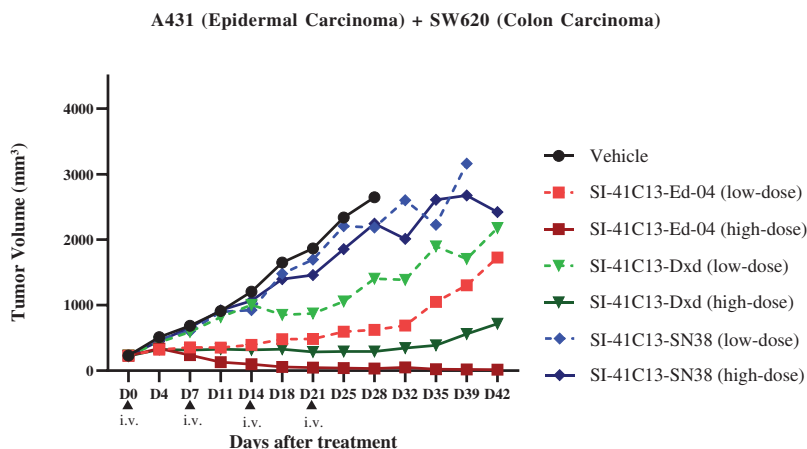
Payload

We have developed proprietary cytotoxic payloads, such as Ed-04, characterized by effective induction of bystander effects and immunogenic cell death (ICD). Ed-04 is used in multiple of our clinical-stage assets, including BL-B01D1, BL-M07D1, BL-M11D1, and BL-M05D1. In an assay measuring the lipid-water partition coefficient in our preclinical studies, Ed-04 showed a higher logP compared to SN38 and Dxd, which indicates greater cell membrane permeability and enhanced diffusion through tissues, thereby facilitating more effective bystander killing effects. Additionally, Ed-04 induced more potent ICD effects than Dxd and MMAE in our preclinical studies.

In a comparative analysis involving multiple subgroups of tumor-bearing mice, only 40% of the mice treated with Ed-04 experienced tumor relapse on Day 61 of the treatment, significantly lower than the relapse rates observed in the MMAE and Dxd subgroups, which were 80% and 100%, respectively. These characteristics contribute to a strong antitumor efficacy of Ed-04 as observed in our *in vivo* studies.

In a xenograft mouse model (Figure 4), we compared an ADC using Ed-04 with two other ADCs that used the same antibody but different payloads — Dxd and SN38. The ADC with Ed-04 achieved stronger tumor inhibition at the same dosage level compared to the other two ADCs.

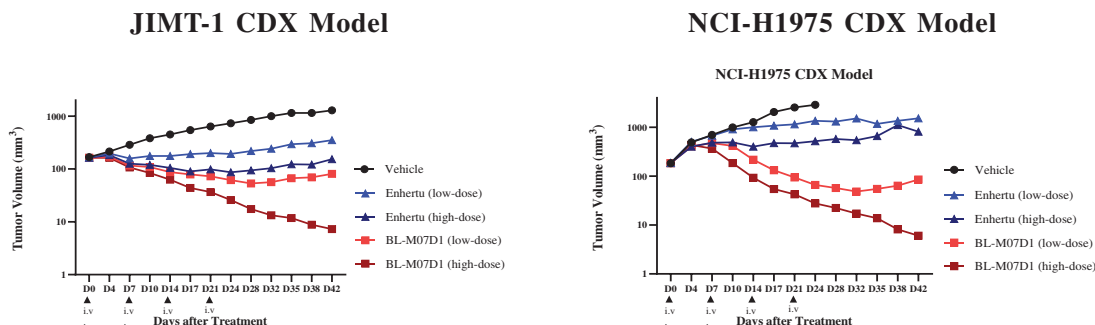
Figure 4: Comparison of *in vivo* efficacy of payloads



Moreover, BL-M07D1 (HER2 ADC with Ed-04) demonstrated stronger tumor inhibition compared to Enhertu at the same dosage level in our *in vivo* studies (Figure 5).

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Figure 5: Comparison of *in vivo* efficacy of BL-M07D1 vs. Enhertu



Source: Company data

Conjugation

Our conjugation technology supports both traditional non-specific and precise site-specific approaches, providing enhanced flexibility in ADC development. Our proprietary site-specific conjugation yields ADCs with superior tumor-killing efficacy, minimal aggregation, high conjugation efficiency, and enhanced molecular and plasma stability.

We have established a fully integrated technology platform for ADC research and development, capable of independently completing all stages of innovative ADC drug development from drug discovery, clinical validation to manufacturing. Leveraging this platform, we aim to develop drug candidates targeting novel antigens or with the potential to be best-in-class, such as those targeting HER2 and CD33.

As of the Latest Practicable Date, our HIRE-ADC platform has produced eight clinical-stage ADC drugs, five of which have received IND approvals from the FDA and four of which are currently in Phase I clinical trials in the U.S.

BL-B01D1 (EGFR × HER3 bispecific ADC)

Overview

Our internally discovered and developed BL-B01D1 is the world’s first and only clinical-stage EGFR × HER3 bispecific ADC intended for the treatment of various solid tumors. It is also the first bispecific ADC to have advanced into Phase III trials in the world and one of the most investigated clinical-stage ADCs, as it has been studied in over 2,000 patients across various cancer types. Based on the clinical data, we believe BL-B01D1 has the potential to be a backbone pan-tumor treatment.

BUSINESS

Early clinical results have demonstrated BL-B01D1’s robust anti-tumor activity and a manageable safety profile across over ten solid tumor types, including NSCLC and BC, the two most prevalent tumor types in the world. In addition, we have observed efficacy in cancer patients who are unresponsive to or have progressed after the PD-(L)1 treatment, potentially offering promising new treatment options to such patients. These interim data suggests that BL-B01D1 may outperform the standard of care and other marketed ADCs in terms of anti-tumor efficacy across a variety of cancers, demonstrating its exceptional potential to become the next backbone cancer therapy either as monotherapy or in combination with immunotherapy, targeted therapy or chemotherapy.

Building on its promising efficacy signals from prior clinical trials in NSCLC and BC, we are expanding the evaluation of BL-B01D1 to other major cancer indications that also express high levels of EGFR and/or HER3, including HNSCC, NPC, GC, CRC, liver cancer, biliary cancer, UC and gynecological cancers. Additionally, we plan to explore BL-B01D1’s use in additional combination therapies, and its potential to advance into earlier lines of treatment. The encouraging preliminary clinical data of BL-B01D1 suggests its potential to replace conventional chemotherapy currently recommended as the standard of care in both mono and combination regimens for various cancer types.

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The figures below illustrate major tumor types studied in clinical trials with BL-B01D1 (highlighted in red in *Figure 8*), and various epithelial tumors that exhibit high expression of EGFR (*Figure 9*) and HER3 (*Figure 10*):

Figure 8: Tumor types studied in clinical studies with BL-B01D1

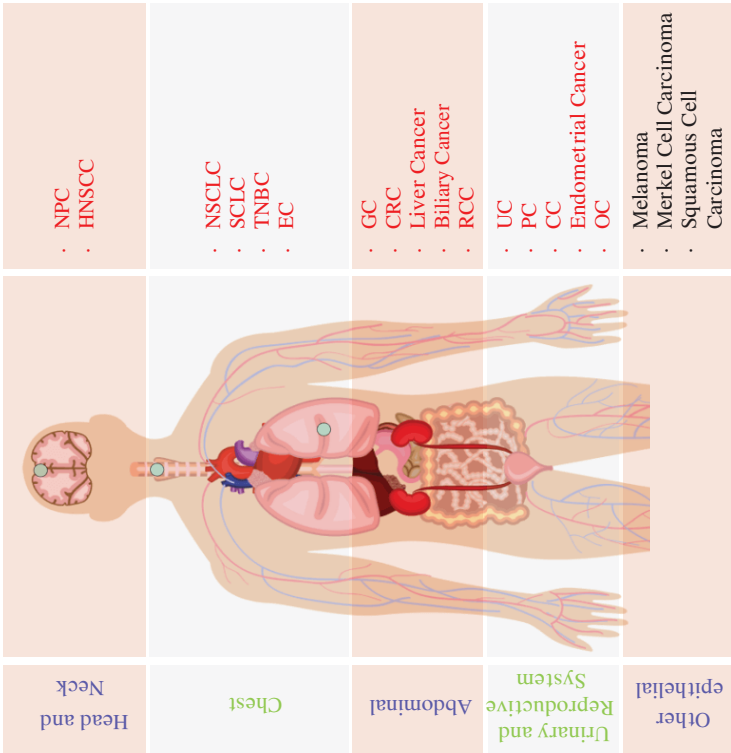


Figure 9: High EGFR expression in epithelial tumors

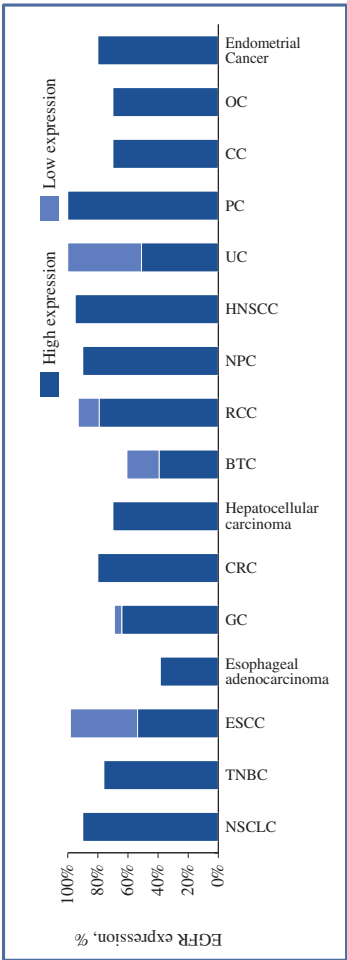
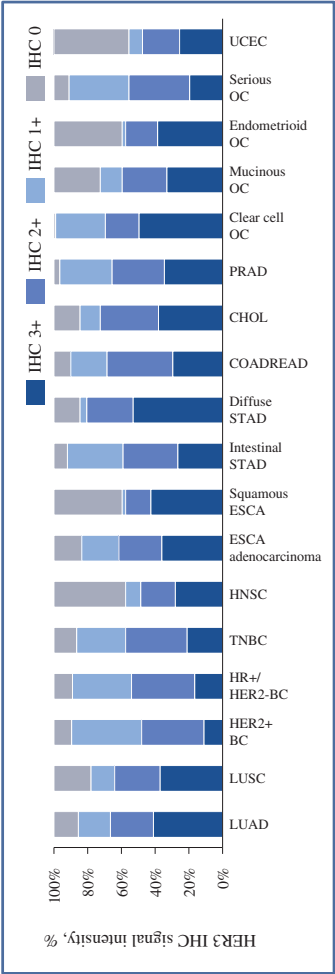


Figure 10: High HER3 expression in epithelial tumors



Source: PLoS One; CIC; Frontiers in Oncology; Expert Review of Anticancer Therapy; British Journal of Cancer; Cancer Res Clinic; Radiation Oncology; Oncology Letters; OncoTargets and Therapy; Nature Cell Biology; World Journal of Gastroenterology; Journal of Pathology, Microbiology and Immunology

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We are committed to making BL-B01D1 available to patients around the world. In December 2023, we entered into a global strategic license and collaboration agreement with BMS to co-develop and co-commercialize BL-B01D1. Both companies will share certain development expenses, profits and losses in the U.S. according to certain agreed-upon percentages, while we will retain exclusive development and commercialization rights in mainland China, and BMS will have the exclusive rights to market and develop BL-B01D1 outside of mainland China and the U.S. As part of the agreement, BMS has paid us US\$800 million in an upfront payment and will pay up to US\$500 million in contingent near-term development milestone payments. In addition, we are eligible to receive additional milestone payments up to US\$7.1 billion, contingent on achieving certain regulatory and sales milestones. The total consideration is the largest ever for a single-asset collaboration transaction in the ADC space as of the Latest Practicable Date, according to CIC. We will also be eligible to receive a tiered royalty on net sales outside of the U.S. and mainland China, while BMS will be eligible to receive a royalty on net sales in mainland China. For details of this agreement, see “— License and Collaboration Agreement with Bristol-Myers Squibb Company.”

BL-B01D1 is currently being evaluated in approximately 30 clinical trials in China and the U.S. for a broad range of tumor types, including lung cancer, BC, HNSCC, NPC, GC, CRC, liver cancer, biliary cancer, UC and gynecological cancers, among others. These include (i) seven Phase III clinical trials evaluating BL-B01D1 as monotherapy for late-line treatment of various cancers, including two NSCLC indications, SCLC, two BC indications, ESCC, and NPC, (ii) eight Phase II clinical trials evaluating its combination with PD-(L)1 therapies for 1L treatment of nine cancer indications (*SCLC, NSCLC, NPC, HNSCC, EC, GC, CRC, BC, and UC*), (iii) two Phase II clinical trial evaluating its combination with TKI for 1L treatment of lung cancer, and (iv) six Phase Ib clinical trials. 17 of these clinical trials were initiated following our collaboration agreement with BMS concluded in December 2023, including 10 Phase II clinical trials and six Phase III clinical trials across a broad spectrum of solid tumors in China. Under our license and collaboration agreement with BMS, we and BMS plan to initiate multiple late-stage clinical trials of BL-B01D1 globally, as a front or late line of treatment, in mono or combo settings, for various solid tumors including lung cancer and BC in the next few years.

Mechanism of Action

Epidermal growth factor receptor (EGFR), also known as ErbB1 or HER1, is a member of the epidermal growth factor receptor (HER) family. This family includes HER1 (ErbB1, EGFR), HER2 (ErbB2), HER3 (ErbB3), and HER4 (ErbB4). The HER family plays a crucial regulatory role in cellular physiological processes. EGFR is associated with tumor cell proliferation, angiogenesis, tumor invasion, metastasis, and inhibition of cell apoptosis. Research indicates that EGFR is highly expressed or abnormally expressed in many solid tumors, including NSCLC, SCLC, BC, NPC, GC, CRC, HNSCC, EC, UC, and other malignant epithelial tissue tumors.

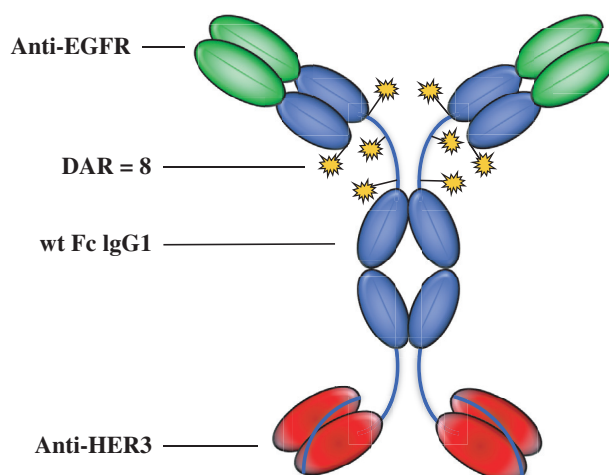
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HER3 (ErbB3) is a transmembrane receptor with membrane tyrosine kinase activity in the HER family, capable of heterodimerizing with EGFR to activate the RAS/RAF/MAPK pathway that promotes proliferation and the PI3K/AKT pathway that supports tumor cell survival. HER3 is also widely expressed in various malignant tumors that often overly express EGFR, such as NSCLC, SCLC, BC, NPC, GC, CRC, HNSCC, EC, and UC.

EGFR and HER3 are targeted in cancer therapy due to their over-expression and pathway dependence in common human epithelial carcinoma tumors. Given their prevalence and critical role in tumors, targeting these receptors has the potential to deliver a therapy with pan-tumor efficacy.

BL-B01D1 is a bispecific ADC designed to inhibit EGFR and HER3 pathways simultaneously. By inhibiting the EGFR \times EGFR homodimers, the overactivation of which leads to abnormal proliferation and survival of tumor cells, BL-B01D1 effectively curtails tumor growth and metastasis. By blocking the EGFR \times HER3 heterodimers simultaneously, BL-B01D1 provides a more comprehensive suppression of the ErbB family signaling pathways, resulting in stronger and more sustained anti-tumor effects against EGFR-driven cancers.

Built on our SEBA and HIRE-ADC platforms, BL-B01D1 consists of an EGFR \times HER3 bispecific antibody linked to a novel TOP-1 inhibitor payload via a cathepsin B cleavable linker. The figure below depicts the molecular structure of BL-B01D1.



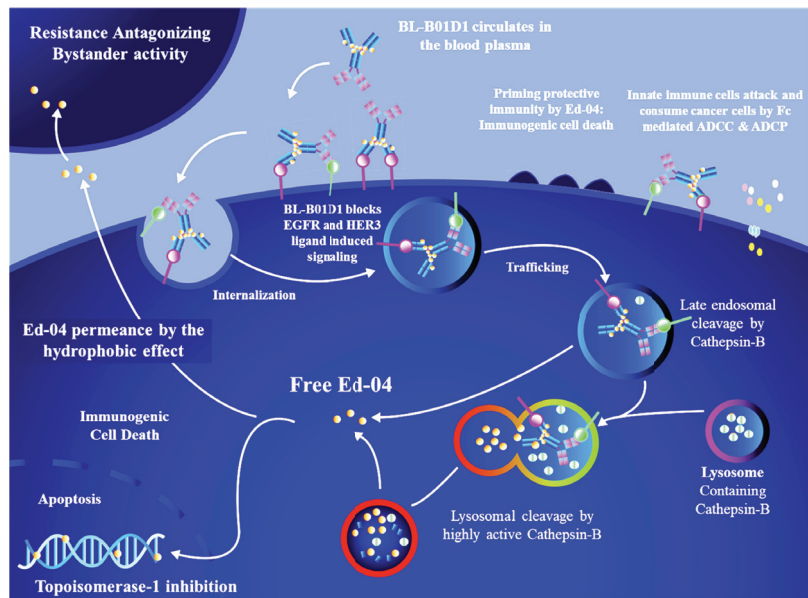
Tetravalent antibody backbone. BL-B01D1 consists of a tetravalent antibody scaffold designed for bispecific targeting. This antibody component features two binding sites for each of EGFR and HER3. The symmetric 2:2 format enhances its dual-targeting capabilities, increasing avidity and specificity for EGFR and HER3 on cancer cells.

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Linker-payload. The bispecific antibody component of BL-B01D1 is linked to the novel TOP-1 inhibitor, Ed-04, via a cathepsin B cleavable linker at a DAR of 8. This conjugation strategy is derived from our proprietary Ex-0115 linker-payload platform. Ed-04 is a derivative of camptothecin that can arrest the cell cycle in the S phase, causing apoptosis of tumor cells. The linker shows enhanced stability in blood circulation until internalized by targeted cells. This design effectively broadens the therapeutic window.

The diagram below illustrates the mechanism of action of BL-B01D1. As shown in this diagram, BL-B01D1 selectively binds to both EGFR and HER3 which are often co-expressed on tumor cells. This bispecificity allows this molecule to concurrently target both EGFR \times EGFR homodimers and EGFR \times HER3 heterodimers on tumor cells, which increases the precision of targeting, allowing for more effective discrimination between cancerous and normal cells. BL-B01D1 is designed to specifically deliver its cytotoxic payload to EGFR/HER3 expressing tumor cells. Upon binding, BL-B01D1 is internalized by the targeted tumor cells and transported to the lysosomes. Its bispecificity creates stronger and more stable binding, triggering more efficient internalization into the cancer cell. After the internalization, the linker is cleaved to release the therapeutic payload, which induces genotoxic stress, leading to cancer cell death. While cancer cells often develop resistance to therapies targeting a single antigen, BL-B01D1 mitigates this issue by targeting two distinct antigens.

Mechanism of Action of BL-B01D1



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Competitive Advantages

Encouraging clinical efficacy shown in the most prevalent cancer types. BL-B01D1 is the first and only clinical-stage EGFR × HER3 bispecific ADC intended for the treatment of various solid tumors and the first bispecific ADC to have advanced into Phase III trials in the world. BL-B01D1 combines the specificity of a bispecific antibody with the potent cytotoxicity of chemotherapy, representing a next-generation therapeutic approach that aims to surpass the efficacy and safety of conventional chemotherapy. In our clinical trials, BL-B01D1 has demonstrated encouraging efficacy in various cancer indications, including the most prevalent tumor types:

- **NSCLC.** NSCLC accounted for approximately 85% of all lung cancer cases. Lung cancer is the most common type of cancer and the leading cause of death globally. In our ongoing Phase I clinical trial for BL-B01D1 in China, the interim data as of August 17, 2023 showed encouraging efficacy and a manageable safety profile in patients with NSCLC who have progressed after the standard of care, such as EGFR TKI or immunotherapy in combination with platinum-based chemotherapy. As of August 17, 2023, in 75 evaluable patients with NSCLC with treated or without CNS metastasis, treatment with BL-B01D1 achieved an ORR of 52.0%, cORR of 41.3%, DCR of 86.7%, mDOR of 12.3 months and mPFS of 6.8 months. BL-B01D1 has shown one of the most promising efficacy among late clinical-stage ADCs being evaluated for NSCLC and a safety profile consistent with the other candidates based on publicly available data. At the 2023 ASCO annual meeting, Professor Kohei Shitara, the discussant of the *Developmental Therapeutics-Molecularly Targeted Agents and Tumor Biology* session, who was invited by ASCO to summarize and comment on the findings presented, analyzed the data of several drug candidates targeting solid tumors. The comparison is reproduced below, demonstrating a better ORR of BL-B01D1 in the treatment of NSCLC and NPC compared to outcomes reported for HER3 or EGFR-targeted drugs in their respective trials for NSCLC and other solid tumors:

	Patritumab Deruxtecan	MRG003	Amivantamab+Lazertinib	BL-B01D1		
MOA	HER3ADC	EGFRADC	EGFR-MET EGFR TKI	EGFR+HER3 ADC		
study	Phase I	Phase I	Phase 1/2	Phase 1		
N	57 EGFRmtNSCLC	22 (15 CRC, 5 head neck)	162 EGFRmt after Osimertinib	38 EGFRmt	49 EGFRwt	28 NPC
ORR (%)	39	<5	33	63.2	44.9	53.6
mPFS (ms)	8.2	NR	5.1	NR	NR	NR
Notable Toxicities ≥G3	Thrombocytopenia 26%, neutropenia 15%, fatigue 10%, an grade ILD 5%	Anemia, AST elevation, anorexia, rash, pruritus	Acne 5%, rash 2%, paronychia 4%, hypoalbuminemia 7%, IRR 8%, dyspnea 8%	Neutropenia 34%, anemia 25%, nausea <1%, diarrhea <1%, anorexia <1 %, stomatitis 2% NoILD		

Abbreviation: EGFRmt = EGFR mutant; NR = not ready

Source: 2023 ASCO Annual Meeting

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Although the foregoing clinical trial data were generated in independent studies and do not come from head-to-head analysis, and there is no assurance that the data of BL-B01D1 programs in later clinical trials will remain favorable, we believe meaningful insight may be drawn that BL-B01D1 could offer a compelling treatment option for NSCLC. Based on the early clinical trial results, we have initiated two Phase III registrational trials to evaluate BL-B01D1 as monotherapy for the 2L treatment of EGFRwt NSCLC and EGFRmut NSCLC. Recognizing its exceptional efficacy, BL-B01D1 monotherapy has been designated as a breakthrough therapy by the CDE of NMPA in September 2024 for second-line treatment of EGFRwt NSCLC patients following the failure of anti-PD-1/PD-L1 monoclonal antibodies and platinum-based chemotherapy, as well as for EGFRmut NSCLC patients after EGFR-TKI failure.

- NPC. BL-B01D1 has also demonstrated promising efficacy for the treatment of NPC in our Phase I trial. As of the data cut-off date (August 17, 2023), among 37 evaluable NPC patients with a median of three prior treatment lines, the treatment with BL-B01D1 achieved an ORR of 59.5%, cORR of 37.8%, DCR of 100%, and mPFS of 6.8 months. In recognition of its outstanding efficacy, BL-B01D1 as monotherapy for 2L+ NPC patients (with at least one platinum-based chemotherapy) who have experienced the treatment of PD-(L)1 as monotherapy has been included in the list of breakthrough therapies by CDE of NMPA in April 2024.
- GIC. BL-B01D1 demonstrated manageable safety with encouraging antitumor activity in patients with locally advanced or metastatic BTC or ESCC in our Phase I trial. As of the data cut-off date (June 30, 2024), 36 response-evaluable patients with locally advanced or metastatic BTC administered with BL-B01D1 showed an overall ORR of 38.9%, cORR of 22.2%, DCR of 88.9%, mPFS of 4.2 months, and mDOR of 5.9 months. As of the same date, in 74 response-evaluable patients with locally advanced or metastatic ESCC, treatment with BL-B01D1 achieved an ORR of 35.1%, cORR of 32.4%, DCR of 70.3%, mPFS of 4.3 months, and mDOR of 6.5 months. Due to its remarkable efficacy, BL-B01D1 monotherapy for second-line ESCC patients who have not responded to PD-1/PD-L1 monoclonal antibody combined with platinum-based chemotherapy was designated as a breakthrough therapy by the CDE of NMPA in October 2024.
- UC. BL-B01D1 showed the encouraging preliminary efficacy and favorable safety profile at 2.2 mg/kg D1D8 Q3W. As of the data cut-off time (June 30, 2024), among 27 response-evaluable patients with locally advanced or metastatic urothelial carcinoma with a median of two prior treatment lines, the treatment with BL-B01D1 at 2.2 mg/kg dose level D1D8 Q3W achieved an ORR of 40.7%, cORR of 33.3%, DCR of 96.3% and the 6-month DOR of 100%. The mDOR and mPFS have not been reached as of the data cut-off date.

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Moreover, the unique mechanism of action of BL-B01D1 offers a novel approach to overcome resistance mechanisms of solid tumors. In our clinical trials, BL-B01D1 has shown efficacy signals in patients who have failed standard treatments, which demonstrates its potential to address the significant unmet medical needs of those who have undergone heavy prior treatments, and potentially provides an effective treatment option for patients who have developed resistance or relapsed following standard therapies.

Manageable safety profile. Benefiting from its differentiated structure design, BL-B01D1 has exhibited a manageable safety and tolerability profile in early clinical trials. By specifically targeting EGFR and HER3 co-expressing tumor cells, BL-B01D1 can potentially minimize systemic exposure and on-target off-tumor toxicity, thereby reducing the risk of toxicities commonly associated with conventional chemotherapies. Moreover, the cleavable linker used in BL-B01D1 plays a crucial role in the controlled release of the cytotoxic payload within cancer cells. This targeted delivery mechanism helps localize the therapeutic effect at the tumor site while sparing healthy tissues, contributing to a more manageable safety profile and larger therapeutic window.

BL-B01D1 has demonstrated a potentially favorable safety profile in the treatment of various solid tumors. Notably, it achieved a favorable safety outcome in the treatment of urothelial carcinoma with neither drug-related death nor cases of ILD observed. The safety data from a Phase I trial in patients with NSCLC and other solid tumors demonstrated a tolerable safety profile of BL-B01D1. Common treatment-related adverse events (TRAE) (>10%, all grades \geq grade 3) included leukopenia, anemia, neutropenia, thrombocytopenia, nausea, asthenia, decreased appetite, alopecia, vomiting, among others. Most TRAEs reported were mild to moderate in severity and could be effectively managed with supportive care or dose adjustments. Notably, only one grade 2 ILD case was reported in 369 patients enrolled in this Phase I clinical trial as of August 17, 2023. While no head-to-head trials have been conducted and no conclusion can be drawn from cross-trial comparisons, BL-B01D1 exhibited a safety profile comparable to other late clinical-stage ADCs being evaluated for NSCLC based on publicly available data. Similar safety profile was observed in the Phase I trial evaluating BL-B01D1 in patients with BC. These preliminary safety data suggests that BL-B01D1 has the potential to offer a safe and well-tolerated treatment option for cancer patients.

Pan-cancer treatment potential. Based on encouraging efficacy and safety data from early clinical trials, we are developing BL-B01D1, either as monotherapy or in combination with other cancer agents, for the treatment of a broad spectrum of cancers, including prevalent types, such as NSCLC, BC and CRC, as well as other varieties such as SCLC, NPC, EC, GC, HNSCC, GIC, UC, and CC. As of the Latest Practicable Date, BL-B01D1 was being evaluated in approximately 30 clinical trials across China and the U.S. for over ten cancer indications, including seven Phase III trials targeting EGFRwt NSCLC, EGFRmut NSCLC, SCLC, HR+/HER2- BC, TNBC, ESCC, and NPC. We have released promising clinical data on NSCLC, NPC, BTC, ESCC and UC. In addition, BL-B01D1 showed anti-tumor activity in BC patients who had some level of expression of either EGFR or HER3 in tumor (*Figure 11*). With over 2,000 patients enrolled across different tumor types in these clinical trials, BL-B01D1 is among one of the most investigated clinical-stage ADCs in the world.

Top Chart: EGFR Expression Levels

Subtype	EGFR 1+ (%)	EGFR 2+ (%)	EGFR 3+ (%)
HER2+	-	~28	-
HER2+ HER2+	-	~10	-
HR+ HER2-	~10	-	-
TNBC	~8	-	-
TNBC	-	-	~-5
TNBC	-	-	~-10
TNBC	-	-	~-15
TNBC	-	~-10	-
HR+ HER2-	-	-	~-18
TNBC	~-25	-	-
TNBC	~-30	-	-
HR+ HER2-	-	-	~-35
HR+ HER2-	~-35	-	-
HR+ HER2-	-	-	~-45
TNBC	-	~-45	-
HR+ HER2-	-	-	~-50
HR+ HER2-	~-50	-	-
HER2+ TNBC	-	-	~-55
TNBC	-	-	~-60
HER2+	-	-	~-70

Bottom Chart: HER3 Expression Levels

Subtype	HER3 1+ (%)	HER3 2+ (%)	HER3 3+ (%)
HER2+	-	~25	-
HER2+ HER2+	-	~10	-
HR+ HER2-	~8	-	-
TNBC	~8	-	-
TNBC	-	-	~-5
TNBC	-	-	~-10
TNBC	-	-	~-15
TNBC	-	-	~-20
HR+ HER2-	-	-	~-25
TNBC	~-30	-	-
TNBC	~-35	-	-
HR+ HER2-	-	-	~-40
HR+ HER2-	~-45	-	-
HR+ HER2-	-	-	~-50
TNBC	-	~-55	-
HR+ HER2-	-	-	~-60
HR+ HER2-	~-65	-	-
HER2+ TNBC	-	-	~-70
TNBC	-	-	~-75
HER2+	-	-	~-80

Collaboration with BMS to accelerate BL-B01D1's global development and expansion.

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Clinical Development

Clinical Development Plan

We are advancing the clinical development of BL-B01D1 with the aim of making it the first bispecific ADC to be approved globally, and eventually a backbone treatment for a broad range of solid tumors. We have adopted the following clinical development strategies for BL-B01D1 to maximize its therapeutic potential and market impact:

- *Demonstrating the pan-tumor efficacy of BL-B01D1:* We plan to advance clinical trials for a wide range of tumor types, in order to establish the effectiveness of BL-B01D1 in treating multiple cancers. By demonstrating BL-B01D1’s pan-tumor efficacy, we aim to position BL-B01D1 as a versatile therapeutic option applicable to numerous cancer indications.
- *Targeting major cancer indications with immense market potential:* Our near-term priority is to confirm BL-B01D1’s efficacy in the most prevalent cancer types, such as NSCLC and BC, in order to maximize the addressable patient population that can potentially benefit from BL-B01D1, as well as enhance its market opportunities.
- *Evaluating BL-B01D1 both as monotherapy and in combination with other treatments, and advancing it into earlier lines of treatment:* We will continue to investigate BL-B01D1 both as a single agent and in combination with immuno-oncology therapies, targeted therapies, or chemotherapy. In addition to testing BL-B01D1 in heavily pre-treated patients who have failed standard treatments, we are also expanding our studies to include patients at earlier stages of their treatment journey.
- *Conducting global clinical trials to reach the worldwide market:* Under our global license and collaboration agreement with BMS, we and BMS plan to initiate multiple late-stage clinical trials of BL-B01D1 globally for various solid tumors in the next few years. This approach aims to thoroughly validate the therapeutic potential of this drug candidate across diverse patient demographics and genetic backgrounds and facilitate regulatory approval in various countries.

We are currently conducting approximately 30 clinical trials for BL-B01D1 in China and the U.S., as of the Latest Practicable Date. These include (i) seven Phase III clinical trials evaluating BL-B01D1 as monotherapy for late-line treatment of various cancers, including two NSCLC indications, SCLC, two BC indications, ESCC, and NPC, (ii) eight Phase II clinical trials evaluating its combination with PD-(L)1 therapies for 1L treatment of nine cancer indications (*SCLC, NSCLC, NPC, HNSCC, EC, GC, CRC, BC, and UC*), (iii) two Phase II clinical trial evaluating its combination with TKI for 1L treatment of lung cancer, and (iv) six Phase Ib clinical trials. Under our license and collaboration agreement with BMS, we and BMS plan to initiate multiple late-stage clinical trials of BL-B01D1 globally, as a front or late line of treatment, in mono or combo settings, for various solid tumors including lung cancer and BC in the next few years.

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In the future, we will (i) proactively advance BL-B01D1’s development in combination with PD-(L)1 therapies, aiming to replace the chemotherapy component in 1L treatment for solid tumors where PD-(L)1 combo therapies are the current standard of care; (ii) proactively advance BLB01D1’s development in combination with TKIs as the new standard of care for cancer indications currently treated with TKI monotherapy in 1L settings; and (iii) continue to develop it in late-line settings, as well as in neoadjuvant and adjuvant settings across over ten epithelial cancers where BL-B01D1’s has shown promising efficacy and manageable safety.

The below table sets forth details of the ongoing trials we are currently conducting for BL-B01D1:

Indication	Type of Therapy	Trial phase	Trial start date	Expected trial end year
Lung Cancer				
Unresectable locally advanced or metastatic EGFRwt NSCLC	mono	Phase III	May 2024	2026
Locally advanced or metastatic EGFRmut NSCLC	mono	Phase III	May 2024	2026
Recurrent SCLC	mono	Phase III	August 2024	2026
EGFRmut NSCLC	combo with osimertinib	Phase II	July 2023	2025
Locally advanced or metastatic NSCLC, NPC and other solid tumors	combo with SI-B003	Phase II	January 2024	2025
Locally advanced or metastatic NSCLC, NPC and other solid tumors	combo with PD-(L)1	Phase II	June 2024	2026
Locally advanced or metastatic NSCLC	combo with osimertinib	Phase II	July 2024	2026
Extensive-stage SCLC	mono; combo with SI-B003	Phase II	November 2023	2025
Extensive-stage SCLC	combo with PD-(L)1	Phase II	June 2024	2026
BC				
Unresectable locally advanced, recurrent or metastatic HR+/HER2- BC	mono	Phase III	April 2024	2026

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Indication	Type of Therapy	Trial phase	Trial start date	Expected trial end year
Unresectable locally advanced or metastatic TNBC	mono	Phase III	June 2024	2026
Unresectable locally advanced or recurrent metastatic TNBC	combo with PD-(L)1	Phase II	August 2024	2026
HER2- BC	combo with SI-B003	Phase II	December 2023	2025
Unresectable locally advanced or metastatic BC and other solid tumors	mono	Phase I	August 2022	2025
GIC				
Recurrent or metastatic ESCC	mono	Phase III	March 2024	2026
Locally advanced or EC, GC, CRC and other GICs	combo with SI-B003/ PD-(L)1	Phase II	November 2023	2025
Locally advanced or metastatic GIC and other solid tumor	mono	Phase I	February 2022	2025
Other Cancer Types				
Recurrent or metastatic NPC	mono	Phase III	December 2023	2025
Recurrent or metastatic HNSCC and other solid tumors	mono; combo with SI-B003	Phase II	October 2023	2025
Recurrent or metastatic HNSCC and other solid tumors	combo with PD-(L)1	Phase II	June 2024	2026
Recurrent or metastatic gynecological malignancies and other solid tumors	mono	Phase I/II	June 2023	2025
Recurrent or metastatic CC and other gynecological malignancies	mono; combo with SI-B003	Phase II	November 2023	2025

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Indication	Type of Therapy	Trial phase	Trial start date	Expected trial end year
Recurrent glioblastoma	mono	Phase II	October 2024	2026
Multiple solid tumors, including locally advanced or metastatic urinary system tumors and other solid tumors	mono	Phase II	April 2023	2025
Locally advanced or metastatic urological tumors and other solid tumors	mono	Phase I	February 2022	2025
Locally advanced or metastatic UC and other solid tumors	combo with SI-B003	Phase II	December 2023	2025
Locally advanced or metastatic UC	combo with PD-(L)1	Phase II	May 2024	2026
Advanced solid tumors	combo with Osimertinib/ pembrolizumab	Phase I/II	December 2024	2026 ¹
Locally advanced or metastatic solid tumor	mono	Phase I	November 2021	2025
Metastatic or unresectable NSCLC and other solid tumors	mono	Phase I	August 2023	2025 ¹

Note:

1. denotes estimated primary completion year.

We expect to file our first NDA with the NMPA for BL-B01D1 in NPC upon completion of the interim analysis of our ongoing Phase III clinical trials in China by 2026. Under our license and collaboration agreement with BMS, we and BMS plan to submit BLAs to the FDA for NSCLC and other indications based on our clinical progress.

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Key Clinical Trial Results

Phase I Clinical Trial of BL-B01D1 as Monotherapy for Locally Advanced or Metastatic Solid Tumors

This is a first-in-human, open-label, multicenter Phase I clinical trial to evaluate the efficacy of BL-B01D1 as monotherapy in patients with locally advanced or metastatic NSCLC, NPC and other solid tumors. The primary endpoints for this trial are DLT, MTD and RP2D. The secondary endpoints are PK, ADA, ORR, DCR, as well as DOR. The exploratory endpoints include PFS, OS, biomarkers, as well as neutralizing antibodies (nAb). The encouraging efficacy and safety results were published in July 2024 in the globally renowned academic journal, *The Lancet Oncology*.

Trial Design

This study includes patients with locally advanced or metastatic NSCLC and other solid tumors who have a performance status score of 0 or 1 according to the ECOG, and have at least one measurable lesion per RECIST v1.1. These patients must have either failed standard therapy or have no feasible treatment available. As of the data cut-off date (August 17, 2023), the dose escalation stage was performed on a 21-day cycle, in which 13 subjects received BL-B01D1 at the dosage of 2.5 mg/kg, 3.0 mg/kg and 3.5 mg/kg D1D8 Q3W, and six subjects received at BL-B01D1 at the dosage of 5.0 mg/kg, and 6.0 mg/kg D1 Q3W. In the dose-expansion phase, subjects received BL-B01D1 with the same dosing levels and schedules as in the dose escalation stage.

Trial Status

We initiated this Phase I study for BL-B01D1 as monotherapy for the treatment of NSCLC and other solid tumors in China in November 2021, and expect to complete this trial in 2025. As of the data cut-off date (August 17, 2023), a total of 369 patients with NSCLC, NPC and other solid tumors have been enrolled in this trial.

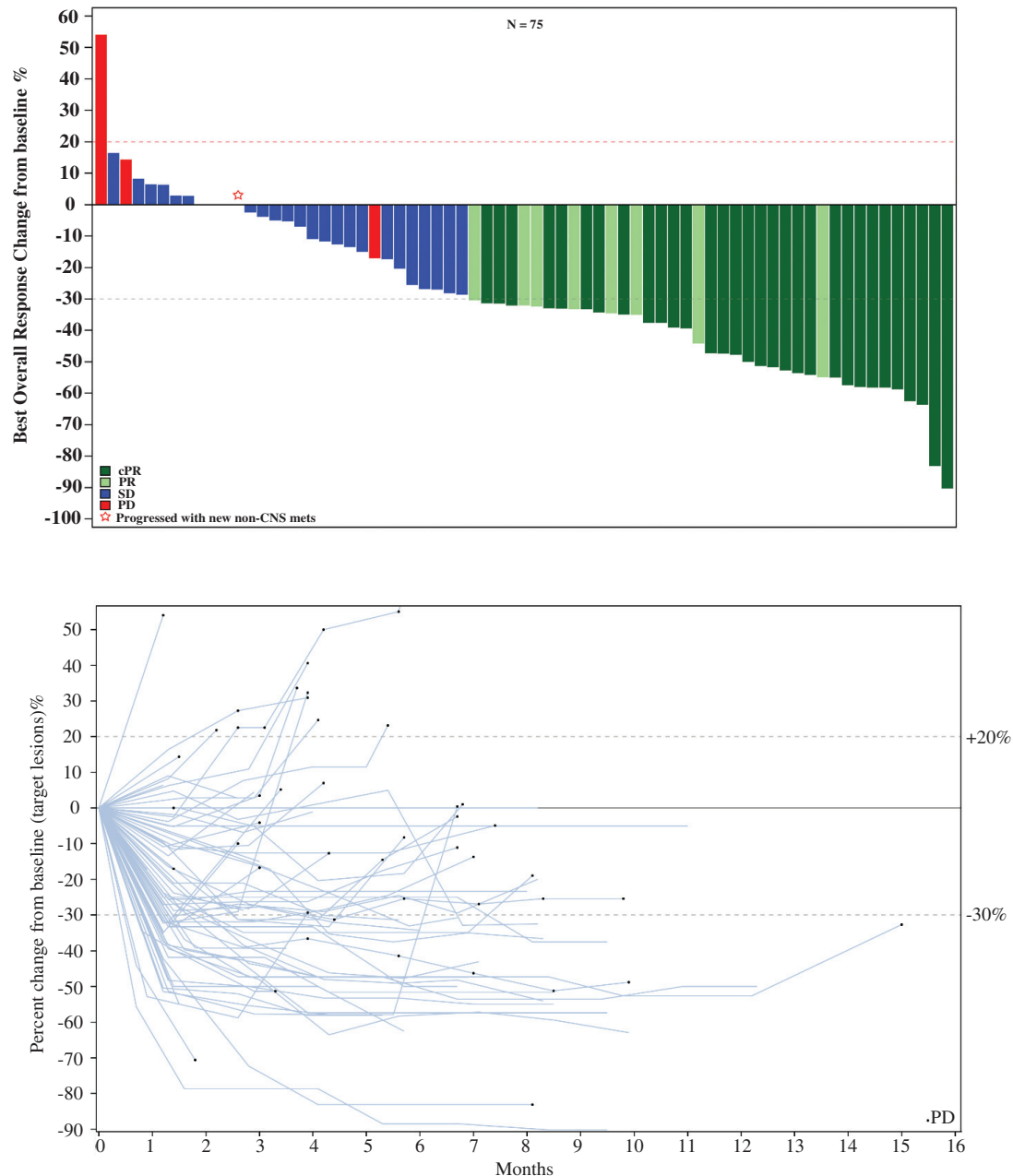
Efficacy Data

We evaluated the efficacy of BL-B01D1 as monotherapy for the treatment of NSCLC and other solid tumors based on the data from response-evaluable patients enrolled between December 8, 2021 and March 13, 2023. Patients enrolled after March 13, 2023 were not included due to the short follow-up period as of the data cut-off date (August 17, 2023).

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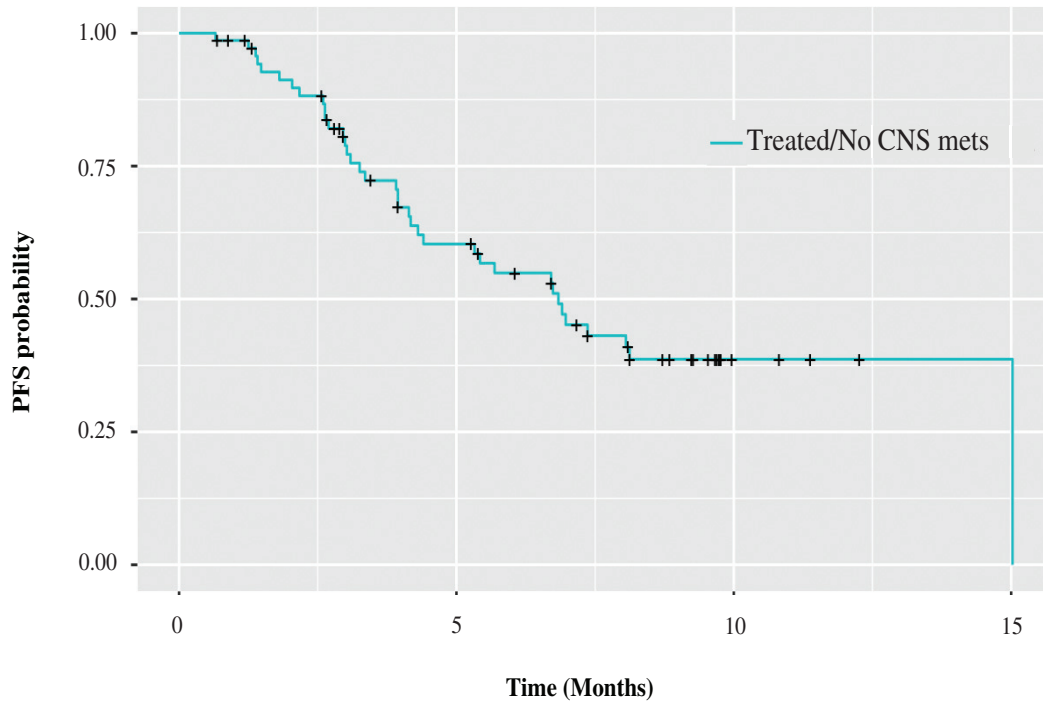
- *NSCLC*

As of the data cut-off date (August 17, 2023), there were 75 response-evaluable NSCLC patients with treated or without CNS metastasis administered with BL-B01D1. Among these patients, the interim Phase I results showed an ORR of 52.0%, cORR of 41.3%, DCR of 86.7%, mDOR of 12.3 months and mPFS of 6.8 months. The below waterfall plot and spider plot show the best overall response change from baseline in target lesions for each evaluable NSCLC patient with treated or without CNS metastasis.

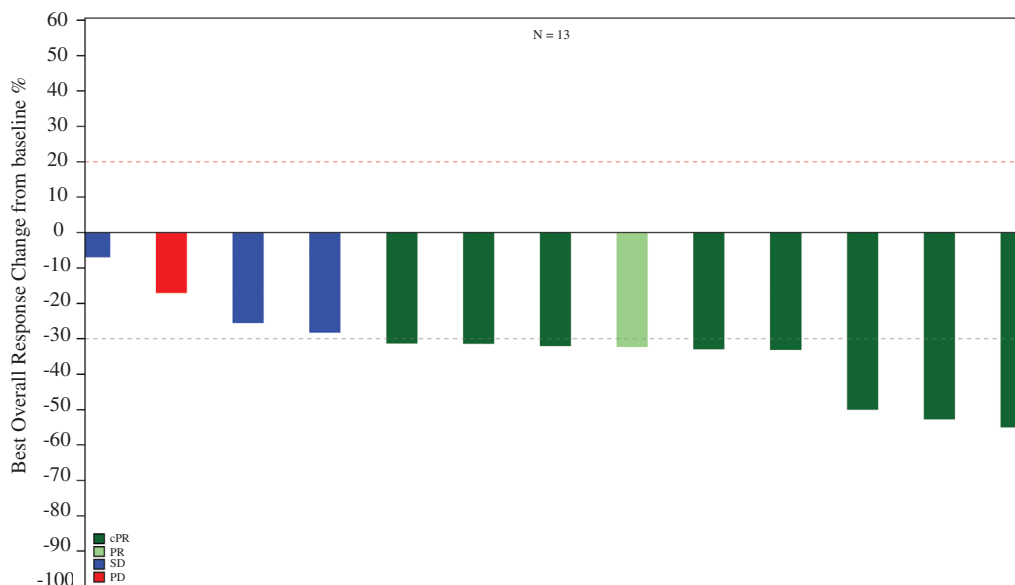


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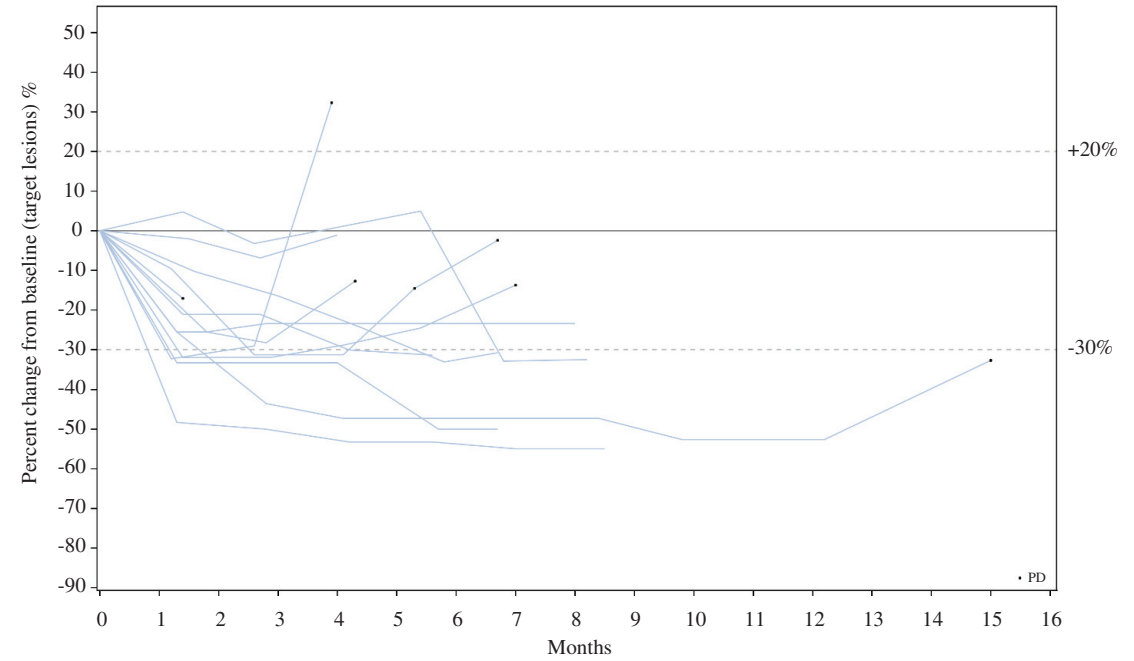
The diagram below illustrates the Kaplan-Meier curve of PFS of NSCLC patients with treated or without CNS metastasis.



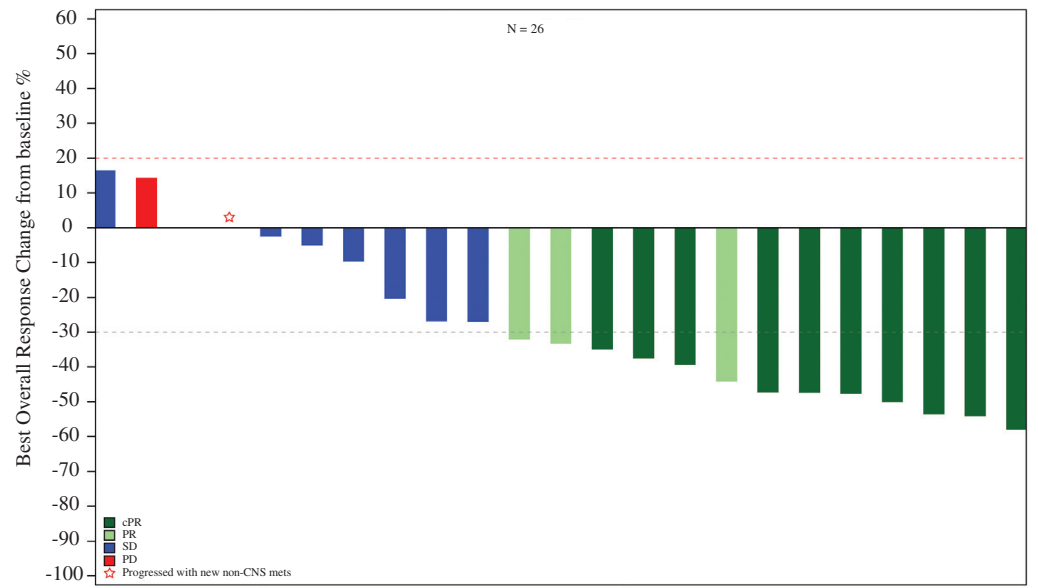
Notably, BL-B01D1 achieved greater efficacy in 13 EGFRmut NSCLC patients with treated or without CNS metastasis, who received the dosages at 2.5mg/kg D1D8 Q3W and 4.5mg/kg D1 Q3W, with an ORR of 69.2%, cORR of 61.5%, DCR of 92.3%, mDOR of 12.3 months and mPFS of 15.0 months. Given the small size of the patient cohort, these results may not be fully representative or reproducible in larger-scale studies. The below waterfall plot and spider plot show the best overall response change from baseline in target lesions for each of these 13 EGFRmut NSCLC patients.



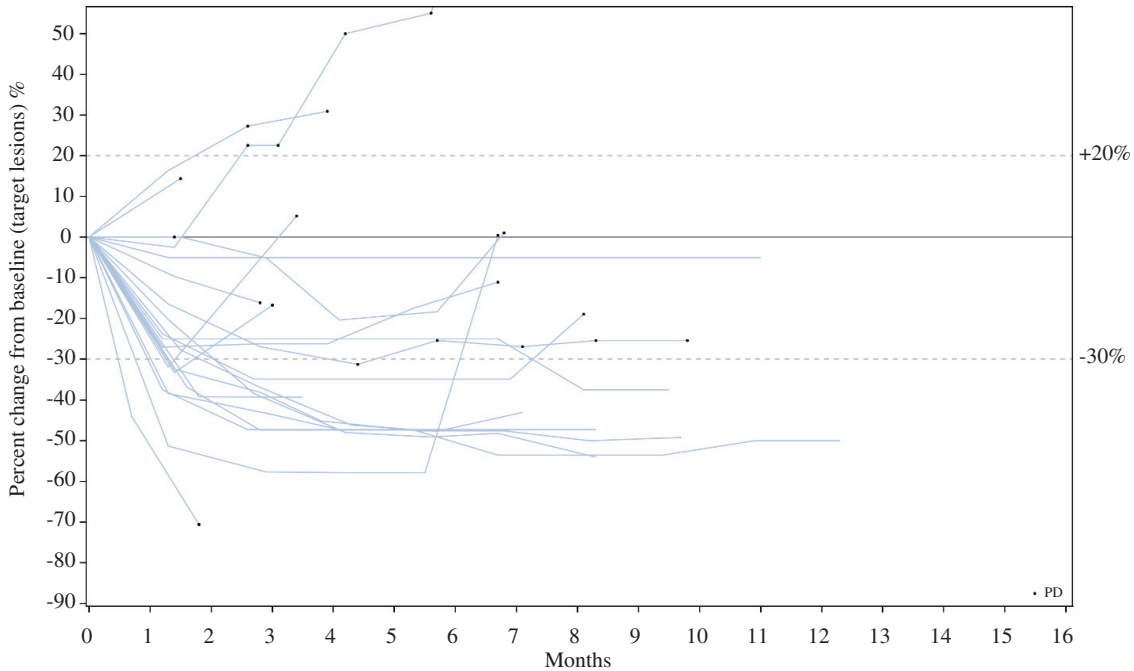
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In addition, 26 of the enrolled EGFRwt NSCLC patients received BL-B01D1 as a systemic 2L treatment, showing an ORR of 50.0%, cORR of 38.5%, DCR of 80.8% and mPFS of 6.7 months. The below waterfall plot and spider plot show the best overall response change from baseline in target lesions for each of such evaluable patients.



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• NPC

As of the data cut-off date (August 17, 2023), among 37 evaluable NPC patients with a median of three prior treatment lines, the treatment with BL-B01D1 achieved an ORR of 59.5%, cORR of 37.8%, DCR of 100%, and mPFS of 6.8 months.

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Safety Data

As of the data cut-off date (August 17, 2023), BL-B01D1 demonstrated a manageable safety profile in previously treated patients with solid tumors. Among 369 enrolled patients with NSCLC, NPC and other solid tumors, 351 patients (95%) experienced TRAE. 226 patients (61%) experienced grade 3 or above TRAE, 115 patients (31%) experienced grade 4 or above TRAE, 108 patients (29%) experienced serious TRAE, and eight patients died due to TRAE. The incidence of ILD is low, with only one case of grade 2 ILD observed. Among all the enrolled 369 patients, as of August 17, 2023, 278 patients received BL-B01D1 at 2.5mg/kg D1D8 Q3W, and 40 patients received 4.5 mg/kg D1D8 Q3W, which were the two largest cohorts. TRAEs related to BL-B01D1 treatment for patients in all Q3W regimens, 2.5 mg/kg D1D8 Q3W, and 4.5 mg/kg D1 Q3W are summarized in the table below.

	All Q3W regimens (N = 369)		2.5 mg/kg D1D8 Q3W (N = 278)		4.5 mg/kg D1 Q3W (N = 40)	
TRAE ≥ 10%, n (%)	All Grade	≥ G3	All Grade	≥ G3	All Grade	≥ G3
Hematological toxicities						
Leukopenia	241 (65%)	118 (32%)	170 (61%)	76 (27%)	29 (73%)	13 (33%)
Anemia	237 (64%)	87 (24%)	177 (64%)	62 (22%)	29 (73%)	10 (25%)
Neutropenia	217 (59%)	132 (36%)	148 (53%)	80 (29%)	28 (70%)	18 (45%)
Thrombocytopenia	204 (55%)	104 (28%)	148 (53%)	76 (27%)	23 (58%)	9 (23%)
Non-hematological toxicities						
Nausea	131 (36%)	3 (<1%)	92 (33%)	3 (1%)	16 (40%)	0
Asthenia	114 (31%)	3 (<1%)	79 (28%)	3 (1%)	13 (33%)	0
Decreased appetite	106 (29%)	2 (<1%)	73 (26%)	2 (<1%)	15 (38%)	0
Alopecia	91 (25%)	0	57 (21%)	0	17 (43%)	0
Stomatitis	93 (25%)	4 (1%)	62 (22%)	3 (1%)	11 (28%)	1 (3%)
Vomiting	82 (22%)	5 (1%)	55 (20%)	4 (1%)	13 (33%)	1 (3%)
Diarrhea	64 (17%)	3 (<1%)	41 (15%)	1 (<1%)	12 (30%)	0
Skin disorders	61 (17%)	2 (<1%)	40 (14%)	1 (<1%)	10 (25%)	1 (3%)
Hypokalemia	56 (15%)	8 (2%)	44 (16%)	3 (1%)	2 (5%)	1 (3%)
Hypoalbuminemia	48 (13%)	0	41 (15%)	0	2 (5%)	0
Hyponatremia	48 (13%)	3 (<1%)	40 (14%)	3 (1%)	1 (3%)	0
Constipation	42 (11%)	0	31 (11%)	0	4 (10%)	0
ALT increased	38 (10%)	2 (<1%)	21 (8%)	1 (<1%)	6 (15%)	0
Dizziness	38 (10%)	0	32 (12%)	0	1 (3%)	0
Hypophagia	37 (10%)	0	23 (8%)	0	1 (3%)	0

Source: Company data

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Conclusion

BL-B01D1 has a manageable safety profile and encouraging clinical antitumor activity in various advanced solid tumors. Importantly, the encouraging antitumor activity was found in patients with previously treated solid tumors, suggesting the significant potential of BL-B01D1 as a treatment option for these previously treated patients.

Notably, BL-B01D1 has exhibited a manageable safety profile and promising antitumor activity in patients with NSCLC who have progressed after standard of care, including EGFR TKI therapy or immunotherapy and platinum-based chemotherapy, as well as promising antitumor activity in NPC.

Phase I Clinical Trial of BL-B01D1 as Monotherapy for Locally Advanced or Metastatic GIC and Other Solid Tumors

This is an open-label, Phase I study designed to evaluate BL-B01D1 safety, tolerability, pharmacokinetic characteristics, and preliminary efficacy in patients with locally advanced or metastatic GIC and other solid tumors, including BTC and ESCC. The primary endpoints of the study are DLT, MTD, and RP2D, and the secondary endpoints are TEAE, pharmacokinetics parameters, ORR, DCR, and DOR. Exploratory endpoints are PFS, OS, biomarker, and nAb.

Trial Design

This study includes patients with locally advanced or metastatic GIC and other solid tumors who have a performance status score of 0 or 1 according to the ECOG and have measurable disease per RECIST v1.1. These patients must have been previously treated with at least one line of therapy. In the dose-expansion phase, subjects with different tumor types were assigned into three treatment arms based on dosing, all of which were performed on a D1D8 Q3W regimen.

As of the data cut-off date (June 30, 2024), 44 patients with BTC and 83 patients with previously treated ESCC were enrolled in the regimen. Among 44 patients with BTC, 31 patients received BL-B01D1 at 2.5 mg/kg, three patients received BL-B01D1 at 3.0 mg/kg, and ten were treated with BL-B01D1 at 3.5 mg/kg. Among 83 patients with previously treated ESCC, 22 patients received BL-B01D1 at 2.0 mg/kg, 60 patients received BL-B01D1 at 2.5 mg/kg, and one patient received BL-B01D1 at 3.0 mg/kg. Treatment continued until disease progression or the development of intolerable toxicity.

Trial Status

This study was initiated in February 2022 in China and is expected to be completed in 2025. As of June 30, 2024, a total of 44 patients have been enrolled in this trial for the treatment of BTC, and a total of 83 patients have been enrolled in the trial for the treatment of ESCC.

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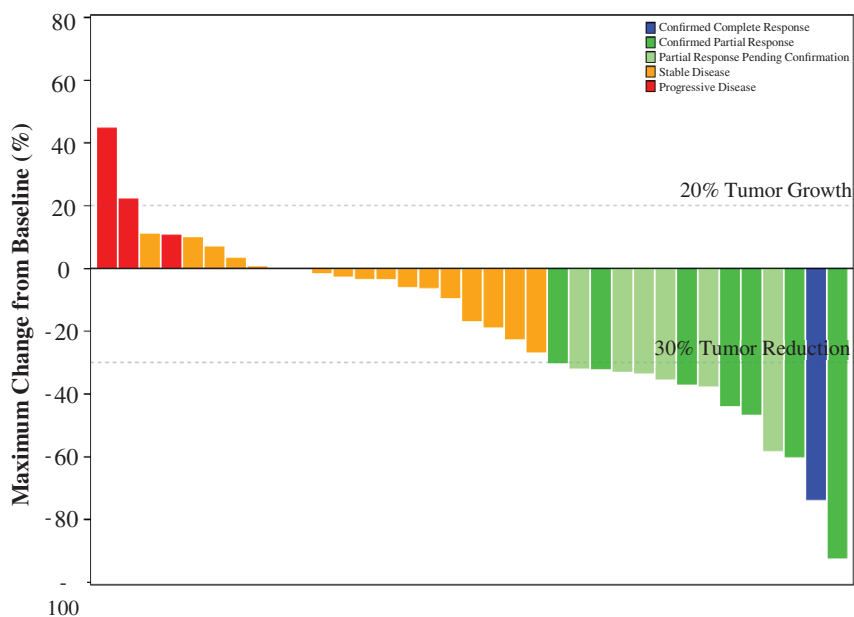
Efficacy Data

- BTC**

As of the data cut-off date (June 30, 2024), there were 36 response-evaluable patients with locally advanced or metastatic BTC administered with BL-B01D1, with an overall ORR of 38.9%, cORR of 22.2%, DCR of 88.9%, mPFS of 4.2 months, and mDOR of 5.9 months. The following table sets forth the efficacy data by treatment cohorts.

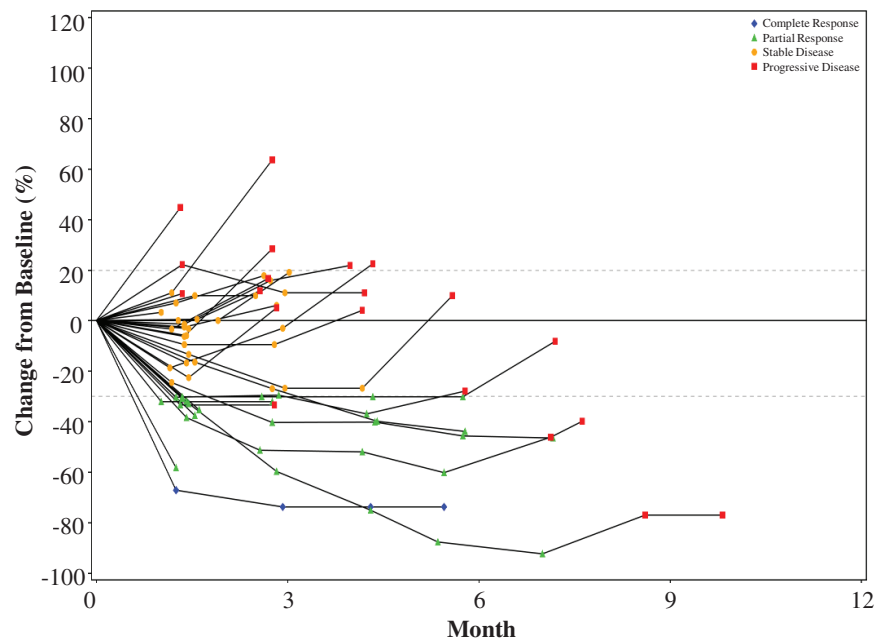
	2.5mg/kg D1D8Q3W (N=25)	3.0mg/kg D1D8Q3W (N=3)	3.5mg/kg D1D8Q3W (N=8)	Total (N=36)
Best Overall Response				
CR	1	0	0	1
PR	7	2	4	13
cPR	4	0	3	7
PR→Ongoing	2	0	0	2
SD	14	1	3	18
PD	3	0	1	4
ORR % (95% CI)	32% (14.9-53.5)	66.7% (9.4-99.2)	50% (15.7-84.3)	38.9% (23.1-56.5)
cORR % (95% CI)	20% (6.8-40.7)	0% (0.0, 70.8)	37.5% (8.5-75.5)	22.2% (10.1-39.2)
DCR % (95% CI)	88% (68.8-97.5)	100% (29.2-100.0)	87.5% (47.3~99.7)	88.9% (73.9-96.9)
mPFS (months, 95% CI)	4.3 (2.7, NR)	3.5 (2.8, NR)	3.4 (1.3, 7.1)	4.2 (2.8, 7.1)
mDOR (months, 95% CI)	7.3 (NR, NR)	NE	5.8 (4.2, NR)	5.9 (4.2, NR)

The below waterfall plot and spider plot show the best overall response change from baseline in target lesions for the 36 patients with BTC administered with BL-B01D1.

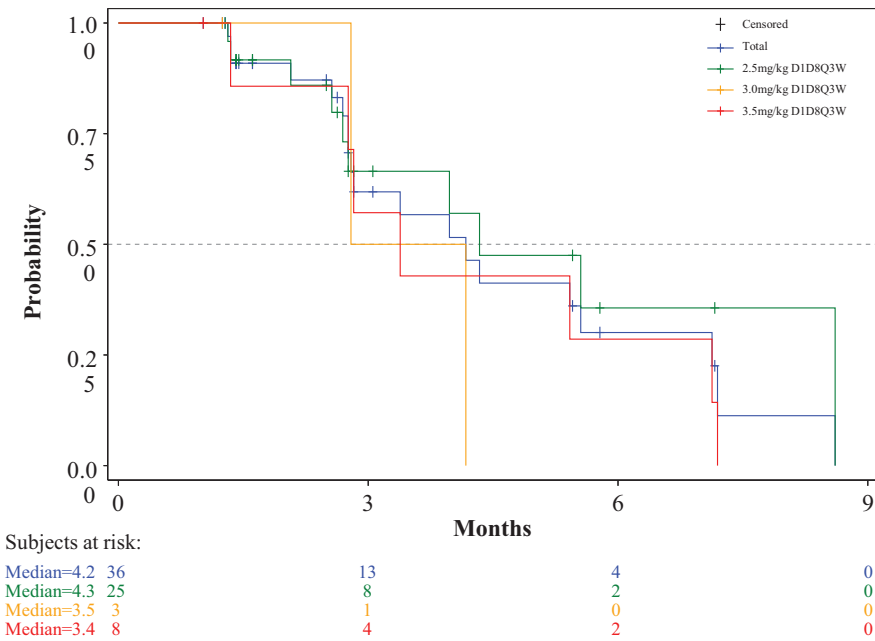


Note: subjects without post baseline sum of target lesion diameter or tumor assessment were not included.

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The diagram below illustrates the Kaplan-Meier curves of PFS of patients with BTC as of the data cut-off date.



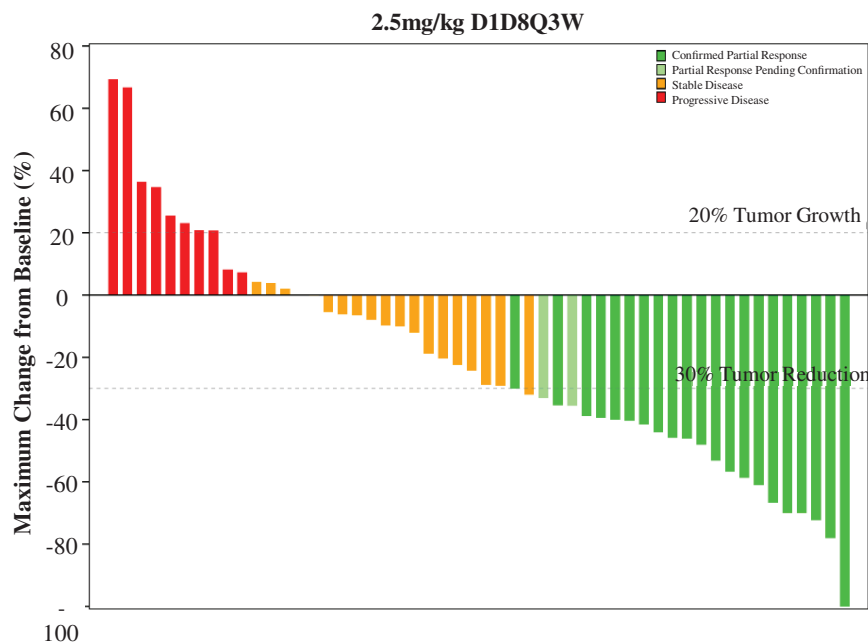
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• ESCC

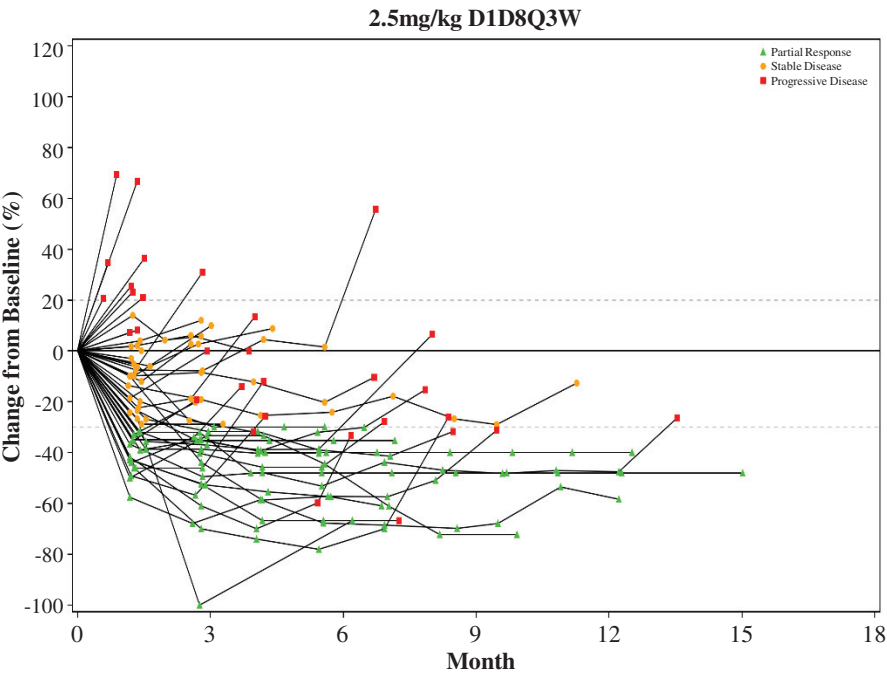
As of the data cut-off date (June 30, 2024), there were 74 response-evaluable patients with locally advanced or metastatic ESCC administered with BL-B01D1, with an overall ORR of 35.1%, cORR of 32.4%, DCR of 70.3%, mPFS of 4.3 months, and mDOR of 6.5 months. The following table sets forth the efficacy data by treatment cohorts.

	2.0mg/kg D1D8Q3W (N=22)	2.5mg/kg D1D8Q3W (N=52)	Total (N=74)
Best Overall Response			
CR	1	0	1
PR	2	23	25
cPR	2	21	23
SD	7	19	26
PD	9	10	19
NE	3	0	3
ORR % (95% CI)	13.6% (2.9, 34.9)	44.2% (30.5, 58.7)	35.1% (24.4, 47.1)
cORR % (95% CI)	13.6% (2.9, 34.9)	40.4% (27.0, 54.9)	32.4% (22.0, 44.3)
DCR % (95% CI)	45.5% (24.4, 67.8)	80.8% (67.5, 90.4)	70.3% (58.5, 80.3)
mPFS (months, 95% CI)	2.7 (1.4, 3.6)	5.4 (4.0, 6.8)	4.3 (3.3, 5.5)
mDOR (months, 95% CI)	4.5 (2.8, NR)	6.6 (5.6, 12.4)	6.5 (4.5, 12.4)

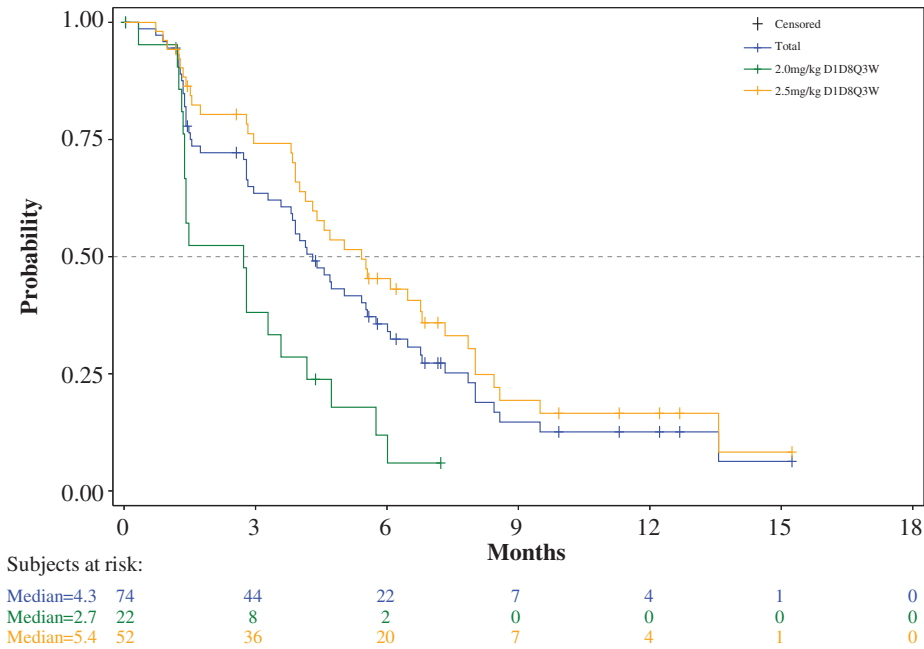
The below waterfall plot and spider plot show the best overall response change from baseline in target lesions for the 74 patients with ESCC administered with BL-B01D1.



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The diagram below illustrates the Kaplan-Meier curves of PFS of patients with ESCC as of the data cut-off date.



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Safety Data

- BTC**

As of the data cut-off date (June 30, 2024), BL-B01D1 showed manageable safety profile in the treatment of BTC. The most common TRAEs were hematological toxicities. No cases of ILD were observed, and no new safety signals were identified during the study. TRAEs related to BL-B01D1 treatment for BTC are summarized in the table below.

TRAE \geq 20 %, n (%)	Total (N=44)	
	All Grade	\geq G3
Hematological toxicities		
Anemia	36 (81.8%)	12 (27.3%)
Thrombocytopenia	33 (75.0%)	14 (31.8%)
Leukopenia	26 (59.1%)	9 (20.5%)
Neutropenia	17 (38.6%)	8 (18.2%)
Lymphocyte count decreased	10 (22.7%)	2 (4.5%)
Non-hematological toxicities		
Nausea	19 (43.2%)	0
Aspartate aminotransferase increased	15 (34.1%)	1 (2.3%)
Alanine aminotransferase increased	11 (25.0%)	1 (2.3%)
Diarrhea	13 (29.5%)	1 (2.3%)
Stomatitis	11 (25.0%)	1 (2.3%)
Weight decreased	10 (22.7%)	0
Hypoalbuminemia	9 (20.5%)	1 (2.3%)
Blood bilirubin increased	9 (20.5%)	0
Alopecia	9 (20.5%)	0

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• ESCC

As of the data cut-off date (June 30, 2024), BL-B01D1 demonstrated manageable safety profile at 2.5 mg/kg D1D8 Q3W. The most common TRAEs were hematological toxicities. Two cases of ILD were observed, and no new safety signals were identified during the study. TRAEs related to BL-B01D1 treatment for ESCC observed in the 2.5mg/kg D1D8 Q3W dosage level are summarized in the table below.

TRAE \geq 15%, n (%)	Total (N=60)	
	All Grade	\geq G3
Hematological toxicities		
Anemia	50 (83.3%)	17 (28.3%)
Leukopenia	34 (56.7%)	11 (18.3%)
Thrombocytopenia	35 (58.3%)	11 (18.3%)
Neutropenia	28 (46.7%)	10 (16.7%)
Lymphocyte count decreased	18 (30.0%)	9 (15.0%)
Non-hematological toxicities		
Nausea	28 (46.7%)	0
Asthenia	23 (38.3%)	1 (1.7%)
Decreased appetite	15 (25.0%)	0
Vomiting	14 (23.3%)	0
Weight decreased	13 (21.7%)	0
Hypoalbuminemia	13 (21.7%)	0
Hyponatremia	13 (21.7%)	0
Hypokalemia	12 (20.0%)	2 (3.3%)
Blood alkaline phosphatase increased	12 (20.0%)	0
Alanine aminotransferase increased	10 (16.7%)	1 (1.7%)
Albumin urine present	9 (15.0%)	0
Stomatitis	9 (15.0%)	0

Conclusion

BL-B01D1 demonstrated manageable safety with encouraging antitumor activity in patients with locally advanced or metastatic BTC or ESCC.

Phase II Clinical Trial of BL-B01D1 as Monotherapy for Locally Advanced or Metastatic Urothelial Carcinoma

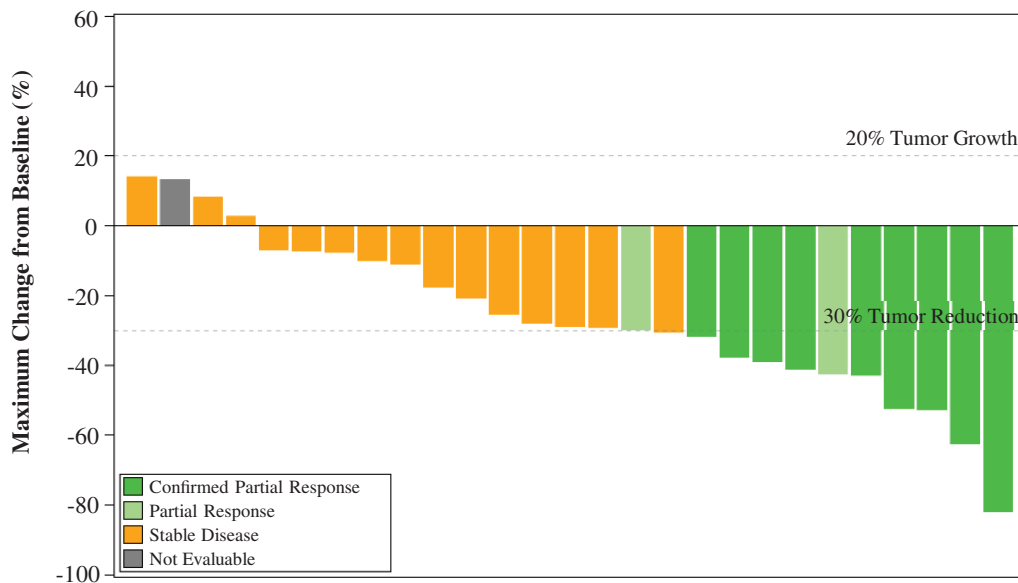
This is a Phase II clinical study to evaluate the safety, tolerability, pharmacokinetics and efficacy of BL-B01D1 for injection in patients with multiple solid tumors such as locally advanced or metastatic urothelial carcinoma. The primary endpoint for this trial is ORR by investigator’s assessment, and the secondary endpoints are DCR, PFS, DOR and safety.

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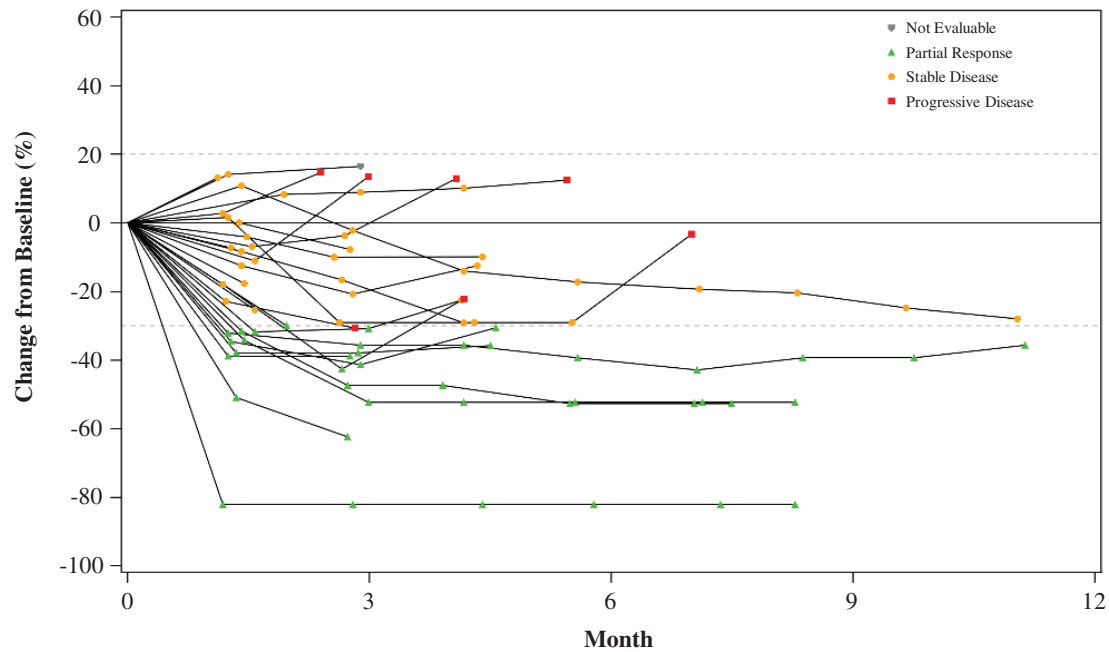
Trial Design. This study includes patients with locally advanced or metastatic urothelial carcinoma who have a performance status score of 0 or 1 according to the ECOG and have measurable disease per RECIST v1.1. These patients must have failed standard therapy or have no feasible treatment available. During the trial, patients were assigned into three treatment arms based on dosing, all of which were performed on a 21-day cycle. As of the data cut-off date (June 30, 2024), 34 patients received BL-B01D1 at 2.2 mg/kg D1D8 Q3W, four patients received BL-B01D1 at 2.5 mg/kg D1D8 Q3W, and three were treated with BL-B01D1 at 2.75 mg/kg D1D8 Q3W. Treatment continued until disease progression or the development of intolerable toxicity.

Trial Status. This study was initiated in April 2023 in China and is expected to be completed in 2025. As of June 30, 2024, a total of 41 patients have been enrolled in this trial. In light of the promising outcomes, we are actively advancing plans to initiate registrational studies.

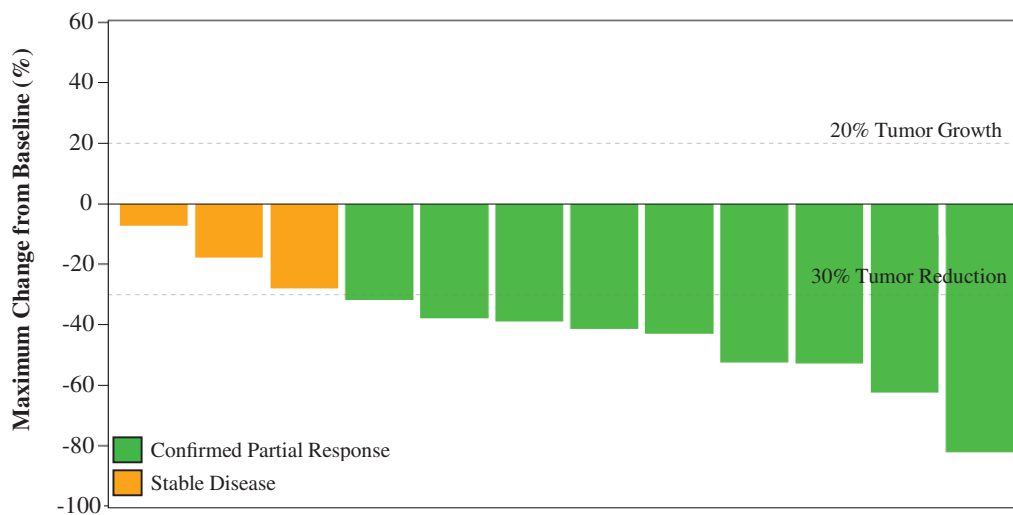
Efficacy Data. As of the data cut-off date (June 30, 2024), there were 27 response-evaluable patients with locally advanced or metastatic urothelial carcinoma administered with BL-B01D1 at 2.2 mg/kg dose level D1D8 Q3W. Findings showed that these 27 patients with a median of two prior treatment lines achieved the ORR of 40.7%, cORR of 33.3%, DCR of 96.3% and the 6-month DOR of 100%. The mDOR and mPFS have not been reached as of the data cut-off date. The below waterfall plot and spider plot show the best overall response change from baseline in target lesions for each evaluable patient.



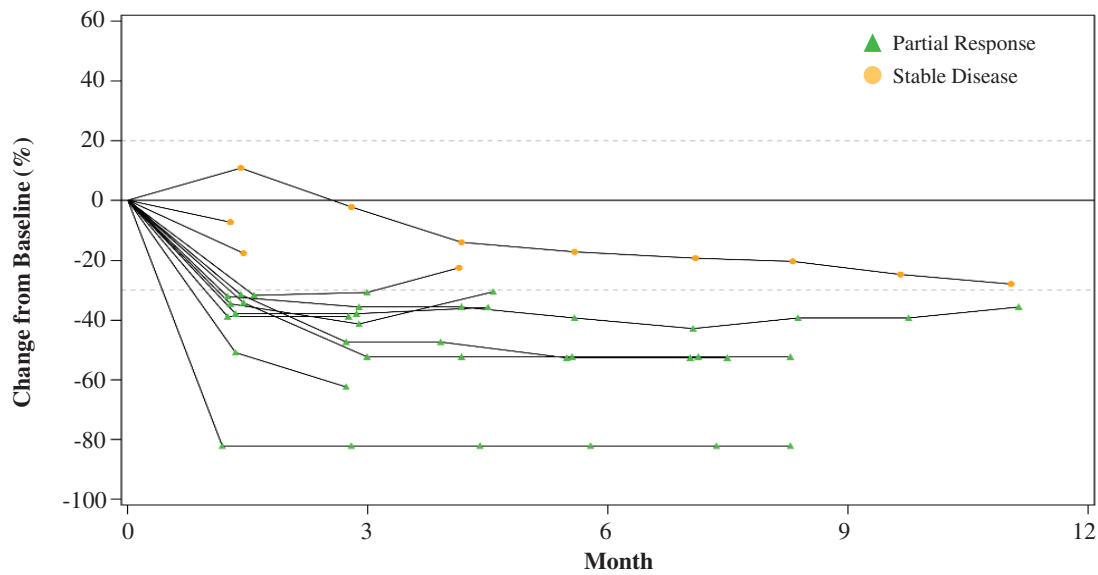
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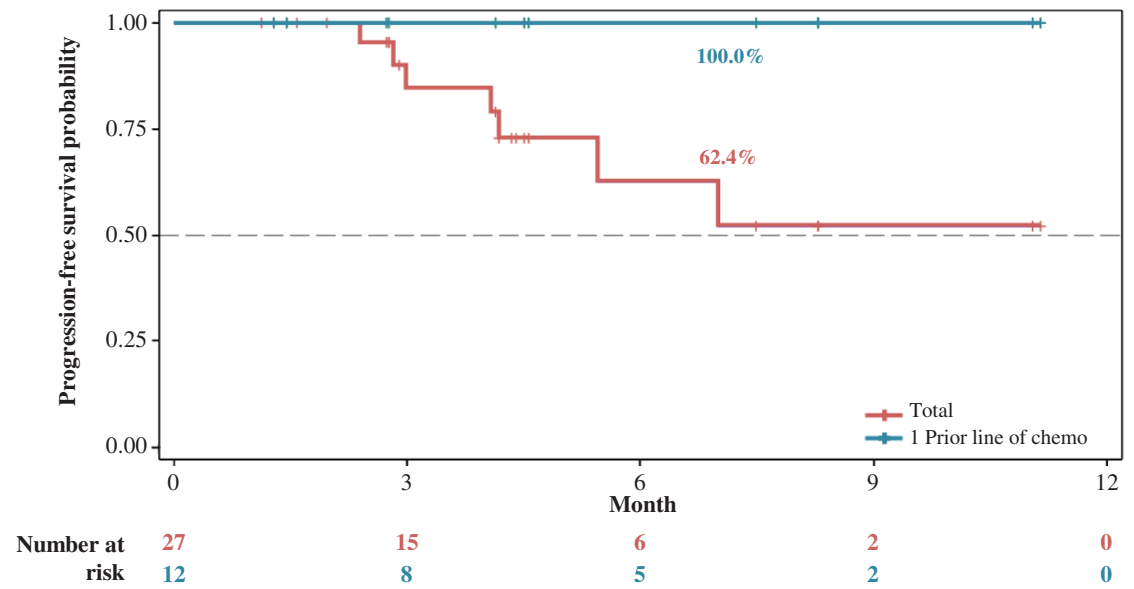
The preliminary efficacy of BL-B01D1 is particularly pronounced in patients with previously treated urothelial carcinoma, with notable results observed in second-line treatment. 12 of the total evaluable patients have received one prior line of chemotherapy via platinum-based therapy or an ADC, showing an ORR of 75%, cORR of 75.0%, DCR of 100%, and 6-month DOR rate of 100%, after administered with BL-B01D1 as of the data cut-off date. The mDOR and mPFS had not been reached as of the data cut-off date. The below waterfall plot and spider plot show the best overall response change from baseline in target lesions for the 12 patients with one prior line of chemotherapy.



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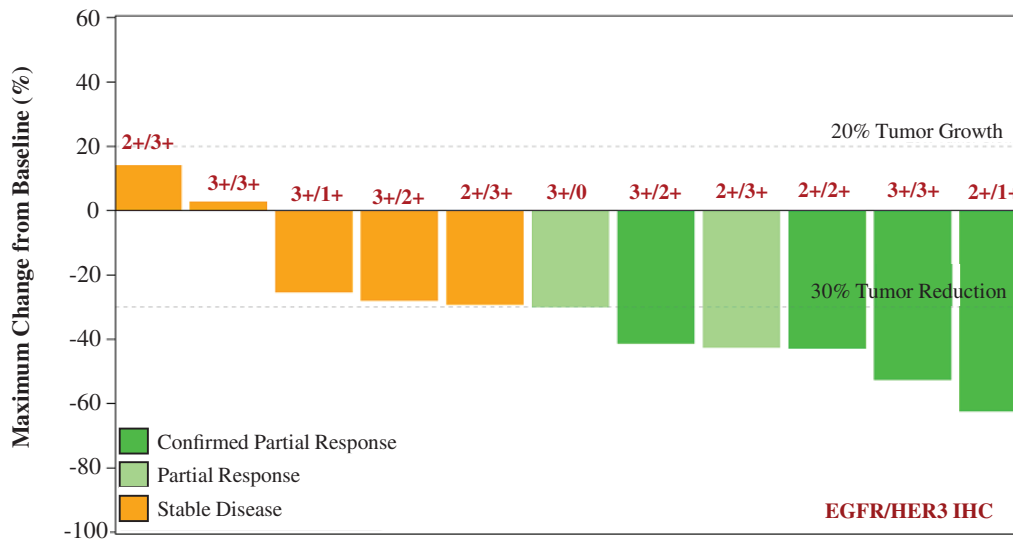


The diagram below illustrates the Kaplan-Meier curves of PFS of patients with urothelial carcinoma with and without one prior line of chemotherapy as of the data cut-off date.



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We performed biomarker analysis for patients with tissue samples. The below biomarker analysis showed that clinical activity in the 2.2 mg/kg cohort was observed across patients with various levels of EGFR and HER3 expression.



Safety Data. As of the data cut-off date (June 30, 2024), BL-B01D1 showed favorable safety profile at 2.2 mg/kg D1D8 Q3W in the treatment of urothelial carcinoma. The most common TRAEs were hematological toxicities, which were manageable, and the non-hematological toxicities were mostly Grade 1 or 2. No drug-related death was observed. The incidence and severity of toxicities related to EGFR and HER3 targeting were relatively low. No cases of ILD were observed, and no new safety signals were identified during the study. TRAEs related to BL-B01D1 treatment for urothelial carcinoma are summarized in the table below.

2.2mg/kg D1D8Q3W (N=34)			
	All Grade	Grade 3	Grade 4
Hematological toxicities			
Anemia	28 (82.4%)	9 (26.5%)	0
Leukopenia	24 (70.6%)	6 (17.6%)	4 (11.8%)
Thrombocytopenia	21 (61.8%)	4 (11.8%)	5 (14.7%)
Neutropenia	19 (55.9%)	7 (20.6%)	4 (11.8%)
Lymphocyte count decreased	7 (20.6%)	2 (5.9%)	0
Non-Hematological toxicities			
Decreased appetite	16 (47.1%)	1 (2.9%)	0
Nausea	15 (44.1%)	1 (2.9%)	0
Hypoalbuminemia	9 (26.5%)	0	0
Vomiting	9 (26.5%)	0	0
Alopecia	8 (23.5%)	0	0

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	2.2mg/kg D1D8Q3W (N=34)		
	All Grade	Grade 3	Grade 4
Asthenia	6 (17.6%)	0	0
Constipation	6 (17.6%)	0	0
Diarrhea	6 (17.6%)	0	0
Stomatitis	6 (17.6%)	0	0

Conclusion. BL-B01D1 represents a potential first-in-class therapeutic option, with the encouraging preliminary efficacy and favorable safety profile at 2.2 mg/kg D1D8 Q3W, for patients with locally advanced or metastatic urothelial carcinoma, which often has high expressions of both EGFR and HER3.

License and Collaboration Agreement with Bristol-Myers Squibb Company

For details, see “— License and Collaboration Agreement with Bristol-Myers Squibb Company.”

BL-M07D1 (HER2 ADC)

Overview

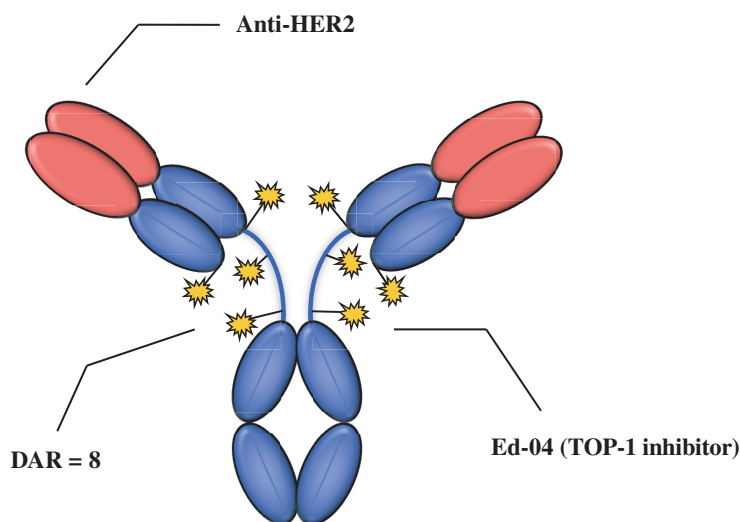
BL-M07D1 is an innovative HER2-specific ADC with best-in-class potential that has demonstrated strong anti-tumor efficacy in clinical trials. BL-M07D1 is currently being evaluated as a single agent and in combination settings in nine Phase I/II/III clinical trials in patients with a variety of HER2-expressing solid tumors, including NSCLC, BC, UC, GIC, gynecological cancers and digestive tract tumors, in China and the U.S.

Mechanism of Action

HER2 is a transmembrane receptor tyrosine kinase and a member of the ErbB family, which also includes HER1 (EGFR), HER3, and HER4. Unlike the other three members, HER2 does not bind to EGF-like ligands but relies on forming heterodimers with other members to activate signaling pathways that regulate cell proliferation and survival. HER2 is overexpressed in various cancers such as BC, GC, lung cancer, ovarian cancer (OC), among others. Studies have shown that approximately 15-30% of BC patients have HER2 gene amplification and overexpression.

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BL-M07D1 is engineered by linking a humanized HER2 antibody, trastuzumab, to our novel TOP-1 inhibitor, Ed-04, with a cleavable linker with a DAR of 8. BL-M07D1 specifically binds to HER2 on the surface of tumor cells. Upon binding to HER2 on tumor cells, BL-M07D1 is internalized by the cell, and subsequently releases the payload, Ed-04, in lysosomes. Moreover, the antibody in BL-M07D1 selectively binds to HER2 on tumor cells, inhibiting downstream signaling pathway activation, thereby enhancing the anti-tumor activity of this ADC. Additionally, the Fc portion of BL-M07D1’s antibody can mediate ADCC effects, further enhancing the killing of tumor cells. The figure below depicts the molecular structure of BL-M07D1:



Competitive Advantages

BL-M07D1 uses our novel TOP-1 inhibitor, Ed-04, and a cleavable, highly stable linker, making the drug more hydrophilic and less prone to aggregation, resulting in more potent antitumor activity and manageable safety. BL-M07D1 exhibited enhanced tumor suppression compared with certain marketed HER2 ADCs in various cell line-derived xenograft (CDX) tumor models. Specifically, BL-M07D1 demonstrated superior anti-tumor activity compared to both T-DM1 and Enhertu in a CDX model for HER2+ BC, and exhibited greater efficacy than Enhertu in two CDX models for HER2-low cancers that are insensitive to T-DM1. Moreover, BL-M07D1 induced potent bystander effects in a CDX model with both HER2+ and HER2-low cancer cells, resulting in tumor inhibition that was superior to T-DM1 and comparable to Enhertu.

BL-M07D1 has shown therapeutic efficacy and manageable safety in Phase I clinical trials for the treatment of BC. In our ongoing Phase I clinical trials for BL-M07D1 in patients with HER2+ metastatic BC, the interim data as of July 1, 2024 showed encouraging efficacy and a manageable safety profile. Among 45 evaluable patients with HER2+ BC, treatment with BL-M07D1 achieved an ORR of 88.9%, cORR of 84.4%, and DCR of 100%. In 16 subjects who have received prior HER2-ADC therapies, BL-M07D1 demonstrated a favorable efficacy profile, with an ORR of 93.8%, cORR of 87.5% and DCR of 100%. In addition, preliminary

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results from the same study also demonstrated an ORR of 62.3%, cORR of 54.7%, and DCR of 94.3% in an analysis of 53 heavily pretreated patients with HER2-low metastatic BC. These interim results indicate BL-M07D1’s encouraging performance in treating heavily pretreated HER2-expressing cancers, in both HER2+ and HER2-low BC with manageable safety and tolerability.

Clinical Development

Clinical Development Plan

We are currently conducting nine clinical trials for BL-M07D1 in China and the U.S., including one Phase III, two Phase II, three Phase I/II, and three Phase I clinical trials. We are evaluating BL-M07D1 as combination therapy in two Phase II clinical trials for the treatment of HER2+ BC and HER2+GC, and as monotherapy in other trials for the treatment of HER2+ BC, HER2-low BC, HER2+GC, HER2+/low expressing urinary and gastrointestinal tumors, NSCLC, gynecological malignancies, digestive tract tumors and other solid tumors. The below table sets forth the ongoing trials we are currently conducting for BL-M07D1:

<u>Indication</u>	<u>Type of Therapy</u>	<u>Trial phase</u>	<u>Trial start date</u>	<u>Expected trial end year</u>
Locally advanced or metastatic HER2+ BC	mono	Phase III	May 2024	2026
Unresectable locally advanced or metastatic HER2+ BC	combo with pertuzumab; combo with pertuzumab and docetaxel	Phase II	June 2024	2026
Locally advanced or metastatic HER2+ gastric or gastroesophageal junction adenocarcinoma	combo with PD-1 monoclonal antibody; combo with PD-1 monoclonal antibody and capecitabine	Phase II	October 2024	2026
Locally advanced or metastatic NSCLC	mono	Phase I/II	April 2024	2026
Locally advanced or metastatic HER2+/HER2-low urinary and GICs	mono	Phase I/II	January 2024	2026
HER2-expressing gynecologic malignancies	mono	Phase I/II	February 2024	2025

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<u>Indication</u>	<u>Type of Therapy</u>	<u>Trial phase</u>	<u>Trial start date</u>	<u>Expected trial end year</u>
Locally advanced or metastatic digestive tract tumors and other solid tumors	mono	Phase I	January 2023	2025
Locally advanced or metastatic HER2+/HER2-low BC and other solid tumors	mono	Phase I	August 2022	2025
HER2-expressing solid tumors	mono	Phase I	February 2024	2027

We will continue to advance clinical trials of BL-M07D1 across different cancer types and treatment settings. Specifically:

- We plan to advance BL-M07D1 as monotherapy to Phase III clinical trials in both China and the U.S. for, among others: (i) adjuvant/neoadjuvant therapy of HER2+ BC; (ii) HER2-low BC, including chemotherapy-naïve HR+/HER2- BC, as well as TNBC after 1L chemotherapy failure; (iii) HER2+ GC as a 2L or later treatment; (iv) HER2-mutant NSCLC as a 2L or later treatment; and (v) HER2+ pan-tumor indications, including UC, biliary cancer, CC, endometrial cancer, OC and others as 2L or later treatment.
- We will also continue to explore the potential synergistic effects of BL-M07D1 with other therapies and advance to Phase III clinical trials for: (i) BL-M07D1 in combination with pertuzumab for HER2+ BC as 1L treatment, and (ii) BL-M07D1 in combination with PD-1 monoclonal antibody for HER2+ GC as 1L treatment.

Key Clinical Trial Results

Phase I Clinical Trial of BL-M07D1 as Monotherapy for Locally Advanced or Metastatic HER2-expressing BC and Other Solid Tumors

This open-label and single-arm Phase I study is designed to evaluate BL-M07D1 safety, tolerability, pharmacokinetic characteristics, and initial efficacy in patients with locally advanced or metastatic HER2-expressing BC and other solid tumors. The trial has two cohorts and the primary endpoints are DLT, MTD and RP2D, and the secondary endpoints are TEAE, pharmacokinetics parameters, ORR, DCR, OS, PFS, and DOR. The exploratory endpoints are biomarker assessment and neutralizing antibodies.

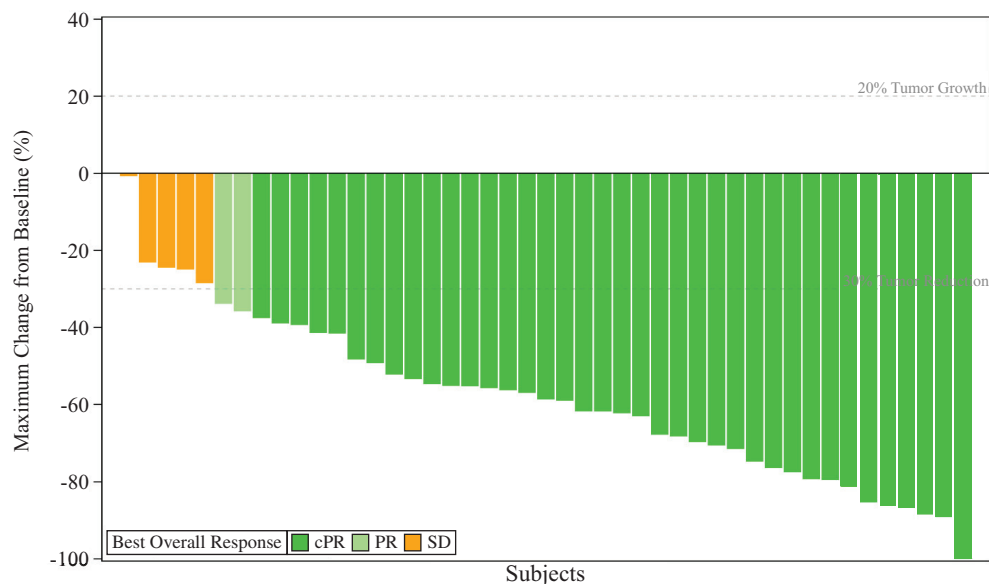
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Trial Design. This study includes patients with locally advanced or metastatic HER2-positive/low-expressing BC and other solid tumors who have a performance status score of 0 or 1 according to the ECOG, and have at least one measurable lesion per RECIST v1.1. These patients must have been previously treated with at least one line of therapy, have adequate organ and marrow function, and have either no brain metastases or stable brain metastases at screening. During dose-escalation, subjects received BL-M07D1 in two different schedules, either D1 Q3W across nine dosage levels of 2.6 mg/kg, 3.2 mg/kg, 3.8 mg/kg, 4.4 mg/kg, 5.0 mg/kg, 5.6 mg/kg, 6.2 mg/kg, 6.8 mg/kg and 7.4 mg/kg, or a fixed dosage of 1.0 mg/kg D1D8 Q3W. In Phase Ib study, one or several dosages will be chosen for further evaluation.

Trial Status. This study was initiated in August 2022 in China and is expected to be completed in 2025. As of July 3, 2024, a total of 210 patients have been enrolled in this trial.

Efficacy Data. As of the data cut-off date (July 1, 2024), there were 98 response-evaluable patients with locally advanced or metastatic HER2 expressing BC administered with BL-M07D1 at 4.4 mg/kg dose level D1 Q3W. In 45 patients with HER2+ BC, the ORR was 88.9%, cORR was 84.4%, DCR was 100%. In 16 patients with HER2+ BC who had received HER2-ADC prior to BL-M07D1, the ORR was 93.8%, cORR was 87.5% and DCR was 100%. In 53 patients with HER2-low BC, the ORR was 62.3%, cORR was 54.7% and DCR was 94.3%. As of the data cut-off date, mPFS was not reached in these cohorts. The below waterfall plots, spider plots and swimmer plots illustrate changes of HER2+ BC from baseline in target lesions for each evaluable patient administered with BL-M07D1 at 4.4mg/kg D1 Q3W.

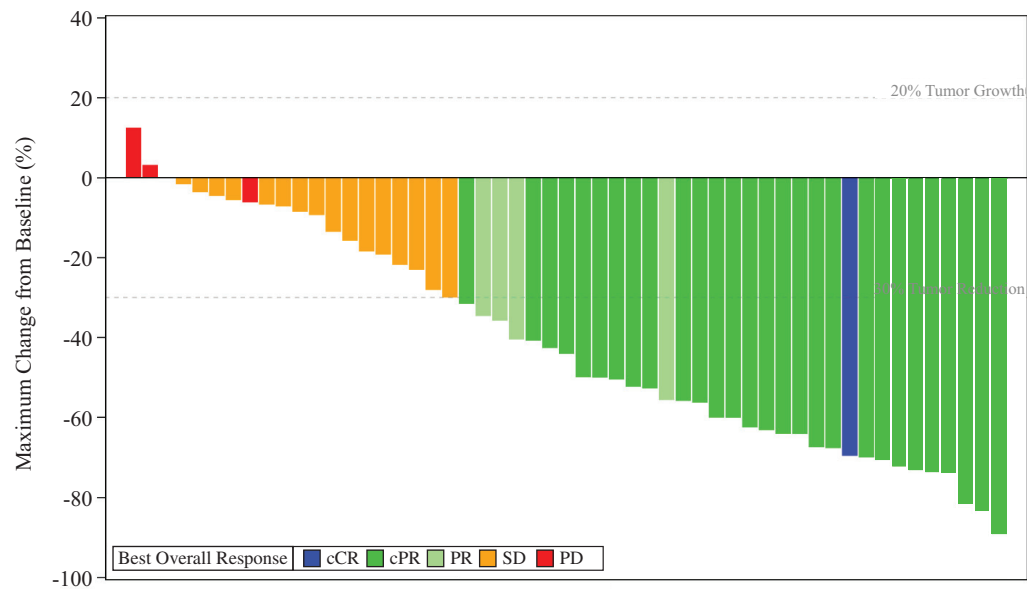
Response Observed in all Evaluable Patients with HER2+ BC



Source: Company data

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Response Observed in all Evaluable Patients with HER2-Low BC



Source: Company data

Safety Data. As of the data cut-off date (July 1, 2024), the observed toxicities were predominantly hematologic. Four cases of ILD were observed, one with grade 3 TRAE, two with grade 2 TRAE and one with grade 1 TRAE. No drug-related death was observed. TRAEs related to BL-M07D1 treatment for HER2 expressing BC and other solid tumors are summarized in the table below.

TRAE ≥ 15%, n (%)	Total (N = 210)		4.4 mg/kg D1 Q3W (N = 121)	
	All Grade	Grade ≥3	All Grade	Grade ≥3
Anemia	181 (86.2)	89 (42.4)	105 (86.8)	50 (41.3)
Leukopenia	178 (84.8)	83 (39.5)	100 (82.6)	47 (38.8)
Neutropenia	168 (80.0)	99 (47.1)	92 (76.0)	53 (43.8)
Thrombocytopenia	143 (68.1)	63 (30.0)	84 (69.4)	36 (29.8)
Nausea	128 (61.0)	3 (1.4)	72 (59.5)	2 (1.7)
Decreased appetite	87 (41.4)	2 (1.0)	46 (38.0)	2 (1.7)
Vomiting	82 (39.0)	6 (2.9)	46 (38.0)	4 (3.3)
Aspartate aminotransferase increased	73 (34.8)	1 (0.5)	35 (28.9)	1 (0.8)
Asthenia	69 (32.9)	4 (1.9)	38 (31.4)	2 (1.7)
Lymphocyte count decreased	66 (31.4)	31 (14.8)	40 (33.1)	20 (16.5)
Alopecia	65 (31.0)	0	38 (31.4)	0

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TRAE \geq 15%, n (%)	Total (N = 210)		4.4 mg/kg D1 Q3W (N = 121)	
	All Grade	Grade \geq 3	All Grade	Grade \geq 3
Gamma-glutamyl transferase increased	59 (28.1)	8 (3.8)	38 (31.4)	6 (5.0)
Alanine aminotransferase increased	58 (27.6)	0	31 (25.6)	0
Blood alkaline phosphatase increased	54 (25.7)	2 (1.0)	32 (26.4)	2 (1.7)
Stomatitis	50 (23.8)	3 (1.4)	23 (19.0)	2 (1.7)
Weight decreased	50 (23.8)	1 (0.5)	28 (23.1)	1 (0.8)
Hypokalemia	46 (21.9)	5 (2.4)	24 (19.8)	2 (1.7)
Hypoalbuminemia	42 (20.0)	0	25 (20.7)	0
Constipation	39 (18.6)	0	17 (14.0)	0
Diarrhea	39 (18.6)	2 (1.0)	24 (19.8)	1 (0.8)

Source: Company data

Conclusion. BL-M07D1 demonstrated promising antitumor activity in patients with HER2+ BC and HER2-low BC and showed comparable antitumor activity in patients with HER2+ BC who had previously been treated with other HER2-ADCs.

BL-M11D1 (CD33 ADC)

Overview

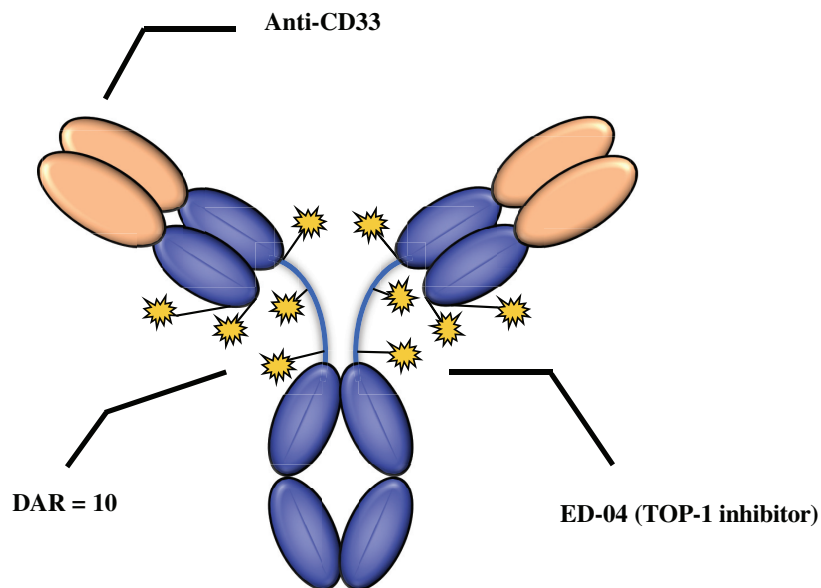
BL-M11D1 is an innovative CD33 specific ADC. BL-M11D1 is currently being evaluated as a single agent in a Phase I clinical trial which includes patients with acute myeloid leukemia (AML).

Mechanism of Action

CD33 is a transmembrane receptor expressed on cells of myeloid lineage. It is broadly over-expressed on cells of hematopoietic cancers. Previous studies have shown that 85% to 90% of AML patients express CD33 on their leukemia cells, making CD33 a promising selective therapeutic target in AML.

BL-M11D1's antibody component is gemtuzumab, a monoclonal antibody targeting CD33, with a wild-type Fc that can mediate ADCC. The CD33 antibody component of BL-M11D1 is linked to our novel TOP-1 inhibitor, Ed-04, via a cathepsin B cleavable linker with a DAR of 10. The figure below depicts the molecular structure of BL-M11D1.

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BL-M11D1 specifically binds to CD33 on the surface of tumor cells and enters the cells through endocytosis. Upon internalization, BL-M11D1 releases the payload, Ed-04, in lysosomes through enzymatic cleavage. Ed-04 blocks DNA synthesis in tumor cell, and leads to tumor cell death. In addition, the Fc portion of BL-M11D1’s antibody can mediate ADCC effect, which further enhances tumor cell killing.

Competitive Advantages

Compared to gemtuzumab ozogamicin, a marketed CD33 ADC, BL-M11D1 offers better tolerability and a wider therapeutic window, with no occurrence of veno-occlusive disease reported thus far. Therefore, after one to two cycles of induction therapy, BL-M11D1 could potentially be used for long-term consolidation and maintenance therapy, presenting greater commercial potential.

BL-M11D1 has shown manageable safety and promising antitumor activity in its early clinical trial. In the ongoing Phase I clinical trial in patients with relapsed/refractory AML, we have completed the assessment of the first five dose levels out of eight doses, and we had been dosing at the sixth dose level as of the Latest Practicable Date. No DLTs were observed in the first five doses and CRs have been observed starting from the third dose level.

Clinical Development

We are currently conducting a Phase I clinical trial for BL-M11D1 in China in patients with relapsed/refractory AML. The Phase I trial was initiated in August 2023, and is expected to be completed in 2025. In addition, we have initiated and completed the dosing of the first patient in the Phase I clinical study for BL-M11D1 for the treatment of patients with relapsed/refractory AML in the U.S., and we expect to complete this trial in 2027.

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BL-B16D1

BL-B16D1 is an innovative bispecific ADC with a proprietary new-generation payload developed on our platform. We are currently conducting three Phase I clinical trials for BL-B16D1 in China. The first trial, for the treatment of HNSCC and other solid tumors, initiated patient enrollment in June 2024. The other two trials, including one for the treatment of solid tumors and one for BC and solid tumors, were initiated in July and August 2024, respectively. All three clinical trials are expected to be completed in 2026. We plan to submit an IND application for BL-B16D1 to FDA in the first quarter of 2025. Within 12 months after IND is approved, we plan to complete our first Phase I clinical trial in the U.S. for BL-B16D1 targeting various solid tumors.

BL-M17D1

BL-M17D1 is an innovative ADC using the same innovative linker-payload technology developed on our platform as BL-B16D1. We are currently conducting two Phase I clinical trials in China for BL-M17D1 for the treatment of HER2+/HER2- BC and other solid tumors, and HER2-positive/low-expression GIC and other solid tumors, respectively. We have also obtained an IND for BL-M17D1 from FDA for the treatment of patients with solid tumors. We expect to commence the enrollment of patients in the Phase I trial for BL-M17D1 for the treatment of various solid tumors in the U.S. in the first quarter of 2025, with the trial projected to span approximately two years.

BL-M05D1 (Claudin 18.2 ADC)

Overview

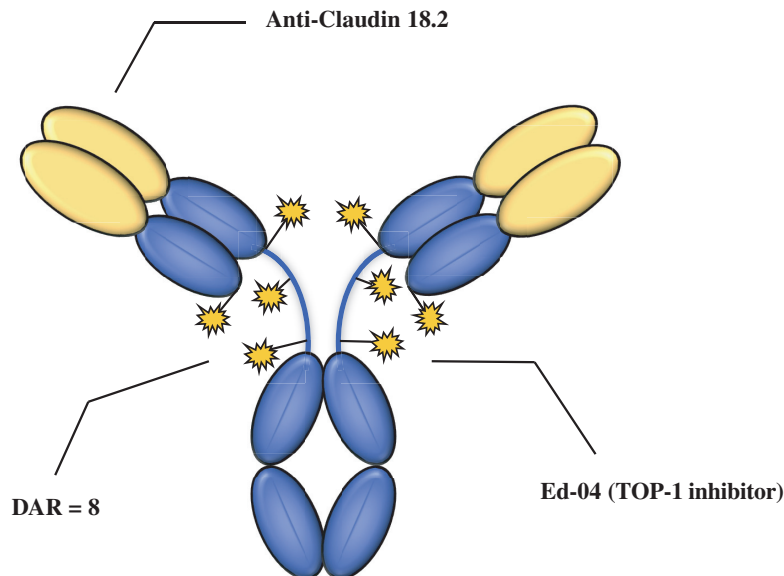
BL-M05D1 is an innovative ADC with an in-house developed Claudin 18.2-targeted monoclonal antibody. BL-M05D1 is currently being evaluated as a single agent in a Phase I clinical trial that includes patients with a variety of Claudin 18.2 expressing malignancies, such as GC.

Mechanism of Action

Claudins are a family of proteins that are critical components of tight junctions in epithelial and endothelial cells. These tight junctions are essential for maintaining the integrity and permeability of cell barriers, regulating the flow of molecules in the intercellular space. Claudin 18.2, a specific isoform of Claudin 18, is predominantly expressed in the gastric mucosa, and is typically not found in healthy tissues outside of the stomach. However, its over-expression has been identified in several types of cancer, including lung cancer, GC, PC, EC and OC. Due to its restricted expression pattern in normal tissues and elevated presence in certain tumors, Claudin 18.2 presents an attractive target for cancer therapies.

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BL-M05D1 is a Claudin 18.2-targeted ADC. It can specifically deliver the cytotoxic payload to cancer cells expressing Claudin 18.2, achieving targeted killing of tumor cells while minimizing damage to normal cells in the body. The figure below depicts the molecular structure of BL-M05D1.



The antibody portion of BL-M05D1 can specifically bind to Claudin 18.2 on cancer cells. Upon binding to Claudin 18.2 on the cancer cell surface, this ADC is internalized by the cell. Once inside the cell, the ADC is trafficked to lysosomes, where the linker between the antibody and the payload is cleaved, releasing the cytotoxic drug Ed-04. Moreover, the Fc portion of the antibody in BL-M05D1 can mediate ADCC/CDC effects, further enhancing the tumor killing effects.

Competitive Advantages

Claudin 18.2 is selectively overexpressed in various solid tumor types, including GC, pancreatic cancer, and EC, making BL-M05D1 a versatile and potentially transformative therapy across multiple cancer types. We have designed the monoclonal antibody in BL-M05D1 to possess a high degree of specificity for the target, leading to more effective tumor cell binding and internalization. This specificity reduces off-target effects, thereby enhancing the safety profile of BL-M05D1. Additionally, our proprietary linker used in BL-M05D1 ensures its stability in the bloodstream and releases the cytotoxic payload only upon internalization by the target cells, maximizing therapeutic efficacy while minimizing systemic toxicity. Furthermore, BL-M05D1 has demonstrated promising preclinical efficacy, with significant tumor growth inhibition and favorable pharmacokinetics.

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Clinical Development Plan

We are currently conducting one Phase I clinical trial for BL-M05D1 for locally advanced or metastatic solid tumors in China. We initiated the trial in April 2024, enrolled the first patient in May 2024 and expect to complete it in 2026. We have also obtained the IND approval from FDA for Phase I clinical trial for BL-M05D1 in the U.S. in June 2024. We plan to complete the dosing of the first patient in the Phase I trial for BL-M05D1 in the U.S. in the first or second quarter of 2025, and aim to complete the Phase I trial within the subsequent two years.

GNC Platform

GNC (Guidance Navigation & Control) is our proprietary, self-developed multi-specific antibody development platform. It is designed to develop multi-specific antibody with symmetrical/asymmetrical structures that can simultaneously target multiple different antigens. Multi-specific GNC molecules developed on this platform coordinate interactions among several tumor/immune-related protein domains to synergistically and comprehensively activate the several mechanisms of the immune system of cancer patients. These GNC compounds guide, navigate, and control the immune cells, ultimately leading to a targeted, stimulatory immune attack against the tumors.

We have initiated three Phase I clinical trials for our multi-specific antibody GNC-077 as of the Latest Practicable Date. Our tetra-specific T cell engagers, GNC-038 (CD3 \times 4-1BB \times PD-L1 \times CD19) and GNC-035 (CD3 \times 4-1BB \times PD-L1 \times ROR1), have advanced to Phase Ib/II clinical trials, while GNC-039 (CD3 \times 4-1BB \times PD-L1 \times EGFRvIII) has entered a Phase Ib clinical trial. These antibodies are the first three tetra-specific antibodies globally to reach the clinical stage, according to CIC. We are committed to advancing the preclinical and clinical trials for our first-generation GNC drug candidates, including GNC-038, GNC-035, GNC-039, as well as GNC-077 and other next-generation preclinical GNC candidates.

GNC-077

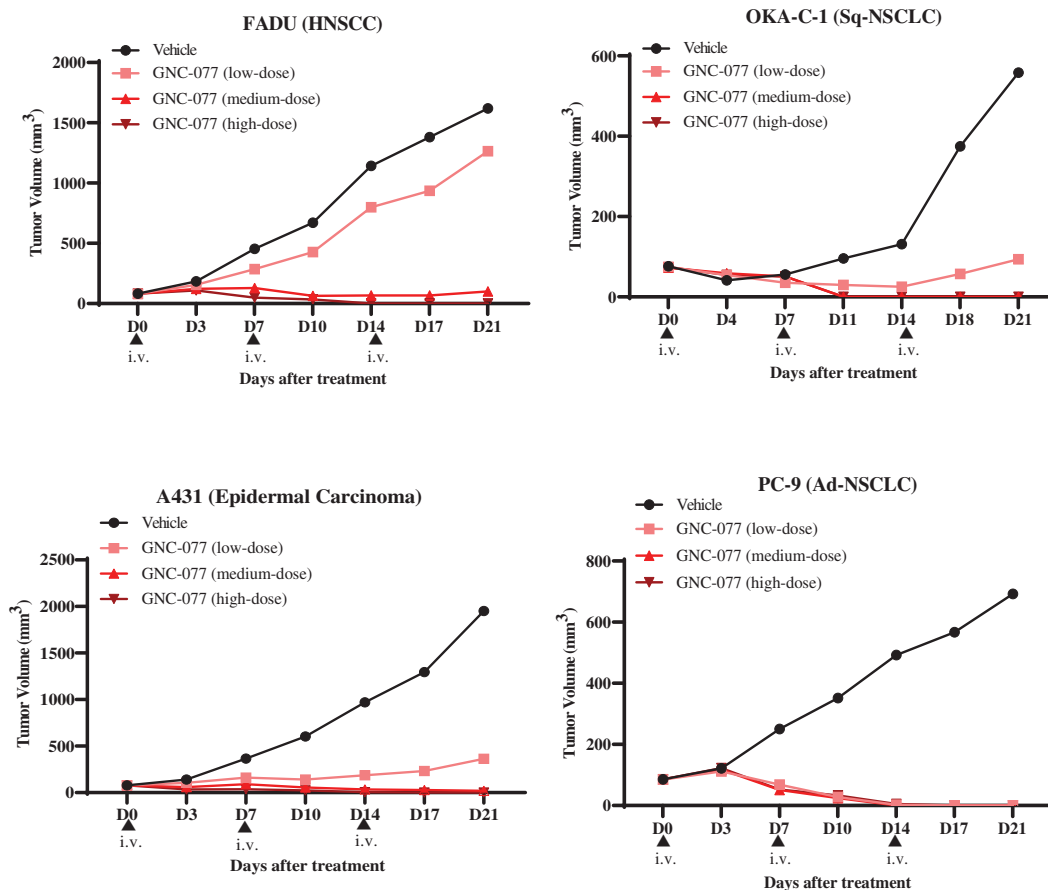
GNC-077 is an innovative multi-specific antibody molecule. We have initiated three Phase I clinical trials for GNC-077 for the treatment of BC, NSCLC, GIC and other solid tumors as of the Latest Practicable Date.

GNC-077's molecular structure features antibody domains targeting T cell CD3 and T cell immune checkpoints, as well as antibody domains targeting tumor antigens. GNC-077 can effectively induce activation, differentiation and proliferation of naive T cells and guide these activated T cells to specifically target and kill antigen-bearing cancer cells.

As shown in the charts below, in our *in vivo* studies, GNC-077 has demonstrated robust anti-tumor efficacy across multiple solid tumors, including HNSCC, NSCLC and epidermal carcinoma.

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In Vivo Efficacy of GNC-077



GNC-038 (CD3 × 4-1BB × PD-L1 × CD19)

Overview

GNC-038 is an innovative, recombinant humanized tetra-specific antibody that targets CD3, 4-1BB, PD-L1 and CD19. GNC-038 is currently being evaluated as a single agent in clinical trials for the treatment of NHL, ALL, systemic lupus erythematosus and rheumatoid arthritis. According to CIC, GNC-038 is the first tetra-specific therapeutic antibody to enter into clinical development and be tested in human globally.

Mechanism of Action

CD3 is a protein complex and T cell co-receptor that is essential for T cell activation and function. CD3-targeted therapies aims to redirect T cells to tumor cells, enabling the immune system to specifically recognize and kill cancer cells.

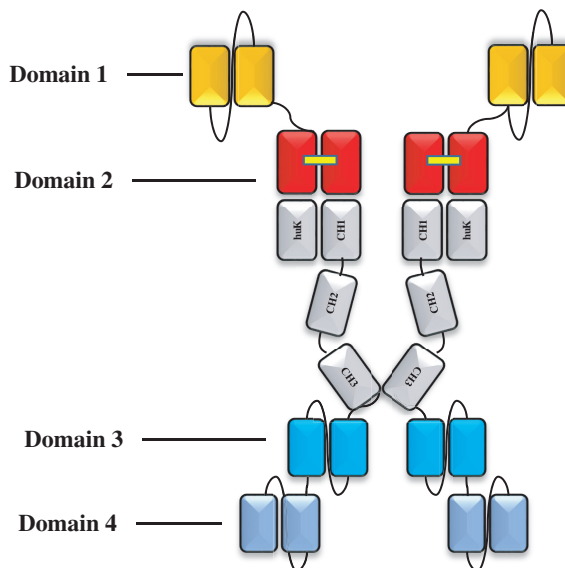
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4-1BB (CD137) is a costimulatory receptor on T cells that enhances T cell proliferation, survival, and cytokine production when engaged. Agonistic antibodies to 4-1BB can enhance the activity of cytotoxic T cells and natural killer (NK) cells, leading to improved anti-tumor activities. This can be particularly beneficial in solid tumors, where stronger and more sustained immune response is needed to deal with the immunosuppressive tumor microenvironment.

PD-L1 is an immune checkpoint protein expressed on tumor cells and tumor-infiltrating immune cells. It binds to the PD-1 receptor on T cells, leading to immune suppression and allowing cancer cells to evade immune detection. Targeting PD-L1 can block this interaction, thereby restoring T cells’ ability to recognize and kill cancer cells. This therapeutic strategy has been effective in various cancers, offering durable responses and survival benefits in cancer patients.

CD19 is a key protein found on the surface of B cells, which plays a crucial role in the development, differentiation, and activation of B cells. CD19 expression starts early in B cell development, and continues through to the mature B cell stage. It is highly expressed in B-cell malignancies, making it an attractive therapeutic target.

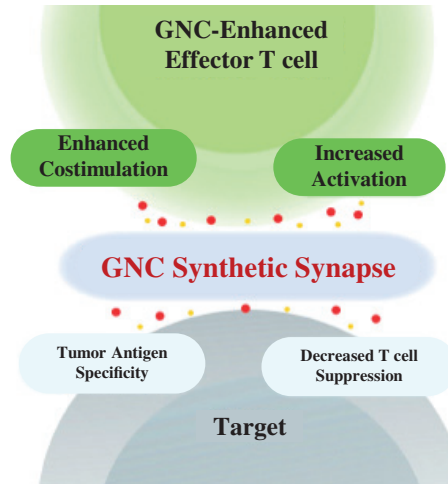
GNC-038 contains domains of anti-CD3 & anti-4-1BB to activate the CD3 and 4-1BB receptors on T-cells. It also has domains targeting CD19 and PD-L1. The figure below depicts the molecular structure of GNC-038.



GNC-038 can redirect and stimulate T cell cytotoxicity toward cancer cells expressing CD19 and/or PD-L1. The molecule can also redirect T cell cytotoxicity toward PD-L1 high-expressing cells, thereby potentially converting cancers cells with adaptive resistance into drug sensitive cancer cells. Additionally, GNC-038 engages 4-1BB in a non-cytolytic manner, delivering a co-stimulatory signal to T cells that enhances their functionality.

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The diagram below illustrates the mechanism of action of GNC drugs:



Competitive Advantages

The tetra-specific nature of GNC-038 enables it to simultaneously engage four different targets to modulate multiple immune responses against a cancer cell. For example, for GNC-038's four targets, CD3 is crucial for T cell activation, 4-1BB enhances T cell proliferation and survival, PD-L1 inhibition releases the brakes on the immune system, and CD19 targets B-cell malignancies. This multi-faceted approach increases the efficacy of the immune response against cancer cells compared to monoclonal or bispecific antibodies.

- *Enhanced immune activation:* By targeting CD3 and 4-1BB, GNC-038 robustly activates T cells, promoting their proliferation and cytotoxic activity. This dual activation can lead to a more potent and sustained anti-tumor response .
- *Immune checkpoint inhibition:* The inclusion of PD-L1 targeting could potentially better prevent cancer cells from immune evasion. This enhances the ability of the immune system to recognize and kill cancer cells.

GNC-038's versatility in targeting both T cell regulation and B-cell biology makes it a promising candidate for treating B-cell malignancies. In our *in vitro* studies, GNC-038 effectively drives T cell mediated killing of malignant B cells. It also induces great PBMC proliferation and high cytokine release in patients with high levels of PD-1 positive T cells, suggesting that GNC-038 may achieve beneficial proliferation of effector cells in patients with more exhausted or effector polarized T cell phenotypes.

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Clinical Development

We are currently conducting five clinical trials for GNC-038 in China. The below table sets forth the ongoing trials for GNC-038:

<u>Indication</u>	<u>Type of Therapy</u>	<u>Trial phase</u>	<u>Trial start date</u>	<u>Expected trial end year</u>
r/r DLBCL	mono	Phase I/II	August 2022	2025
r/r NHL	mono	Phase I/II	September 2022	2025
Primary CNS lymphoma and r/r secondary CNS lymphoma	mono	Phase I/II	February 2023	2025
r/r NK/T cell lymphoma, angioimmunoblastic, and other NHL	mono	Phase I/II	February 2023	2025
NHL or ALL	mono	Phase I	November 2020	2025

We have obtained an IND approval from NMPA for GNC-038 for the treatment of systemic lupus erythematosus and rheumatoid arthritis in January 2025. We expect to commence this trial in March 2025.

GNC-035 (CD3 × 4-1BB × PD-L1 × ROR1)

Overview

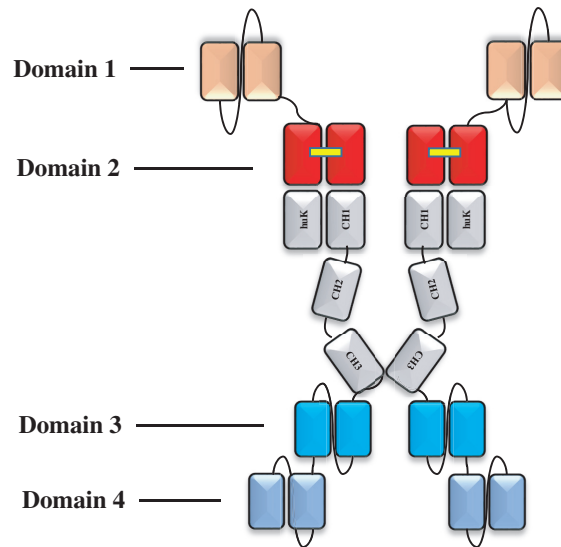
GNC-035 is an innovative, recombinant humanized tetra-specific antibody that targets CD3, 4-1BB, PD-L1 and ROR1. GNC-035 is currently being evaluated as a single agent in clinical trials for patients with a variety of ROR1 positive solid tumors and hematologic malignancies.

Mechanism of Action

The receptor tyrosine kinase-like orphan receptor 1 (ROR1) is a cancer embryonic antigen expressed during embryonic development physiologically but absent in mature stages. Data indicates that ROR1 plays a role in tumor growth, metastasis, inducing tumor cell resistance, and inhibiting apoptosis, with high expression observed in various solid tumors and lymphomas. Therefore, ROR1 is an ideal target for anti-tumor therapy.

GNC-035 incorporates anti-CD3 & anti 4-1BB domains to activate the CD3 and 4-1BB domains of T-cells. It also has domains targeting malignant tumor antigens ROR1 and PD-L1. The figure below depicts the molecular structure of GNC-035.

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Competitive Advantages

GNC-035’s tetra-specific design enables it to orchestrate a multi-pronged attack on cancer cells. CD3 and 4-1BB engagement activates and proliferates T cells, enhancing their cytotoxic activity. PD-L1 inhibition lifts immune suppression, allowing T cells to function more effectively. The 3 prongs create potent synergies that maximize therapeutic efficacy. The addition of ROR1 leads to targeting of cancer cells.

- *Enhanced tumor microenvironment targeting:* Targeting PD-L1 helps GNC-035 modulate the tumor microenvironment by overcoming immune evasion strategies employed by cancer cells. This results in a more hospitable environment for immune cells to attack the tumor, potentially leading to better clinical outcomes compared to treatments that do not modulate the tumor microenvironment as effectively.
- *Reduced likelihood of resistance:* The multi-target approach of GNC-035 decreases the likelihood of cancer cells developing resistance. By attacking cancer through multiple pathways—T cell activation (CD3, 4-1BB), immune checkpoint blockade (PD-L1), and direct tumor targeting (ROR1)—GNC-035 presents a formidable challenge for cancer cells to adapt and survive.
- *Versatile applications across cancer types:* While ROR1 is prominently expressed in hematologic cancers like CLL and certain solid tumors, its expression in other cancers broadens the potential application of GNC-035. This versatility makes GNC-035 a valuable therapeutic candidate across a wide range of malignancies, potentially addressing unmet needs in both hematologic and solid tumors.

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Clinical Development

We are conducting four clinical trials for GNC-035 in China. The below table sets forth the ongoing trials for GNC-035:

<u>Indication</u>	<u>Type of Therapy</u>	<u>Trial phase</u>	<u>Trial start date</u>	<u>Expected trial end year</u>
r/r CLL and other hematological malignancies	mono	Phase I/II	August 2023	2025
r/r NHL and other hematological malignancies	mono	Phase I/II	November 2023	2025
Locally advanced or metastatic BC	mono	Phase I	November 2021	2025
r/r hematological malignancies	mono	Phase I	February 2022	2025

GNC-039 (CD3 × 4-1BB × PD-L1 × EGFRvIII)

Overview

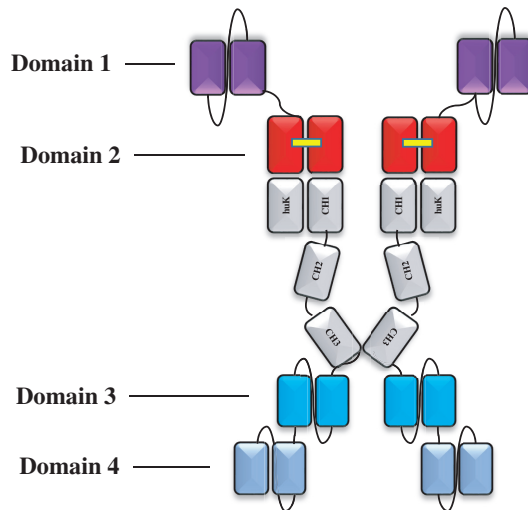
GNC-039 is an innovative, recombinant humanized tetra-specific antibody that targets CD3, 4-1BB, PD-L1 and EGFRvIII. GNC-039 is currently being evaluated as a single agent in clinical trials for patients with a variety of EGFRvIII solid tumors.

Mechanism of Action

EGFRvIII is the most common mutation of EGFR in cancer, characterized by a deletion of exons 2-7 of the EGFR gene. Research shows that EGFRvIII is highly expressed in solid tumors such as glioblastoma, OC, BC, and NSCLC, while is not expressed in normal tissues, making it an ideal tumor-specific target. Currently, various drugs and therapies targeting EGFRvIII are in clinical research stages.

GNC-039 incorporates domains of anti-CD3 and anti 4-1BB to activate CD3 and 4-1BB domains on T cells. It also has domains targeting solid tumor antigens EGFRvIII and PD-L1. The figure below depicts the molecular structure of GNC-039.

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Competitive Advantages

GNC-039’s ability to target EGFRvIII allows for precise tumor targeting, sparing normal cells and reducing off-target effects. This specificity enhances the therapeutic index and safety profile of GNC-039. GNC-039’s ability to target EGFRvIII expands its applicability to cancers with this specific mutation, including certain brain tumors and other solid malignancies. This versatility makes GNC-039 a valuable candidate for treating a variety of cancers that express EGFRvIII.

Clinical Development

We are currently conducting a Phase I clinical trial for GNC-039 in China for relapsed/refractory or metastatic solid tumors, which was initiated in April 2021 and is expected to be completed in 2025.

We are committed to advancing all pre-clinical and clinical trials for our first-generation GNC drug candidates, including GNC-077, GNC-038, GNC-035, GNC-039, as well as other next-generation pre-clinical GNC candidates.

SEBA Platform

Our “Specificity Enhanced Bispecific Antibody,” or SEBA, platform is our proprietary, self-developed bispecific antibody platform. SEBA molecules are able to not only block growth signals that cancer cells rely on for survival, but also induce greater immune system activity for greater potency and selectivity while minimizing off-target effects.

Products developed from our SEBA platform include SI-B001 (EGFR × HER3 bispecific antibody) and SI-B003 (PD-1 × CTLA-4 bispecific antibody).

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SI-B001 (EGFR × HER3 bispecific antibody)

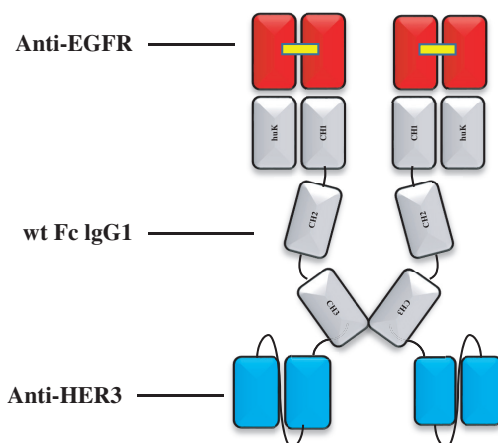
Overview

SI-B001, also known as izalontamab, is a first-in-class EGFR × HER3 bispecific antibody. According to CIC, SI-B001 is currently the only clinical-stage bispecific antibody in the world that simultaneously targets EGFR and HER3. As of the Latest Practicable Date, SI-B001 is undergoing clinical studies for several solid tumor indications, including NSCLC and HNSCC, as a single agent or in combination settings.

Mechanism of Action

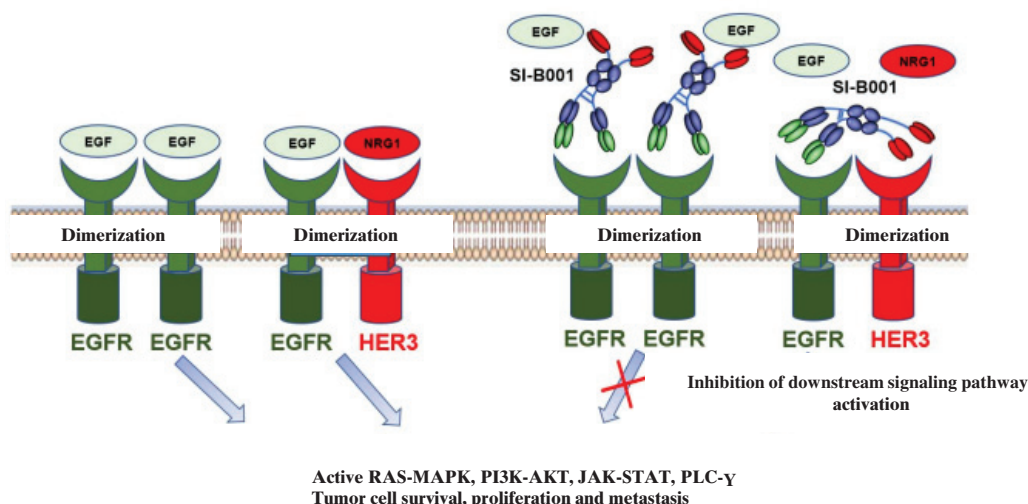
EGFR and HER3 are both members of the human epidermal growth factor receptor (HER/ErbB) family and are targeted in cancer therapy due to their over-expression and pathway dependence in common human epithelial carcinoma tumors. Given their prevalence and critical role in tumors, targeting these receptors has the potential to deliver a therapy with the ability to treat a broad range of tumors. For details, see “— HIRE-ADC Platform — BL-B01D1 (EGFR × HER3 bispecific ADC) — Mechanism of Action.”

SI-B001 is a tetravalent bispecific antibody with two different binding domains for both EGFR and HER3. By optimizing the distance and angle between the two binding sites, its spatial configuration is carefully designed to ensure that it only binds to HER3 after it has successfully bound to EGFR. Its structure is also configured to minimize interaction with HER3 in normal tissues, accomplished by fine-tuning the binding affinity of the antibody so that it preferentially binds to cells that overexpress both EGFR and HER3, which are typically cancerous cells. It also has an Fc region, which can interact with immune cells and other proteins.



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The diagram below illustrates the mechanism of action of SI-B001. As shown in this diagram, SI-B001 is designed to simultaneously bind to EGFR and HER3, inhibiting signaling from ligand-induced formation of EGFR × EGFR homodimers and EGFR × HER3 heterodimers, as well as downstream pathways. SI-B001 also induces internalization of EGFR and HER3, reducing the levels of these receptors in tumor cells. Additionally, SI-B001 can mediate ADCC effects through a wild-type FC.



Competitive Advantages

SI-B001 has a unique construct, where after adjusting its spatial structure and target affinity, SI-B001 binds to HER3 only after it has targeted and bound to EGFR. This design enables SI-B001 to minimize side effects by selectively accumulating in and effectively inhibiting tumor cells expressing both EGFR and HER3 to minimize its binding to or inhibition of HER3 in normal tissues. SI-B001 provides a novel mechanism that achieves stronger tumor inhibition with less impact on normal tissues compared to the combination of two monoclonal antibodies.

Clinical studies have shown that SI-B001 as monotherapy and in combination with chemotherapy can exhibit favorable safety and robust anti-tumor activity. The clinical studies have shown potent anti-tumor efficacy in NSCLC and HNSCC with a favorable safety profile.

As monotherapy, SI-B001 exhibited superior anti-tumor activity compared to parental anti-EGFR in the FaDu xenograft model. SI-B001 in combination with paclitaxel and carboplatin induced greater *in vivo* antitumor effect than the combination of parental anti-EGFR, paclitaxel and carboplatin. In addition, SI-B001 in combination with docetaxel demonstrated antitumor activity and manageable safety profile in patients with EGFR/ALK wild-type NSCLC who failed on prior 1L combination treatment with PD-(L1) inhibitor and platinum-based chemotherapy. These clinical results have demonstrated SI-B001's potential to be used for the treatment of various cancer indications.

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Clinical Development

Clinical Development Plan

We are currently conducting ten clinical trials for SI-B001 in China. The below table sets forth these ongoing trials:

Indication	Type of Therapy	Trial phase	Trial start date	Expected trial end year
EGFR/ALK wild-type recurrent or metastatic NSCLC	combo with chemotherapy	Phase II	December 2021	2025
Recurrent metastatic NSCLC	combo with osimertinib	Phase II/III	January 2022	2025
Non-small cell lung adenocarcinoma and lung squamous cell carcinoma	combo with docetaxel	Phase III	July 2023	2026
Recurrent and metastatic HNSCC	mono	Phase II	October 2021	2025
Recurrent and metastatic HNSCC	combo with paclitaxel	Phase II	December 2021	2025
Recurrent metastatic ESCC	combo with irinotecan	Phase II	December 2021	2025
Locally advanced or metastatic NSCLC	combo with SI-B003	Phase I/II	October 2023	2025
Locally advanced or metastatic HNSCC	combo with SI-B003	Phase I/II	February 2023	2025
Recurrent and metastatic HNSCC	combo with SI-B003 and platinum-based chemotherapy	Phase II	November 2024	2026
Locally advanced or metastatic epithelial tumors	mono	Phase I	April 2020	2025

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Key Clinical Trial Results

(i) Phase II Clinical Trial of SI-B001 in Combination with Chemotherapy for EGFR/ALK Wild-type NSCLC

This multi-center, open-label Phase II study is designed to investigate the efficacy and safety of SI-B001 in combination with chemotherapy in patients with locally advanced or metastatic EGFR/ALK wild-type NSCLC. The primary endpoints are to determine the ORR in evaluable patients and to identify the optimal dose, and the secondary endpoints include assessment of PFS, DCR, DOR and safety.

Trial Design. This study includes patients with locally advanced or metastatic EGFR/ALK wild-type who have a performance status score of 0 or 1 according to the ECOG, and have at least one measurable lesion per RECIST v1.1. Particularly, the enrolled patients should not have any autoimmune or inflammatory illnesses and have been previously treated with PD-(L)1 therapy and remain docetaxel-naive. These patients must have adequate organ and marrow function and have either no brain metastases or stable brain metastases at screening. Patients participating in this study are divided into three cohorts, depending on the treatment lines and methods. In Cohort A, patients received SI-B001 plus platinum-based chemotherapy as 2L treatment after failing 1L PD-(L)1 therapies; Cohort B patients received SI-B001 plus docetaxel as 2L treatment after failing 1L PD-(L)1 therapy plus platinum-based chemotherapy; Cohort C patients received SI-B001 plus docetaxel as 3L+ treatment after failing 1L PD-(L)1 therapy and platinum-based chemotherapy. Three dosing schedules were designed to evaluate SI-B001, where patients were administered SI-B001 in combination with corresponding chemotherapy at 16+9mg/kg QW, 14mg/kg D1D8 Q3W or 21+12mg/kg QW.

Trial Status. This study was initiated in December 2021 in China, and 55 patients have been enrolled, with one in Cohort A, 45 in Cohort B, eight in Cohort C, and one based on the investigator’s discretion. The study is expected to be completed in 2025.

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Efficacy Data. As of the data cut-off date (April 17, 2023), there were 52 response-evaluable patients among all 55 enrolled patients with EGFR/ALK wild type NSCLC administered with SI-B001 in combination with chemotherapy, with an overall DCR of 75.0% and ORR of 28.9%. The following table sets forth the efficacy data by treatment cohorts.

	Cohort A	Cohort B	Cohort C	Other	Total
	(N = 1)	(N = 42)	(N = 8)	(N = 1)	(N = 52)
Best Overall Response					
CR	0	0	0	0	0
PR	1	13	1	0	15
SD	0	17	7	0	24
PD	0	9	0	1	10
NE	0	3	0	0	3
ORR % (95% CI)	100%	31.0% (17.6~47.1)	12.5% (0.3~52.7)	0	28.9% (17.1~43.1)
DCR % (95% CI)	100%	71.4% (55.4~84.3)	100%	0	75.0% (61.1~86.0)
DOR (m) (median, range)	5.5	4.2 (0.2~13.1+)	4.1	/	4.2 (0.2~13.1+)

Source: Company data

The clinical data of Cohort B, SI-B001 in combination with docetaxel as 2L treatment after failing 1L PD-(L)1 therapy in combination with platinum-based chemotherapy, represented an overall DCR of 71.4% and ORR of 31.0%. Among 42 patients assigned to Cohort B, 23 patients who were treated at 16+9mg/kg QW, showed an ORR of 43.5% and a DCR of 69.6%. 18 patients in Cohort B receiving the dosage at 14mg/kg D1D8 Q3W, showed ORR of 16.7% and DCR of 72.2%, The one patient receiving 21+12mg/kg QW showed an DCR of 100%. The following table sets forth the efficacy data by dosage in Cohort B.

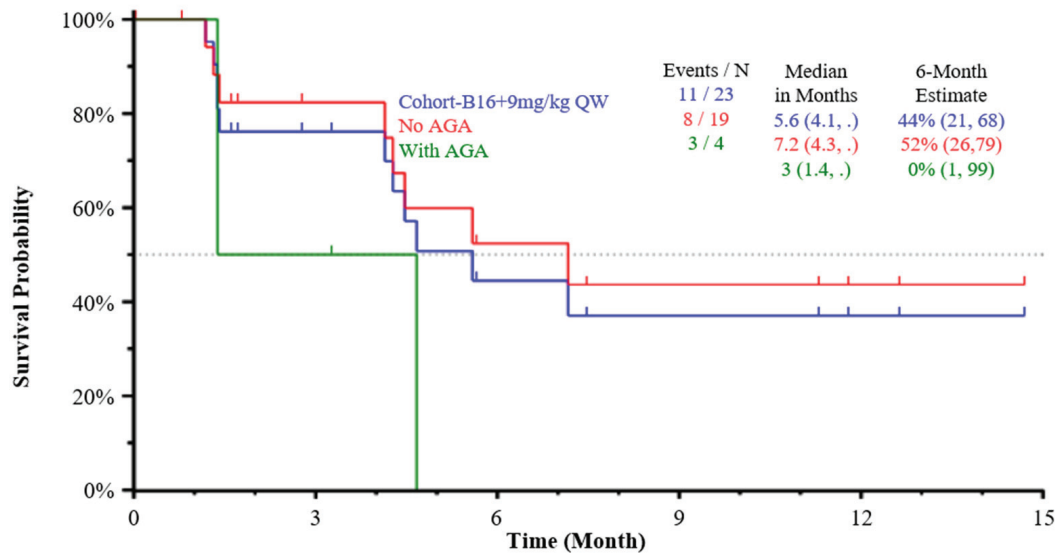
	16+9mg/kg QW	14mg/kg D1D8 Q3W	21+12mg/kg QW	Total
	(N = 23)	(N = 18)	(N = 1)	(N = 42)
Best Overall Response				
CR	0	0	0	0
PR	10	3	0	13
SD	6	10	1	17
PD	4	5	0	9
NE	3	0	0	3
ORR % (95% CI)	43.5% (23.2~65.5)	16.7% (3.6~41.4)	0	31.0% (17.6~47.1)
DCR % (95% CI)	69.6% (47.1~86.8)	72.2% (46.5~90.3)	100%	71.4% (55.4~84.3)
DOR (m) (median, range)	NR (0.2~13.1+)	2.9 (0.9~4.2)	/	4.2 (0.2~13.1+)

Source: Company data

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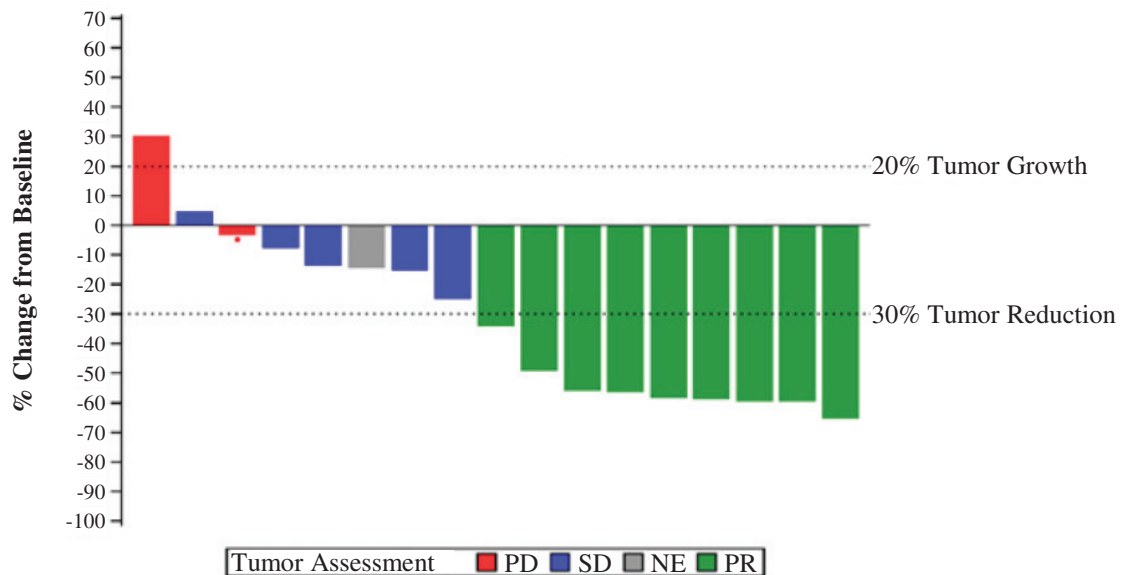
Among the 23 evaluable patients in Cohort B receiving 16+9mg/kg QW, 19 were without AGA. In these patients, the ORR, DCR, and mPFS were 47.4%, 73.7% and 7.2 months. The following charts illustrate PFS, change in tumor size and tumor response by months in patients without AGA in Cohort B as of April 17, 2023.

Cohort B 16+9mg/kg QW Patient Progression Free Survival by AGA status



Source: Company data

Change (%) in Tumor Size from Baseline

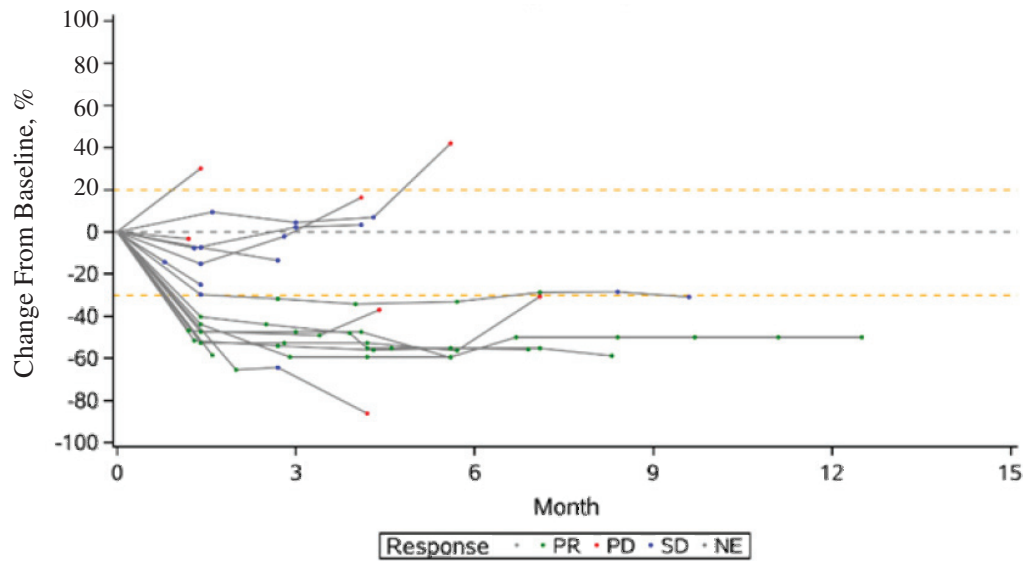


* new lesion

Source: Company data

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Tumor Response by Months



Source: Company data

Safety Data. As of the data cut-off date (April 17, 2023), the most common grade ≥ 3 TRAEs were neutropenia (15%), myelosuppression (13%), and leukopenia (9%). No drug related death was observed. TRAEs related to SI-B001 treatment for EGFR/ALK wild-type NSCLC are summarized in the table below.

	SI-B001 plus chemotherapy (N = 55)				
	G1	G2	G3	G4	All Grade
Rash	20 (36%)	10 (18%)	3 (5%)		33 (60%)
Mouth ulceration	6 (11%)	7 (13%)	1 (2%)		14 (25%)
Leukopenia	6 (11%)	2 (4%)	5 (9%)		13 (24%)
Anemia	6 (11%)	5 (9%)	2 (4%)		13 (24%)
Pyrexia	9 (16%)	3 (5%)	1 (2%)		13 (24%)
Neutropenia	4 (7%)		7 (13%)	1 (2%)	12 (22%)
Diarrhea	8 (15%)	3 (5%)	1 (2%)		12 (22%)
Myelosuppression	1 (2%)	2 (4%)	2 (4%)	5 (9%)	10 (18%)
Paronychia	5 (9%)	2 (4%)	1 (2%)		8 (15%)
Hypokalemia	3 (5%)	2 (4%)	2 (4%)		7 (13%)
Dermatitis acneiform	6 (11%)		1 (2%)		7 (13%)
Pneumonia		2 (4%)	4 (7%)		6 (11%)
Asthenia	3 (5%)	2 (4%)	1 (2%)		6 (11%)

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	SI-B001 plus chemotherapy (N = 55)				
	G1	G2	G3	G4	All Grade
Lymphopenia	3 (5%)		2 (4%)		5 (9%)
Chest discomfort	2 (4%)	2 (4%)	1 (2%)		5 (9%)
Hypersensitivity			4 (7%)		4 (7%)
Hypoesthesia	1 (2%)		1 (2%)		2 (4%)
Respiratory failure	1 (2%)		1 (2%)		2 (4%)
Cardiomyopathy			1 (2%)		1 (2%)
Gastritis			1 (2%)		1 (2%)
Soft tissue infection			1 (2%)		1 (2%)
Heart rate increased			1 (2%)		1 (2%)
ILD			1 (2%)		1 (2%)
Tachypnoea			1 (2%)		1 (2%)
Cardiac failure				1 (2%)	1 (2%)
Septic shock				1 (2%)	1 (2%)

Source: Company data

Conclusion. The clinical data from the Phase II trial for the combination of SI-B001 with chemotherapy has demonstrated promising efficacy and favorable safety profile and supports continued development of SI-B001 plus chemotherapy treatment.

(ii) Phase II Clinical Trial of SI-B001 with Chemotherapy in Patients with Recurrent and Metastatic HNSCC

We are conducting a multi-center, open label Phase II clinical trial to evaluate SI-B001 in treatment of recurrent and metastatic HNSCC, with a total of 31 patients enrolled. The primary endpoint is ORR by investigator per RECIST v1.1. Secondary endpoints are ORR by independent central review, PFS, DCR, DOR, OS, and safety.

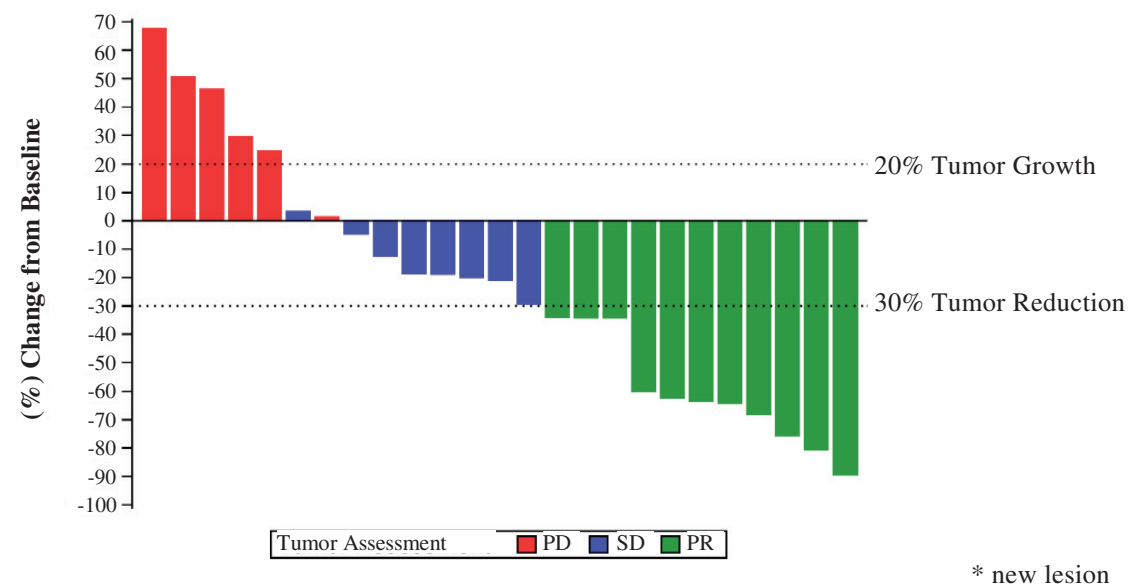
Trial Design. The trial included patients with recurrent and metastatic HNSCC progressed on prior PD-(L)1 with or without platinum-based chemotherapy and who received no more than two lines of treatment. Among patients enrolled, 21 patients without prior exposure to paclitaxel were treated with SI-B001 at 12mg/kg IV QW plus paclitaxel at 80mg/m² IV QW, and 10 patients with prior exposure to paclitaxel were treated with SI-B001 at 12mg/kg IV QW plus docetaxel at 35mg/m² IV D1D8D15 Q4W.

Trial Status. We initiated the trial in December 2021, and is expected to be completed in 2025.

Efficacy Data. The waterfall plots below show the best overall response change from baseline in target lesions for each evaluable patient in treatment with SI-B001 plus chemotherapy combination.

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Patients from SI-B001 plus chemotherapy combination



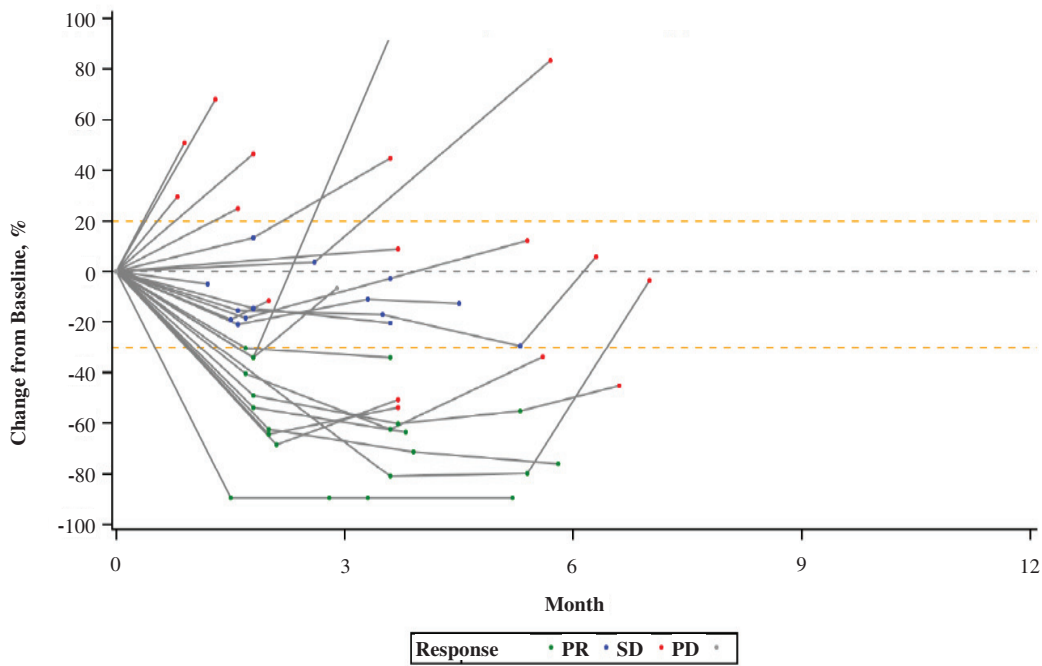
Source: Company data

As of the data cut-off date (April 17, 2023), patients receiving SI-B001 in combination with paclitaxel showed an ORR of 58.2%, DCR of 82.4%, mDOR of 3.9 months and mPFS was 5.4 months.

The spider plot shows significant durability of objective responses and disease stabilization of the evaluable patients administered with SI-B001 in combination with chemotherapy combination as measured by percent change from baseline in target lesions over time.

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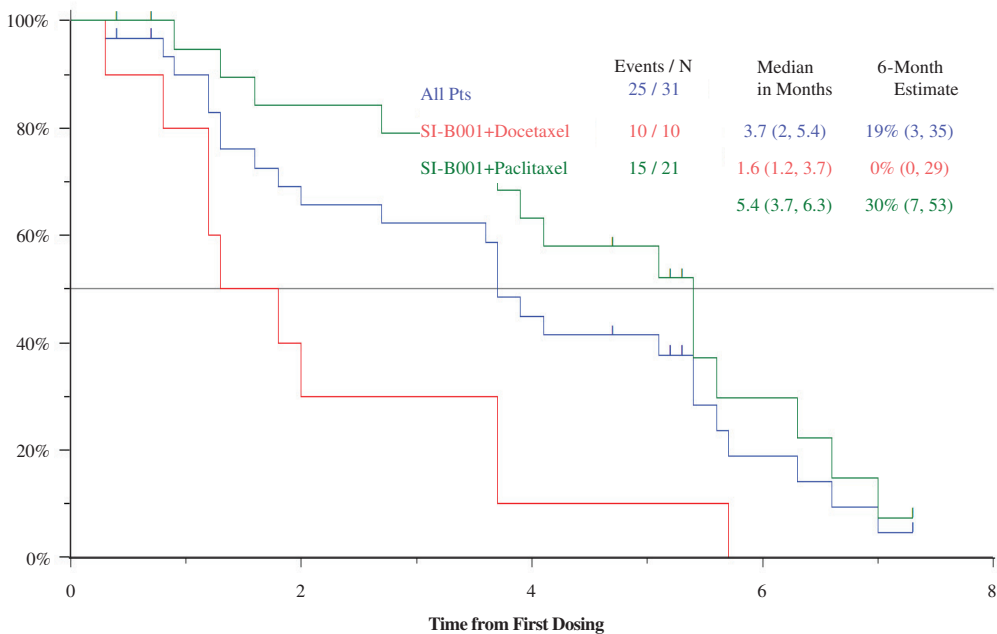
Patients from SI-B001 in combination with chemotherapy



Source: Company data

The diagram below illustrates the Kaplan-Meier curve of PFS of patients in the trial.

PFS K-M plot of patients from SI-B001 in combination with chemotherapy



Source: Company data

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Safety Data. As of the data cut-off date (April 17, 2023), the majority of adverse events were grade 1, indicating a manageable and tolerable toxicity of SI-B001 in combination with taxane-based chemotherapy in HNSCC. The most common grade ≥ 3 TRAEs in the trial were rash (13%), leukopenia (9%), anemia (6%), and neutropenia (6%). No SI-B001 drug-related deaths occurred in this study. The most commonly observed TRAEs, affecting more than 15% of patients, included rash (61%), anemia (32%), leukopenia (32%), and proteinuria (23%). The following table summarized the safety data observed in the trials.

	SI-B001 plus Chemotherapy (N = 31)				
	G1	G2	G3	G4	All Grade
Rash	13 (42%)	2 (6%)	4 (13%)		19 (61%)
Anemia	7 (23%)	1 (3%)	2 (6%)		10 (32%)
Leukopenia	5 (16%)	2 (6%)	2 (6%)	1 (3%)	10 (32%)
Proteinuria	7 (23%)				7 (23%)
Stomatitis	2 (6%)	3 (10%)	1 (3%)		6 (19%)
Asthenia	3 (10%)	3 (10%)			6 (19%)
Weigh decreased	6 (19%)				6 (19%)
Mouth ulceration		4 (13%)	1 (3%)		5 (16%)
Paronychia	2 (6%)	1 (3%)	1 (3%)		4 (13%)
Skin fissures	1 (3%)	2 (6%)	1 (3%)		4 (13%)
Nausea	1 (3%)	3 (10%)			4 (13%)
Dermatitis acneiform	2 (6%)		1 (3%)		3 (10%)
Hypoaesthesia	1 (3%)	1 (3%)	1 (3%)		3 (10%)
Neutropenia	1 (3%)		1 (3%)	1 (3%)	3 (10%)
ALT increased	3 (10%)				3 (10%)
Pyrexia	2 (6%)	1 (3%)			3 (10%)
Jaw fistula			1 (3%)		1 (3%)
Skin infection			1 (3%)		1 (3%)
Skin ulcer			1 (3%)		1 (3%)

Source: Company data

Conclusion. The clinical data from the Phase II trial of SI-B001 with chemotherapy in treatment of HNSCC has demonstrated promising efficacy and favorable safety profile and supports continued development.

SI-B003 (PD-1 \times CTLA-4 bispecific antibody)

Overview

SI-B003 is a bispecific antibody targeting both PD-1 and CTLA-4, with potential immune checkpoint inhibitory and antineoplastic activities.

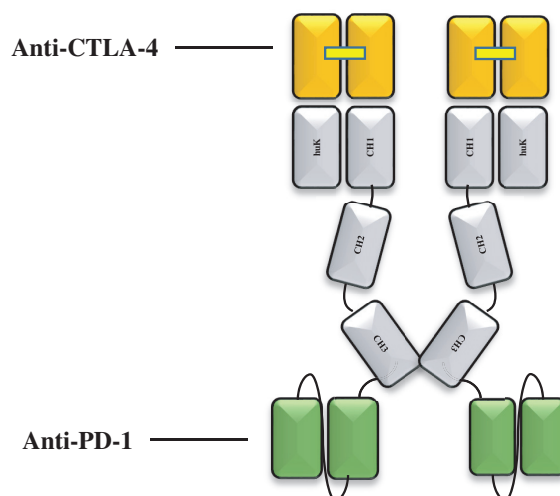
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Mechanism of Action

Tumors and immune cells in tumors often have high levels of PD-L1, which under normal conditions helps maintain immune balance but in cancer, can hinder immune response in two ways: by preventing activation of cytotoxic T cells in lymph nodes and deactivating them in the tumor microenvironment. This interaction between PD-L1 and PD-1 on T cells inhibits their function, induces changes, promotes tolerance, and reduces cytokine secretion, hampering T cell recognition of tumors.

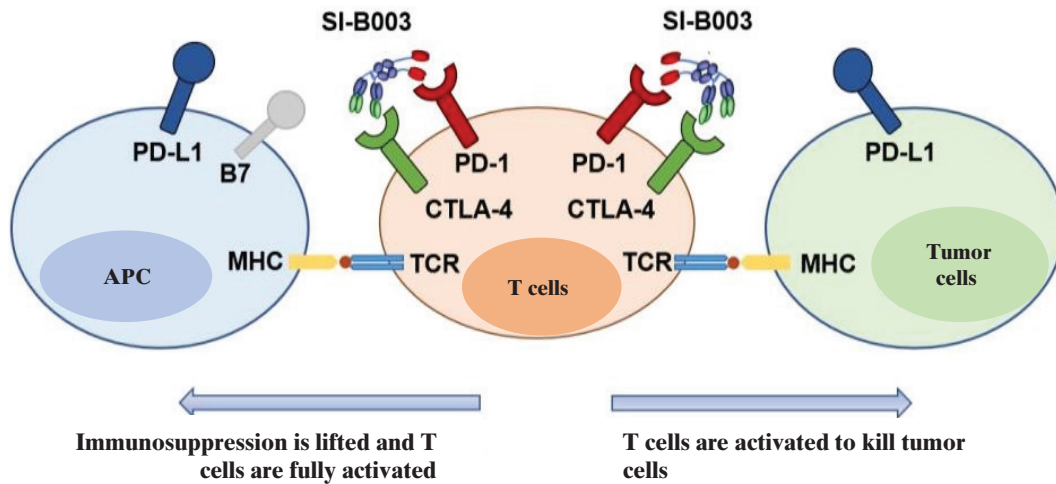
CTLA-4, a protein on T cells, is crucial for Treg function and inhibits anti-tumor activities. Blocking CTLA-4 reduces Treg activity, enhancing immune response against tumors, making it a focus of tumor-targeted immunotherapy.

The tetravalent SI-B003 has two binding domains for both PD-1 and CTLA-4. The primary targets for this molecule are exhausted tumor-specific T cells which demonstrate enhanced functionality upon treatment with PD-1 and CTLA-4 blocking antibodies, restoring their anti-tumor activity.



The diagram below illustrates the mechanism of action of SI-B003. As shown in this diagram, SI-B003 targets and binds to both PD-1 and CTLA4 expressed on tumor-infiltrating lymphocytes (TILs), and inhibits the PD-1- and CTLA4-mediated downregulation of T cell activation and proliferation. This restores immune function and activates a sustained cytotoxic T-lymphocyte (CTL)-mediated immune response against tumor cells. With a tetravalent format, the dual checkpoint molecule utilizes avidity and bispecificity to improve anti-cancer immune cell function. The specificity enhancement both synergistically enhances and expands the breadth of immune cell activity that is diminished in cancer patients. The spatio-temporal control of bispecificity ensure that synergistic blocking of inhibitory receptors is happening in the right place for better effect.

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Competitive Advantages

As a dual checkpoint inhibitor targeting PD-1 and CTLA-4, SI-B003 demonstrates promising efficacy, outperforming individual PD-1 or CTLA-4 inhibitors. It acts on both PD-1 and CTLA-4, alleviating immune suppression and activating T cells in lymph nodes and the tumor microenvironment, thus reducing toxicity effectively. SI-B003's Fc region has been redesigned and modified to minimize toxicity by reducing the potential for ADCC. SI-B003 as monotherapy have shown encouraging efficacy and favorable safety profiles in patients with various solid tumors.

In addition, SI-B003 is positioned as a key component in combination therapies, alongside our first-in-class EGFR × HER3 bispecific antibody and EGFR × HER3 bispecific ADC, SI-B001 and BL-B01D1. The combination of SI-B001, BL-B01D1 and/or chemotherapy with SI-B003 is expected to achieve synergistic anti-tumor effects, leading to more efficient eradication of tumor cells.

Clinical Development

Clinical Development Plan

We are currently conducting one Phase I clinical trial for SI-B003 as monotherapy for advanced solid tumors in China. The Phase I trial was initiated in November 2020 and is expected to be completed in 2025. We are also committed to exploring the combination therapy of SI-B003 with our other pipeline drug candidates. For details, see “— HIRE-ADC Platform — BL-B01D1 (EGFR × HER3 bispecific ADC) — Clinical Development — Clinical Development Plan” and “— SEBA Platform — SI-B001 (EGFR × HER3 bispecific antibody) — Clinical Development — Clinical Development Plan.”

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OUR MARKETED PRODUCTS

During the Track Record Period, all of our innovative drug candidates were in clinical and preclinical development. All of our revenues in 2021, 2022 and 2023 and a portion of our revenue in the nine months ended September 30, 2024 were generated from the sale of generics and traditional Chinese medicine drug products. During the Track Record Period, we generated revenue from the sales of 29 approved drug products with over 100 specifications, which includes both generics (covering a wide range of therapeutic areas such as anesthesia, parenteral nutrition, anti-infective and pediatrics) and traditional Chinese medicine products. Revenue from our marketed products has played a crucial role in funding our innovative drug development. We expect new products to be approved for commercialization in the future. As of the Latest Practicable Date, we had submitted around ten generic drug applications for production registration with the NMPA.

The following table sets forth our revenue from the sale of our pharmaceutical products by product for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
	(RMB in thousands, except for percentages)									
	(Unaudited)									
Anesthesia										
Leweijing	258,356	32.5	313,652	44.7	212,429	37.9	149,888	39.8	96,801	29.6
Leweitai	116,805	14.7	28,414	4.0	19,636	3.5	14,464	3.8	18,549	5.7
Youmeining	26,729	3.4	23,272	3.3	11,400	2.0	8,655	2.3	12,240	3.7
Parenteral nutrition										
Tianze	115,555	14.5	61,554	8.8	39,864	7.1	30,874	8.2	19,159	5.9
Anti-infectives										
Xinbolin	34,500	4.3	58,724	8.4	33,492	6.0	13,336	3.5	10,461	3.2
Aobolin	10,408	1.3	8,427	1.2	1,988	0.4	1,516	0.4	1,632	0.5
Pediatric drugs										
Dulabao	14,058	1.8	8,590	1.2	13,877	2.5	11,346	3.0	6,819	2.1
Leyeping and Pujikang	15,593	2.0	19,623	2.8	31,407	5.6	23,071	6.1	14,907	4.6
Traditional Chinese medicine										
Astragalus granule	160,988	20.3	134,148	19.1	155,696	27.8	97,953	26.0	92,331	28.2
Chaihuang granule	24,303	3.1	28,870	4.1	21,317	3.8	15,251	4.0	9,685	3.0
Other chemical drugs and traditional Chinese medicines										
	17,660	2.1	16,559	2.4	19,310	3.4	10,246	2.7	44,352	13.6
Total	794,955	100.0	701,833	100.0	560,416	100.0	376,599	100.0	326,936	100.0

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The following table sets forth the sales volume and average selling price of our major marketed products for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Average		Average		Average		Average		Average	
	Sales volume	selling price	Sales volume	selling price	Sales volume	selling price	Sales volume	selling price	Sales volume	selling price
	('000 units)	(RMB/unit)	('000 units)	(RMB/unit)	('000 units)	(RMB/unit)	('000 units)	(RMB/unit)	('000 units)	(RMB/unit)
Leweijing	17,569	14.7	22,929	13.7	17,671	12.0	12,604	11.9	10,804	9.0
Leweitai	2,458	47.5	1,075	26.4	1,715	11.4	1,190	12.2	1,869	9.9
Yuomeining	525	50.9	600	38.8	433	26.3	319	27.1	410	29.9
Tianze	3,526	32.8	2,196	28.0	1,485	26.8	1,134	27.2	687	27.9
Xinbolin	6,143	5.6	11,758	5.0	5,884	5.7	2,135	6.2	1,718	6.1
Aobolin	848	12.3	710	11.9	260	7.7	200	7.6	208	7.9
Dulabao	1,290	10.9	738	11.6	1,298	10.7	1,043	10.9	499	13.7
Leyeping and Pujikang	449	34.7	785	25.0	1,286	24.4	900	25.6	471	31.7
Astragalus granule	6,424	25.1	5,423	24.7	6,099	25.5	4,027	24.3	3,427	26.9
Chaihuang granule	1,489	16.3	1,736	16.6	1,281	16.6	923	16.5	555	17.5

Note:

(1) Average selling price is calculated by dividing revenue by sales volume.

During the Track Record Period, the sales volume and average selling price of our major marketed products were affected by various regulatory regimes including the centralized tender process and the VBP, both governing the purchase of drugs by public hospitals and public medical institutions. See “— Pricing — Centralized Tender Process and Volume-based Procurement” for more details.

Generic Drugs

Anesthesia Drugs

As of the Latest Practicable Date, our major anesthesia portfolio consists of three approved products: propofol injectable emulsion, propofol medium and long chain fat emulsion injection, and dexmedetomidine hydrochloride injection. Propofol injectable emulsion, propofol medium and long chain fat emulsion injection and dexmedetomidine hydrochloride injection were all listed in the 2023 NRDL, and propofol injectable emulsion was also listed in the 2018 NEDL. Multiple authoritative guidelines have recommended both propofol and dexmedetomidine hydrochloride injection for sedation therapy, including the Guidelines for

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Pain and Sedation Management in Adult ICUs in China (《中國成人ICU鎮痛和鎮靜治療指南》), the Expert Consensus on Sedation Management in Regional Anesthesia (《區域麻醉鎮靜管理專家共識》), and the Expert Consensus on Pediatric Anesthesia and Sedation Outside the Operating Room (《小兒手術室外麻醉鎮靜專家共識》), highlighting its potential for widespread clinical adoption and sustained market growth. In 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, our revenue from sales of anesthesia products amounted to RMB401.9 million, RMB365.3 million, RMB243.5 million, RMB173.0 million and RMB127.6 million, respectively, representing 50.6%, 52.0%, 43.4%, 45.9% and 39.0% of our total revenue from the sale of pharmaceutical products for the respective periods.

Leweijing 乐维静® (propofol injectable emulsion)

Our propofol injectable emulsion, under the brand name Leweijing (乐维静®), was first approved by the NMPA in September 2001. According to CIC, there were 29 propofol emulsion injection products in China as of the Latest Practicable Date, and Leweijing was ranked fourth in China’s propofol emulsion injection market, with a market size of approximately 12.1% in 2023. Propofol injectable emulsion was included in the 2023 NRDL. We produce our propofol injectable emulsion at our Guorui Base, with the current PRC manufacturing permit valid until September 2025. We provide Leweijing in three specifications, including 10ml:0.1g, 20ml:0.2g, and 50ml:0.5g., all of which successfully passed consistency evaluation in December 2021. As of September 30, 2024, Leweijing was sold in 31 provinces across China.

The drug class of Leweijing, i.e., propofol injectable emulsion, was included in the ninth batch of national VBP scheme in November 2023, which lasts four years. Our product Leweijing participated in this national VBP scheme. During the Track Record Period, Leweijing participated in the following VBP schemes:

VBP Scheme	Provinces Covered	VBP Cycle Start Time	Cycle Duration	VBP Cycle End Time
Provincial VBP scheme A	Shandong	February 2021	More than one year	March 2024 ⁽¹⁾
Provincial VBP scheme B	Guangxi	December 2019	More than one year	March 2024 ⁽¹⁾
Provincial VBP scheme C	Hunan	January 2022	More than one year	March 2024 ⁽¹⁾
Provincial VBP scheme D	Anhui	July 2022	More than one year	March 2024 ⁽¹⁾
Provincial VBP scheme E	Jiangxi	May 2022	More than one year	March 2024 ⁽¹⁾
Provincial alliance VBP Scheme F	Shanxi, Guangdong, Henan, Hainan, Qinghai, Xinjiang	From December 2022 to January 2024	Normally two years	March 2024 ⁽¹⁾
National VBP scheme ninth batch	Guangdong, Sichuan, Hebei, Yunnan, Hunan, Xinjiang, Gansu	March 2024	Four years	December 2027

Note:

- (1) Relevant provincial VBP schemes ended in March 2024 as the drug class of Leweijing was included in the ninth batch of the national VBP scheme, which was implemented beginning from March 2024. Our product Leweijing participated in the ninth batch of the national VBP scheme.

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During the Track Record Period, our product Lewejing was sold primarily through in-hospital channel. The following table sets forth the amount of sales, sales volume and average selling price (ASP) of Lewejing during the Track Record Period:

Lewejing	Year ended December 31,									Nine months ended September 30,		
	2021 ⁽¹⁾			2022 ⁽²⁾			2023 ⁽³⁾			2024 ⁽⁴⁾		
	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP
	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)
Sales to hospitals	258.3	17,565.6	14.7	313.6	22,928.2	13.7	212.4	17,670.6	12.0	96.8	10,802.2	9.0
– Under VBP schemes	28.3	3,748.5	7.5	56.9	7,343.8	7.8	61.1	7,433.4	8.2	69.0	8,551.2	8.1
– Outside of VBP schemes	230.1	13,817.1	16.6	256.7	15,584.4	16.5	151.3	10,237.2	14.8	27.8	2,251.0	12.3
Other ⁽⁵⁾	0.0	3.1	4.5	0.0	1.2	5.3	0.0	0.6	5.0	0.0	1.8	4.7
Total	258.4	17,568.7	14.7	313.7	22,929.4	13.7	212.4	17,671.2	12.0	96.8	10,804.1	9.0

Notes:

- (1) In 2021, Lewejing participated in VBP schemes in the provinces of Guangxi and Shandong.
- (2) In 2022, Lewejing participated in VBP schemes in the provinces of Guangxi, Shandong, Hunan, Anhui, Jiangxi and Shanxi.
- (3) In 2023, Lewejing participated in VBP schemes in the provinces of Guangxi, Shandong, Hunan, Anhui, Jiangxi, Guangdong, Shanxi, Hainan, Henan, Qinghai and Xinjiang.
- (4) In 2024, Lewejing (50ml:0.5g) participated in the ninth batch of the national VBP scheme.
- (5) Representing sales from products used for drug testing.

Fluctuation 2022 Compared to 2021

Analysis: *Sales to hospitals under VBP schemes.* In 2022, Lewejing entered into new provincial VBP schemes covering more provinces as compared to 2021. This led to an increase in the sales volume of Lewejing under VBP schemes from 3.7 million units in 2021 to 7.3 million units in 2022. As a result, the sales amount of Lewejing under VBP schemes increased from RMB28.3 million in 2021 to RMB56.9 million in 2022.

Sales to hospitals outside of VBP schemes. In 2022, the market demand for propofol injectable emulsion increased. This shift followed the inclusion of its competing drug class, propofol medium and long chain fat emulsion injection, in the fourth batch of the national VBP scheme in February 2021. The inclusion in the VBP scheme led to a substantial reduction in the price and profit margin of the propofol medium and long chain fat emulsion injection. Consequently, distributors, aiming to maintain profitability, reduced their purchases of the propofol medium and long chain fat emulsion injection and instead turned to propofol injectable emulsion, which is in line with the market practice as advised by CIC. As such, sales volume of Lewejing outside of VBP schemes increased from 13.8 million units in 2021 to 15.6 million units in 2022. As a result, the sales amount of Lewejing outside of VBP schemes increased from RMB230.1 million to RMB256.7 million.

In general, in 2022, Lewejing achieved an increase in sales volume under VBP schemes and outside of VBP schemes, with total sales volume increasing from 17.6 million units to 22.9 million units. Due to the higher proportion of sales generated under the VBP schemes, the average selling price of Lewejing per unit decreased from RMB14.7 in 2021 to RMB13.7 in 2022, but the overall revenue generated from Lewejing increased from RMB258.4 million to RMB313.7 million.

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2023 Compared to 2022

Sales to hospitals under VBP schemes. In 2023, although Lewejing entered into more provinces implementing VBP schemes, due to the implementation of the provincial alliance VBP scheme F beginning from December 2022, as a market practice, distributors increased their purchases of Lewejing in late 2022, and reduced their orders in the subsequent period as these pre-stocked products were gradually sold off in 2023; according to the Industry Consultant, it is common for distributors to increase their purchases of a product that has won bids in the VBP scheme before its implementation. As a result of the foregoing, the sales volume of Lewejing under VBP schemes slightly increased from 7.3 million units in 2022 to 7.4 million units in 2023. Additionally, the average selling price of Lewejing per unit under VBP schemes slightly increased from RMB7.8 to RMB8.2. As a result, the sales amount of Lewejing under VBP schemes increased from RMB56.9 million in 2022 to RMB61.1 million in 2023.

Sales to hospitals outside of VBP schemes. With the increase in the number of provinces implementing VBP schemes in 2023, hospitals in the provinces that implemented the new VBP scheme purchased Lewejing primarily through the VBP scheme, leading to a decline in sales volume of Lewejing to hospitals outside of VBP schemes. As a result of the foregoing, further due to increased competition and changes in market conditions in several provinces, Lewejing experienced a decrease in the sales volume outside of VBP schemes from 155.8 million units in 2022 to 102.4 million units in 2023. As a result, the sales amount of Lewejing outside of VBP schemes decreased from RMB256.7 million in 2022 to RMB151.3 million in 2023.

In general, the sales volume of Lewejing decreased from 22.9 million units in 2022 to 17.7 million units in 2023. Due to the higher proportion of sales generated under the VBP schemes, the average selling price of Lewejing per unit decreased from RMB13.7 in 2022 to RMB12.0 in 2023. As a result, the overall revenue generated from Lewejing decreased from RMB313.7 million in 2022 to RMB212.4 million in 2023.

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

Our revenue generated from Lewejing decreased by RMB53.1 million, or 35.4%, from RMB149.9 million in the nine months ended September 30, 2023 to RMB96.8 million in the nine months ended September 30, 2024, which was primarily due to (i) a decrease of the average selling price of Lewejing per unit from RMB11.9 in the nine months ended September 30, 2023 to RMB9.0 in the nine months ended September 30, 2024; and (ii) a decrease of the sales volume of Lewejing from 12.6 million units in the nine months ended September 30, 2023 to 10.8 million units in the nine months ended September 30, 2024. The decrease in the average selling price of Lewejing was largely due to a significant price reduction of a large specification (50 ml:0.5g) of Lewejing included in the ninth batch of the national VBP scheme starting in March 2024. Before winning the bids in the national VBP scheme, the sales revenue of Lewejing ranked 4th nationally in 2023 with a market share of 12.1% of the propofol emulsion injection market in China, according to CIC. Under the national VBP, each winning bidder will mainly supply the products for certain designated provinces. Therefore, Lewejing’s sales volume outside of the seven provinces for which it is the primary supplier declined after the implementation of the national VBP. Additionally, smaller specification products (10ml:0.1g, 20ml:0.2g) contributed to a majority of sales volume of Lewejing in the past, and post national VBP, larger specification products (50ml:0.5g) became more mainstream than smaller ones, leading to further decrease of the total number of units sold, regardless of specifications.

Leweitai 乐维泰® (propofol medium and long chain fat emulsion injection)

Our propofol medium and long chain fat emulsion injection, under the brand name Leweitai (乐维泰®), was first approved by the NMPA in July 2014. According to CIC, there were 50 propofol medium and long chain fat emulsion injection products in China as of the Latest Practicable Date, and Leweitai was ranked third in China’s propofol medium and long chain fat emulsion injection market, with a market share of approximately 20.1% in 2023. Propofol medium and long chain fat emulsion injection was included in 2023 NRDL. We produce propofol medium/long chain fat emulsion injection at our Guorui Base, with the current PRC manufacturing permit valid until March 2029. We provide Leweitai in five

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specifications, including 10ml:0.1g, 20ml:0.1g, 20ml:0.2g, 50ml:0.5g, and 100ml:1.0g. Except specification at 20ml:0.1g, all the other specifications of Leweitai successfully passed consistency evaluation in February 2021. As of September 30, 2024, Leweitai was sold in 31 provinces across China.

The drug class of Leweitai, i.e., propofol medium and long chain fat emulsion injection, was included in the fourth batch of national VBP scheme in February 2021, which lasted one year. Our product Leweitai did not participate in this national VBP scheme. During the Track Record Period, Leweitai participated in the following VBP schemes:

VBP Scheme	Provinces Covered	VBP Cycle Start Time	Cycle Duration	VBP Cycle End Time
Provincial VBP scheme A	Shandong	February 2021	More than one year	May 2021 ⁽¹⁾
Provincial VBP scheme B	Guangxi	December 2019	More than one year	May 2021 ⁽¹⁾
Provincial VBP scheme G	Fujian	April 2020	More than one year	May 2021 ⁽¹⁾
Provincial VBP scheme H	Hubei	May 2020	More than one year	June 2022
Provincial alliance VBP Scheme I	Henan, Shanxi, Inner Mongolia, Hubei, Hunan, Guangxi, Hainan, Chongqing, Guizhou, Qinghai, Ningxia, Xinjiang	From July 2022 to January 2024	Normally two to three years	From July 2024 to January 2025
Procurement continuation following the expiry of national VBP scheme fourth batch ⁽²⁾	Jiangsu, Liaoning, Beijing, Shandong, Shaanxi, Yunnan, Tianjin, Xizang, Sichuan	From August 2022 to March 2024	Normally one to three years	From March 2024 to July 2026
Provincial VBP scheme	Guangdong	April 2023	Normally two years	December 2025

Notes:

- (1) Relevant provincial VBP schemes ended in May 2021 as the drug class of Leweitai was included in the fourth batch of the national VBP scheme, which was implemented beginning from May 2021 and in which we did not participate in the bidding process.
- (2) Referring to the continuation of the national VBP scheme initiated by provinces or province alliances after the initial national VBP scheme cycle ends. This process ensures that certain benefits of the national VBP scheme such as reduced drug prices and stable supply are sustained over time. The exact VBP cycle start time and duration may differ from province to province in such procurement continuation.

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During the Track Record Period, our product Leweitai was sold primarily through in-hospital channel. The following table sets forth the amount of sales, sales volume and average selling price (ASP) of Leweitai during the Track Record Period:

Leweitai	Year ended December 31,									Nine months ended September 30,		
	2021 ⁽¹⁾			2022 ⁽²⁾			2023 ⁽³⁾			2024 ⁽³⁾		
	Sales	Sales	ASP	Sales	Sales	ASP	Sales	Sales	ASP	Sales	Sales	ASP
	amount	volume		amount	volume		amount	volume		amount	volume	
	(RMB	('000		(RMB	('000		(RMB	('000		(RMB	('000	
	million)	units)	(RMB)	million)	units)	(RMB)	million)	units)	(RMB)	million)	units)	(RMB)
Sales to hospitals	116.8	2,456.8	47.5	28.4	1,074.9	26.4	19.6	1,713.4	11.5	18.5	1,868.8	9.9
– Under VBP schemes	8.2	368.6	22.3	3.8	413.1	9.2	12.9	1,498.8	8.6	14.5	1,683.4	8.6
– Outside of VBP schemes	108.6	2,088.2	52.0	24.6	661.8	37.2	6.7	214.6	31.4	4.0	185.3	21.7
Other ⁽⁴⁾	0.0	1.1	6.2	0.0	0.4	7.5	0.0	1.9	6.8	0.0	0.3	7.1
Total	116.8	2,457.9	47.5	28.4	1,075.3	26.4	19.6	1,715.3	11.4	18.5	1,869.1	9.9

Note:

- (1) In February 2021, propofol medium and long chain fat emulsion injection was included in the fourth batch of national VBP scheme in which Leweitai did not participate. This fourth batch of the national VBP scheme was implemented beginning from May 2021 and lasted one year. Prior to the implementation of this national VBP scheme, Leweitai participated in VBP schemes in the provinces of Fujian, Guangxi, Hubei and Shandong.
- (2) With the fourth batch of the national VBP scheme ending in mid-2022, Leweitai began to participate in VBP schemes in the provinces of Henan, Shanxi, Hubei, Hunan, Guangxi, Hainan, Chongqing, Qinghai, Guizhou, Ningxia, Xinjiang, Jiangsu, Liaoning and Beijing.
- (3) In 2023 and the nine months ended September 30, 2024, Leweitai participated in VBP schemes in the provinces of Henan, Shanxi, Hubei, Hunan, Guangxi, Hainan, Guizhou, Ningxia, Xinjiang, Jiangsu, Liaoning, Shandong, Beijing, Guangdong, Inner Mongolia, Shaanxi, Sichuan, Tianjin, Yunnan, Qinghai, Xizang, and Chongqing.
- (4) Representing sales from products used for drug testing.

Fluctuation 2022 Compared to 2021

Analysis: *Sales to hospitals under VBP schemes.* With the national VBP scheme for propofol medium and long chain fat emulsion injection ending in mid-2022, we began to participate in various provincial VBP schemes and gradually captured the relevant market under VBP schemes. This led to an increase in the sales volume of Leweitai under VBP schemes from 0.37 million units in 2021 to 0.41 million units in 2022. However, as certain provinces required the lowest price to win the bid, the average selling price of Leweitai per unit under VBP schemes decreased from RMB22.3 in 2021 to RMB9.2 in 2022. As a result, the sales amount of Leweitai under VBP schemes decreased from RMB8.2 million in 2021 to RMB3.8 million in 2022.

Sales to hospitals outside of VBP schemes. In February 2021, propofol medium and long chain fat emulsion injection was included in the fourth batch of national VBP scheme. Leweitai did not participate this VBP scheme because, despite passing the consistency evaluation, it was still awaiting certification documents required for the bidding process. By the time Leweitai received the necessary certification, the bidding period had already ended. As Leweitai held a sizable market size prior to the national VBP, its exclusion from the scheme resulted in a significant loss of market share as the VBP-winning bidders captured a significant portion of the market. Furthermore, the average selling prices of Leweitai were also substantially reduced since it was included in the multiple continuation procurement schemes in 2022, and its prices under the centralized tender process in certain provinces were adjusted to align with the lowest prices under the centralized tender process across various provinces. As a result, the sales volume of Leweitai outside of VBP schemes decreased from 2.1 million units to 0.7 million units, and the corresponding sales amount decreased from RMB108.6 million to RMB24.6 million.

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2023 Compared to 2022

Sales to hospitals under VBP schemes. In 2023, Leweitai entered into more provinces implementing VBP schemes and further captured the relevant market under VBP schemes. This led to an increase in the sales volume of Leweitai under VBP schemes from 0.4 million units in 2022 to 1.5 million units in 2023. As a result, the sales amount of Leweitai under VBP schemes increased from RMB3.8 million in 2022 to RMB12.9 million in 2023.

Sales to hospitals outside of VBP schemes. With the increase in the number of provinces implementing VBP schemes in 2023, hospitals in the provinces that implemented the new VBP scheme purchased Leweitai primarily through the VBP scheme, leading to a decline in sales volume of Leweitai to hospitals outside of VBP schemes. As a result, the sales volume of Leweitai outside of VBP schemes decreased from 0.7 million units in 2022 to 0.2 million units in 2023, leading to a decline in the sales amount of Leweitai outside of VBP schemes from RMB24.6 million in 2022 to RMB6.7 million in 2023.

In general, despite the sales volume of Leweitai increasing from 1.1 million units to 1.7 million units, due to the higher proportion of sales generated under the VBP schemes, the average selling price of Leweitai per unit decreased from RMB26.4 in 2022 to RMB11.4 in 2023. As a result, the overall revenue generated from Leweitai decreased by RMB8.8 million in 2023 compared to 2022.

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

Our revenue generated from Leweitai increased by RMB4.1 million, or 28.2%, from RMB14.5 million in the nine months ended September 30, 2023 to RMB18.5 million in the nine months ended September 30, 2024, which was primarily due to an increase of the sales volume of Leweitai from 1.2 million units in the nine months ended September 30, 2023 to 1.9 million units in the nine months ended September 30, 2024 as Leweitai gradually expanded its market share in the provinces where it was participating in those provincial procurement schemes. Such increase was partially offset by higher proportion of sales generated under the VBP schemes following its participation in the provincial procurement continuation schemes in certain markets beginning from April 2023.

Youmeining 右美宁® (dexmedetomidine hydrochloride injection)

Our dexmedetomidine hydrochloride injection, under the brand name Youmeining (右美宁®), was first approved by the NMPA in August 2011, and there were over 30 dexmedetomidine hydrochloride injection products in China as of the Latest Practicable Date, and Youmeining was ranked eighth in dexmedetomidine hydrochloride injection market, with a market share of approximately 1.2% in 2023. Dexmedetomidine hydrochloride injection was included in 2023 NRDL. We produce our dexmedetomidine hydrochloride injection at our Guorui Base, with the current PRC manufacturing permit valid until June 2028. We provide Youmeining in four specifications, including 1ml:0.1mg and 2ml:0.2mg, which passed consistency evaluation in January 2021, and 4ml:0.4mg and 10ml:1.0mg which passed consistency evaluation in June 2023. As of September 30, 2024, Youmeining was sold in 29 provinces across China.

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The drug class of Youmeining, i.e., dexmedetomidine hydrochloride injection, was included in the first “4+7” national VBP scheme in December 2018 and the expanded “4+7” national VBP scheme in September 2019, which lasted one year respectively. Our product Youmeining did not participate in these national VBP schemes. During the Track Record Period, Youmeining participated in the following VBP schemes:

VBP Scheme	Provinces Covered	VBP Cycle Start Time	Cycle Duration	VBP Cycle End Time
Provincial VBP scheme	Henan	May 2023	Normally two years	June 2025
Procurement continuation following the expiry of national VBP scheme	Chongqing, Inner Mongolia, Sichuan, Xizang, Yunnan, Shaanxi	From November 2022 to January 2023	Normally three years	From November 2025 to January 2026
	Beijing	November 2022	Normally two years	March 2024
	Jiangsu	January 2022 and August 2024	Normally two years	December 2025

Note:

- (1) Referring to the continuation of the national VBP scheme initiated by provinces or province alliances after the initial national VBP scheme cycle ends. This process ensures that certain benefits of the national VBP scheme such as reduced drug prices and stable supply are sustained over time. The exact VBP cycle start time and duration may differ from province to province in such procurement continuation.

During the Track Record Period, our product Youmeining was sold primarily through in-hospital channel. The following table sets forth the amount of sales, sales volume and average selling price of Youmeining during the Track Record Period:

Youmeining	Year ended December 31,									Nine months ended September 30,		
	2021			2022 ⁽¹⁾			2023 ⁽²⁾			2024 ⁽²⁾		
	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP
	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)
Sales to hospitals	26.7	523.6	51.0	23.3	598.9	38.8	11.4	430.1	26.5	12.2	409.7	29.9
– Under VBP schemes	–	–	–	7.6	204.0	37.3	8.0	299.0	26.8	10.7	339.1	31.6
– Outside of VBP schemes	26.7	523.6	51.0	15.7	394.9	39.6	3.4	131.1	25.6	1.5	70.6	21.4
Other ⁽³⁾	0.0	1.3	7.0	0.0	0.9	7.1	0.0	2.8	7.2	–	–	–
Total	26.7	524.9	50.9	23.3	599.9	38.8	11.4	432.9	26.3	12.2	409.7	29.9

Note:

- (1) In 2022, Youmeining participated in VBP schemes in the provinces of Jiangsu, Chongqing, Yunnan and Shaanxi.

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- (2) In 2023 and the nine months ended September 30, 2024, Youmeining participated in VBP schemes in the provinces of Jiangsu, Chongqing, Yunnan, Shaanxi, Beijing, Xizang, Henan, Inner Mongolia and Sichuan.
- (3) Representing sales from products used for drug testing.

Fluctuation 2022 Compared to 2021

Analysis: *Sales to hospitals under VBP schemes.* In 2022, Youmeining participated in VBP schemes in some provinces, leading to an increase in sales amount under VBP schemes in 2022.

Sales to hospitals outside of VBP schemes. With the increase in the number of provinces implementing VBP schemes in 2022, hospitals in the provinces that implemented the new VBP scheme purchased Youmeining primarily through the VBP scheme, leading to a decline in sales volume of Youmeining to hospitals outside of VBP schemes. The average selling price of Youmeining outside of VBP schemes in certain provinces decreased as adjusted to align with the lowest prices under the centralized tender process across various provinces. As a result, the sales amount of Youmeining outside of VBP schemes decreased from RMB26.7 million in 2021 to RMB15.7 million in 2022.

In general, despite the sales volume of Youmeining increasing from 0.5 million units to 0.6 million units, due to the higher proportion of sales generated under the VBP schemes and the decline of the average selling price outside of VBP schemes, the average selling price of Youmeining per unit decreased from RMB50.9 to RMB38.8. As a result, the overall revenue generated from Youmeining decreased by RMB3.5 million in 2022.

2023 Compared to 2022

Sales to hospitals under VBP schemes. In 2023, Youmeining further captured the relevant market under VBP schemes, leading to an increase in the sales volume of Youmeining. However, as certain provinces required the lowest price to win the bid, the average selling price of Youmeining per unit under VBP schemes decreased from RMB37.3 in 2022 to RMB26.8 in 2023. As a result, the sales amount of Youmeining under VBP schemes increased from RMB7.6 million in 2022 to RMB8.0 million in 2023.

Sales to hospitals outside of VBP schemes. With the increase in the number of provinces implementing VBP schemes in 2023, hospitals in the provinces that implemented the new VBP scheme purchased Youmeining primarily through the VBP scheme, leading to a decline in sales volume of Youmeining to hospitals outside of VBP schemes. Additionally, Youmeining lost its market share in certain provinces that implemented provincial VBP schemes, of which we did not win in the bidding process. The average selling price of Youmeining outside of VBP schemes in certain provinces decreased as adjusted to align with the lowest prices under the centralized tender process across various provinces. As a result, the sales amount of Youmeining outside of VBP schemes decreased from RMB15.7 million in 2022 to RMB3.4 million in 2023.

In general, the sales volume of Youmeining decreased from 0.6 million units to 0.4 million units. Due to the higher proportion of sales generated under the VBP schemes and the decline of the average selling price outside of VBP schemes, the average selling price of Youmeining per unit decreased from RMB38.8 to RMB26.3. As a result, the overall revenue generated from Youmeining decreased by RMB11.9 million in 2023.

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

Our revenue generated from Youmeining increased by RMB3.6 million, or 41.4%, from RMB8.7 million in the nine months ended September 30, 2023 to RMB12.2 million in the nine months ended September 30, 2024, which was primarily due to an increase of the sales volume of Youmeining from 0.3 million units in the nine months ended September 30, 2023 to 0.4 million units in the nine months ended September 30, 2024 as Youmeining gradually expanded its market share in the provinces where it was participating in those provincial procurement schemes.

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Parenteral Nutrition Drugs

Tianze 天泽® (medium and long chain fat emulsion injection)

Our medium and long chain fat emulsion injection, under the brand name Tianze (天泽®), was first approved by the NMPA in August 2012. The medium and long chain fat emulsion injection has been highlighted as an ideal parenteral nutrition drug for preventing oxidative stress, which downregulates inflammatory responses and maintains organ function. The medium and long chain fat emulsion injection was listed in the 2023 NRDL and 2018 NEDL and is recommended by several clinical guidelines and expert consensus, including the Consensus of Chinese Experts on Adult Supplemental Parenteral Nutrition (《成人補充性腸外營養中國專家共識》), the Expert Consensus on Perioperative Nutritional Support Treatment in Adult Cardiac Surgery in China (《中國成人心臟外科圍手術期營養支援治療專家共識》), the Clinical Pharmacy Consensus on Parenteral Nutrition (Second Edition) (《腸外營養臨床藥學共識(第二版)》), the ESPEN Practical Guideline Clinical Nutrition in Surgery, and the Guideline for Clinical Application of Parenteral Nutrition Fat Emulsion Injection For Adults (《成人腸外營養脂肪乳注射液臨床應用指南》).

According to CIC, there were over 50 medium and long chain fat emulsion injection products in China as of the Latest Practicable Date, and Tianze ranked the sixth in China’s medium and long chain fat emulsion injection market, with a market size of approximately 5.1% in 2023. We produce our medium/long chain fat emulsion injection at our Guorui Base, with the current PRC manufacturing permit for valid until June 2027. We provide Tianze (天泽®) in four specifications, including 100ml:20%, 250ml:10%, 250ml:20%, and 500ml:10%. In January 2024, specifications at 100ml:20% and 250ml:20% successfully passed the consistency evaluation. As of September 30, 2024, Tianze was sold in 28 provinces across China.

The drug class of Tianze was not included in any national VBP scheme. The competing drug class of Tianze, i.e., medium and long chain fat emulsion injection (C8-24Ve), was included in the fifth batch of national VBP scheme in June 2021, which lasted two years. During the Track Record Period, Tianze participated in the following VBP schemes:

<u>VBP Scheme</u>	<u>Provinces Covered</u>	<u>VBP Cycle Start Time</u>	<u>Cycle Duration</u>	<u>VBP Cycle End Time</u>
Provincial VBP scheme J	Guangxi	April 2021	More than one year	February 2024

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During the Track Record Period, our product Tianze was sold primarily through in-hospital channel. The following table sets forth the amount of sales, sales volume and average selling price of Tianze during the Track Record Period:

Tianze	Year ended December 31,									Nine months ended September 30,		
	2021 ⁽¹⁾			2022 ⁽¹⁾			2023 ⁽¹⁾			2024 ⁽¹⁾		
	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP
	(RMB million)	(‘000 units)	(RMB)	(RMB million)	(‘000 units)	(RMB)	(RMB million)	(‘000 units)	(RMB)	(RMB million)	(‘000 units)	(RMB)
Sales to hospitals	115.5	3,524.0	32.8	61.6	2,195.8	28.0	39.9	1,484.9	26.8	19.2	687.0	27.9
– Under VBP schemes	6.2	299.3	20.8	8.8	428.7	20.5	6.7	326.5	20.5	0.1	7.9	17.1
– Outside of VBP schemes	109.3	3,224.7	33.9	52.7	1,767.1	29.8	33.2	1,158.4	28.6	19.0	679.0	28.0
Other ⁽²⁾	0.0	1.5	12.5	0.0	0.3	10.1	0.0	0.3	11.3	0.0	0.1	8.2
Total	115.6	3,525.5	32.8	61.6	2,196.1	28.0	39.9	1,485.2	26.8	19.2	687.1	27.9

Note:

(1) During the Track Record Period, Tianze only participated in VBP scheme in Guangxi province.

(2) Representing sales from products used for drug testing.

Fluctuation 2022 Compared to 2021

Analysis: *Sales to hospitals under VBP schemes.* Tianze was exclusively sold under VBP schemes in Guangxi province. The sales revenue generated from Tianze under VBP schemes increased in 2022 as compared to 2021 mainly due to increased market demand.

Sales to hospitals outside of VBP schemes. In June 2021, the competing drug class of Tianze was included in the fifth batch of national VBP scheme. Unlike the significant price and profit margin reductions observed for Lewejing’s competing drug class, this inclusion did not lead to a substantial decrease in price or profit margin for Tianze’s competitors. For more details, see “— Anesthesia Drugs — Lewejing.” As a result, distributors preferred to purchase products from this competing drug class under the national VBP scheme, which guarantees sales volume. Consequently, they were unlikely to shift their focus to Tianze’s drug class, aligning with market practices as advised by CIC. This preference affected market demand and exerted price pressure on our product. The sales volume of Tianze outside of VBP schemes decreased from 3.2 million units to 1.8 million units. As a result, the sales amount of Tianze outside of VBP schemes decreased from RMB109.3 million in 2021 to RMB52.7 million in 2022.

2023 Compared to 2022

Sales to hospitals under VBP schemes. Tianze was exclusively sold under VBP schemes in Guangxi province. The sales revenue generated from Tianze under VBP schemes decreased in 2023 as compared to 2022 mainly due to decreased market demand.

Sales to hospitals outside of VBP schemes. The sales volume of Tianze decreased from 1.8 million units in 2022 to 1.2 million units in 2023, primarily because of (i) this product losing its market share in certain provinces as Tianze did not obtain the certification of consistency evaluation for centralized tender process in those provinces in 2023 due to incomplete application materials and the evaluation application being resubmitted; and (ii) the prolonged period for the market to fully consume the volume of its competing drug class included in the fifth batch of national VBP scheme in June 2021. The VBP cycle duration of the fifth batch of national VBP scheme lasted normally two years and continued to affect the market demand for Tianze in 2023. As a result, the sales amount of Tianze outside of VBP schemes decreased from RMB52.7 million in 2022 to RMB33.2 million in 2023.

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Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023
Our revenue generated from Tianze decreased by RMB11.7 million, or 37.9%, from RMB30.9 million in the nine months ended September 30, 2023 to RMB19.2 million in the nine months ended September 30, 2024, which was primarily due to a decrease of sales volume of Tianze from 1.1 million units in the nine months ended September 30, 2023 to 0.7 million units in the nine months ended September 30, 2024. This decrease was primarily because (i) the provincial VBP scheme J of which Tianze participated expired in early 2024, (ii) the competing drug class of Tianze continued to occupy the market by participating various provincial VBP schemes and procurement continuation following the expiry of national VBP scheme, while Tianze losing its market share in certain provinces that require certification of consistency evaluation for participation in centralized tender processes in those provinces. With two of the four specifications of Tianze passing the consistency evaluation in January 2024, we expect to regain the market share by participating in the centralized tender process of additional provinces after a phase-in period.

Anti-Infective Drugs

As of the Latest Practicable Date, our anti-infective product portfolio mainly comprised two products, ribavirin granule and ornidazole capsule. In 2021, 2022, and 2023, and the nine months ended September 30, 2023 and 2024, our revenue from sales of anti-infective products amounted to RMB44.9 million, RMB67.2 million, RMB35.5 million, RMB14.9 million and RMB12.1 million, respectively, representing 5.6%, 9.6%, 6.4%, 3.9% and 3.7% of our total revenue from the sale of pharmaceutical products for the respective periods.

Xinbolin 新博林® (ribavirin granule)

Ribavirin has been widely acknowledged as an early intervention for broad-spectrum RNA and DNA virus infections and is recommended in the Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 8 Revised) (《新型冠状病毒肺炎診療方案(試行第八版修訂版)》) for use in combination with interferon or lopinavir/ritonavir in the treatment of COVID-19. Our ribavirin granule, under the brand name Xinbolin (新博林®), was first approved by the NMPA in January 2003. According to CIC, there were over 700 ribavirin products in China as of the Latest Practicable Date, and Xinbolin was ranked as the sixth most popular ribavirin product in China, with a market share of approximately 3.4% in 2023. We produce our ribavirin granule at our Baili Base, with the current PRC manufacturing permit valid until February 2025. We provide Xinbolin in three specifications, 50mg, 0.1g and 0.15g. As of September 30, 2024, Xinbolin was sold in 28 provinces across China.

The drug class of Xinbolin was not included in any national VBP scheme. During the Track Record Period, Xinbolin participated in the following VBP schemes:

VBP Scheme	Provinces Covered	VBP Cycle Start Time	Cycle Duration	VBP Cycle End Time
Provincial alliance VBP scheme K	Guangdong, Shanxi, Qinghai, Xinjiang, Guizhou, Hainan, Ningxia, Chongqing	From November 2022 to August 2023	Normally two years	From November 2024 to September 2025

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During the Track Record Period, our product Xinbolin was sold through both in-hospital and outside-of-hospital channels. The following table sets forth the amount of sales, sales volume and average selling price of Xinbolin during the Track Record Period:

Xinbolin	Year ended December 31,									Nine months ended September 30,		
	2021			2022			2023 ⁽¹⁾			2024 ⁽¹⁾		
	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP
	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)
Sales to hospitals	2.5	549.1	4.6	2.1	487.3	4.4	1.7	391.0	4.2	1.0	223.5	4.3
– Under VBP schemes	–	–	–	–	–	–	0.5	120.8	4.1	0.5	107.4	4.2
– Outside of VBP schemes	2.5	549.1	4.6	2.1	487.3	4.4	1.2	270.2	4.3	0.5	116.1	4.4
Sales outside of hospitals	32.0	5,594.2	5.7	56.6	11,270.9	5.0	31.8	5,492.8	5.8	9.5	1,494.4	6.4
Other ⁽²⁾	0.0	0.0	2.7	0.0	0.0	2.0	0.0	0.0	3.7	0.0	0.0	5.2
Total	34.5	6,143.3	5.6	58.7	11,758.2	5.0	33.5	5,883.8	5.7	10.5	1,717.9	6.1

Note:

- (1) In 2023 and the nine months ended September 30, 2024, Xinbolin participated in VBP schemes in provinces of Guangdong, Shanxi, Qinghai, Xinjiang, Guizhou, Hainan, Ningxia and Chongqing.
- (2) Representing sales from products used for drug testing.

Fluctuation 2022 Compared to 2021

Analysis:

Sales outside of hospitals. During the Track Record Period, the sales of Xinbolin primarily focuses on the outside-of-hospital market. In 2022, the sales volume of Xinbolin increased primarily due to the increased market demand of and sales for anti-infective drugs in light of the increased COVID-19 cases in the fourth quarter of 2022 as compared to 2021. In 2022, the outside-of-hospital sales volume of Xinbolin amounted to 11.3 million units, as compared to 5.6 million units in 2021. As a result, the outside-of-hospital sales revenue generated from Xinbolin increased from RMB32.0 million in 2021 to RMB56.6 million in 2022.

2023 Compared to 2022

Sales to hospitals. In 2023, Xinbolin was sold under VBP schemes in certain provinces. With the increase in the number of provinces implementing VBP schemes in 2023, hospitals in the provinces that implemented the new VBP scheme purchased Xinbolin primarily through the VBP scheme, leading to a decline in sales volume of Xinbolin to hospitals outside of VBP schemes.

Sales outside of hospitals. The sales volume and sales revenue of Xinbolin in the outside-of-hospital market decreased in 2023, primarily because distributors increased their purchases of Xinbolin in late 2022, anticipating increased market demand in light of the increased COVID-19 cases in late 2022 and the first few months of 2023.

As a result of foregoing, our revenue generated from Xinbolin decreased from RMB58.7 million in 2022 to RMB33.5 million in 2023.

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Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

Our revenue generated from Xinbolin decreased by RMB2.9 million, or 21.6%, from RMB13.3 million in the nine months ended September 30, 2023 to RMB10.5 million in the nine months ended September 30, 2024, which was primarily due to the decrease of the sales volume of Xinbolin from 2.1 million units in the nine months ended September 30, 2023 to 1.7 million units in the nine months ended September 30, 2024. This decrease was primarily due to a relatively higher sales volume of Xinbolin in May and June 2023 as the purchased stocks by distributors in late 2022 were sold during the first few months of 2023 and distributors restocked in anticipating recurring COVID-19 infections. The fluctuations in Xinbolin’s revenue during the Track Record Period were largely influenced by the COVID-19 pandemic.

Aobolin 奧博林® (ornidazole capsule)

Ornidazole capsule is noted for its efficacy in treating anaerobic bacterial and protozoal infections and is recommended by several clinical guidelines and expert consensus documents, including the Guidelines for Clinical Application of Antibacterial Drugs (2015 Edition) (《抗菌藥物臨床應用指導原則(2015版)》), the Expert Consensus on Off-Label Use of Antibacterial Drugs (2015 Edition) (《抗菌藥物超說明書用法專家共識(2015版)》), and the Expert Consensus on Standardized Application of Antibiotics in Biliary Tract Surgery (2019 edition) (《膽道外科抗菌藥物規範化應用專家共識(2019版)》). It was included in the 2023 NRDL. Our ornidazole capsule, under the brand name Aobolin (奧博林®), was first approved by the NMPA in March 2003, being the first-to-market generic drug of this medication in China. According to CIC, there were over 100 ornidazole products in China as of the Latest Practicable Date, and Aobolin was ranked 17th in China’s ornidazole market, with a market share of approximately 0.5% in 2023. We produce our ornidazole capsule at our Baili Base, with the current PRC manufacturing permit valid until March 2025. We provide Aobolin in two specifications, 125mg and 250mg. As of September 30, 2024, Aobolin was sold in 29 provinces across China.

The drug class of Aobolin, i.e., ornidazole capsule, was included in the seventh batch of national VBP scheme in July 2022, which lasts three years. Aobolin was not included in this national or any provincial VBP schemes. During the Track Record Period, our product Aobolin was sold through both in-hospital and outside-of-hospital channels. The following table sets forth the amount of sales, sales volume and average selling price of Aobolin during the Track Record Period:

	Year ended December 31,									Nine months ended September 30,		
	2021			2022			2023			2024		
	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP
	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)
Aobolin												
Sales to hospitals	8.8	628.4	14.0	6.8	512.8	13.2	0.8	114.9	7.1	0.7	85.5	7.9
Sales outside of hospitals	1.6	219.3	7.5	1.7	197.6	8.4	1.2	144.7	8.1	1.0	122.3	7.9
Other ⁽¹⁾	0.0	0.0	4.6	0.0	0.0	10.1	0.0	0.0	13.1	0.0	0.0	15.9
Total	10.4	847.7	12.3	8.4	710.4	11.9	2.0	259.6	7.7	1.6	207.8	7.9

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Note:

- (1) Representing sales from products used for drug testing.

Fluctuation 2022 Compared to 2021

Analysis: *Sales to hospitals.* The sales volume of Aobolin to hospitals decreased from 0.6 million units in 2021 to 0.5 million units in 2022 as a result of the reduced outpatient visits in light of the impact of the COVID-19 pandemic in 2022. As a result, the sales amount of Aobolin to hospitals decreased from RMB8.8 million in 2021 to RMB6.8 million in 2022.

Sales outside of hospitals. Revenue generated from Aobolin in outside-of-hospital market remained relatively stable.

As a result of the foregoing, our revenue generated from Aobolin decreased from RMB10.4 million in 2021 to RMB8.4 million in 2022.

2023 Compared to 2022

Sales to hospitals. The sales volume of Aobolin to hospitals decreased from 0.5 million units in 2022 to 0.1 million units in 2023, and the average selling price of Aobolin per unit to hospitals decreased from RMB13.2 in 2022 to RMB7.1 in 2023. The decreases were primarily due to the inclusion of ornidazole in the seventh batch of national VBP scheme in July 2022, of which Aobolin was not included because it did not participate in the consistency evaluation required for the bidding process at that time, as part of a strategic cost-benefit consideration.

Sales outside of hospitals. Revenue generated from Aobolin in outside-of-hospital market remained relatively stable.

As a result of the foregoing, the revenue generated from Aobolin decreased from RMB8.4 million in 2022 to RMB2.0 million in 2023.

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

Our revenue generated from Aobolin remained relatively stable at RMB1.5 million and RMB1.6 million in the nine months ended September 30, 2023 and 2024, respectively.

Pediatric Drugs

As of the Latest Practicable Date, our pediatric drugs product portfolio mainly comprised two products, racecadotril granule and glucose electrolyte effervescent tablet. In 2021, 2022, and 2023, and the nine months ended September 30, 2023 and 2024, our revenue from sales of pediatric drugs amounted to RMB29.7 million, RMB28.2 million, RMB45.3 million, RMB34.4 million and RMB21.7 million, respectively, representing 3.8%, 4.0%, 8.1%, 9.1% and 6.6% of our total revenue from the sale of pharmaceutical products for the respective periods.

Dulabao 杜拉宝® (racecadotril granule)

Racecadotril granule is widely acknowledged by its effectiveness in improving diarrhea symptoms and shortening the duration of the illness and is recommended by several clinical guidelines and expert consensus documents, including the Consensus of Experts on the Prevention and Treatment of Rotavirus Gastroenteritis in Children (《兒童輪狀病毒胃腸炎預防診療專家共識》) and the Clinical Practice Guidelines for Acute Infectious Diarrhea in Chinese Children (《中國兒童急性感染性腹瀉病臨床實踐指南》). It was included in the 2023 NRDL. Our racecadotril granule, under the brand name Dulabao (杜拉宝®), was first approved by the NMPA in February 2005, being the first-to-market generic drug of this medication in China. According to CIC, there were 12 racecadotril products in China as of the Latest Practicable Date, and Dulabao was the best-selling racecadotril products in China, with a

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market share of approximately 66.6% in 2023. We produce our racecadotril granule at our Baili Base, with the current PRC manufacturing permit valid until March 2025. As of September 30, 2024, Dulabao was sold in 29 provinces across China.

The drug class of Dulabao was not included in any national or provincial VBP scheme. Our product Dulabao was sold through both in-hospital and outside-of-hospital channels. The following table sets forth the amount of sales, sales volume and average selling price of Dulabao during the Track Record Period:

Dulabao	Year ended December 31,									Nine months ended September 30,		
	2021			2022			2023			2024		
	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP
	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)
Sales to hospitals	8.3	518.3	16.1	6.2	407.9	15.2	8.4	552.7	15.2	5.3	349.0	15.3
Sales outside of hospitals	5.7	771.4	7.4	2.4	330.3	7.3	5.5	745.2	7.4	1.5	149.7	9.9
Other ⁽¹⁾	0.0	0.1	6.6	0.0	0.1	8.0	0.0	0.0	9.1	0.0	0.0	16.7
Total	14.1	1,289.8	10.9	8.6	738.3	11.6	13.9	1,297.9	10.7	6.8	498.8	13.7

Note:

(1) Representing sales from products used for drug testing.

Fluctuation 2022 Compared to 2021

Analysis: *Sales to hospitals.* The sales volume of Dulabao to hospitals decreased from 0.5 million units in 2021 to 0.4 million units in 2022 as a result of the reduced outpatient visits in light of the impact of the COVID-19 pandemic in 2022. As a result, the sales amount of Dulabao to hospitals decreased from RMB8.3 million in 2021 to RMB6.2 million in 2022.

Sales outside of hospitals. The sales volume of Dulabao outside of hospitals decreased from 0.8 million units in 2021 to 0.3 million units in 2022 as a result of the reduced customer traffic at pharmacies in light of the impact of the COVID-19 pandemic in 2022. As a result, the sales amount of Dulabao outside of hospitals decreased from RMB5.7 million in 2021 to RMB2.4 million in 2022.

As a result of the foregoing, our revenue generated from Dulabao decreased from RMB14.1 million in 2021 to RMB8.6 million in 2022.

2023 Compared to 2022

Sales to hospitals. The sales volume of Dulabao to hospitals increased from 0.4 million units in 2022 to 0.6 million units in 2023, in line with the increased outpatient visits after the COVID-19 pandemic eased in 2023. As a result, the sales amount of Dulabao to hospitals increased from RMB6.2 million in 2022 to RMB8.4 million in 2023.

Sales outside of hospitals. The sales volume of Dulabao outside of hospitals increased from 0.3 million units in 2022 to 0.7 million units in 2023, as we intensified promotion efforts to large pharmaceutical retail chains after the COVID-19 pandemic eased in 2023, leading to an increase in foot traffic and market demand at pharmacies for our product Dulabao. As a result, the sales amount of Dulabao outside of hospitals increased from RMB2.4 million in 2022 to RMB5.5 million in 2023.

As a result of the foregoing, our revenue generated from Dulabao increased from RMB8.6 million in 2022 to RMB13.9 million in 2023.

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Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

Our revenue generated from Dulabao decreased by RMB4.5 million, or 39.9%, from RMB11.3 million in the nine months ended September 30, 2023 to RMB6.8 million in the nine months ended September 30, 2024, which was primarily due to a decrease of the sales volume of Dulabao from 1.0 million units in the nine months ended September 30, 2023 to 0.5 million units in the nine months ended September 30, 2024. This decrease was primarily due to the increased market demand of and sales for anti-diarrheal drugs in light of the increased COVID-19 cases in the first few months of 2023.

Leyeping 乐液平® and Pujikang 朴吉康® (glucose electrolyte effervescent tablet)

Glucose electrolyte effervescent tablet is well recognized by its effectiveness in preventing and treating dehydration and is recommended by several clinical guidelines and expert consensus documents, including the Standards for Diagnosis and Treatment of Acute Infectious Diarrhea in Children (《兒童急性感染性腹瀉病診療規範》), the Consensus of Experts on the Prevention and Treatment of Rotavirus Gastroenteritis in Children (《兒童輪狀病毒胃腸炎預防診療專家共識》), and the Clinical Practice Guidelines for Acute Infectious Diarrhea in Chinese Children (《中國兒童急性感染性腹瀉病臨床實踐指南》). It was included in the 2023 NRDL. Our glucose electrolyte effervescent tablet, under the brand name Leyeping (乐液平®) and Pujikang (朴吉康®), was first approved by the NMPA in June 2013. According to CIC, our glucose electrolyte effervescent tablet is the only glucose electrolyte product in China. We produce these two types of electrolyte effervescent tablet at our Baili Base, with the current PRC manufacturing permits which are valid until January 2028. As of September 30, 2024, Leyeping and Pujikang was sold in 27 provinces across China.

The drug class of Leyeping and Pujikang was not included in any national or provincial VBP scheme. Our product Leyeping and Pujikang was sold through both in-hospital and outside-of-hospital channels. The following table sets forth the amount of sales, sales volume and average selling price of Leyeping during the Track Record Period:

Leyeping and Pujikang	Year ended December 31,									Nine months ended September 30,		
	2021			2022			2023			2024		
	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP
	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)
Sales to hospitals	9.1	213.1	42.9	7.2	174.2	41.4	10.3	249.7	41.4	7.1	186.6	38.3
Sales outside of hospitals	6.5	235.8	27.4	12.4	610.5	20.3	21.1	1,036.0	20.3	7.8	283.9	27.4
Other ⁽¹⁾	0.0	0.1	2.3	–	–	–	–	–	–	0.0	0.1	42.8
Total	15.6	448.9	34.7	19.6	784.7	25.0	31.4	1,285.7	24.4	14.9	470.5	31.7

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Note:

- (1) Representing sales from products used for drug testing.

Fluctuation From 2021 to 2023

Analysis: *Sales to hospitals.* From 2021 to 2023, revenue generated from sales of Leyeping and Pujikang to hospitals remained relatively stable.

Sales outside of hospitals. From 2021 to 2023, revenue generated from sales of Leyeping and Pujikang outside of hospitals increased steadily which was in line with the increased market demand as we intensified promotion efforts to large pharmaceutical retail chains.

As a result, our revenue from sales of Leyeping and Pujikang amounted to RMB15.6 million, RMB19.6 million and RMB31.4 million in 2021, 2022 and 2023, respectively.

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

Our revenue generated from Leyeping and Pujikang decreased from the nine months ended September 30, 2023 to the nine months ended September 30, 2024, which was primarily due to the increased market demand of and sales for anti-diarrheal drugs in light of the increased COVID-19 cases in the first few months of 2023.

Traditional Chinese Medicine

As of the Latest Practicable Date, our traditional Chinese medicine product portfolio mainly comprised two products, astragalus granule and chaihuang granule. In 2021, 2022, and 2023, and the nine months ended September 30, 2023 and 2024, our revenue from sales of traditional Chinese medicine products amounted to RMB185.3 million, RMB163.0 million, RMB177.0 million, RMB113.2 million and RMB102.0 million, representing 23.4%, 23.2%, 31.6%, 30.1% and 31.2% of our total revenue from the sale of pharmaceutical products for the same periods, respectively.

Astragalus granule

Astragalus granule is an essential product for improving overall health and resilience against chronic ailments. It was included in the 2023 NRDL. According to CIC, there were 19 types of medicines containing astragalus, with 58 approved drug products in China as of the Latest Practicable Date, and our astragalus granule was ranked second in China’s astragalus market with a market share of approximately 30.0% in 2022. This dominant market presence underscores the efficacy and widespread acceptance of our astragalus granule in clinical practice. Our astragalus granule was first approved by the NMPA in October 2002, and we produce our astragalus granule at our Baili Base, with the current PRC manufacturing permit valid until April 2025. As of September 30, 2024, our astragalus granules was sold in 30 provinces across China.

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Astragalus granule was not included in any national or provincial VBP scheme. Our product astragalus granule was sold through both in-hospital and outside-of-hospital channels. The following table sets forth the amount of sales, sales volume and average selling price of astragalus granule during the Track Record Period:

Astragalus granule	Year ended December 31,									Nine months ended September 30,		
	2021			2022			2023			2024		
	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP
	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)
Sales to hospitals	37.2	1,865.6	19.9	37.9	1,899.3	20.0	31.5	1,611.9	19.5	25.9	1,329.3	19.5
Sales outside of hospitals	123.8	4,558.4	27.2	96.2	3,523.1	27.3	124.2	4,487.2	27.7	66.4	2,097.9	31.7
Other ⁽¹⁾	0.0	0.1	45.9	0.0	0.2	31.9	0.0	0.0	60.0	0.0	0.1	57.2
Total	161.0	6,424.1	25.1	134.1	5,422.5	24.7	155.7	6,099.2	25.5	92.3	3,427.4	26.9

Note:

(1) Representing primarily sales from products used for drug testing.

Fluctuation 2022 Compared to 2021

Analysis: *Sales to hospitals.* Revenue generated from sales of astragalus granule to hospitals remained relatively stable from 2021 to 2022.

Sales outside of hospitals. Revenue generated from sales of astragalus granule outside of hospitals decreased from RMB123.8 million in 2021 to RMB96.2 million in 2022, which was primarily due to a decrease of the sales volume from 4.6 million units in 2021 to 3.5 million units in 2022 as a result of the reduced customer traffic at pharmacies in light of the impact of the COVID-19 pandemic in 2022.

As a result, our revenue generated from astragalus granule decreased from RMB161.0 million in 2021 to RMB134.1 million in 2022.

2023 Compared to 2022

Sales to hospitals. Revenue generated from sales of astragalus granule to hospitals remained relatively stable from 2022 to 2023.

Sales outside of hospitals. The sales volume of astragalus granule outside of hospitals increased from 3.5 million units in 2022 to 4.5 million units in 2023, as we intensified promotion efforts to large pharmaceutical retail chains after the COVID-19 pandemic eased in 2023, leading to an increase in foot traffic and market demand at pharmacies for our astragalus granule. As a result, the sales amount of astragalus granule outside of hospitals increased from RMB96.2 in 2022 to RMB124.2 million in 2023.

As a result, our revenue generated from astragalus granule increased from RMB134.1 million in 2022 to RMB155.7 million in 2023.

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Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

Our revenue generated from astragalus granule decreased by RMB5.6 million, or 5.7%, from RMB98.0 million in the nine months ended September 30, 2023 to RMB92.3 million in the nine months ended September 30, 2024. The sales volume of astragalus granule decreased from 4.0 million units in the nine months ended September 30, 2023 to 3.4 million units in the nine months ended September 30, 2024, which was primarily due to the increased market demand of and sales for astragalus granule as immune-supporting supplement in light of the increased COVID-19 cases in the first few months of 2023.

Chaihuang granule

Chaihuang granule can be used alone or in conjunction with Western medicine to treat persistent high fever, recurrent fever, and prolonged low-grade fever. It was included in the 2023 NRDL. According to CIC, there were seven types of medicines containing chaihuang, with 35 approved drug products in China as of the Latest Practicable Date, and our chaihuang granule was best-selling chaihuang granule product in China with a market share of approximately 92.4% in 2022. This dominant market presence underscores our product’s efficacy and widespread acceptance in clinical practice. Our chaihuang granule was first approved by the NMPA in October 2002, and we produce our chaihuang granule at our Baili Base, with the current PRC manufacturing permit valid until June 2025. As of September 30, 2024, our chaihuang granule was sold in 29 provinces across China.

Chaihuang granule was not included in any national or provincial VBP scheme. Our product chaihuang granule was sold through both in-hospital and outside-of-hospital channels. The following table sets forth the amount of sales, sales volume and average selling price of chaihuang granule during the Track Record Period:

	Year ended December 31,									Nine months ended September 30,		
	2021			2022			2023			2024		
	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP	Sales amount	Sales volume	ASP
Chaihuang granule	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)	(RMB million)	('000 units)	(RMB)
Sales to hospitals	13.1	711.7	18.5	13.9	811.8	17.1	11.4	644.9	17.8	7.1	396.5	17.9
Sales outside of hospitals	11.2	777.3	14.4	15.0	923.8	16.3	9.9	636.5	15.5	2.6	158.2	16.4
Other ⁽¹⁾	0.0	0.1	8.5	0.0	0.1	10.2	0.0	0.0	7.2	0.0	0.0	27.4
Total	24.3	1,489.1	16.3	28.9	1,735.7	16.6	21.3	1,281.4	16.6	9.7	554.7	17.5

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Note:

- (1) Representing primarily sales from products used for drug testing.

Fluctuation 2022 Compared to 2021

Analysis: *Sales to hospitals.* Revenue generated from sales of chaihuan granule to hospitals remained relatively stable from 2021 to 2022.

Sales outside of hospitals. Our revenue generated from chaihuan granule increased from RMB11.2 million in 2021 and RMB15.0 million in 2022, which was primarily due to the increased market demand of and sales for chaihuan granule to treat fever in light of the increased COVID-19 cases in the fourth quarter of 2022 as compared to 2021.

As a result, our revenue generated from chaihuan granule increased from RMB24.3 million in 2021 to RMB28.9 million in 2022.

2023 Compared to 2022

Sales to hospitals and outside of hospitals. The sales volume of chaihuan granule to hospitals and outside of hospitals decreased from 1.7 million units in 2022 to 1.3 million units in 2023. This decrease was primarily due to the increased market demand of and sales for chaihuan granule to treat fever in light of the increased COVID-19 cases in the fourth quarter of 2022 as compared to 2023. As a result, our revenue generated from chaihuan granule decreased from RMB28.9 million in 2022 to RMB21.3 million in 2023.

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

Our revenue generated from chaihuan granule decreased by RMB5.6 million, or 36.5%, from RMB15.3 million in the nine months ended September 30, 2023 to RMB9.7 million in the nine months ended September 30, 2024. The sales volume of chaihuan granule decreased from 0.9 million units in the nine months ended September 30, 2023 to 0.6 million units in the nine months ended September 30, 2024, which was primarily due to the increased market demand of and sales for anti-fever drugs in light of the increased COVID-19 cases in the first few months of 2023.

Pipeline of Generics Drugs

We are dedicated to expanding our product range by introducing generic drugs that not only have substantial commercial potential but also address critical, underserved medical needs. Notable examples include our sevoflurane for inhalation (an inhalation anesthetic drug), approved in May 2023, and our structural fat emulsion injection product (a parenteral nutrition drug), approved in June 2024. According to CIC, the market size for sevoflurane for inhalation and structural fat emulsion injection (C6-24) within China’s public medical institutions reached RMB3,056.6 million and RMB1,038.7 million in 2023, respectively. Our sevoflurane product has been included in the provincial VBP scheme of Fujian since December 2023. As of the Latest Practicable Date, only one other structural fat emulsion injection product was being sold in China. Further enhancing our portfolio, dexmedetomidine hydrochloride sodium chloride injection, approved in June 2023, quickly established a significant market presence and is included in the national medical insurance negotiation list, propelling the product into a realm of substantial potential and meeting a clear clinical demand, particularly benefiting from a priority hospital admission policy. Despite competition from three other companies, we have achieved fast penetration into hospitals, establishing a competitive edge in a market of considerable size. Additionally, our lineup features the uniquely positioned nifekalant hydrochloride for injection, initially approved in October 2014 for life-threatening ventricular tachycardia and ventricular fibrillation for which we are currently investigating for other

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indications such as atrial fibrillation. There are currently no other nifekalant hydrochloride product approved in China, which provides us with a significant market opportunity as we continue to expand its indications and increase the market education and physician awareness for the product.

As of the Latest Practicable Date, we had over 20 generic drug candidates under development, among which nine had submitted applications for production registration. These candidates cover various therapeutic areas, including oncology, anesthesia, parenteral nutrition, anti-infective, pediatric, cardiovascular, radiology and respiratory. The following table sets forth certain information of selected near-to-market generics candidates:

Therapeutic area	Generic name	Indication	Current status	Date of application	(Estimated) timeline of approval ⁽¹⁾
Oncology Drugs	Calcium levofolinate for injection	Treatment of GC, CC, small intestine cancer, and PC	Application of production registration approved	March 2023	Approved in October 2024
	Cytarabine for injection	Induction remission and maintenance treatment of acute non-lymphocytic leukemia in adults and children	Application of production registration approved	November 2023	Approved in October 2024
	Carboplatin injection	Treatment of OC, SCLC and HNSCC	Application of production registration approved	September 2023	Approved in December 2024
	Pemetrexed disodium for injection	Treatment of NSCLC and malignant pleural mesothelioma	Application of production registration submitted	September 2023	February 2025
	Gemcitabine hydrochloride for injection	Treatment of NSCLC, PC and BC	Application of production registration submitted	December 2023	February 2025
	Raltitrexed for injection	Treatment of advanced colorectal cancer patients unsuitable for 5-FU/leucovorin	Application of production registration submitted	January 2025	April 2026

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Therapeutic area	Generic name	Indication	Current status	Date of application	(Estimated) timeline of approval ⁽¹⁾
Anesthesia Drugs	Etomidate	Intravenous general anesthesia induction agent or anesthesia adjunct	Application of production registration approved	February 2023	Approved in October 2024
	Atracurium besylate	Adjunct in general anesthesia or for sedation in intensive care, this medication enhances muscle relaxation, thereby simplifying tracheal intubation and mechanical ventilation	Application of production registration submitted	July 2024	December 2025
	Dexmedetomidine hydrochloride	Short-acting general anesthetic for the induction and maintenance of general anesthesia in adult and pediatric patients over the age of one month, and for sedation in patients over 16 years of age undergoing mechanical ventilation in intensive care	Application of production registration submitted	May 2024	August 2025
Pediatric Drugs	Guanfacine hydrochloride extended-release tablets	Attention deficit hyperactivity disorder in children and adolescents	Application of production registration submitted	February 2024	February 2025
Cardiovascular Drugs	Nicorandil for injection	Unstable angina, acute heart failure (including acute exacerbation of chronic heart failure)	Application of production registration approved	March 2023	Approved in September 2024
	Nicardipine hydrochloride injection	Emergency management of abnormally high blood pressure during surgery Hypertensive emergency	Application of production registration submitted	August 2024	December 2025
	Sacubitril valsartan sodium tablets	Chronic heart failure, primary hypertension	Application of production registration submitted	January 2025	April 2026

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Therapeutic area	Generic name	Indication	Current status	Date of application	(Estimated) timeline of approval ⁽¹⁾
Radiology	Gadopentetate dimeglumine injection	Whole-body magnetic resonance imaging contrast agent	Application of production registration submitted	July 2023	Approved in January 2025
Respiratory Disease Drugs	Salbutamol sulfate injection	Treatment of respiratory diseases with bronchospasm such as bronchial asthma or wheezing bronchitis	Application of production registration submitted	August 2023	February 2025

(1) The estimated timeline of approval is our best forecast based on past experience and the current application status, which is subject to uncertainties.

LICENSE AND COLLABORATION AGREEMENT WITH BRISTOL-MYERS SQUIBB COMPANY

Overview

On December 11, 2023, we entered into an exclusive license and collaboration agreement with Bristol-Myers Squibb Company (“BMS”), effective as of February 8, 2024 (the “BMS Agreement”), under which we and BMS will conduct a global strategic license and collaboration to co-develop and co-commercialize BL-B01D1, a bispecific ADC which targets both EGFR and HER3 (the “Licensed Product”). Under the BMS Agreement, BMS agreed to pay to us a US\$800 million upfront payment and up to US\$500 million in contingent near-term payments. In addition, we are eligible to receive additional payments of up to US\$7.1 billion contingent upon the achievement of certain development, regulatory and sales performance milestones for a total potential consideration of up to US\$8.4 billion. We and BMS will jointly develop and commercialize the Licensed Product in the U.S. by which we will share certain global development expenses and profits and losses in the U.S., we retained exclusive rights to develop and commercialize the Licensed Product in mainland China where BMS will receive a royalty on net sales, and we granted BMS an exclusive license to develop and commercialize the Licensed Product in the rest of the world (“ROW”) where we will receive a tiered royalty on net sales, subject to certain specified conditions and limitations. As of the signing of the BMS Agreement, we had conducted multiple Phase I/II clinical trials of the License Product in China, targeting a wide range of solid tumors including, among others, NSCLC, SCLC, BC, HNSCC, NPC and EC, and initiated a Phase I study of the Licensed Product in the U.S. The U.S. Phase I study is currently investigating NSCLC, SCLC, BC, EC and NPC.

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Background of the Transaction

BMS, an Independent Third Party, is a leading global pharmaceutical company with US\$45 billion in revenue in 2023. BMS is renowned for its robust clinical development capabilities, extensive sales and distribution network, and a comprehensive oncology portfolio featuring two of the top ten best-selling oncology drugs globally in 2023. After reviewing our publicly available clinical data, BMS initiated discussions about a potential collaboration on the Licensed Product. Recognizing the complexity and significant costs associated with developing a pan-tumor treatment such as the Licensed Product, we entered into the BMS Agreement on December 11, 2023. We believe this collaboration allows us to combine resources, expertise and infrastructure to expedite development and commercialization while effectively managing the associated costs and risks.

Co-development and Co-commercialization by Geographical Regions

In mainland China, we will have the exclusive right to develop and commercialize the Licensed Product at our cost and will have the final decision-making authority with respect to the conduct of such development and commercialization activities, subject to certain specified conditions and limitations. In the ROW, BMS will have the exclusive right to develop and commercialize the Licensed Product at its cost and will have the final decision-making authority with respect to the conduct of such development and commercialization activities, subject to certain specified conditions and limitations.

In the U.S., pursuant to the BMS Agreement, we and BMS have established a joint steering committee as a forum to oversee and coordinate the parties’ activities with regard to the development, manufacture and commercialization of the Licensed Product in the U.S. The joint steering committee will also coordinate and resolve specified issues relating to each party’s activities related to the development, manufacture and commercialization of the Licensed Product in each party’s respective territories that may adversely affect the development, manufacture and commercialization of the Licensed Product in the U.S.

In addition to the joint steering committee, we and BMS have also established (a) a joint development committee, which will oversee and coordinate the development of the Licensed Product in the U.S. and to resolve disputes regarding safety concerns with respect to the development of the Licensed Products in mainland China and ROW and (b) a joint finance committee, which will facilitate and coordinate the reporting of financial information under the BMS Agreement. Prior to the Licensed Product receiving regulatory approval in the U.S., we and BMS will also establish a joint commercialization committee, which will oversee and coordinate the commercialization of the Licensed Product in the U.S. and review and coordinate pricing, discounting and reimbursement matters in mainland China. Each of the foregoing committees consists of equal representation from us and BMS and operates under the oversight and decision-making authority of the joint steering committee.

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Development and Commercialization Activities in the U.S.

In the U.S., the parties shall jointly develop the Licensed Product in accordance with the global development plan as determined by the joint development committee, and share the relevant global development costs according to an agreed-upon percentage, with our share being less than 50%. The joint development committee will review the global development plan for the purpose of considering appropriate amendments to the plan, which sets out, among other things: (a) the targeted indications, proposed clinical studies and related protocols; (b) the estimated timeline and budget; and (c) the allocation of development responsibilities between the parties. All development activities in the U.S. may be conducted jointly by BMS and us, primarily by either party, or outsourced to a third-party, as determined by the joint development committee based on each party's resources and capabilities with the intent of not duplicating efforts. We and BMS have agreed on the initial global development plan and budget for the next few years. Currently, we are designated by the joint development committee as the lead party for conducting the ongoing global, multi-center, dose escalation, dose expansion Phase I clinical trial of the Licensed Product in the U.S.

Prior to the anticipated date of the regulatory approval for the Licensed Product in the U.S., we and BMS will jointly develop and finalize a commercialization plan and budget which will govern the commercialization of the Licensed Product in the U.S. BMS will have the lead role for commercialization of the Licensed Product in the U.S., subject to our right to participate in the commercialization activities in the U.S. that are allocated to us under the commercialization plan.

Manufacturing

For each party's development activities under the BMS Agreement, we are initially responsible for the manufacture and supply of the Licensed Product pursuant to a clinical supply agreement entered between us and BMS, which includes a supply schedule consistent with the global development plan and budget. We will manufacture such Licensed Product via our facilities in China and will ship such Licensed Product to BMS's designated location in accordance with the terms under such clinical supply agreement. BMS has the right to request a transfer of the manufacturing technology. If BMS so requests, following completion of the technology transfer and subject to BMS's reasonable determination, BMS will be responsible for the manufacture and supply of the Licensed Product for the development activities in the U.S. and the ROW, and, upon our request and approval from the joint development committee, for the development activities in mainland China. As of the Latest Practicable Date, we have initiated such manufacturing technology transfer process and expect the initial transfer to be completed by 2025 or 2026. For commercialization in mainland China, we will be responsible for the manufacturing and supply of the Licensed Product, subject to certain rights retained by BMS and specified conditions. For commercialization in the U.S. and ROW, we will manufacture and supply linker and payload for the Licensed Products as well as other components as the parties may agree; and BMS will be responsible for the manufacturing and supply of the finished Licensed Product subject to certain specified conditions, provided that the parties shall discuss in good faith using us as a source for supply.

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Commercial Terms

Pursuant to the BMS Agreement, on March 7, 2024, we received a non-refundable and non-creditable upfront payment of US\$800 million from BMS, which is not subject to any further conditions, and BMS is required to pay up to US\$500 million in contingent near-term payments, which payment amounts are adjusted based on when each prescribed milestone is achieved. Specifically, we are eligible to receive a nonrefundable milestone payment of US\$250 million upon the initiation of the first Phase II or Phase III trial of the Licensed Product as 1L or 2L treatment in the U.S. on or before December 31, 2025, and another nonrefundable milestone payment of US\$250 million upon the initiation of the first Phase III trial of the Licensed Product as 1L treatment in the U.S. on or before December 31, 2026. Such milestones were established through mutual agreement. In the U.S., we initiated a Phase I clinical trial for BL-B01D1 in August 2023 for various solid tumors including NSCLC, BC, SCLC, EC, and NPC, and a Phase I/IIa clinical trial for BL-B01D1 in combination with osimertinib/pembrolizumab in December 2024 for advanced solid tumors. Based on the current pace of clinical progress, we reasonably anticipate that we will be eligible to receive the contingent near-term payments. We and BMS have conducted a Type B end-of-Phase I meeting with the FDA to discuss the clinical development strategy for a registration-enabling study of BL-B01D1 as a 2L treatment of a certain solid tumor, which we and BMS plan to initiate in 2025. Furthermore, we and BMS have conducted a Type B pre-IND meeting with the FDA to discuss the clinical development strategy for a registration-enabling study of BL-B01D1 as a 1L treatment of a certain solid tumor, which we and BMS also plan to initiate in 2025. The initiation of these registration-enabling studies will potentially qualify as the milestone events that will trigger the foregoing two contingent near-term payments by BMS. According to CIC, Type B meetings are typically held at critical junctures in the development process to align development strategies with regulatory expectations, reduce the risk of delays, and ensure readiness for transitioning to the next clinical phase. We are also eligible to receive up to an aggregate of US\$7.1 billion contingent upon the achievement of certain specified regulatory and sales performance milestones for a total potential consideration of up to US\$8.4 billion.

BMS is also required to pay us tiered royalties based on a percentage of aggregate annual net sales of the Licensed Product in ROW ranging from high single-digit to low double-digits, subject to certain customary reductions and a royalty floor. Such royalties are payable on a country-by-country basis from the first commercial sale of such Licensed Product in such country until the latest of (a) the expiration of all valid claims of certain licensed patents and joint patents covering the composition of matter of the Licensed Product in its entirety or its antibody portion in such country, (b) the tenth anniversary of the first commercial sale of such Licensed Product in such country, and (c) the expiration of regulatory exclusivity for such Licensed Product in such country. Under the BMS Agreement, we are required to pay BMS a single-tier royalty of a mid-single-digit percentage of aggregate annual net sales of such Licensed Product in mainland China. Further, under the BMS Agreement, we and BMS will share net profits/losses related to the sales of the Licensed Product in the U.S. according to certain agreed-upon percentages, with our share being less than 50%, which percentage is higher than our proportion of the shared development costs in the U.S.

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Intellectual Property

Under the BMS Agreement, each party retains the sole and exclusive ownership of its respective intellectual property rights, including all intellectual property rights that are solely developed by such party, its affiliates or its and its affiliates’ sublicensees under the BMS Agreement or are owned or otherwise controlled by such party, its affiliates of its or its affiliates’ sublicensees independent of the BMS Agreement. The parties will jointly own any intellectual property rights that are developed jointly by the parties under the BMS Agreement. BMS has the first right to prosecute, maintain, defend and enforce against any infringement by a competing product, certain specified licensed patent rights and joint patents in the U.S. and the ROW, but we have the first right to prosecute, maintain, defend and enforce against any infringement by a competing product, any licensed patent rights and joint patents in mainland China.

Dispute Resolution

If there is any dispute between the parties (a) with respect to approval of the development of the Licensed Product in mainland China or ROW in a dose, formulation or indication that is not substantially similar to the dose, formulation or indication for which the Licensed Product is being developed under the development plan and budget or for which it receives regulatory approval in the U.S., subject to certain specified exceptions, we and BMS will have final decision-making authority in our respective territories, (b) with respect to any action proposed by us in mainland China or by BMS in ROW, for which the other party raises a concern that such proposed action has a material adverse impact on the development or commercialization of the Licensed Product in the U.S., such dispute shall be resolved by the expedited dispute resolution procedures set forth in the BMS Agreement, which is an expedited arbitration procedure where the parties will jointly select an independent, impartial and conflicts-free neutral to preside in the resolution of issues with specific timeframe for each step and deadlines as prescribed in the BMS Agreement; and (c) except for (i) amending the global development plan and budget to allocate activities to us without our consent, (ii) amending the aggregate budget under the global development plan and budget or the commercialization plan for the U.S. without our consent, (iii) developing any fixed dose combination product of the Licensed Product with another active ingredient controlled by BMS or its affiliates or sublicensees in the U.S. or certain European countries without our consent, and (iv) determining whether any action of a party is reasonably expected to have materially negative impact on the development or commercialization of the Licensed Product in the other party’s respective territory (collectively, the “Exclusion Matters”), with respect to all other issues under the purview of the joint steering committee, if such issues cannot be resolved through a collaborative process, BMS shall have the final decision-making authority. For the Exclusion Matters, BMS may not exercise final decision-making authority without our consent. If the parties cannot reach an agreement on the Exclusion Matters, such dispute shall be resolved by the aforementioned expedited dispute resolution procedures.

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Termination

Unless earlier terminated by either party, the BMS Agreement will expire on the later of (a) the expiration of all of our and BMS’s royalty payment obligations in mainland China and ROW, respectively or (b) upon the parties’ mutual agreement to cease all exploitation of the Licensed Product in the U.S. Each Party has the right to terminate the BMS Agreement for the other party’s certain specified uncured material breach or insolvency. We may terminate the BMS Agreement in its entirety if BMS or any of its affiliates and its and their sublicensees commences a legal action challenging the validity, enforceability or scope of any of certain specified patent rights that are owned or otherwise controlled by us. BMS may terminate the BMS Agreement, in its entirety or on a country-by-country basis, without cause by giving us at least 90 days’ prior written notice, if such termination is before the first commercial sale of the Licensed Product in the U.S. or ROW, or at least 6 months’ prior written notice, if such termination is thereafter, subject to our right to extend the effective date of such termination up to a specified time period. In addition, BMS may terminate the BMS Agreement immediately by written notice to us if such termination is necessary to protect the safety of patients due to a material safety issue.

RESEARCH AND DEVELOPMENT

Research and development is a fundamental pillar of our business and will continue to be critical to our future growth and our ability to remain competitive in the global biopharmaceutical market. In 2021, 2022, 2023 and the nine months ended September 30, 2024, our research and development expenses were RMB278.6 million, RMB375.0 million, RMB746.2 million and RMB931.7 million, respectively. Our in-house R&D capabilities revolve around our three core technology platforms: HIRE-ADC, GNC, and SEBA, which in turn serve as the foundation for our continued drug innovation. These platforms underpin our capabilities in ADCs and bispecific and multi-specifics and can be applied for a broad range of oncological indications and other diseases.

Our R&D Capabilities

Our R&D Facilities

We currently have three R&D facilities, namely our SystImmune R&D Center in Seattle, U.S., and Baili Pharm R&D Center and Baili-Bio R&D Center in Chengdu, Sichuan Province, PRC. These facilities collaborate closely to drive the development of innovative therapeutics from early discovery to clinical application, ensuring that our drug development remains robust, efficient, and geared towards meeting global healthcare needs.

SystImmune R&D Center. Our SystImmune R&D Center is dedicated to the development of cutting-edge biopharmaceuticals. With a GFA of nearly 1,300 sq.m. housing an array of cutting-edge R&D equipment, our SystImmune R&D Center is capable of antibody discovery, engineering and construction of antibodies, initial high-throughput screening, and further

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humanization, selection, and optimization processes. By conducting these research activities, the SystImmune R&D Center plays a crucial role in identifying and developing innovative drug compounds for our subsequent development efforts.

Baili-Bio R&D Center. Building on the 0-to-1 innovations made in SystImmune R&D Center, our Baili-Bio R&D Center takes charge of the advanced development stages of innovative drug candidates. Covering a total GFA of approximately 3,500 sq.m., our Baili-Bio R&D Center is responsible for our preclinical pharmacology and toxicology evaluations, pilot-scale process development, quality research, and clinical studies in China. The Baili-Bio R&D center features a range of advanced equipment, this center is furnished with to enhance efficiency and drive our research and development efforts forward.

Baili Pharm R&D Center. Our Baili Pharm R&D Center mainly focuses on the research and development of complex generic drug candidates, with a total GFA of nearly 2,800 sq.m. This center leads the development of essential and specialized chemical formulations in anesthesia, parenteral nutrition, anti-infectives, and pediatrics. Our investment in the research and development of complex generics has yielded significant breakthroughs, enhancing quality while maintaining stringent cost control.

Our R&D Team

Aiming to validate innovative ideas efficiently and cost-effectively, we have structured our R&D capabilities across U.S. and China. As of September 30, 2024, we had an R&D team of 1,006 members across our offices in China and the U.S., accounting for approximately 41.9% of our total employees. As of the same date, 69.9% of our R&D staff focuses on innovative drug discovery and development, while 30.1% focuses on the R&D of generics and traditional Chinese medicines. Over 200 of them held a master’s or higher degree, mainly in medical science, pharmacology, biology, and chemistry. Our R&D team comprises talents with extensive experience in drug discovery, preclinical development, CMC, clinical development and regulatory affairs, spanning the entire R&D cycle for innovative drugs. Many of them have years of experience in driving drug discovery and development programs at leading multinational companies and domestic biopharmaceutical companies, such as BMS, Merck, Eli Lilly, Pfizer, Novartis, Amgen, Sanofi, Hengrui and BeiGene, and renowned research institutes such as MD Anderson Cancer Center and Fred Hutchinson Cancer Center, as well as the FDA.

Our R&D team is spearheaded by Dr. Zhu Yi, the visionary founder of our Group, who also serves as the chairman of the Board, the executive director, general manager and Chief Scientific Officer of our Company. With over three decades of experience in the healthcare industry, Dr. Zhu’s academic journey began with a bachelor’s degree in radio physics from Sichuan University (四川大學) in 1984, followed by a master’s degree in biology from Fudan University (復旦大學) in 1987, and culminating in a doctoral degree in management from Sichuan University (四川大學) in 2008. Before establishing our Group, Dr. Zhu taught in the Department of Microbiology and Immunology at West China University of Medical Sciences

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(華西醫科大學) (currently known as West China Medical Center of Sichuan University (四川大學華西醫學中心)) from 1987 to 1990. For further details of Dr. Zhu Yi’s biographies, please refer to the section headed “Directors, Supervisors and Senior Management.”

In addition to Dr. Zhu Yi, core members of our R&D team who specializes in the R&D of innovative drugs include Dr. Jie D’Elia, Dr. Jonathan Cheng, Dr. Jahan Khalili, Dr. Zhu Hai, and Mr. Zhuo Shi. Dr. Jie D’Elia has been the chief executive officer of SystImmune since April 2024, bringing extensive experience from her previous roles, including senior vice president for business development in oncology, hematology, and cell therapy at BMS, as well as positions at AstraZeneca, Boston Consulting Group, Baxter Healthcare, and Simcere Pharmaceutical. Dr. Jie D’Elia holds a Ph.D. from the College of Pharmacy at the University of Texas at Austin and an MBA from Columbia Business School.

Dr. Jonathan Cheng, the chief medical officer of SystImmune, boasts a rich background in both the pharmaceutical industry and academia. Before joining SystImmune, he served as senior vice president and therapeutic area oncology head at BMS, where he led the late-stage clinical development of several key oncology treatments. Dr. Cheng has also held a significant role at Merck Research Laboratories. His academic tenure includes research at Fox Chase Cancer Center. Dr. Cheng earned his bachelor’s degree from Marquette University and his medical degree from the University of Minnesota.

Dr. Jahan Khalili, who serves as R&D senior vice president, principal scientist and head of immune-oncology department of SystImmune, joined SystImmune in May 2018. Dr. Khalili previously worked at Gregory Lizee’s Lab at the University of Texas Health Science Center, Houston & MD Anderson Cancer Center, and served as a postdoctoral researcher in the Department of Melanoma Medical Oncology at MD Anderson Cancer Center. He received his doctoral degree in immunology from the University of Texas Health Science Center at MD Anderson Cancer Center.

Dr. Zhu Hai, the executive director of our Group and the Chief Technology & Data Officer of SystImmune, is deeply involved in research and development and management of SystImmune. Prior to joining SystImmune, Dr. Zhu Hai served as a researcher at the Center of Drug Evaluation and Research of FDA from June 2019 to August 2019. Dr. Zhu Hai obtained a bachelor’s degree in astronomy and space science from Nanjing University (南京大學) in the PRC in June 2011, a master’s degree in mathematics and statistics from Georgetown University in the United States in May 2013 and a doctoral degree in biostatistics from the University of Texas Health Science Center at Houston in the United States in December 2019. For further details of Dr. Zhu Hai’s biographies, please refer to the section headed “Directors, Supervisors and Senior Management.”

Mr. Zhuo Shi, the executive director of our Group and the general manager of Baili-Bio, has over 13 years of experience in the biopharmaceutical industry. He joined Baili Pharmaceutical in 2011 and has been successively serving as its researcher at research and development center, project manager, director and the deputy general manager at the research and development center since then to 2019. Mr. Zhuo obtained a bachelor’s degree in

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biotechnology from Peking University (北京大學) in the PRC in July 2008 and a master’s degree in ecology from Indiana University Bloomington in the United States in December 2010. For further details of Mr. Zhuo’s biographies, please refer to the section headed “Directors, Supervisors and Senior Management.”

In China, we also have a highly skilled chemical drug R&D team led by our deputy general manager, Dr. Wan Weili. From September 2014 to June 2023, Dr. Wan held various positions, including the project manager, department manager, and director of the small molecule drug division at the new drug R&D center of Baili Pharmaceutical and the director of the small molecule drug division of Baili-Bio. Since July 2023, he has served as the deputy general manager of our Group and the general manager of our R&D centers located in Chengdu, responsible for building the ADC linker-payload platform and overseeing the comprehensive management of active pharmaceutical ingredient (API) and formulation research and development. Mr. Wan obtained a doctoral degree in medical chemistry from Sichuan University (四川大學) in the PRC in June 2014.

We have established a comprehensive and well-rounded drug research and development system comprising various core departments, which include research departments focusing on biologics, small molecules, formulations, and quality standards, among others. Additionally, with our commitment to advancing drug development through collaboration and extensive expertise, our U.S. subsidiary, SystImmune, established a clinical scientific advisory committee consisting of four globally renowned oncology clinical experts, Dr. Hope Rugo, Dr. Sara Tolaney, Dr. Pasi Jänne, and Dr. Helena A. Yu. Serving as our external clinical trial advisors, these experts provide invaluable insights and guidance to enhance our clinical programs, particularly in ADC drug development.

Embracing a paradigm of project-oriented governance and matrix-style management, our R&D teams integrate their specialized knowledge to develop projects from conception to fruition under the leadership of project managers. Each R&D project begins with research and evaluation conducted by key members from each technology platform, and will take into account factors such as clinical value, market trends, competitive landscape, and technological barriers, to select product candidates for approval. These proposals are then carefully scrutinized and assessed for approval by a committee comprising leaders from each technology platform. For projects that are approved for further development, we designate a project manager, who will establish and lead a core project R&D team comprising of members from pharmaceutical research, pharmacology and toxicology research, process development, and quality control within the technology platforms. This core team then develops detailed R&D plans and strategies to ensure the smooth execution of the R&D project in a time- and cost-efficient manner.

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Collaboration with Third Parties

Collaboration with external R&D partners is a major component of our R&D strategy. Our strong in-house R&D capabilities, proven track record, and established manufacturing and commercial operations make us a preferred partner in the pharmaceutical market. In addition to our collaboration with BMS for BL-B01D1, we also have joint R&D collaborations with universities and research institutions.

We maintain strong cooperative relationships with a variety of trial sites (i.e., hospitals) and principal investigators (PIs) to support our clinical trials for different indications at various stages. Our medical and clinical trial team is tasked with formulating trial protocols and selecting and engaging trial sites and PIs to carry out these trials. The PIs, who are generally physicians or researchers at the trial sites, lead the clinical trial activities for our drug candidates.

We do not have direct agreements with PIs other than confidentiality agreements to ensure they meet confidentiality obligations. In accordance with the laws and regulations, we enter into clinical trial cooperation agreements with the clinical trial sites that the PIs belong to and settle the fees and expenses with those sites. The below sets forth key terms of our framework agreements with clinical trial sites on clinical trial cooperation:

- ***Trial Materials.*** We furnish the clinical trial sites with trial protocols and other trial-related documents, investigational drugs, consumables, and necessary research funding.
- ***Monitoring and Compliance.*** We appoint qualified monitors to oversee the adherence to Good Clinical Practice (GCP) standards, review protocol deviated cases, and review clinical data to protect the safety of subjects and ensure the integrity of trial results.
- ***Qualification of PI.*** The clinical trial site is responsible for reviewing the qualifications of PIs and their research team to ensure their qualification.
- ***Data Management and Reporting.*** The clinical trial site shall organize all related trial documents and provide us with accurate case report forms and other required written materials. These materials must comply with the clinical research protocol, national regulations, and our requirements as stipulated in the agreement.
- ***Costs and Funding.*** We typically cover the expenses for trial participants, typically include the costs of medical examinations and treatment, and compensation for time and effort to participants, such as their meals and travel costs.
- ***Confidentiality.*** The clinical trial site is obliged to maintain the confidentiality of the agreements and any trial-related materials.

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- ***Intellectual Property.*** We retain full intellectual property rights and associated interests over all case report forms, original records, trial content and results, and any other technical data generated during the clinical trial at the clinical trial site. The clinical trial site is prohibited from using or transferring these materials without our explicit permission.
- ***Insurance and Liability.*** We provide clinical trial liability insurance for participants, as mandated by law. In the event of trial-related injuries, both parties shall share responsibility for economic compensation and other consequences based on the degree of fault.
- ***Termination.*** Typically, we have the right to terminate the clinical trial provided we give the prior written notice to the clinical trial site.

While we primarily rely on our in-house capabilities in managing and conducting preclinical and clinical studies of our pipeline drug candidates, in line with industry practice, we also engage domestic and international CROs and site management organizations (SMOs) to support our internal team.

Our in-house team conducts most of our preclinical drug R&D activities and clinical development activities, while engaging contractors for tasks that are either not cost-effective to manage internally or require specialized licenses and qualifications. In the preclinical stage, we internally develop our drug candidates from discovery to IND submission. We mainly engage preclinical CROs to conduct toxicology studies on animals, which require specific licenses and qualifications, along with certain testing activities related to CMC. In the clinical stage, our internal clinical development team handle most of the critical functions of a clinical trial, including the trial design, clinical research monitoring, data monitoring and analysis, as well as decision-making, thereby ensuring the quality and efficiency of our clinical trials. We mainly involve SMOs to coordinate patient screening and enrollment and support the day-to-day site management, and also engages some contractors to test clinical samples. Additionally, we engaged clinical CROs in the U.S. to provide a comprehensive suite of services to support the implementation and management of our ongoing Phase I trial of BL-B01D1. At the trial’s inception, we had limited INDs abroad and were in the early stage of establishing our clinical operations capacity in the U.S. As the number of international trials has grown, we have progressively enhanced our in-house clinical research capabilities in the U.S.

For preclinical R&D, our expenses attributable to preclinical CROs accounted for 14.5%, 7.5%, 10.3% and 7.0% of our total research and development expenses in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively. For clinical trials, the expenses attributable to SMOs and CROs accounted for 3.9%, 6.2%, 10.8% and 10.6% of the total research and development expenses for the same periods, respectively.

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We have established a comprehensive mechanism for the selection, evaluation, and management of these partnerships, ensuring compliance while reducing R&D costs and enhancing the efficiency of our development efforts. Based on the service requirements of each project, we typically select at least two or more CROs to participate in competitive bidding and negotiations, and have alternatives in place for each service supplier. We generally enter into framework agreements with CROs and we have executed statements of work on a project basis. The below sets forth key terms of our framework agreements with CROs:

- ***Service.*** The CROs provide us with specified services related to product development, including clinical trial management, patient recruitment, data collection and analysis, monitoring and reporting, among others, according to the project requirements agreed in advance.
- ***Term.*** The CROs shall deliver their product development services at an acceptable quality within the specified timeframe, typically ranging from one and a half years to five years.
- ***Payments.*** We typically pay CROs an initial payment upon the execution of the agreement and make subsequent payments contingent upon the CRO meeting specific project milestones. We generally reconcile all payments against the deliverables provided by the CRO at the conclusion of the project.
- ***Intellectual property rights.*** All intellectual property rights arising from the product development project and any derivative intellectual property rights therein shall be owned by us.
- ***Confidentiality.*** The CROs shall comply with Good Clinical Practice (GCP) guidelines to protect participant privacy and shall not disclose any trial-related information, including trial plans, progress reports, or related data, to unauthorized personnel or entities, as stipulated in the contract.
- ***Quality assurance.*** In the event of any issues, the CRO shall be required to implement corrective actions within a specified timeframe, ensuring compliance with GCP guidelines and the predefined acceptance standards of the project.
- ***Allocation of liability.*** CROs must adhere to all applicable laws, regulations, and industry standards throughout the research process. Generally, CROs shall indemnify us losses resulting from their negligence, intentional misconduct or breach of its obligations under the agreement.

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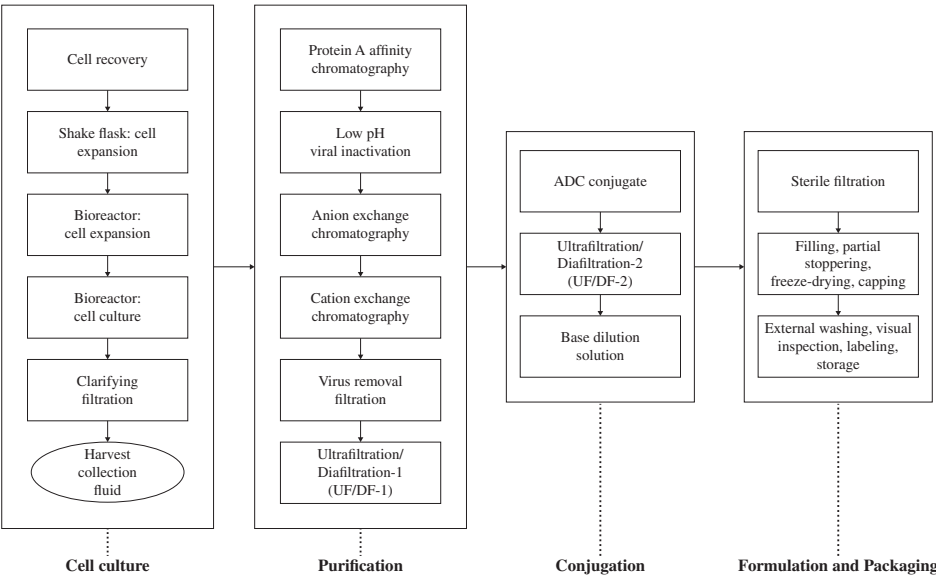
Manufacturing Process

We manufacture all of our innovative drug candidates and our marketed drug products on our own, which are in a variety of dosage forms, including injections, tablets, capsules, and granules. As part of our manufacturing operations, we continuously devise strategies to efficiently manage costs, maintain quality standards, and ensure consistent market supply.

We operate different production processes for our pharmaceutical products and active pharmaceutical ingredients.

Biologics

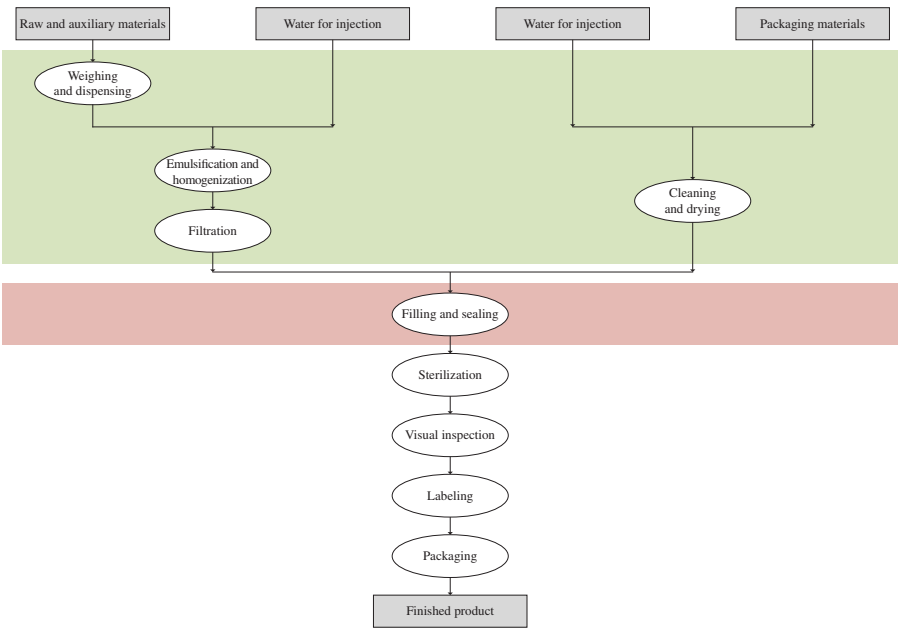
Our biologics drug candidates under development mainly include ADCs, bispecific and multi-specific antibodies. The typical production process for ADCs is illustrated in the following flowchart:



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Fat Emulsion Products

The fat emulsion products manufactured by us include propofol medium and long chain fat emulsion injection, propofol injectable emulsion, and medium and long chain fat emulsion injection, among others. The typical production process for these products is illustrated in the following flowchart:

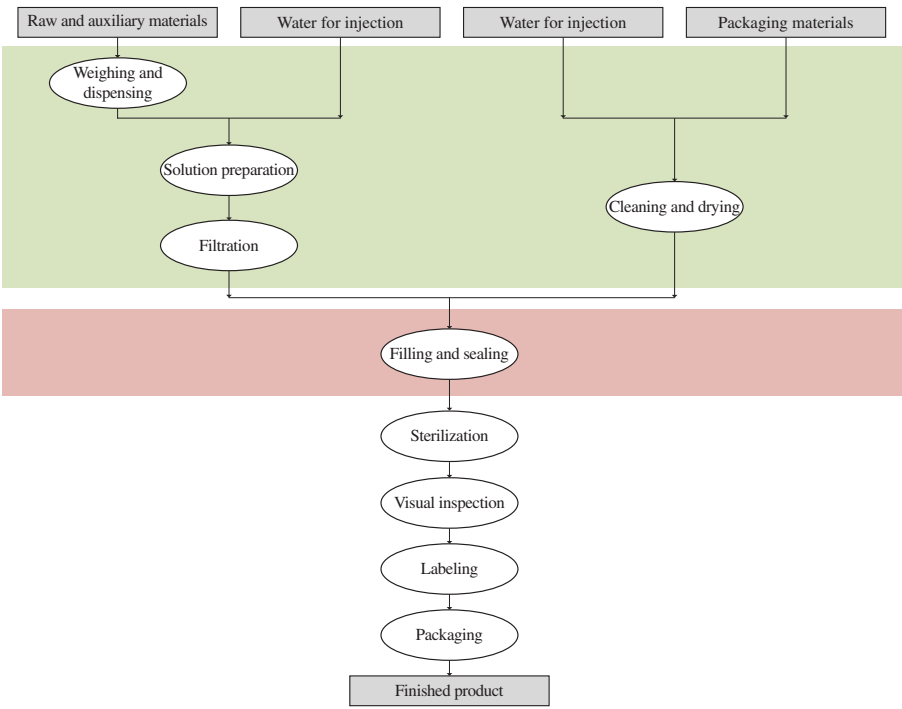


Notes  denotes operating in a Class C clean area;  denotes operating in a Class A clean area with a Class C background.

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Injectable Products

The injectable products manufactured by us mainly include, among others, dexmedetomidine hydrochloride injection. The typical production process for these products is illustrated in the following flowchart:

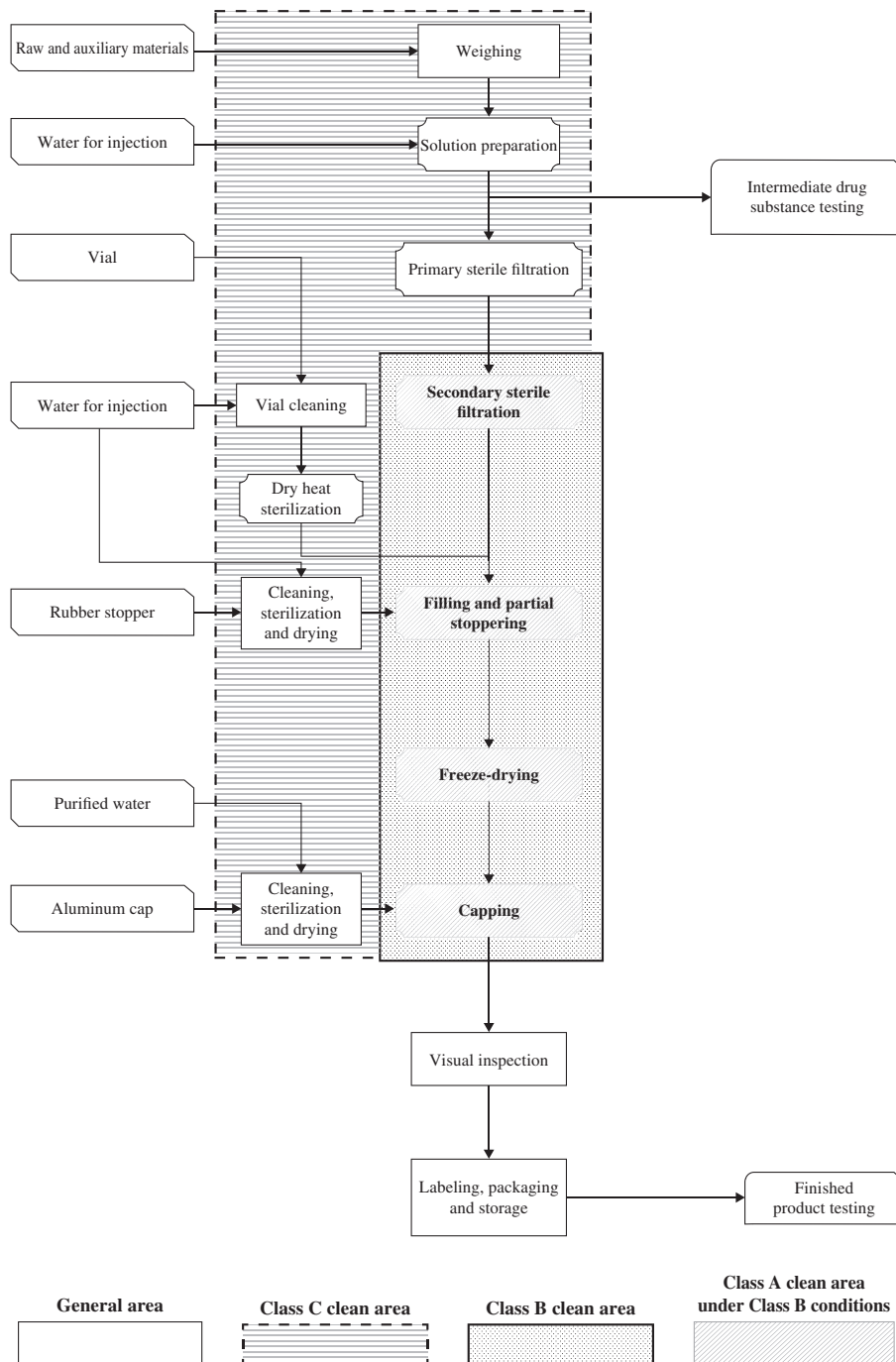


Notes: denotes operating in a Class C clean area; denotes operating in a Class A clean area with a Class C background;

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Lyophilized Powder Injection Products

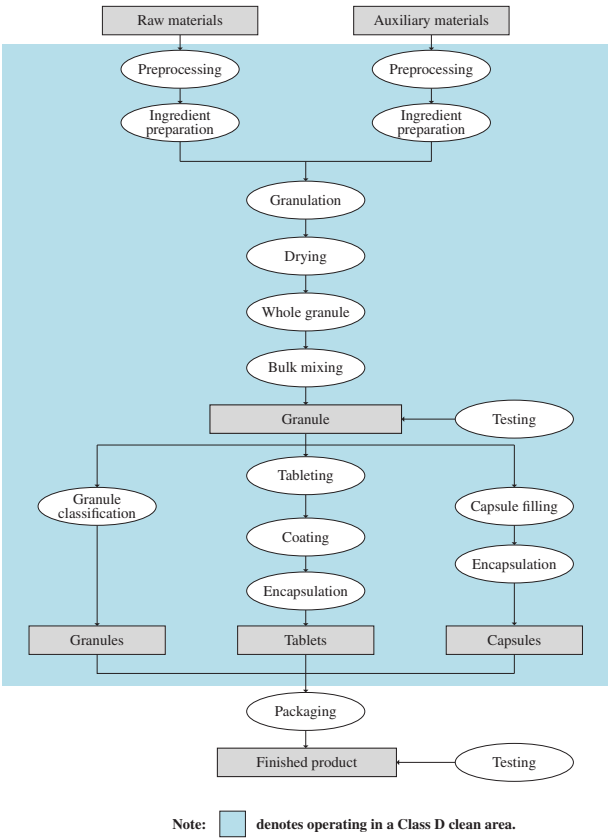
We also manufacture certain lyophilized powder injection products. The typical production process for these products is illustrated in the following flowchart:



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Granules, Tablets, and Capsules

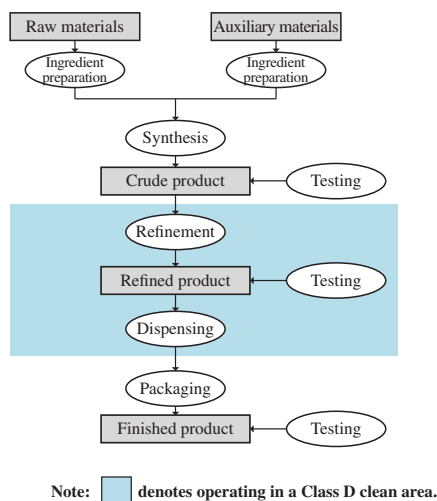
We manufacture a variety of granules, tablets and capsules, such as astragalus granules, ornidazole capsules and enocitabine capsules. The typical production process for these products is illustrated in the following flowchart:



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Active Pharmaceutical Ingredients (“APIs”)

The majority of the APIs used in our drug products are obtained through our own chemical synthesis processes. The typical production process for our APIs is illustrated in the following flowchart:



Manufacturing Facilities

We currently have four manufacturing facilities, namely Guorui Base, Baili Base, Hiatt/Jingxi Base and Baili-Bio Base, all of which are located in the Sichuan Province. We strictly carry out maintenance and repair work in compliance with applicable requirements and we replace or upgrade our production equipment when necessary to enhance productivity. During the Track Record Period and up to the Latest Practicable Date, we obtained production licenses for all of our production bases and marketing approvals for each of our marketed products. For details, see “— Licenses, Permits and Approvals.” With comprehensive and advanced manufacturing system and facilities, we believe we can swiftly and seamlessly support clinical trials of our drug candidates and supply for our commercialized products.

Innovative Biologics

We have established several production workshops for our innovative drugs in our Baili-Bio Base in Chengdu, Sichuan Province, which forms a robust foundation for our clinical studies. As of September 30, 2024, our manufacturing team focusing on the production of innovative biologics in our Baili-Bio Base consisted of over 250 employees. With a GFA of approximately 23,000 sq.m., our Baili-Bio Base houses various workshops, covering the full cycle of cell culture, antibody purification, ADC conjugation, filling, lyophilisation and packaging.

We have established a cell culture workshop and a purification workshop for the production of high-quality antibodies. Our cell culture workshop features six 2,000 L bioreactors and one 1,000 L bioreactor, which provides a precisely controlled and scalable

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environment for large-scale cell growth. These single-use bioreactors significantly reduce the cross-contamination between batches and products, further enhancing the flexibility of our production facilities and ensures the sustainability and reliability of our R&D efforts. Our purification workshop houses various advanced equipment, such as the AKTA process chromatography system and ultrafiltration equipment, allowing us to efficiently separate and purify cell products and further produce antibodies with high quality and purity.

Further, we conjugate such antibodies produced in-house with payload in our ADC conjugation workshop. The advanced 1,000 L conjugation reactor and automated conjugation systems in this conjugation workshop ensures the efficient synthesis and consistency of ADCs. Together with the ultrafiltration system and isolator system that effectively ensure the quality of the ADC drug substance, our facility is designed to produce more than 100 batches of ADC drug substance annually.

In addition, we have one preparation production line for final product filling and lyophilization. With advanced, fully automated production equipment such as automatic vacuum freeze dryer (自動真空冷凍乾燥機), standing ultrasonic cleaning machine (立式超聲波清洗機), and tunnel sterilization dryer (隧道式滅菌乾燥機), we possess advanced large-scale production capabilities for lyophilized powder injections. Through stringent quality control procedures, we ensure the safety and stability of our final products. The annual production capacity of our Baili-Bio Base is up to 100 IND or clinical batches (each batch being 1,000L/2,000L), depending on the candidate drug being produced. We are confident that with the current production capacity of our Baili-Bio Base, we are prepared to support IND applications, clinical trials and future commercialization for our pipeline drug candidates.

To further support the clinical trials and future commercialization of our innovative drugs, we are rigorously assessing the expansion of our Baili-Bio Base. We plan to build new production workshops to facilitate the conjugation of our ADCs and the production of lyophilized powder injection. We believe this expansion will allow us to meet the growing demand for ADC and antibody drug candidates, including BL-B01D1, in clinical trials and future commercial sales. Construction of these new production workshops is expected to be completed in the second half of 2025. We estimate the total cost of the constructions at approximately RMB80 million, which will be funded by our own resources.

Marketed Drugs

We have strategically established an “API — finished pharmaceutical products” manufacturing platform for generic drugs and traditional Chinese medicine through synergy among three facilities: Hiatt/Jingxi Base for intermediates and chemical APIs, Guorui Base for injection products and oral preparation products, and Baili Base for oral solid preparations and freeze-dried powder injection products. These production facilities are fully equipped with advanced automated equipment, which enables us to conduct commercial-scale manufacturing in an efficient manner, such as boiling granulator (沸騰制粒機), liquid filling and capping machine (液體灌裝旋蓋聯體機), standing ultrasonic washing machine (立式超聲波清洗機), tunnel sterilization dryer (隧道式滅菌乾燥機), high-pressure homogenizer (高壓均質機) and

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YK-160 Pharmaceutical Swing Pellet Granulator Machine (YK160搖擺式顆粒機), and double layered glass reactor (雙層玻璃反應釜). This manufacturing platform integrates the manufacturing processes from raw materials to finished drug products, ensuring consistent and sufficient supply for commercial sales of our products.

As of the Latest Practicable Date, our manufacturing facilities for commercialized drug products occupied an aggregate site area of approximately 240,209 sq.m. and had an aggregate GFA of approximately 132,145 sq.m, housing a total of 20 production lines for our major approved drugs. The following table sets forth a summary of our manufacturing facilities for our major products as of the Latest Practicable Date.

<u>Facility</u>	<u>Location</u>	<u>Site Area</u> (sq.m.)	<u>GFA</u> (sq.m.)	<u>Major Products Produced</u>
Guorui Base	Leshan, Sichuan Province	79,920	50,086	Propofol injectable emulsion, dexmedetomidine hydrochloride injection, propofol medium and long chain fat emulsion injection, and medium and long chain fat emulsion injection
Baili Base	Wenjiang, Sichuan Province	126,940	61,430	Astragalus granule, ornidazole capsule, chaihuan granule, glucose electrolyte effervescent tablet, ribavirin granule, and racecadotril granule
Hiatt/Jingxi Base	Qionglai, Sichuan Province	33,349	19,840	Propofol crude drugs

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increase in its market demand, and our medium and long chain fat emulsion injection did not participate in the national VBP scheme in 2021, we reallocated the majority of our production capacity to 50ml injection specifications in 2022, resulting in more vials designed to be produced. Thus, the designed production capacity, measured in vials, increased in 2022, and following that, the utilization rate decreased in 2022 and 2023.

Driven by the increased demand of Lewejing (propofol injectable emulsion) following its specification 50ml:0.5g winning in the bidding process under the ninth batch of the national VBP scheme at the end of 2023, our production volume of the 50ml propofol injectable emulsion specifications significantly increased in the nine months ended September 30, 2024, while our production volume of injections with a specification over 50ml decreased in the same period. Therefore, the aggregate production volume of large volume injections exceeds the vials designed to be produced, leading to the utilization rate over 100% in the nine months ended September 30, 2024, while the production capacity measured by milliliters (ml) remained relatively stable.

(4) Small volume injections refer to injections with a specification less than 50ml.

The utilization rate decreased in the nine months ended September 30, 2024, primarily due to reduced production of our 10ml:0.1g and 20ml:0.2g propofol injectable emulsion, following a decline in demand as these specifications were not included in the ninth batch of the national VBP scheme.

(5) The utilization rate of capsule production line decreased from 2022 to the nine months ended September 30, 2024, primarily due to reduced production of our ornidazole capsules as we observed declined demand in the respective period.

(6) The utilization rate of tablet production line decreased in the nine months ended September 30, 2024, primarily due to reduced production of our glucose electrolyte effervescent tablets as we observed declined demand in the respective period.

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We meticulously monitor our production capacity in real-time and dynamically make adjustments based on current conditions and future projections. We also plan to establish new production lines to meet the ever-evolving market demand for our marketed products as needed.

Supply Chain Management

We have a dedicated procurement team overseeing our supply chain management and procurement practice. In alignment with GMP standards, we have established comprehensive systems for our procurement processes and supplier management.

We have stringent supplier selection procedures in place. Our suppliers are required to hold all the necessary licenses and permits for their operations and need to pass our assessment in terms of various criteria, including product types, quality control, corporate management, reputation, business scale and pricing. We require all suppliers that pass such assessment to deliver sample products in small batches first, so that we can carefully inspect them to ensure they can meet our stringent quality standards. Suppliers that pass the documents and sample inspection tests are included in our qualified supplier list. We only source our raw materials for such qualified supplier list. We routinely assess our suppliers’ performance and verify their qualifications and update the approved suppliers list regularly. Suppliers that fail to meet our requirements will be removed from the approved list.

We strategically designed two procurement strategies based on the different characteristics of our products. For our established products with stable market demand and production scale, our procurement team makes annual tender procurement plans based on the annual material requirements and purchasing schedules provided by the production department, as adjusted on a regular basis in response to changes in production demands. For our new products, as well as for major raw materials with significant price fluctuations, auxiliary materials, and materials required for new drug development, the procurement team efficiently manages the procurement of relevant materials in response to the demands from the production or research departments.

SALES AND MARKETING

During the Track Record Period, we generated revenue from the sales of 29 approved drug products with over 100 specifications, which includes both generics (covering a wide range of therapeutic areas such as anesthesia, parenteral nutrition, anti-infective and pediatric drugs) and traditional Chinese medicine products. We generate demand for our pharmaceutical products mainly through our in-house sales and marketing team, which conducts comprehensive marketing activities to promote our products. In addition, we have built strong collaborations with local promoters and distributors to enhance the brand recognition and market acceptance of our products.

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In-House Sales and Marketing Team

Our sales and marketing network is a key component of our sales and marketing strategy. We have established a comprehensive sales and marketing system that spans over 30 provinces and 200 cities across China, which ensures that our products reach all major markets as well as urban, county, and township areas.

Our sales and marketing strategies are implemented by our in-house sales and marketing team that are aligned across various therapeutic areas and geographic regions. As of September 30, 2024, our dedicated sales and marketing team comprised of 174 experienced professionals with strong sales capabilities and experience to support systematic planning and efficient network operations.

Our sales and marketing team is responsible for product positioning research, market planning, business policy formulation, academic education activities, product tendering, price maintenance, sales contract management, and all other critical supporting functions for our marketing channels. To achieve deep and specialized marketing in differentiated markets, we have implemented a business division structure within our sales and marketing team, with each business division responsible for sales and promotion of specific products across various sales channels. For example, the prescription only pediatrics business division specializes in the sales of pediatric prescription drugs, and the cardiovascular business division is devoted to selling cardiovascular prescription drugs. This specialization ensures focused expertise, effective marketing strategies, and agile responses to market changes, enhancing our overall market effectiveness and customer satisfaction.

We regularly provide in-house and external trainings to enhance the industry knowledge and marketing skills of our sales and marketing team. We place a particular emphasis on training our sales representatives, who are categorized into different levels based on their experience and capabilities and receive tailored mandatory and elective training. We have also put in place strict compliance measures and policies for our sales and marketing personnel. Our employment agreements contain standard compliance clauses and we regularly organize trainings to emphasize the importance of regulatory compliance with the applicable PRC laws and regulations.

Marketing Activities

We organize, sponsor and participate in a wide variety of academic conferences, seminars and symposia to continuously enhance our brand recognition. We also engage in routine academic discussion with medical experts and other healthcare professionals in our target therapeutic areas. Through these active communications and interactions, knowledge sharing sessions and discussions on the clinical benefits and potential of our products with KOLs and other healthcare professionals, we believe we are able to enhance their understanding of the clinical efficacy, safety and potentials of our drug products, and improve our brand image. In addition, collaborating with leading academic institutions and research organizations to conduct clinical trials increases our visibility.

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To supplement our in-house sales and marketing capabilities, we engage third-party promoters to collect market data relating to hospitals, product flow, and other market conditions. This allows us to gain a deep understanding of regional markets, while also helping us track the distribution of our products. Data gathered through this process effectively guides our future product promotion plans and resource allocation for market expansions. Additionally, we also engage third-party promoters for their research and consultation services, in order to stay updated on changes in the pharmaceutical market and the drug market size. Leveraging targeted market research based on promotional needs or changes in market conditions and sales performance, we perform timely analysis and strategically plan our promotional efforts for the next phase.

Further, we continuously enhance and refine our marketing strategies for generic drug products to align with national policies and regulatory requirements. Our robust marketing infrastructure and dedicated team efficiently cater to diverse market segments, including both the prescription drug market and OTC drug market where we reinforce our established product brands and increase the market penetration of our approved products.

We carry out the marketing activities in strict compliance with relevant laws and regulations in PRC. We have never engaged in any form of payment or commercial bribery to any medical institutions, regulatory agencies, or healthcare professionals through organizing or sponsoring academic conferences, seminars, or other promotional activities. Furthermore, we have never paid any fees to other entities or individuals through promotion service providers. Our agreements with third-party promoters include anti-bribery clauses where both parties commit to opposing all forms of commercial bribery, which explicitly prohibit the use of money or other means in the name of any company, individuals, or their relatives to bribe medical institutions, healthcare professionals, regulatory agencies, or individuals (including their relatives) during the promotion of our products. During the Track Record Period and up to the Latest Practicable Date, neither we nor any of our directors, supervisors, or senior management have been penalized by regulatory authorities for commercial bribery, nor have they been investigated by the PRC authorities or found guilty by the PRC courts for such conduct. Also, there are no legal proceedings related to commercial bribery involving us. We believe anti-corruption campaigns targeting China’s medical sector launched by the PRC authorities will not have a significant adverse impact on us. For further details on our internal anti-bribery controls, please see “— Risk Management and Internal Control — Internal Controls — Anti-bribery.”

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Sales

We generate revenue from the sale of pharmaceutical products primarily by selling our products to distributors who, in turn, sell our products to hospitals, pharmacies and other medical institutions. We also sell directly to retail pharmacy chains. Our sales strategy is in line with the industry norm in the pharmaceutical industry, according to CIC. The following table sets forth a breakdown of our revenue from the sale of pharmaceutical products by distribution channels for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
<i>(RMB in thousands, except for percentages)</i>										
<i>(unaudited)</i>										
Distributors	788,031	99.1	697,712	99.4	554,687	99.0	371,489	98.6	325,030	99.4
Direct sales to retail pharmacies	6,924	0.9	4,121	0.6	5,729	1.0	5,110	1.4	1,906	0.6
Total	794,955	100.0	701,833	100.0	560,416	100.0	376,599	100.0	326,936	100.0

Distributors

We primarily sell our drug products through third-party distributors, who are our direct customers and are responsible for subsequently selling and delivering our products to hospitals, pharmacies, and other medical institutions. We believe our distribution strategy helps extend our coverage in a cost-effective manner while retaining proper control over our distribution network and marketing and promotion activities.

Distribution Network

Our distributors include hundreds of nationally known pharmaceutical distributors with widespread sales presence across the country, as well as regional distributors with deep market penetration within specific geographic areas, all of which are located in China. As of the Latest Practicable Date, our distribution network comprised of more than 1,000 distributors across more than 30 provinces and over 200 cities. This extensive network and close collaboration with distributors have cultivated a dynamic, open marketing system that effectively stimulates cooperation and sales, ensuring strong sales capabilities across various regional and local markets. In 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, sales to our distributors amounted to approximately RMB788.0 million, RMB697.7 million, RMB554.7 million, RMB371.5 million and RMB325.0 million, which approximately accounted for 99.1%, 99.4%, 99.0%, 98.6% and 99.4% of our revenue from the sale of pharmaceutical products, respectively.

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To the best knowledge of our Directors, all of our distributors during the Track Record Period and up to the Latest Practicable Date were independent third parties; and none of our distributors transacted with us during the Track Record Period and up to the Latest Practicable Date are controlled by our former or current employees, uses our brand or name, or has received any material advance or financial assistance from us.

The following table sets forth the movement of the number of our distributors for the periods indicated below.

	Year ended December 31,			Nine months ended September 30,
	2021	2022	2023	2024
Number of distributors at the beginning of the period	2,158	1,939	1,676	1,742
Addition of new distributors ⁽¹⁾⁽³⁾	336	288	516	277
Termination of existing distributors ⁽²⁾⁽⁴⁾	555	551	450	639
Net increase/(decrease) in distributors	(219)	(263)	66	(362)
Number of distributors at the end of the period	1,939	1,676	1,742	1,380

Notes:

- (1) New distributors refer to distributors who (i) had at least one transaction with us in the relevant period; and (ii) did not have any transaction with us in the immediately preceding calendar year.
- (2) Terminated distributors refer to distributors who (i) did not have any transaction with us in the relevant period; and (ii) had at least one transaction with us in the immediately preceding calendar year.
- (3) The distribution agreements we enter with distributors generally have a term of one year. In 2021, 2022 and 2023, distributors who had at least one transaction with us in the respective year and did not have any transaction with us in the immediately preceding year amounted to 336, 288 and 516, respectively, primarily due to our increasing need to engage distributors mainly for distributing our major products Lewejing, Xinbolin and astragalus granule in line with the growth of market demand. Distributors who had at least one transaction with us in the nine months ended September 30, 2024, and did not have any transaction with us in 2023 amounted to 277, primarily due to (i) the engagement of new distributors for Lewejing sales in the seven provinces covered by the ninth batch of the national VBP scheme, and (ii) the increasing need to engage distributors for distributing our new product lines, such as sevoflurane.

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- (4) In 2021, 2022 and 2023, distributors who did not have any transaction with us in the respective year and had at least one transaction with us in the immediately preceding year amounted to 555, 551 and 450, respectively, primarily due to (i) the inclusion of the drug class of Leweitai in the fourth batch of national VBP scheme in February 2021, in which we did not participate in the bidding process, and (ii) the inclusion of the competing drug class of Tianze in the fifth batch of national VBP scheme in June 2021, which collectively affected the market demand for our products, resulting in our decreased demand of engaging distributors in distributing such products. Distributors who did not have any transaction with us in the nine months ended September 30, 2024, and had at least one transaction with us in 2023 amounted to 639, primarily due to (i) the participation of our product Lewejing in the ninth batch of national VBP, which reduced our need to engage distributors in provinces outside the seven covered by such VBP scheme, and (ii) the inclusion of the competing compound of Tianze in the fifth batch of national VBP scheme.

Distributor Management

Each business division of our sales and marketing team is responsible for the overall management of distributors of the specific products within its responsibility, ranging from selecting, monitoring, reviewing and managing risks associated with our distributors. We choose our distributors based on their demonstrated distribution capabilities, knowledge of their respective markets, financial stability, creditworthiness, and operational scale. All distributors must hold the necessary licenses and permits for pharmaceutical sales and distribution. Additionally, our distributors are required to comply with the latest GSP standards for cold-chain storage and transportation, ensuring that our products are delivered safely and promptly to the targeted medical institutions and pharmacies.

Terms of Distribution Agreements

We have a seller-buyer relationship with our distributors under the buy-out sale model. We retain no ownership over the products that we sell to them, and all significant risks and rewards associated with these products are transferred to them upon delivery to and acceptance by them. We enter into distribution agreements with our distributors. Individual sales contracts or purchase orders are generally separately entered into or placed for each purchase. The following sets forth salient terms of our distribution agreements:

- ***Term.*** The typical duration of distribution agreements is one year.
- ***Designated distribution area.*** Distributors are generally not allowed to sell or distribute our products outside of their designated distribution areas.
- ***Exclusivity.*** Distributors are granted the distributorship of specified certain types of products in their designated distribution areas generally on a non-exclusive basis.
- ***Sales target and minimum purchase requirement.*** Our agreements with distributors generally do not specify an agreed annual sales target or minimum annual purchase amount.
- ***Resale price management.*** We generally do not control the prices at which our distributors resell our products to their customers.

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- ***Inventory level.*** We generally do not require our distributors to maintain a minimum inventory level. We have the right to take stock of distributors’ inventory of the products sold by us from time to time.
- ***Return of products.*** Our distributors are required to inspect the products on delivery. Returns and exchanges are generally not allowed except for defective products, incorrect deliveries or damages.
- ***Access to information.*** We require major distributors to provide us with access to information at our request, usually on a monthly basis, including providing us with sales data of our products or with access to such information through their information technology system.
- ***Credit terms.*** We generally grant our major distributors credit terms of 30 to 120 days, with longer terms granted to selected distributors with whom we have built a strong business and financial track record. We also require prepayments for product deliveries to our distributors in certain instances.
- ***Confidentiality.*** Both parties have non-disclosure obligations and undertake to only use each other’s trade secrets and other business information to the extent necessary and not to disclose such trade secrets or other business information to any third party.
- ***Termination.*** We may terminate the distribution agreements in the event of, among others, (i) any material breach by our distributors, such as sales outside of their designated distribution areas and providing falsified sales data; or (ii) any other breach by our distributors that is not remedied within a prescribed time-period.

Prevention of Cannibalization and Channel Stuffing

We believe that our sales correspond to actual market demand and therefore our products are at low risk of channel stuffing in our distribution network, because:

- (i) We generally do not have mandatory sales targets for distributors, which we believe encourages distributors to order based on actual market demand and sales forecasts.
- (ii) We adopt a sales model that transfer the full ownership of the goods at the time of acceptance, and normally there are no return rights for unsold inventory during the contract term, except for product defects, incorrect deliveries, damages, or policy-related factors. This model shifts the responsibility and risk of unsold inventory to the distributors. Since their capital is tied up in the inventory, the distributors are incentivized to order based on actual sales demand, thus reducing holding costs and the risk of obsolescence. Our cumulative amount of actual product return for the revenue recognized during the Track Record Period was RMB47.9 million, accounting for 2.0% of the total revenue from the sales of pharmaceutical products, which was in line with prevailing industry practices as advised by CIC.

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- (iii) During the Track Record Period, a large portion of our products were sold under VBP schemes through distributors. This provided a high degree of transparency and certainty in sales volume and pricing. Consequently, the role of our distributors for these products was primarily logistical, focusing on delivering products according to the orders placed by public hospitals, which reduced the incentive for distributors to overstock.

We have implemented a multifaceted approach to minimize the risk of sales cannibalization among our distributors. We enforce geographic limitations, which clearly specify the designated distribution areas in our distribution agreements for each of our distributors and forbid sales beyond these zones. Together with the detailed information regarding the flow of monthly sales of our products through our major distributors, we diligently oversee their sales to end customers or sub-distributors (if any), and spot any abnormalities in a timely manner. Once we detect such sales anomalies, including cross-regional or cross-channel sales, we will immediately require our distributors to halt all sales and shipments, and return their stock to us. If, under these circumstances, distributors continue to sell the products externally, we will impose penalties for the unauthorized sales, including financial sanctions and potential termination of distribution agreements.

We have also adopted various measures to avoid channel stuffing. According to our distribution agreements, product returns are not allowed unless there is a product quality issue, which helps us to minimize channel stuffing risk. We regularly sample for different products and review information including sales and/or inventory data from our distributors, and may request further information if we identify any irregularities. We also consider purchase volumes, historical data, regulatory changes, and other market factors to monitor our product sales. Further, we actively adjust our sales strategy and geographic or product coverage of each distributor based on market demand and each distributor’s capacity. During the Track Record Period and up to the Latest Practicable Date, we did not notice any unusually large procurements that were inconsistent with distributors’ past practices, nor did we notice any abnormally high inventory level of our distributors.

Anti-corruption and Anti-bribery Measures

Distributors are subject to anti-corruption and anti-bribery obligations pursuant to the terms of our distribution agreements, under which distributors (i) are required to comply with PRC laws and regulations, including anti-corruption and anti-bribery laws and regulations; and (ii) shall bear integrity obligation. See “— Risk Management and Internal Controls.”

Implication of and Compliance with the “Two-Invoice System”

We are subject to the “Two-Invoice System” in China, under which invoices are issued by drug manufacturers to drug distributors on a one-off basis while invoices are issued by drug distributors to medical institutions on a one-off basis. Public medical institutions are required to adopt the “Two-Invoice System,” while private medical institutions are encouraged but not

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required to adopt the “Two-Invoice System.” Pharmaceutical manufacturers and distributors who fail to implement the two-invoice system may be disqualified from attending future bidding events or providing distribution for hospitals and blacklisted for drug procurement practices.

In our agreements with distributors, we specify the regions and types of end-customer, such as hospitals, pharmacies and clinics, to which each distributor is authorized to sell our products. Under the circumstances where public hospitals are the end-customers, which are subject to the Two-Invoice System, we strictly comply with the “Two-Invoice System” and our distributors can only sell our products directly to public hospitals without involving any sub-distributors, as required by the relevant policy. Some of our prescription drug products, such as Lewejing, Leweitai, Youmeining and Tianze, are predominantly sold to public hospitals and therefore such sales are subject to the Two-Invoice System.

Under the circumstances where the end-customers are not public hospitals but pharmacies, clinics and private hospitals, since the Two-Invoice System is not required to be adopted, we do not prohibit our distributors to engage sub-distributors. Some of our distributors may use sub-distributors to extend the product reach due to the typically large number and scattered distribution of pharmacies, clinics and private hospitals, which is in line with the industry norm, according to CIC. For some of our non-prescription drug products, such as astragalus granule, the majority of end-customers are private hospitals, pharmacies and other medical institutions, which are not subject to the Two-Invoice System. Generally, we do not have contractual relationships with sub-distributors engaged by our distributors, who hold primary supervisory responsibilities over their respective sub-distributors. We enter into agreements with a small number of sub-distributors, whom we consider responsible for distribution in key locations while handling a substantial quantity of sales. We entered into agreements with 279, 186, 201 and 187 sub-distributors in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively.

We have implemented a series of internal control measures to monitor the implementation of the Two-Invoice System across different areas, ensuring our ongoing adherence to relevant rules, regulations and policies. For example, we provide training to our management and sales and marketing teams to enhance their understanding of the Two-Invoice System and related regulations, and we require our sales and marketing teams to adjust distribution strategies promptly according to the latest implementation status of the Two-Invoice System. We also closely communicate with distributors to gain insight into the distribution of products. Generally, we request the identities of their end-customers or sub-distributors from our major distributors monthly, and we typically require those with sub-distributors to provide us with the identities of end-customers of their sub-distributors as well. By monitoring sales to end customers, we gain an understanding of our sales situation and continuously oversee our distribution network’s adherence to the Two-Invoice System. Should we detect any violations, we will enforce stringent penalties, including but not limited to suspension of the distributor’s contract, liquidated damages, and potential legal action.

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Our Directors confirm that during the Track Record Period and up to the Latest Practicable Date, we (i) had not been deemed to have violated or circumvented any law, regulations, rules or policies in relation to the “Two-Invoice System”, (ii) had not been disqualified from participating in public tendering processes in any province, (iii) were not subject to any administrative fines or penalties by the competent authorities in relation to the “Two-Invoice System”, and (iv) had not received any warning or notice from any competent authorities in relation to the compliance of the “Two-Invoice System.”

Direct Sales to Retail Pharmacies

Our direct sales to retail pharmacies primarily focuses on promotion and direct engagement with pharmacy customers. For around 1% of our revenue from sale of pharmaceutical products during the Track Record Period, we sell our products directly to major domestic pharmaceutical retail chains enterprises, which then allocate these products to the affiliated retail outlets operated by them. We support our direct sales customers in the external promotion and display of our products and conduct regular training sessions for pharmacy sales staff. These training programs are designed to enhance their knowledge of our products, enabling effective promotion and sales, and ensuring that patients use our medications appropriately. As of December 31, 2021, 2022 and 2023, and September 30, 2024, the number of our direct sales customers amounted to 77, 48, 57, and 25, respectively.

We enter into standard framework agreements with our direct sales customers, and/or sales contracts on an annual basis. Pursuant to the direct sales agreements, we are responsible for the delivery of our products to our direct sales customers at our own cost. Generally, we do not allow product returns or exchanges except for defective products, which is subject to approval by our designated personnel. Our major direct sales customers are required to regularly confirm their inventory levels with us to avoid the sale of expired products. We typically grant our major direct sales customers a credit term of 30 to 90 days and direct sales customers typically pay us via wire transfer or bank acceptance bills.

Logistics Arrangement

We generally engage third-party logistics service providers to transport our products to our distributors and other direct customers. We have entered into logistics service agreements with these providers, pursuant to which they are responsible for furnishing comprehensive logistics services, encompassing storage, secondary packaging, and timely shipment to specified destinations. Our prerequisites mandate that such logistics service providers maintain contemporary pharmaceutical storage and distribution facilities. Moreover, they must hold third-party pharmaceutical logistics qualifications sanctioned by competent authorities. Pursuant to the logistics arrangements, these providers bear responsibility for any loss, damage, or contamination of transported drugs resulting from their negligence during the provision of logistics services. Breach of contract by the logistics providers, including failure to meet these obligations, may result in the imposition of liquidated damages.

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PRICING

We formulate and implement a reasonable pricing strategy for our marketed products to stay competitive and profitable. We take into account a number of factors in determining our prices, which primarily include our R&D, production and marketing costs and expenses, the perceived value of products, our market share and the competitive landscape. In addition, our pricing strategies are also affected by the regulations and policies on the pharmaceutical industry, including medical insurance reimbursement standards and regulation of medical and pricing practices. The regulatory regimes that are relevant to our business and results of operations mainly include the centralized tender process and the VBP, both governing the purchase of drugs by public hospitals and public medical institutions, as well as the NRDL and NEDL, both governing drug coverage and reimbursement.

We are dedicated to closely monitoring new policies affecting the pricing of pharmaceuticals in China and formulating strategies to stay competitive and profitable.

Centralized Tender Process and Volume-based Procurement

The centralized tender process and volume-based procurement (VBP) are two distinct but interrelated mechanisms in China’s pharmaceutical procurement system, both aimed at reducing healthcare costs and increasing access to medications. The centralized tender process is a provincial or regional system used in China for public hospitals to purchase most medications at the bid prices. The procurement volume under centralized tender process is not guaranteed, and depends on hospital preferences and market demand. The VBP is a national or regional procurement mechanism that leverages large-volume government procurement to lower the prices of the selected medications. The VBP typically guarantees a large procurement volume, which encourages pharmaceutical companies to offer lower prices in exchange for assured sales.

The centralized tender process covers a broad range of drugs, whereas the VBP tends to focus on a select number of commonly used drugs, especially generic drugs. If a drug is included in VBP, its prices and sales volume to public hospitals will primarily be determined through the VBP scheme. Once a VBP cycle ends or for provinces not participating in VBP, such drugs can still be procured through the centralized tender process. If a drug does not win bids in VBP, it may still be procured through the centralized tender process, but it may experience a sharp decline in demand as public hospitals prioritize purchasing VBP-winning drugs. Out of the VBP scope, public hospitals primarily procure drugs at bid prices determined through the centralized tender process based on their needs.

Centralized Tender Process

Prices of most pharmaceutical products in China sold to public hospitals and public medical institutions are determined through a competitive centralized tender process at the provincial or municipal level. The centralized tender process is held in different regions across China with varying terms and procedures. Generally, pharmaceutical companies bid to have

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their drugs listed on an online procurement platform operated at provincial or regional level, where public hospitals can choose to purchase the listed drug at the negotiated prices. Participants eligible for submitting bids in the centralized tender process include all pharmaceutical manufacturers, sole agents of imported drugs and holders of marketing authorizations for drugs. We, as the pharmaceutical manufacturer and the holder of marketing authorizations for drugs covered by the centralized procurement program, submit bids in a centralized tender process to supply our applicable products to these institutions at specified prices. These bids are generally considered based on, among other things, price competitiveness, product quality, clinical effectiveness, as well as qualifications and reputation of the manufacturer. If we are successful in winning bids in a centralized tender process, the relevant products will be sold to the public medical institutions at the bid prices, which is the primary determinant of prices at which we sell our products to our distributors. The centralized tender process has created pricing pressure among substitute products.

During the Track Record Period, we generated revenue from the sales of 29 approved drug products with over 100 specifications, which includes both generics and traditional Chinese medicine products. A substantial portion of these products is sold to distributors, who then supply them to public hospitals and other medical institutions in China. Consequently, we actively participate in the centralized tender process, carefully considering various factors, including the trade-off between price levels and sales volumes. The centralized tender process present both challenges and opportunities for us. Challenges include potential declines in revenue and profit for products that do not win bids, loss of market share in regions where we fail to secure bids, and the pressure to adjust prices, which can affect profit margins. However, by leveraging our product differentiation bidding strategy, opportunities arise from cost and efficiency advantages from reduced selling and marketing expenses and expanded market access through successful bids. Our success in the centralized tender process relies on differentiating our products and pricing bids profitably, supported by national-level recognitions and quality evaluations. Failure to do so would result in lost revenue from sales to public medical institutions, impacting our financial performance.

VBP

Prices of certain pharmaceutical products in China sold to public hospitals and public medical institutions are affected by the VBP scheme. The VBP scheme aims to achieve a lower price of pharmaceuticals with mature, high-volume clinical usage and sufficient market competition through a competitive bidding process for large-volume procurement. The VBP scheme has rolled out at both national and regional levels.

The national VBP is a centralized procurement system initiated by the national government to secure large volumes of essential drugs at significantly lower prices. Drugs selected for national VBP must have one originator and at least six manufactures of generic versions that pass consistency evaluation with the originator to ensure competition in the bidding process. Passing consistency evaluation is essential for generics to be eligible for bidding process. Pharmaceutical companies compete to win bids by offering a substantial price reduction in exchange for guaranteed sales volumes across various provinces and regions. By

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centralizing the procurement process, this mechanism also minimizes the role of distributors and intermediaries, improving efficiency and transparency of supply to public hospitals. As a result, the inclusion in the national schemes generally exerts substantial downward pricing pressure of the selected drugs. The total procurement volume will be shared among the winning bidders. Its impact on the sales volume of a bid-winning drug depends on such drug’s market share among its drug class prior to the implementation of such national schemes. Specifically, the national VBP scheme for pharmaceuticals imposes certain limitations on the number of provinces each winning bidder are entitled to supply. Therefore, pharmaceutical manufacturers which have a smaller market share prior to winning the VBP bid will usually experience a bump in sales volume. For pharmaceutical manufacturers which have a large market share, however, their sales volume may decrease after winning the bid in national VBP scheme for pharmaceuticals, as they have to share a smaller market with the other winning bidders. For example, our product Lewejing participated in the ninth batch of the national VBP scheme in 2024. Before winning the bids in the national VBP scheme, the sales revenue of Lewejing ranked 4th nationally in 2023 with a market share of 12.1% of the propofol emulsion injection market in China, according to CIC. Under the national VBP, each winning bidder will mainly supply the products for certain designated provinces. Therefore, Lewejing’s sales volume outside of the seven provinces for which it is the primary supplier declined after the implementation of the national VBP. See “— Our Marketed Products — Generic Drugs — Anesthesia Drugs — Lewejing” for details. For drugs in the same drug class that are not included in such scheme (i.e. they do not win the bidding), they typically lose significant market share in public hospitals, while they are not mandatorily required to lower selling prices to align with the low-priced bid-winning drugs. A national VBP scheme typically lasts for a term ranging from one to three years.

Following the completion of contract period of national VBP schemes, a process known as continuation procurement often follows at provincial or regional level to stabilize the supply and pricing structure established during the national VBP. If a drug was not previously included in the national schemes, it may expand its market share through participating in the continuation procurement. So far, the national government has never initiated a new round of national VBP after the drugs enter provincial continuation procurement stage.

Besides national VBP and continuation procurement, provincial governments also roll out VBP schemes at provincial or regional level to complement the national schemes by expanding the reach of volume-based procurement beyond the drugs selected for national bidding. Similar to national VBP, the provincial VBPs exert downward pressure on drug price with a guaranteed procurement volume by public hospitals in the relevant province or region.

During the Track Record Period, a number of our products were subject to national or provincial VBP schemes. For example, propofol medium and long chain fat emulsion injection, dexmedetomidine hydrochloride injection, ornidazole capsule were subject to the national VBP scheme; Lewejing (propofol injectable emulsion) participated in provincial VBP schemes and later the national VBP scheme; Tianze (medium and long chain fat emulsion injection) and Xinbolin (ribavirin granule) participated in provincial VBP schemes. For further details, please see “— Our Marketed Drugs — Generic Drugs.” While the VBP scheme sometimes allows us

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to sell our products in larger volumes, it typically exerts downward pressure on the prices at which we sell our products to our distributors. To mitigate such impact, we continue to diversify our product portfolio by introducing new marketed drugs.

NRDL

Participants of the national public medical insurance programs and their employers, if any, are required to contribute to the payment of insurance premium on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of drugs included in the NRDL which sets forth the payment standard for drugs under the basic medical insurance, work-related injury insurance and maternity insurance funds. The National Healthcare Security Administration of the PRC, together with other government authorities, have the power to determine the drugs included in the NRDL. For details of the mechanism, selection criteria, evaluation and approval procedures of the NRDL, see “Regulatory Overview — Laws and Regulations in Relation to New Drugs — NRDL.”

As of September 30, 2024, certain of our marketed products were included in the NRDL, including propofol injectable emulsion, propofol medium and long chain fat emulsion injection, dexmedetomidine hydrochloride injection, medium and long chain fat emulsion injection, ornidazole capsule, racecadotril granule, astragalus granule and chaihuang granule. To achieve this, our products undergo a rigorous evaluation and approval procedure based on the NRDL’s selection criteria. Being part of the NRDL has substantial implications for our company as it determines the medical insurance reimbursement standards for our products. However, this may also lead to a decrease in the price of our products in certain provinces due to the transparent, multi-party negotiation mechanism for pricing.

NEDL

The NEDL is issued by the Ministry of Health and eight other ministries and commissions in the PRC, aiming at promoting essential drugs sold to patients at fair prices in the PRC and ensuring that the general public in the PRC has equal access to the essential drugs. Basic medical institutions funded by the government, which primarily include country-level hospitals, country-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in the NEDL. The selection of drugs listed in the NEDL shall be in accordance with the principles of necessity for prevention and treatment, safety and effectiveness, reasonable price, easy to use and clinical preference. For details of the mechanism, selection criteria, evaluation and approval procedures of the NEDL, see “Regulatory Overview — Laws and Regulations in Relation to New Drugs — NEDL.”

Propofol injectable emulsion and medium and long chain fat emulsion, covering two of our marketed products, were included in the 2018 NEDL. This involves a stringent evaluation and approval process. Inclusion in the NEDL comes with its own set of implications. While it ensures that our products are deemed essential and are therefore more likely to be purchased

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even in times of economic downturn, this process can also exert downward pressure on our pricing strategy. It is worth noting that the prices at which we can sell our products may decrease due to the fixed or maximum retail prices set by the NEDL.

Our pricing strategy and regulation are a delicate balance of participation in these four mechanisms. We strive to meet the criteria in each process, but we also must navigate the potential downward pressure on our pricing. For further details of risks associated with pricing regulation. See “Risk Factors — Key Risks Relating to Our Business and Industry — We may experience difficulties in our sales efforts as a result of pricing regulations or other policies that are intended to reduce healthcare costs, which could adversely affect our operations, revenue and profitability.”

QUALITY CONTROL AND ASSURANCE

We have implemented comprehensive quality control procedures and protocols that span across the entire production lifecycle from raw material sourcing till the final products are delivered to customers. In strict compliance with the laws and regulations, including but not limited to, Pharmaceutical Administration Law the People’s Republic of China (《中華人民共和國藥品管理法》) and GMP of Medical Products Standards (《藥品生產質量管理規範》), we have established a comprehensive pharmaceutical quality management system that is aligned with GMP standards. For details about our major licenses, permits and approvals, please see “— Licenses, Permits and Approvals” for more details. We have established an organizational structure tailored to pharmaceutical production, including an independent quality management department that fulfills both Quality Assurance (“QA”) and Quality Control (“QC”) roles, participating in all quality-related activities. The QA team is primarily responsible for the establishment, continuous optimization, and monitoring of the quality management system, while the QC team focuses on the inspection and testing of materials, intermediate products, and finished goods. Other departments, such as departments of human resources, material supply, and sales services, each with clearly defined responsibilities, also serve as the backbones of our quality control and assurance process. Importantly, our Qualified Person (“QP”) is responsible for independently ensuring that each batch of our pharmaceutical products meets all quality and regulatory standards before it is released for distribution, ensuring the integrity and autonomy of the quality management process. This structure not only reinforces our commitment to quality but also aligns with regulatory expectations and best practices in the pharmaceutical industry, positioning us as a reliable partner in healthcare.

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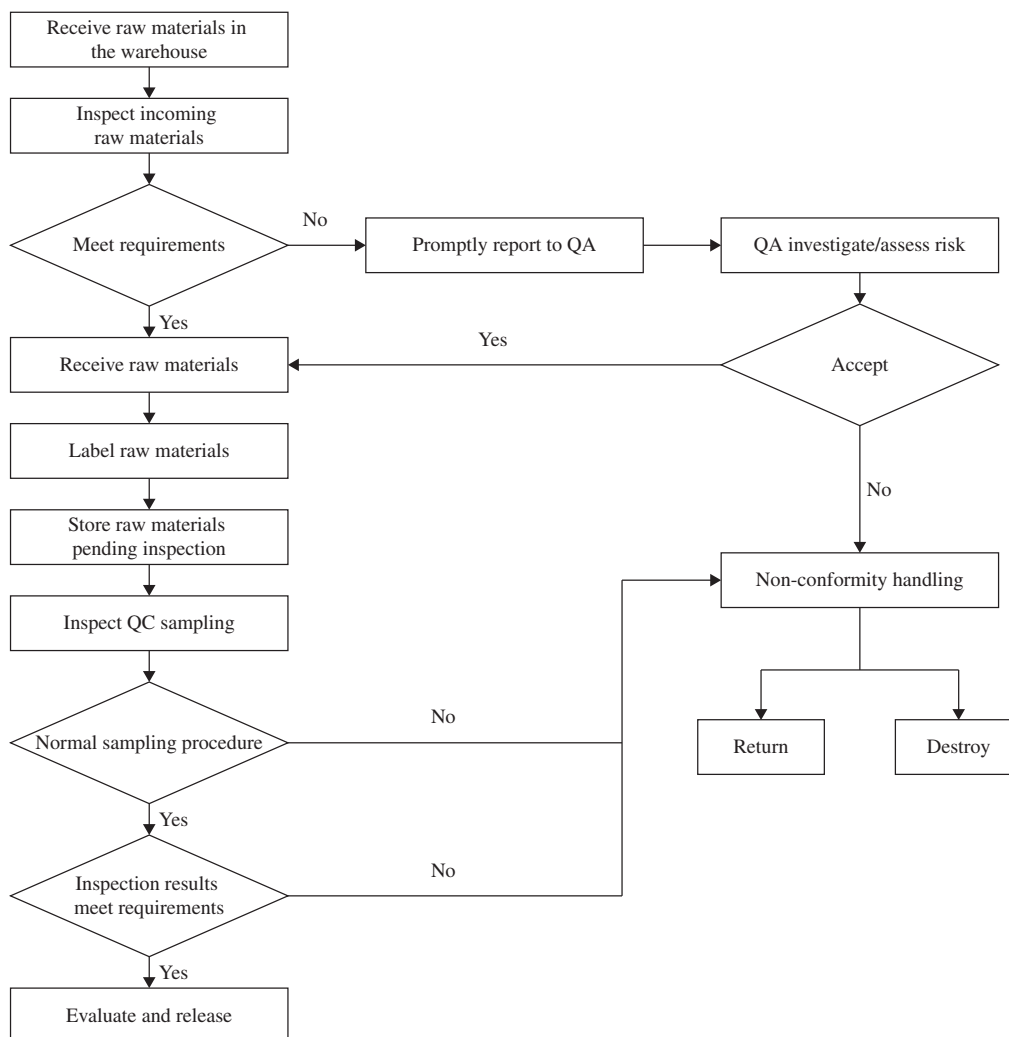
Supply Chain Quality Control

We apply meticulous approach to material management, which underscores our commitment to maintaining high standards of quality and operational excellence across all phases of our production process. We have adopted a comprehensive supplier management procedure elaborating on the qualifications of suppliers, selection criteria, QA methods and standards, supplier approval procedures, and quality audit plans. The QA department, in collaboration with relevant departments, conducts quality evaluations of all suppliers providing raw materials. For major material suppliers, the QA conducts both on-site and off-site quality audits and vetoes suppliers failing to meet our quality assessment criteria. Only those suppliers who pass our evaluation and are approved are included in our approved supplier list, and we purchase raw materials used in our production only from approved suppliers. For details about our supply chain management, please see “— Manufacturing — Supply Chain Management.”

All materials purchased by our procurement team are subject to inspection upon receipt according to our standard procedures. Our QC personnel conducts sampling inspections in batches, and issues inspection reports indicating whether the materials meet quality standards within specified time limits. The QA personnel reviews these inspection reports alongside the material acceptance records and testing records to conduct a material audit assessment. Based on the assessment result, our quality management department head decides whether to approve the release of materials. We store the materials that are approved for release by category according to specified storage conditions and use such materials within their designated shelf lives. With instructions to control the issuance and receipt of materials, we are able to minimize the risk associated with our supply chain, ensuring precise management of material types and quantities.

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The following flow chart illustrates our raw material quality control procedures:



Manufacturing Quality Control

All of our manufacturing processes are conducted in accordance with our detailed production instructions, protocols and the GMP standards. Our QA personnel conduct rigorous quality monitoring at each stage of the production process to ensure complete compliance with all operational procedures, which guarantees that there are no deviations from the established standards in processes or quality.

Upon completion of the batch production of intermediate and pre-packaged products, operational personnel proceed with the weighing and rechecking processes. The products are then stored at designated intermediate stations, and the operational personnel is required to complete the inspection records of intermediate products, and submit samples to the QC

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department for testing. Following the sampling management procedures to collect and test samples, the QC personnel issue intermediate product inspection reports. These reports, along with batch inspection records, are reviewed by the QC director and then forwarded to the QA department for further audit.

The QA personnel, upon receiving the intermediate product inspection reports, conduct a comprehensive audit that evaluates the inspection results, adherence to process protocols, operator performance, process control, environmental monitoring, deviation handling, and change management. This review process aims to ensure that every aspect of the production process is compliant and that any deviations are explicitly explained or have been thoroughly investigated and addressed. Based on the outcomes of these evaluations, onsite QA personnel make a final decision on whether the intermediate products can be approved for further processing or distribution by issuing either a release or a non-release notice for the intermediate products, along with corresponding certificates of conformity or non-conformity.

Finished Product Quality Control

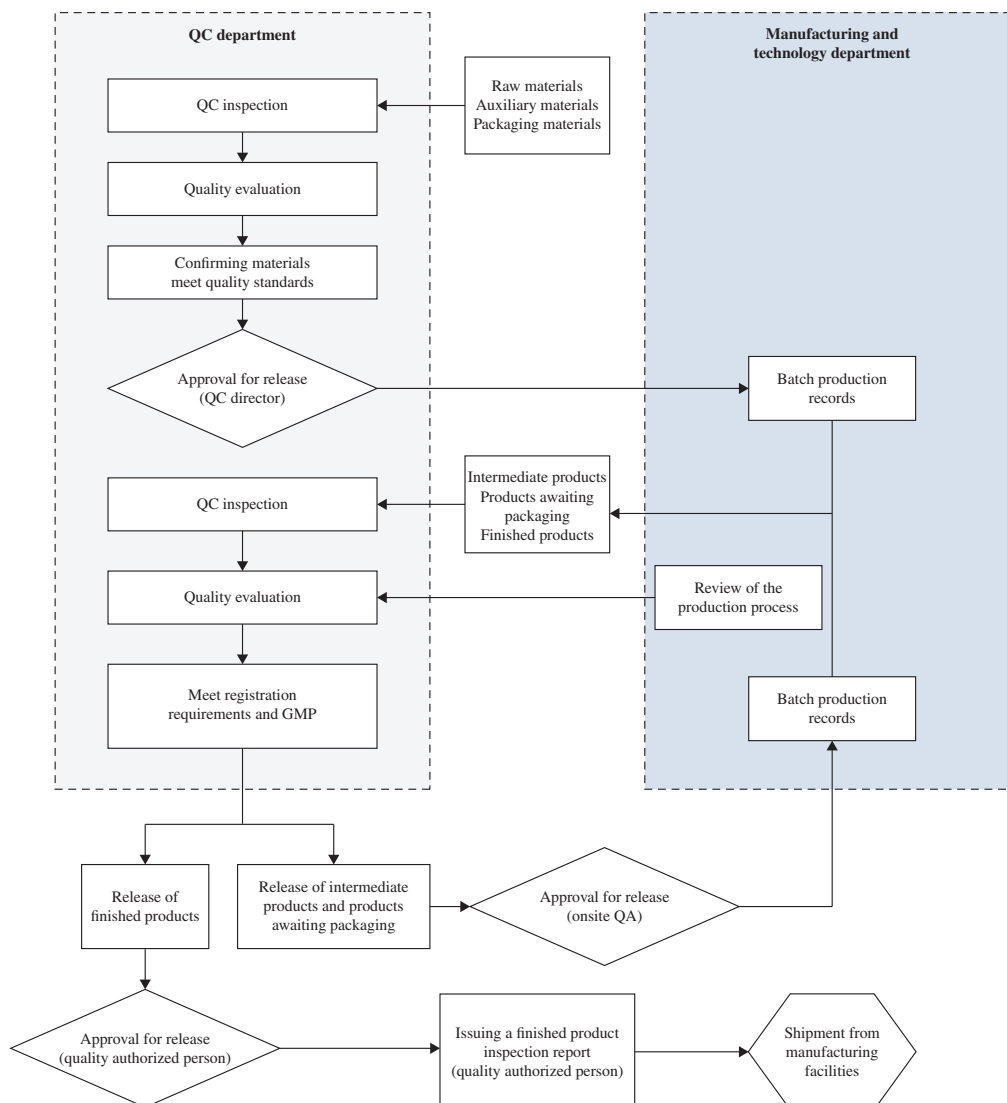
Upon completion of the finished products in the production workshop, QC personnel collect and test samples according to the sampling management procedure, as well as the specified internal quality standards and inspection procedures, and issue a finished product inspection report. The QC director reviews both the batch inspection records and the finished product inspection reports and forward them, together with an environmental monitoring report if such monitoring is required during the production process, to the QA department for further review.

In addition, our production workshop conducts a review of the batch production and packaging records after the production to timely investigate and resolve any deviations. Upon completion of these reviews, the workshop submits the batch production records, batch packaging records, and related deviation investigation records to the QA department.

The QA department plays a crucial role in the master of quality control, reviewing various records, including the batch production records prepared by manufacturing and technology department, batch inspection records prepared by QC department, monitoring records, and related records of deviations, out-of-specification results, changes, and monitoring. This thorough evaluation ensures that each batch of finished products meets quality standards consistent with registration requirements and GMP. The QA department confirms the evaluation results, and the authorized quality person issues either a release or a non-release notice for based on these results, making clear decisions regarding approval, rejection, or other necessary actions. The QA department then issues documents such as certificates of compliance, inspection reports, and release orders along with the products to the warehouse. Only accompanied with such documents will the warehouses release products for shipment, thereby moving the products into the sales phase.

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The following flow chart illustrates our quality control procedures for our in-process and final products:



After-sales Supervision

We have implemented a thorough management framework to oversee the quality and safety of our products in the post-marketing phase, including product complaints, product recalls, adverse drug reaction reporting, and monitoring. To this end, we have adopted a series of procedures, such as Product Complaint Handling Standard Operating Procedure, Recall Standard Operating Procedure, and Adverse Drug Reaction Reporting and Monitoring Standard Operating Procedure. These systems are designed to conduct pharmacovigilance activities and significantly minimize the risk associated with drug quality and safety. We have staffed specialized personnels responsible for monitoring and reporting adverse drug reactions. These personnel systematically collect and meticulously record adverse reactions, regularly conduct drug safety risk assessments, and compile and submit safety update reports. This proactive approach allows us to swiftly implement necessary measures to mitigate risks and uphold the highest standards of product safety and patient care.

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PRODUCT RETURNS

We have established a comprehensive internal control system to minimize the risks related to drug quality and safety to the greatest extent possible. For details about our after-sales supervision, please see “— Quality Control and Assurance — After-sales Supervision.” During the Track Record Period and up to the Latest Practicable Date, we did not have any product recall due to quality issues.

We generally do not accept any product returns and exchanges, except for defective products, incorrect deliveries, damages, or policy-related factors. The primary responsibility for handling returns and exchanges lies with the respective business divisions, with support from the finance department, the quality control department and warehouses. Typically, the return process begins with a return request submitted by the business manager of the business division, and the business manager will coordinate the return with the distributors for the subsequent transportation to our warehouses after obtaining the approval of the head of that business division and our finance department. Upon arrival, our warehouse staff inspects the returned goods against the commercial delivery note, followed by a quality inspection and final review by the quality control department. For defective products, we are fully responsible for the cost of return and replacement of these products. For details of the return policy with our distributors, see “— Sales and Marketing — Sales — Distribution — Distributor Management.”

We have established a dedicated section named “drug vigilance” at our website, which is accessible to the public. This section allows any patient who suspects they have experienced adverse reactions potentially linked to our medications to complete a form, enabling the reporters to provide their original medical condition, suspected drug name, manufacturer details, batch number, and a detailed description of the adverse reaction observed. We also encourage end customers to report adverse events via telephone and email channels for enhanced accessibility and responsiveness. Once our backend system receives these reports, our specialized team promptly initiates coordination efforts, ensuring thorough communication and support throughout the process. We have implemented detailed procedures on how to handle quality complaints and provide for the contingency for any adverse patient reaction to our products. In addition, our sales and marketing team is responsible for following up customer complaints to ensure that they have been dealt with appropriately.

During the Track Record Period, when the product returns occurred and were accepted, the amount of actual product returns would offset the sales revenue. We estimated the future sales return of the products sold based on the historical experience at the end of each reporting period and recorded refund liability for the expected returns, and simultaneously recognized an asset for the right to returned goods asset. As of December 31, 2021, 2022 and 2023 and September 30, 2024, our refund liabilities amounted to RMB15.8 million, RMB14.1 million, RMB11.2 million and RMB10.2 million, respectively; our right to returned goods assets amounted to RMB6.9 million, RMB6.6 million, RMB6.0 million and RMB6.1 million, respectively. The cumulative amount of actual product return for the revenue recognized during the Track Record Period was RMB47.9 million, accounting for 2.0% of the total revenue from

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the sales of pharmaceutical products, which was in line with the industry practice as advised by CIC. During the Track Record Period and up to the Latest Practicable Date, the amounts of our product returns and exchanges did not have a material adverse effect on our operations of business, and we had not experienced any material complaint or product liability or other legal claims from our customers due to problems associated with the quality of our products.

SUPPLIERS

During the Track Record Period, our suppliers primarily consisted of CROs and suppliers of raw materials, equipment, devices and construction services. We select our suppliers by considering cost and their capability, quality, reputation, delivery and regulatory compliance. For details of our procurement process, please see “— Quality Control and Assurance — Supply Chain Quality Control.”

Purchases from our five largest suppliers were RMB108.8 million, RMB111.5 million, RMB165.2 million and RMB151.0 million in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively, representing 16.8%, 16.2%, 16.8% and 17.3% of our total purchases for the corresponding periods. Purchases from our largest supplier in 2021, 2022 and 2023 and the nine months ended September 30, 2024, were RMB32.3 million, RMB35.8 million, RMB58.8 million and RMB53.2 million, respectively, representing 5.0%, 5.2%, 6.0% and 6.1% of our total purchases for the corresponding periods. Our suppliers generally provide us credit terms of 30 to 270 days, and we generally settle with them by bank transfer and bills. The following table sets forth details of our five largest suppliers for each year/period during the Track Record Period.

Suppliers	Background	Products/ Services Purchased	Commencement of Business Relationship	Purchase Amount (RMB in thousands)	% of Total Purchase
<i>For the year ended December 31, 2021</i>					
Supplier A	A limited company established in 2013 and headquartered in Deyang, Sichuan, primarily focusing on the development and sales of traditional Chinese medicine, with a registered capital of RMB15.0 million	Raw materials	2013	32,263	5.0
Supplier B	A joint stock company established in 2010 and headquartered in Shanghai, primarily focusing on providing medical science technology consulting and development services, with a registered capital of RMB105.7 million	R&D services	2018	27,476	4.2

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Suppliers	Background	Products/ Services Purchased	Commencement of Business Relationship	Purchase Amount (RMB in thousands)	% of Total Purchase
Supplier C	A limited company established in 1998 and headquartered in Guangzhou, Guangdong, primarily focusing on providing manufacturing of chemical APIs, with a registered capital of RMB252.6 million	Raw materials	2010	21,241	3.3
Supplier D	A joint stock company established in 2002 and headquartered in Changsha, Hunan, primarily focusing on manufacturing of specialized packaging equipment. Supplier D is listed on the Shenzhen Stock Exchange, with a registered capital of RMB590.3 million	Construction services and fixed assets	2012	18,682	2.9
Supplier E	A public hospital located in Guangzhou, Guangdong, with an initial capital of RMB260.2 million	R&D services	2019	9,149	1.4
Total				108,811	16.8

For the year ended December 31, 2022

Supplier A	A limited company established in 2013 and headquartered in Deyang, Sichuan, primarily focusing on the development and sales of traditional Chinese medicine, with a registered capital of RMB15.0 million	Raw materials	2013	35,833	5.2
Supplier E	A public hospital located in Guangzhou, Guangdong, with an initial capital of RMB260.2 million	R&D services	2019	26,761	3.9
Supplier C	A limited company established in 1998 and headquartered in Guangzhou, Guangdong, primarily focusing on providing manufacturing of chemical APIs, with a registered capital of RMB252.6 million	Raw materials	2010	20,378	3.0

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Suppliers	Background	Products/ Services Purchased	Commencement of Business Relationship	Purchase Amount (RMB in thousands)	% of Total Purchase
Supplier B	A joint stock company established in 2010 and headquartered in Shanghai, primarily focusing on providing medical science technology consulting and development services, with a registered capital of RMB105.7 million	R&D services	2018	17,206	2.5
Supplier F	A limited company established in 2012 and headquartered in Chengdu, Sichuan, focusing on the development, manufacturing and sales of traditional Chinese medicine, with a registered capital of RMB20.0 million	Raw materials	2021	11,325	1.6
Total				111,503	16.2

For the year ended December 31, 2023

Supplier B	A joint stock company established in 2010 and headquartered in Shanghai, primarily focusing on providing medical science technology consulting and development services, with a registered capital of RMB105.7 million	R&D services	2018	58,839	6.0
Supplier G	A limited company established in 2003 and headquartered in Chongqing, focusing on industrial and mining engineering construction, with a registered capital of RMB38.0 million	Construction services and fixed assets	2022	28,345	2.9
Supplier F	A limited company established in 2012 and headquartered in Chengdu, Sichuan, focusing on the development, manufacturing and sales of traditional Chinese medicine, with a registered capital of RMB20.0 million	Raw materials	2021	26,495	2.7

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Suppliers	Background	Products/ Services Purchased	Commencement of Business Relationship	Purchase Amount (RMB in thousands)	% of Total Purchase
Supplier A	A limited company established in 2013 and headquartered in Deyang, Sichuan, primarily focusing on the development and sales of traditional Chinese medicine, with a registered capital of RMB15.0 million	Raw materials	2013	26,043	2.6
Supplier E	A public hospital located in Guangzhou, Guangdong, with an initial capital of RMB260.2 million	R&D service	2019	25,455	2.6
Total				165,177	16.8

For the nine months ended September 30, 2024

Supplier B	A joint stock company established in 2010 and headquartered in Shanghai, primarily focusing on providing medical science technology consulting and development services, with a registered capital of RMB105.7 million	R&D services	2018	53,244	6.1
Supplier K	A U.S.-based leading global provider of advanced analytics, technology solutions, and clinical research services, ranking among the top 10 global CROs by revenue in 2023	R&D services	2023	30,071	3.4
Supplier E	A public hospital located in Guangzhou, Guangdong, with an initial capital of RMB260.2 million	R&D services	2019	25,697	2.9
Supplier H	A public hospital located in Shanghai, with an initial capital of RMB168.46 million	R&D services	2021	22,182	2.5
Supplier I	A limited company established in 2020 and headquartered in Xiamen, Fujian, primarily focusing on providing technology development and consulting services, with a registered capital of RMB10.0 million	R&D services	2023	19,806	2.3
Total				151,000	17.3

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To the best of our knowledge, (i) all of our five largest suppliers for each year/period 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 for each year/period during the Track Record Period.

CUSTOMERS

In 2021, 2022 and 2023, our revenue was primarily derived from the sales of pharmaceutical products, mainly to third-party distributors. In the nine months ended September 30, 2024, our revenue was primarily derived from the license fee income representing part of the Upfront Payment received from BMS in March 2024 under the BMS Agreement. We sell a substantial portion of our products to third-party distributors, who are our direct customers and are responsible for subsequently selling and delivering our products to hospitals, other medical institutions and pharmacies. We generally grant credit terms of 30 to 120 days to our major distributors, and they generally settle with us by bank transfer and bills.

Our revenue from our five largest customers, calculated on the group level with entities controlled by the same group combined together, were RMB314.1 million, RMB266.8 million, RMB199.1 million and RMB5,476.6 million in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively, representing 39.5%, 38.0%, 35.5% and 96.7% of our total revenue for the corresponding periods. Our revenue from our largest customer in 2021, 2022 and 2023 and the nine months ended September 30, 2024 were RMB150.2 million, RMB110.1 million, RMB83.6 million and RMB5,334.3 million, respectively, representing 18.9%, 15.7%, 14.9% and 94.2% of our total revenue for the corresponding periods. The following table sets forth details of our five largest customers for each year/period during the Track Record Period.

Customers	Background	Products/ Services/ License Provided	Commencement of Business Relationship	Revenue Contribution	% of Total Revenue
(RMB in thousands)					

For the year ended December 31, 2021

Customer A	A joint stock company established in 2003 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals and medical devices. Customer A is listed on the Hong Kong Stock Exchange, with a registered capital of RMB3,120.7 million	Pharmaceutical products	2008	150,156	18.9
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Customers	Background	Products/ Services/ License Provided	Commencement of Business Relationship	Revenue Contribution (RMB in thousands)	% of Total Revenue
Customer B	A joint stock company established in 2007 and headquartered in Beijing, primarily focusing on sale of pharmaceuticals. Customer B is listed on the Hong Kong Stock Exchange, with a registered capital of RMB19,646.5 million	Pharmaceutical products	2011	58,352	7.3
Customer C	A joint stock company established in 1999 and headquartered in Chongqing, primarily focusing on sale of pharmaceuticals. Customer C is listed on the Shenzhen Stock Exchange, with a registered capital of RMB1,728.2 million	Pharmaceutical products	2010	42,016	5.3
Customer D	A joint stock company established in 1994 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals. Customer D is listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange, with a registered capital of RMB3,702.8 million	Pharmaceutical products	2010	32,482	4.1
Customer E	A joint stock company established in 1999 and headquartered in Wuhan, Hubei, primarily focusing on sale of pharmaceuticals. Customer E is listed on the Shanghai Stock Exchange, with a registered capital of RMB5,042.5 million	Pharmaceutical products	2010	31,135	3.9
Total				314,141	39.5

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Customers	Background	Products/ Services/ License Provided	Commencement of Business Relationship	Revenue Contribution (RMB in thousands)	% of Total Revenue
<i>For the year ended December 31, 2022</i>					
Customer A	A joint stock company established in 2003 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals and medical devices. Customer A is listed on the Hong Kong Stock Exchange, with a registered capital of RMB3,120.7 million	Pharmaceutical products	2008	110,106	15.7
Customer B	A joint stock company established in 2007 and headquartered in Beijing, primarily focusing on sale of pharmaceuticals. Customer B is listed on the Hong Kong Stock Exchange, with a registered capital of RMB19,646.5 million	Pharmaceutical products	2011	49,630	7.1
Customer C	A joint stock company established in 1999 and headquartered in Chongqing, primarily focusing on sale of pharmaceuticals. Customer C is listed on the Shenzhen Stock Exchange, with a registered capital of RMB1,728.2 million	Pharmaceutical products	2010	39,469	5.6
Customer E	A joint stock company established in 1999 and headquartered in Wuhan, Hubei, primarily focusing on sale of pharmaceuticals. Customer E is listed on the Shanghai Stock Exchange, with a registered capital of RMB5,042.5 million	Pharmaceutical products	2010	39,337	5.6
Customer D	A joint stock company established in 1994 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals. Customer D is listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange, with a registered capital of RMB3,702.8 million	Pharmaceutical products	2010	28,303	4.0
Total				266,845	38.0

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Customers	Background	Products/ Services/ License Provided	Commencement of Business Relationship	Revenue Contribution (RMB in thousands)	% of Total Revenue
<i>For the year ended December 31, 2023</i>					
Customer A	A joint stock company established in 2003 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals and medical devices. Customer A is listed on the Hong Kong Stock Exchange, with a registered capital of RMB3,120.7 million	Pharmaceutical products	2008	83,550	14.9
Customer B	A joint stock company established in 2007 and headquartered in Beijing, primarily focusing on sale of pharmaceuticals. Customer B is listed on the Hong Kong Stock Exchange, with a registered capital of RMB19,646.5 million	Pharmaceutical products	2011	40,328	7.2
Customer C	A joint stock company established in 1999 and headquartered in Chongqing, primarily focusing on sale of pharmaceuticals. Customer C is listed on the Shenzhen Stock Exchange, with a registered capital of RMB1,728.2 million	Pharmaceutical products	2010	31,539	5.6
Customer D	A joint stock company established in 1994 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals. Customer D is listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange, with a registered capital of RMB3,702.8 million	Pharmaceutical products	2010	26,281	4.7
Customer F	A joint stock company established in 1981 and headquartered in Liuzhou, Guangxi, primarily focusing on sale of pharmaceuticals. Customer F is listed on the Shanghai Stock Exchange, with a registered capital of RMB399.0 million	Pharmaceutical products	2010	17,379	3.1
Total				199,077	35.5

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Customers	Background	Products/ Services/ License Provided	Commencement of Business Relationship	Revenue Contribution (RMB in thousands)	% of Total Revenue
<i>For the nine months ended September 30, 2024</i>					
BMS	A multinational pharmaceutical company headquartered in the U.S. BMS is a leading global pharmaceutical company with US\$45 billion in revenue in 2023	Licensing of BL-B01D1	2023	5,334,291	94.2
Customer A	A joint stock company established in 2003 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals and medical devices. Customer A is listed on the Hong Kong Stock Exchange, with a registered capital of RMB3,120.7 million	Pharmaceutical products	2008	55,444	1.0
Customer B	A joint stock company established in 2007 and headquartered in Beijing, primarily focusing on sale of pharmaceuticals. Customer B is listed on the Hong Kong Stock Exchange, with a registered capital of RMB19,646.5 million	Pharmaceutical products	2011	48,361	0.9
Customer D	A joint stock company established in 1994 and headquartered in Shanghai, primarily focusing on sale of pharmaceuticals. Customer D is listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange, with a registered capital of RMB3,702.8 million	Pharmaceutical products	2010	20,286	0.4
Customer C	A joint stock company established in 1999 and headquartered in Chongqing, primarily focusing on sale of pharmaceuticals. Customer C is listed on the Shenzhen Stock Exchange, with a registered capital of RMB1,728.2 million	Pharmaceutical products	2010	18,182	0.3
Total				5,476,564	96.7

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To the best of our knowledge, (i) all of our five largest customers for each year/period 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 customers for each year/period during the Track Record Period.

COMPETITION

We operate in a highly competitive industry. While we believe that our drug candidates, technology platforms and management team provide us with significant competitive advantages, we face potential competition from many others who are working to develop therapies targeting the same indications. These include multinational biopharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, academic institutions, government agencies and research institutions. Any drug candidates that we successfully develop and commercialize will compete with both existing drugs and any new drugs that may become available in the future.

We believe that the primary competitive factors in our markets include the identification of promising targets, mechanisms, and pathways for drug development, molecule screening and design, efficacy and safety of drug candidates, manufacturing efficiency, and commercialization.

We believe our continued success will depend on our following capabilities: the capability to develop innovative products and advanced technologies; the capability to apply technologies to all production lines; the capability to develop an extensive product portfolio; the capability to maintain a highly efficient operational model; the capability to attract, retain and cultivate talent; the capability to maintain high quality standards; the capability to obtain and maintain regulatory approvals; and the capability to effectively market and promote products.

EMPLOYEES

As of September 30, 2024, we had a total of 2,400 full-time employees with 2,322 employees located in China and the rest in the U.S. The following table sets forth a breakdown of our employees by function as of September 30, 2024:

Function	Number	% of Total
R&D	1,006	41.9%
Manufacturing	683	28.5%
General and Administrative	537	22.4%
Sales and Marketing	174	7.3%
Total	2,400	100.0

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Relationship with Employees

We enter into standard labor, confidentiality and non-compete agreements with our employees. As of the Latest Practicable Date, our employees were represented by a labor union. We believe that we have maintained good working relationships with our employees. During the Track Record Period and up to the Latest Practicable Date, we did not experience any material labor disputes or strikes that may have a material and adverse effect on our business, financial condition or results of operations.

Training and Development

We provide our employees with a diverse array of professional development opportunities and foster a performance-driven environment. We have a comprehensive talent development mechanism that nurtures employees from entry-level to expert proficiency. Every new employee undergoes comprehensive and systematic onboarding training tailored to their specific roles and responsibilities. During daily operations, direct supervisors provide targeted training and guidance based on the employee’s performance, proficiency in handling tasks, and work results. This continuous and focused training ensures that employees are well-prepared and supported in their roles, contributing to their professional growth and the overall success of our projects.

We place a strong emphasis on nurturing talent, particularly in R&D area. We provide both internal and external training for our technical staff, which enables us to foster a diversified, multi-level, and well-structured talent pool. To motivate our R&D personnel to improve their work efficiency and expedite project progress while ensuring the quality of project deliverables, we have also implemented various measures such as Performance Management Measures and Invention and Innovation Reward Measures. These policies form a comprehensive talent incentive system that includes both short-term performance rewards and long-term career advancement opportunities.

Employee Benefits

We believe we offer our employees competitive compensation packages, reflecting our stakeholder-centric ethos which we believe leads to sustainable and durable growth. As required by PRC regulations, we participate in various government statutory employee benefit plans, including social insurance, namely pension insurance, medical insurance, unemployment insurance, work-related injury insurance, maternity insurance, and housing provident funds. Additionally, for certain of our employees in Chengdu, we provide supplementary insurance through the Chengdu Medicare (惠蓉保補充保險) to support their health and well-being. We also adhere to legal requirements by offering maternity leave, paternity leave, and other related benefits. We ensure a safe working environment that complies with safety standards, and we provide daily meal subsidies, transportation, and communication allowances. We have also enrolled each employee in the U.S. in the 401(K) retirement benefit plan, striving to ensure that every employee has financial security in their later years.

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AWARDS AND RECOGNITION

Throughout our corporate history, we have received a number of major awards and accolades. The table sets forth a summary of the major awards and recognition we received as of the Latest Practicable Date:

Year(s) of Grant	Award/Recognition	Issuing Authority
2024	Sichuan Provincial Specialized and New Small and Medium — Sized Enterprises (四川省專精特新中小企業)	Sichuan Provincial Economic and Information Department (四川省經濟和信息化廳)
2023	High-tech Enterprise (高新技術企業)	Science & Technology Department of Sichuan Province (四川省科學技術廳), Sichuan Provincial Finance Department (四川省財政廳), and Sichuan Provincial Tax Service, State Taxation Administration (國家稅務總局四川省稅務廳)
2022	Sichuan Province technology innovation demonstration enterprise (四川省技術創新示範企業)	Sichuan Provincial Economic and Information Department (四川省經濟和信息化廳)
2022	National intellectual property demonstration enterprise (國家知識產權示範企業)	China National Intellectual Property Administration (國家知識產權局)
2022	National Enterprise Technology Center (國家企業技術中心)	National Development and Reform Commission (國家發改委)
2015-2022	China’s innovative pharmaceutical enterprises (中國創新力醫藥企業)	China General Institute of Pharmaceutical Industry Research (中國醫藥工業研究總院)
2015-2023	China pharmaceutical research and development product line best industrial enterprises (中國醫藥研發產品線最佳工業企業)	China Pharmaceutical Industry Information Center (中國醫藥工業信息中心)
2017-2021	Sichuan enterprise technology innovation and development ability top 100 (四川企業技術創新發展能力100強)	Sichuan Enterprise Federation (四川省企業聯合會)

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Year(s) of Grant	Award/Recognition	Issuing Authority
2018, 2019	Sichuan enterprise technology innovation development ability research and experimental development fund investment top 100 (四川企業技術創新發展能力研究與試驗發展經費投入100強)	Sichuan Enterprise Federation (四川省企業聯合會)
2018-2021	The number of invention patents of Sichuan enterprises is top 100 (四川企業發明專利擁有量100強)	Sichuan Enterprise Federation (四川省企業聯合會)
2020	Ranked 12th among the top 100 enterprises of technological innovation ability in Sichuan Province (四川省技術創新能力百強企業第12名)	Sichuan Enterprise Federation (四川省企業聯合會)
2018	The 10th Annual Brand Performance Award of the Health China General Evaluation List (第十屆健康中國總評榜年度品牌表現獎)	Co-sponsor Committee of Healthy China 2030 Brand Plan (健康中國2030品牌計劃聯合發起委員會)
2017	China Health Industry clinical most trusted brand award (中國健康產業臨床最信賴品牌獎)	China Pharmaceutical Industry Information Center (中國醫藥工業信息中心)

INTELLECTUAL PROPERTY

Our intellectual property rights are critical to 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 invention patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we owned (i) 183 issued invention patents, including 80 in China, 13 in the U.S., and 90 in other jurisdictions, and (ii) 461 patent applications, including 65 in China, 39 in the U.S., 16 under the Patent Cooperation Treaty (PCT) and 341 in other jurisdictions. The invention patents granted to, or under application by, us cover all material aspects of BL-B01D1 and other innovative drug candidates and technologies.

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The following table summarizes the details of the material granted patents and patent applications in connection with our innovative drug candidates.

Product	Scope of Patent Protection	Patent Number/ Application Number	Jurisdiction	Patent Holder/Applicant	Estimated Expiration Year*
Products on HIRE-ADC platform, including BL-B01D1	Antibody-Drug Conjugate Having Acidic Self-Stabilization Junction (一種帶酸性自穩定接頭的抗體-藥物偶聯物)	ZL201810620856.7	China	Baili-Bio	June 2038
		16971219	U.S.	SystImmune	N/A*
		18820589.2	EU	SystImmune	N/A*
	A Camptothecin Drug and Its Antibody Conjugate Thereof (一種喜樹鹼類藥物及其抗體偶聯物)	AU2020442003	Australia	SystImmune	September 2040
		17601055	U.S.	SystImmune	N/A*
		20928032	EU	SystImmune	N/A*
		2020104461426	China	Baili-Bio	N/A*
	Bispecific Antibody-camptothecin Drug Conjugate and Pharmaceutical Use thereof (雙特異性抗體-喜樹鹼類藥物偶聯物及其醫藥用途)	18710044	U.S.	SystImmune	N/A*
		2022114255725	China	Baili-Bio	N/A*
		22892173.0	EU	SystImmune	N/A*
	Bispecific Tetravalent Antibody Targeting EGFR and HER3 (靶向EGFR和HER3的雙特異性四價抗體)	18681827	U.S.	SystImmune	N/A*
		202280059981X	China	Baili-Bio, SystImmune	N/A*
Products on GNC platform	Bispecific Tetravalent Antibodies and Methods of Making and Using Thereof (雙特異性四價抗體及其製造和使用方法)	ZL201580036408.7	China	Baili-Bio	December 2035
		US10919977B2	U.S.	SystImmune	December 2035
		17143204	U.S.	SystImmune	N/A*
	Multi-Specific Antibodies and Methods of Making and Using Thereof (多特異性抗體及其製備和使用方法)	ZL201880039401.4	China	Baili-Bio	June 2038
		ZL201880039406.7	China	Baili-Bio	June 2038
		US11787863	U.S.	SystImmune	March 2040
		US11649286	U.S.	SystImmune	June 2039
Products on SEBA platform	Anti-CD3 Antibodies and Methods of Making and Using Thereof (抗CD3抗體及其製備和使用方法)	16615117	U.S.	SystImmune	N/A*
		US11535667	U.S.	SystImmune	September 2039
		ZL201880038306.2	China	Baili-Bio	June 2038
		16615109	U.S.	SystImmune	N/A*
	Bispecific Antibodies and Methods of Making and Using Thereof (雙特異性抗體及其製備和使用方法)	AU2018358138	Australia	SystImmune	June 2038
		ZL201880059130.9	China	Baili-Bio	November 2038
		16760466	U.S.	SystImmune	N/A*
	Anti-PD-1 Antibodies and Methods of Making and Using Thereof (抗PD-1抗體及其製備和使用方法)	ZL201880038220.X	China	Baili-Bio	June 2038
		US11466084	U.S.	SystImmune	November 2038

* Patent application.

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any proceedings in respect of our intellectual property rights, 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. Furthermore, our legal advisers as to intellectual property law have conducted the freedom-to-operate searches and

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analysis on BL-B01D1 in mainland China and the United States, and believe that we have the freedom to operate in connection with BL-B01D1 without infringing any valid and enforceable patent rights of third parties, and did not identify any known blocking patents which would preclude us from proceeding with the planned activities related to BL-B01D1.

DATA PRIVACY AND PROTECTION

We have established procedures to protect the confidentiality of patients’ data. We collect data of patients who enroll in our clinical trials. We store such data unless required by relevant laws and regulations or requested by the relevant patient to delete them.

We maintain policies requiring our personnel to be trained to legally collect and safeguard personal information and require our CROs to have data protection clauses in our agreements with them, under which they are responsible for safeguarding data in their possession. Additionally, we require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Personal information of patients enrolled in our clinical trials and the corresponding clinical trial data are processed solely in accordance with the informed consent form (ICF) agreed upon by the patients.

We have a number of ongoing or planned clinical studies in China and the U.S. For the purpose of the research and development of our innovative drug candidates, we provide online access of certain clinical data to SystImmune, our wholly-owned subsidiary in the U.S., and SystImmune transmitted certain clinical data to us. Any cross-border transmission of clinical trial data in connection with our product development efforts and regulatory communications is subject to the applicable local data and privacy protection laws, including those in China and the U.S. Together with our CROs and other collaboration partners, we have implemented controls and arrangements designed to ensure a data management and transfer plan is developed and implemented to govern the transfer of all clinical trial data. Related measures include, as applicable, ensuring that the cross-border transfer of clinical trial data and information is permitted, and the applicable filings for the export of human genetic resource information is made with the competent health department of the State Council in accordance with applicable laws and regulations. We have reported and completed filing for the clinical trial data of human genetic resources transmitted to our U.S. subsidiary and submitted information backup, according to the HGR Regulations. SystImmune’s legal advisor as to U.S. laws, upon reviewing the facts presented, is of the view that, as of the Latest Practicable Date, the transfers of properly deidentified clinical data from and to SystImmune or its Chinese affiliates made in connection of its ongoing clinical operations with existing U.S. partners, including BMS and clinical sites, are not restricted by U.S. federal or state laws as applicable to SystImmune and its affiliates. We continue to diligently monitor the regulatory landscape to ensure compliance with applicable laws and regulations. We had not been subject to any claims, lawsuits, penalties or administrative actions relating to cross-border clinical data transfer activities as of the Latest Practicable Date.

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During the Track Record Period and up to the Latest Practicable Date, to the best of our knowledge, we had not encountered any material data or personal information leakage. Our Directors confirm that we were not subject to any material claims, lawsuits, penalties or administrative actions relating to non-compliance with applicable laws and regulations for data privacy and protection as of the Latest Practicable Date.

PROPERTIES

We occupy certain properties in the PRC in connection with our business operation. According to section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice, this document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which requires a valuation report with respect to all our interests in land or buildings, for the reason that, as of the date of the most recent audited combined balance sheet of our Group, none of the properties owned and leased by us had a carrying amount of 15% or more of our combined total assets.

Owned Properties

As of the Latest Practicable Date, we obtained 41 land use right certificates for properties with an aggregate site area of 242,332.91 sq.m. As of the Latest Practicable Date, we obtained 75 real estate ownership certificates for properties with total site area of approximately 139,321.73 sq.m. in the PRC. These parcels of properties mainly are located at Chengdu, Sichuan Province, and are primarily used as our production facilities, administrative offices and R&D buildings. Among all of our owned properties, 32 of land use rights with buildings on them were pledged to secure our bank borrowings.

In addition, as of the Latest Practicable Date, we had not obtained the real estate ownership certificates for two properties occupied by us used for dormitories and warehouses, with an aggregate GFA of approximately 279.52 sq.m., representing around 0.2% of the total GFAs of our owned properties. We acquired these two properties through a judicial auction in November 2007, and their safety conditions were satisfactory as of the Latest Practicable Date. Since the previous owner did not obtain the real estate ownership certificates of the two properties, it was impracticable for us to obtain the relevant real estate ownership certificates upon their acquisition. Besides, as dormitories and warehouses on these two properties with title defects were already constructed before our acquisition, it is practically impossible for us to eliminate the impact through remedial measures and subsequently obtain the relevant real estate ownership certificates.

As advised by our PRC Legal Advisor, properties without real estate ownership certificates are prohibited from being transferred and cannot be pledged pursuant to the Civil Code of the PRC (《中華人民共和國民法典》) and the Urban Real Estate Management Law of the PRC (《中華人民共和國城市房地產管理法》). In addition, should disputes arise due to title encumbrances to such properties or government action, we may encounter difficulties in

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continuing to use such properties and may be required to relocate. However, considering that these properties are primarily used for dormitories and warehouses, which are not directly related to our production and operations and only account for a small proportion of our owned properties, our Directors believe that (i) in the event that relocation becomes necessary, we will not incur significant time or cost to identify and relocate our operations to comparable alternative properties, and (ii) such identification and relocation would not have a material adverse impact on our business operations and financial condition. In addition, our Controlling Shareholder has committed to compensating us for any losses incurred in connection with these properties. Our Directors also confirm that, during the Track Record Period and up to the Latest Practicable Date, we had not received any notification from the government authorities requiring us to demolish and/or relocate from the properties with defective titles. Pursuant to the confirmations issued by the relevant competent authorities, during the Track Record Period, we had complied with other relevant laws and regulations with respect to real estate management in all material aspects and had not been subject to any penalties resulting from non-compliance of these laws and regulations. Based on the above, we believe, and our PRC Legal Advisor concurs, that the title defects, either individually or collectively, will not have a material adverse impact on our business operations. See “Risk Factors — Other Risks Relating to Our Operations — Our legal right to certain properties may be challenged.”

Leased Properties

As of the Latest Practicable Date, we leased 14 properties from third parties with an aggregate GFA of approximately 10,462.30 sq.m., which were primarily used as production facilities and administrative offices. Our leases generally have a term ranging from one to three years. We will consider renewal of the leases upon their expiry.

Pursuant to the applicable PRC laws and regulations, both lessors and lessees must register lease agreements with the relevant authorities and obtain property leasing filing certificates. As of the Latest Practicable Date, six of our lease agreements between us and third parties which are leased from third parties and used for production or office, with an aggregate GFA of approximately 5,174.88 sq.m., had not been registered with the relevant local authorities. As advised by our PRC Legal Advisor, failure to register an executed lease agreement will not affect its validity. However, we may be subject to a fine of no less than RMB1,000 and not exceeding RMB10,000 for each unregistered lease agreement if the relevant PRC governmental authorities require us to rectify it and we fail to do so within the prescribed time period. As of the Latest Practicable Date, we have not received any order from the relevant government authorities requiring us to register these lease agreements. We undertake to cooperate fully to facilitate the registration of lease agreements once we are notified of any requirements by the relevant government authorities. See “Risk Factors — Other Risks Relating to Our Operations — Our legal right to certain properties may be challenged.”

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INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business to safeguard against risks and unexpected events in both China and U.S. Our insurance coverage comprises personnel-related policies such as pension, medical, work-related injury, maternity, and unemployment insurance. We have also secured comprehensive property insurance to cover losses arising from natural or other disasters affecting our manufacturing facilities or other assets. For each clinical trial, we have purchased clinical trial liability insurance to ensure comprehensive protection for the safety and legal rights of trial participants. Additionally, we have voluntarily purchased insurance to address safety concerns, including environmental pollution liability insurance for compensation in case of pollution incidents. We believe our existing insurance coverage is adequate for our present operations and in line with the industry practice in China and U.S.

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. During the Track Record Period and as of 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. The table below sets forth the relevant details of the material licenses, approvals and permits we hold for our operations.

License/Permit	Holder	Issuing Authority	Issue Date	Expiration Date
Drug Production License (藥品生產許可證) (川20160266)	Baili Pharmaceutical	Sichuan MPA	December 10, 2020	December 9, 2025
Drug Production License (藥品生產許可證) (川20160289)	Guorui Pharmaceutical	Sichuan MPA	December 2, 2020	December 1, 2025
Drug Production License (藥品生產許可證) (川20190504)	Jingxi Pharmaceutical	Sichuan MPA	January 25, 2024	January 24, 2029
Drug Production License (藥品生產許可證) (川20230590)	Baili-Bio	Sichuan MPA	August 28, 2023	March 27, 2028
Drug Production License (藥品生產許可證) (藏20240051)	Tianze Pharmaceutical	Xizang MPA	August 21, 2024	August 20, 2029
Drug Distribution License (藥品經營許可證) (川AA0280803)	Our Company	Sichuan MPA	December 8, 2020	December 7, 2025
Drug Distribution License (藥品經營許可證) (藏AA8910042)	Lhasa Xinbo	Xizang MPA	March 4, 2024	March 3, 2029

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During the Track Record Period, we possessed relevant export licenses for our R&D activities and business expansion plan in overseas market. Our subsidiaries, Baili Pharmaceutical, Guorui Pharmaceutical, and Baili-Bio maintain long-term Recordation of Customs Declaration Entities (海關報關單位備案), the registration dates of which are September 30, 2011, June 29, 2018, and March 10, 2020, respectively.

LEGAL PROCEEDINGS AND COMPLIANCE

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 as of the Latest Practicable Date, there was no litigation, arbitration or administrative proceedings pending or threatened against the Company or any of our Directors which could have a material and adverse effect on our financial condition or results of operations. We believe that, 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. For potential impact of legal or administrative proceedings on us, see “Risk Factors — Other Risks Relating to Our Operations — If we, our management or directors become party to litigation, legal disputes, claims or administrative proceedings, our management or directors’ attention may be diverted and our operations, reputation, revenue and profitability could be adversely affected.”

RISK MANAGEMENT AND INTERNAL CONTROLS

We are committed to developing and maintaining risk management and internal control systems comprised of policies and procedures tailored to our business operations. Our dedication lies in the continual enhancement of these systems to ensure their effectiveness.

Risk Management

We are exposed to various risks in our business operations, and we believe that risk management is important to our success. See “Risk Factors — Key Risks Relating to Our Business and Industry” for more details. We have established our risk management systems to identify, assess, monitor and mitigate the risks that may hinder our success including strategic risks, operational risks, financial risks and legal risks.

To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [REDACTED], we have adopted or will continue to adopt, among other things, the following risk management measures:

- establish an Audit Committee to review and supervise our financial reporting process and internal control system;

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- adopt various policies to ensure compliance with the Listing Rules, including but not limited to aspects related to risk management, connected transactions and information disclosure;
- provide anti-corruption and anti-bribery compliance training periodically to our senior management and employees to enhance their knowledge and compliance with applicable laws and regulations;
- organize training sessions for our Directors and senior management in respect of the relevant requirements of the Listing Rules and duties of directors of companies [REDACTED] in Hong Kong;
- enhance our reporting and records system for production facilities, including centralizing their quality control and safety management systems and conducting regular inspections of the facilities;
- establish a set of emergency procedures in the event of major quality-related issues; and provide enhanced training programs on quality assurance and product safety procedures.

Internal Controls

Our management team is responsible for establishing our internal controls system and the audit committee of our Board is responsible for reviewing its effectiveness. We have engaged an independent internal control consultant to perform the internal review procedures 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 review procedures in May and June 2024. As of the Latest Practicable Date, there were no material outstanding issues relating to our Group’s internal controls.

We are committed to establishing and maintaining risk management and internal control systems. We have adopted and implemented a comprehensive risk management policy encompassing risks that may arise in research and development, procurement management, production management, and sales management. Our risk management and internal control systems also cover the general functional operations such as human resources, financial management, asset management, warehousing and logistics management, information system management and corporate governance as well as decision-making processes. Meanwhile, we are committed to supervising and evaluating the effectiveness of risk management and internal control system to ensure that the system is rectified and effectively controlled as our business develops.

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Anti-bribery

We maintain a strict code of conduct and anti-corruption policies among our employees. We also require our distributors to bear integrity obligation pursuant to the distribution agreements with such distributors. We believe we will be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry. We strictly prohibit bribery or other improper payments in our business operations. This prohibition applies to all business activities, anywhere globally, whether involving government officials or healthcare professionals. Improper payments prohibited by this policy include bribes, kickbacks, excessive gifts or entertainment, or any other payment made or offered to obtain an undue business advantage. We keep accurate books and records that reflect transactions and asset dispositions in reasonable detail. Requests for false invoices or payment of unusual, excessive or inadequately described expenses should be rejected and promptly reported. Misleading, incomplete or false entries in our books and records are not acceptable. We will also ensure that future sales team personnel comply with applicable promotion and advertising requirements, including restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

Besides, our agreements with third-party promoters include anti-bribery clauses where both parties commit to opposing all forms of commercial bribery, which explicitly prohibit the use of money or other means in the name of any company, individuals, or their relatives to bribe medical institutions, healthcare professionals, regulatory agencies, or individuals (including their relatives) during the promotion of our products. In particular, employees responsible for academic promotion and third-party promoters in interactions with healthcare professionals or organizations are prohibited from engaging in any activities intended to secure product approvals, establish inappropriate relationships, generate business, or induce or reward prescription behaviors. Additionally, we mandate that all personnel involved in our marketing and promotional activities must refrain from providing gifts or services for personal use to healthcare professionals.

Non-Competition

We have instituted rigorous protocols to safeguard the proprietary information that arises during the development and production of our projects, which encompasses product formulations, preparation techniques, methodologies, and research strategies. The employment agreements between us and our senior management and key technical personnel include confidentiality clauses and non-compete agreements. We assign code names to our core projects in order to obscure their true nature and purpose. In addition, researchers are strictly prohibited from removing electronic or physical records of experimental results and data from the laboratory premises. Through these meticulous steps, we diligently protect our intellectual property and maintain the integrity of our innovative endeavors.

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SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

We recognize our responsibility to uphold high standards in health, safety, social and environmental practices. Following our [REDACTED], we are committed to complying with environmental, social, and governance (ESG) reporting requirements. We understand the environmental and social-related risks that will affect our business and have therefore established an ESG work group for addressing such risks and formulated corresponding working rules to supervise our corporate social responsibility and measures for sustainable development. The ESG work group is responsible for (i) assessing and managing our ESG-related risks and opportunities, and deliberating on the formulation of, among others, our ESG strategic plans, management structure, systems, strategies and implementation rules so as to ensure the continuous execution and implementation of our ESG policies; (ii) making guidelines for and reviewing the identification and ranking of our important ESG issues; (iii) determining our key ESG issues; (iv) reviewing our ESG work and internal monitoring systems, and making recommendations on their appropriateness and effectiveness; (v) reviewing our ESG-related disclosure documents, including but not limited to the annual ESG reports; (vi) monitoring our ESG-related risks and making inquiries on and formulating corresponding measures for major issues that affect our performance of ESG-related work, and reviewing and supervising how such issues are handled; and (vii) providing ESG-related training and materials to the Board of Directors.

Governance on ESG Matters

The Board has collective responsibility for managing the impact of the material ESG risks and opportunities affecting the Group, formulating and establishing the Group’s ESG-related mechanisms, policies and objectives, and reviewing the Group’s performance against the ESG objectives on an annual basis and revising the ESG policy as appropriate if significant deviations from the objectives are identified.

The Board assesses ESG risks, review the Group’s existing strategies, objectives and internal controls, and implement necessary improvements to mitigate the risks on a regular basis. The Board and ESG work group will continue to monitor the Group’s strategic planning for risk management, including climate-related risks and those risks that were monitored as part of standard operating procedures, to ensure that appropriate mitigation measures are implemented as part of regular management reviews. Our ESG working group consists of 20 members, including our Director, senior managements and department heads who will gain experience for monitoring ESG-related matters with the assistance of our independent ESG consultant.

For the board governance structure for overseeing the ESG risks, the Group has established three-tiered ESG management structure consisting of the Board, the ESG work group and the departments. The Board will be informed of the ESG work group’s assessment on ESG matters through regular reports, which include quarterly reports, interim reports and annual reports. When there are important changes in the external ESG environment or policies, ESG working group will report to the Board through special ESG reports. ESG working group meetings are divided into regular and ad hoc meetings. Regular meetings are held twice a year, and ad hoc meetings are held at the initiative of work group members.

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Metrics and Targets on Environmental Matters

The Company strictly abides by the relevant national environmental protection laws and regulations in the production and operation, has established and strictly implemented the internal control system of environmental protection, and has increased investment in pollution control, constantly optimize the process and equipment, and reduce the pollution in the production process. During the Track Record Period, the production business of the company was implemented by four subsidiaries engaged in production business: Baili Pharmaceutical, Guorui Pharmaceutical, Baili-Bio Pharmaceutical and Jingxi Pharmaceutical. Consequently, our operations result in air pollution, wastewater, solid waste, or other hazardous wastes. To ensure compliance with national, industrial, and local environmental standards, laws, regulations, and policies, we have implemented internal policies for environmental risk prevention. These policies include: (i) strict adherence to GMP regulations and relevant pollutant emissions standards; (ii) conducting periodic environmental assessments on exhaust gas emissions, hazardous waste disposal, noise emissions, and wastewater emissions.

When setting targets for our ESG-related KPIs, we will carefully consider our historical consumption and discharge levels during the Track Record Period, along with our plans for future business expansion. Our approach aims to balance business growth with environmental protection to achieve sustainable development.

Pollutant Disposals

The waste we produce is divided into hazardous waste (such as chemical waste and liquid) and non-hazardous waste (such as waste from general office operations). In 2021, 2022, 2023 and for the nine months ended September 30, 2024, our solid hazardous waste discharge levels were approximately 441.9 tons, 587.4 tons, 1,007.8 tons and 1,441.2 tons, respectively. We mainly generated more solid hazardous waste in line with the growth of our research, development and manufacturing activities. To the extent feasible, we plan to further improve our operational efficiency to reduce the amount of solid waste generated from our operations.

Household garbage is collected and disposed of by sanitation services, while general packaging materials are sold externally. Hazardous waste is collected and then entrusted to qualified units for disposal. We have also contracted with qualified third-party waste disposal company for the disposal of hazardous material and waste. We establish clear contractual obligations that mandate compliance with environmental laws and safety standard. The third parties we collaborate with are required to maintain detailed records and provide proof of proper waste disposal. We have implemented the Hazardous Waste Management Policy to monitor the handling, use, storage, treatment and disposal of hazardous waste and material, including contractor management. Upon transferral of the hazardous materials and waste, both the contracted parties and us check the weight at the designated weighing spot. Related records are documented in the information system that is linked to the government’s information platform. Contracted parties are also required to follow the designated routes set by us for the transportation. Site inspections are conducted to ensure our contracted parties handle, use, store, treat and dispose of hazardous material and waste that complies with our contractual agreements and laws and regulations related to hazardous material and waste handling,

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including but not limited to checking on the labelling and records of the hazardous material and waste. Contracted parties are also required to answer inquiries from us upon our on-site inspections. In addition, we implement continuous environmental monitoring to track potential contamination and enforce strict incident response plans.

We have strengthened internal controls, including the implementation of the Environmental Protection Facilities Management System and Sewage Station Operation Procedures to standardize the operation of environmental protection facilities and ensure compliance. We have also set up an online monitoring system to monitor real-time wastewater discharge and a water treatment system to pre-treat concentrated wastewater for collection. Wastewater from office, life, ground cleaning, production process, quality testing etc., after being treated in advance at our self-built sewage treatment plant is discharged into the sewage treatment plant for further treatment and compliant discharge. Waste liquids from quality testing are managed as hazardous waste and are collected and disposed of by qualified units.

Greenhouse Gases Emissions

Air pollution is treated at appropriate gas treatment facilities and then discharged in compliance with standards. We aim to reduce our greenhouse gases (“GHG”) emissions and contribute to the transition to a low-carbon economy. Our greenhouse gas emissions primarily consist of Scope 1, Scope 2 and Scope 3 emissions. Scope 1 emissions mainly include the direct greenhouse gas emissions from our own R&D and other facilities. Scope 2 emissions primarily include the indirect greenhouse gas emissions from our usage of purchased electricity. Scope 3 emissions mainly consist of indirect emissions outside of Scope 2 emissions that occur in our value chain. Our Scope 1 emissions amounted to approximately 5,710.2 tonnes carbon dioxide equivalent (“tCO₂e”), 5,508.3 tCO₂e, 7,139.5 tCO₂e and 4,901.9 tCO₂e in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively. Our Scope 2 emissions amounted to approximately 8,439.4 tCO₂e, 8,957.8 tCO₂e, 12,268.8 tCO₂e and 10,472.9 tCO₂e in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively. Our Scope 3 emissions mainly consist of indirect emissions generated from freshwater and sewage treatment and business air travel amounted to approximately 765.7 tCO₂e, 553.1 tCO₂e, 1,076.0 tCO₂e and 770.1 tCO₂e in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively. As the data for upstream and downstream consumption or emissions becomes more comprehensive, we will continue to refine and improve our consumption and emissions accounting in the future following our [REDACTED] and referencing the latest climate reporting requirement.

We will implement measures in mitigating the GHG emissions, including (i) providing trainings and educate our employees on the concept of energy efficiency; (ii) posting water-saving or power-saving signs in eye-catching areas to cultivate our employees’ awareness of environment protection; (iii) promoting paperless environment, encourage the usage of electronic copies instead of hard copies, the use of double-sided printing, and the use of single-sided printed paper when there is no confidential information on it; (iv) requiring employee to turn off all electrical appliances when they are not in use; and (v) implementing policies regarding waste management.

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Resource Consumption

In pursuit of our sustainable development objectives, we rigorously oversee our environmental protection performance across various domains, including resource efficiency and energy consumption. We closely monitor our electricity and water consumption levels and actively implement strategies to enhance energy efficiency and promote water conservation. In aggregate, our electricity consumption levels were approximately 15.2 million kWh, 15.7 million kWh, 21.5 million kWh and 18.4 million kWh in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively. Our water consumption levels amounted to approximately 692.9 thousand tons, 594.0 thousand tons, 845.9 thousand tons and 524.1 thousand tons in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively.

Climate Change

We believe that we are not susceptible to climate change. Moreover, we consider that potential changes to the regulations in the PRC regarding climate change will not adversely impact our business operations. We will continue to pay attention to risks regarding climate change and formulate emergency plans to safeguard us from climate change and extreme weather conditions, such as hurricane and rainstorms. As of the Latest Practicable Date, we had not experienced any material impact on our business operations or financial performance as a result of climate change or extreme weather conditions.

Targets

With the expansion of production and development of our business, we anticipate ongoing disposal needs and are committed to strictly managing pollutants. In 2024, we aim to control (i) our pollutant disposals at approximately 118% of that recorded in 2023, (ii) our greenhouse gas (Scope 1 and 2) emissions at approximately 118% of that recorded in 2023, and (iii) resource consumption level at approximately 105% of that recorded in 2023. In 2025, we aim to control (i) our pollutant disposals at approximately 105% of that recorded in 2023, (ii) our greenhouse gas (Scope 1 and 2) emissions at approximately 105% of that recorded in 2023, and (iii) resource consumption level at approximately 105% of that recorded in 2023.

Work Safety

We are dedicated to ensuring a safe working environment for our employees. We firmly believe that a safe and healthy workplace is not only crucial for the well-being of our employees but also indispensable for the sustainability of our business. We implement the following measures to ensure production safety and prevent accidents and personnel injuries:

- Personnel undergo training before taking up positions.
- We conduct annual safety training and organizes safety month activities.

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- Regular emergency drills are conducted by us every year.
- Safety protection and emergency facilities such as gas alarms and emergency eyewash stations are provided.
- Employees are provided with labor protection supplies.

During the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any material non-compliance incidents regarding occupational health and safety laws and regulations, and there had not been and were not any material safety issues, accidents and claims relating to our business operations.

Workplace Diversity

Within our company, we are steadfast in our commitment to fostering an open and inclusive workplace that champions equality. We adhere to a corporate policy of hiring employees based solely on their merits, offering equal opportunities regardless of gender, age, race, religion, or any other social or personal characteristics.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDER

OUR CONTROLLING SHAREHOLDER

As of the Latest Practicable Date, Dr. Zhu directly held approximately 74.35% of our total issued Shares. Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), Dr. Zhu will directly hold approximately [REDACTED]% of our total issued Shares. Accordingly, Dr. Zhu will remain as our Controlling Shareholder upon the completion of the [REDACTED].

Dr. Zhu is our executive Director, chairman of the Board, general manager and Chief Scientific Officer. See “Directors, Supervisors and Senior Management” for further details.

CONFIRMATION OF NO COMPETING INTEREST

Dr. Zhu confirms that, as of the Latest Practicable Date, he did not have any interest in a business, apart from the business of the Group, which competes or is likely to compete, directly or indirectly, with our business, which would require disclosure under Rule 8.10 of the Listing Rules.

Non-competition Undertaking in connection with the A Shares Listing

For the purpose of the listing of our A Shares on the SSE STAR Market in January 2023 and in order to avoid any potential competition between Dr. Zhu and our Company, Dr. Zhu entered into a non-competition undertaking in favor of our Company on October 29, 2021, pursuant to which he has undertaken, among others, that, (i) he will not, and will procure his controlled entities (other than our Group) not to engage in any business in competition with the business of our Group; (ii) in the event that any business opportunity that may compete with the business of our Group becomes available to him or his controlled entities (other than our Group), our Group will have the priority to take up such business opportunity; (iii) in the event that he fails to comply with the above undertaking, he agrees to account to our Group for gains that may be obtained, and compensate our Group for all direct losses that our Group may suffer, as a result of such breach.

INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDER

Taking into consideration the following factors, our Directors are of the view that our Group can conduct our business independently from our Controlling Shareholder after the [REDACTED].

Management Independence

Our Board comprises five executive Directors, one non-executive Director and four independent non-executive Directors. Our Company has three Supervisors and a senior management team comprising four members. See “Directors, Supervisors and Senior Management” for further details.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDER

The executive Directors and senior management team are responsible for the day-to-day management of our operations. Save for the relationship between Dr. Zhu and Dr. Zhu Hai as disclosed in “Directors, Supervisors and Senior Management”, the other executive Directors and other members of our senior management team are independent of Dr. Zhu. Notwithstanding the role of Dr. Zhu in our Group as described above, our Directors are of the view that our Company is able to function independently from Dr. Zhu for the following reasons:

- (i) each Director is aware of his or her fiduciary duties and responsibilities as a director, which require that he or she acts for the benefit and in the best interest of our Company and does not allow any conflict between his or her duties as a Director and his or her personal interests;
- (ii) other than Dr. Zhu Hai, all of the other Directors are independent of Dr. Zhu and decisions of the Board require the approval of a majority vote from the Board. Therefore, the Board can manage the operation of our Company independently of our Controlling Shareholder;
- (iii) the day-to-day management and operations of our Group are carried out by our executive Directors and senior management team, most of whom are independent of our Controlling Shareholder and have substantial experience in the industry in which our Group is engaged, and will therefore be able to make business decisions that are in the best interests of our Group. For details of the background of the executive Directors and senior management, see “Directors, Supervisors and Senior Management”;
- (iv) we have appointed four independent non-executive Directors, comprising more than one-third of the total members of our Board, who have sufficient knowledge, experience and competence, so that there is a balanced composition of executive, non-executive Directors and independent non-executive Directors to ensure the independence of the Board in making decisions affecting our Company and to promote the interests of our Company and the Shareholders as a whole. For details of the background of independent non-executive Directors, see “Directors, Supervisors and Senior Management”;
- (v) our Company has established internal control mechanisms to identify connected transactions to ensure that our Shareholders or Directors with conflicting interests in a proposed transaction will abstain from voting on the relevant resolutions. In the event that there is a potential conflict of interest arising out of any transaction to be entered into between our Company and our Directors or their respective close associates, the interested Director is obliged to declare and fully disclose such potential conflict of interest and shall abstain from voting at the relevant Board meetings of our Company in respect of such transactions and shall not be counted in the quorum; and

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDER

- (vi) we have adopted a series of corporate governance measures to manage conflicts of interest, if any, between our Group and the Controlling Shareholder which would support our independent management. For details, see “— Corporate Governance” below.

Based on the above, we believe that our Board and senior management as a whole are able to perform the managerial role independently from our Controlling Shareholder.

Operational Independence

We have established our own organizational structure, with each department assigned to specific areas of responsibilities which have been in operation and are expected to continue to operate independently from our Controlling Shareholder. We have independent access to suppliers and customers, and have independent production capabilities. We are also in possession of all relevant assets, licenses trademark and other intellectual property necessary to carry on and operate our business and we have sufficient operational capacity in terms of capital and employees to operate independently.

Our Directors are of the view that there is no operational dependence by us on our Controlling Shareholder, and our Group is able to operate independent from our Controlling Shareholder after the [REDACTED].

Financial Independence

We have independent internal control, financial and accounting systems. We also have an independent finance department as well as implemented strong and independent audit, accounting and financial management systems. We have opened accounts with banks independently and do not share any bank accounts with our Controlling Shareholder or his close associates. We have made tax filings and paid tax independently from our Controlling Shareholder and his close associates pursuant to applicable laws and regulations.

During the Track Record Period, the Controlling Shareholder had provided guarantees in respect of our certain bank facilities and lease agreements. As of the Latest Practicable Date, all such guarantees provided by our Controlling Shareholder were released. As of the Latest Practicable Date, the Controlling Shareholder or his close associates did not provide any loans, guarantees or pledges to our Group, and our Group did not provide any loans, guarantees or pledges to our Controlling Shareholder or his close associates.

CORPORATE GOVERNANCE

Our Company will comply with the provisions of the Corporate Governance Code in Appendix C1 to the Listing Rules (“**Corporate Governance Code**”), which sets out principles of good corporate governance in relation to, among other matters, directors, the chairman and executive officer, board composition, the appointment, re-election and removal of directors, their responsibilities and remuneration and communications with shareholders.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDER

Our Directors recognize the importance of good corporate governance to protect the interests of our Shareholders. We have adopted the following corporate governance measures to safeguard good corporate governance standards and to avoid potential conflict of interests between our Group and our Controlling Shareholder:

- (i) our Company has established internal control mechanisms to identify connected transactions. Upon [REDACTED], if our Company enters into connected transactions with the Controlling Shareholder or his close associates, our Company will comply with the applicable Listing Rules;
- (ii) in the event that any of our Directors and/or their respective close associates has material interest in any matter to be deliberated by our Board, he/she/they may not vote on the resolutions of our Board considering and approving the matter and shall not be counted towards the quorum for the voting pursuant to the applicable provisions in the Articles of Association;
- (iii) our Board consists of a balanced composition of executive, non-executive and independent non-executive Directors, with more than one-third of independent non-executive Directors to ensure that our Board is able to effectively exercise independent judgment in its decision-making process and provide independent advice to our Shareholders. Our independent non-executive Directors individually and collectively possess the requisite knowledge and experience to perform their roles. They will review whether there is any conflict of interests between our Group and our Controlling Shareholder and provide impartial and professional advice to protect the interest of our minority Shareholders;
- (iv) where the advice from an independent professional, such as that from financial or legal advisor, is reasonably requested by our Directors (including the independent non-executive Directors), the appointment of such independent professional will be made at our Company’s expenses; and
- (v) we have appointed Messis Capital Limited as our compliance advisor, which will provide advice and guidance to us in respect of compliance with the applicable laws and the Listing Rules, including various requirements relating to directors’ duties and internal control.

Based on the above, our Directors are satisfied that sufficient corporate governance measures have been put in place to manage conflicts of interest between our Group and our Controlling Shareholder and his close associates, and to protect the interests of our Shareholders, in particular, the minority Shareholders after the [REDACTED].

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and assuming that the [REDACTED] is not exercised, and no other changes are made to the issued share capital of our Company between the Latest Practicable Date and the [REDACTED], the following persons will have an interest and/or short position (as applicable) in our Shares or the underlying Shares which would fall to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or, will be, directly or indirectly, interested in 10% or more of the nominal value of any class of our share capital carrying rights to vote in all circumstances at general meetings of our Company:

Shareholder	Capacity/Nature of interest	Description of Shares	Number of Shares directly or indirectly held	As of the Latest Practicable Date		Immediately following the completion of the [REDACTED]	
				Approximate percentage of shareholding in our A Shares	Approximate percentage of shareholding in our total Share capital	Approximate percentage of shareholding in our A Shares ⁽¹⁾	Approximate percentage of shareholding in our total Share capital ⁽²⁾
Dr. Zhu	Beneficial owner	A Shares	298,159,400	74.35%	74.35%	[REDACTED]%	[REDACTED]%
OAP III (HK) Limited ⁽³⁾	Beneficial owner	A Shares	28,527,171	7.11%	7.11%	[REDACTED]%	[REDACTED]%
OrbiMed Asia Partners III, L.P. ⁽³⁾	Interest held by controlled corporation	A Shares	28,527,171	7.11%	7.11%	[REDACTED]%	[REDACTED]%
OrbiMed Asia GP III, L.P. ⁽³⁾	Interest held by controlled corporation	A Shares	28,527,171	7.11%	7.11%	[REDACTED]%	[REDACTED]%
OrbiMed Advisors III Limited ⁽³⁾	Interest held by controlled corporation	A Shares	28,527,171	7.11%	7.11%	[REDACTED]%	[REDACTED]%

Notes:

- (1) The calculation is based on the total number of A Shares in issue immediately following the completion of the [REDACTED], assuming that no other changes are made to the number of issued Shares of our Company between the Latest Practicable Date and the [REDACTED].
- (2) The calculation is based on the total number of Shares in issue immediately following the completion of the [REDACTED], assuming that the [REDACTED] is not exercised, and no other changes are made to the issued Share capital of our Company between the Latest Practicable Date and the [REDACTED].
- (3) OAP III (HK) Limited beneficially owns 28,527,171 A Shares. OAP III (HK) Limited is a limited company organized under the laws of Hong Kong and wholly owned by OrbiMed Asia Partners III, L.P. OrbiMed Asia Partners III, L.P. is an exempted limited partnership incorporated under the laws of the Cayman Islands. OrbiMed Asia GP III, L.P., an exempted limited partnership incorporated under the laws of the Cayman Islands, is the general partner of OrbiMed Asia Partners III, L.P. OrbiMed Advisors III Limited, an exempted company incorporated in the Cayman Islands, is the general partner of OrbiMed Asia GP III, L.P.

SUBSTANTIAL SHAREHOLDERS

Save as disclosed above, our Directors are not aware of any person who will, immediately following completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), have any interest and/or short position (as applicable) in the Shares or underlying Shares of our Company which would fall to be disclosed to our Company and the Stock Exchange pursuant to 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 any class of share capital carrying rights to vote in all circumstances at general meeting of the Company.

SHARE CAPITAL

This section presents certain information regarding our share capital before and upon completion of the [REDACTED].

BEFORE THE COMPLETION OF THE [REDACTED]

As of the Latest Practicable Date, our registered and issued share capital was RMB401,000,000 comprising 401,000,000 A Shares at the nominal value of RMB1.00 each, all of which are listed on the SSE STAR Market.

UPON THE COMPLETION OF THE [REDACTED]

Immediately following the completion of the [REDACTED], assuming that the [REDACTED] is not exercised, the issued share capital of our Company will be as follows:

Description of Shares	Number of Shares	Approximate percentage to the total share capital of our Company (%)
A Shares in issue	401,000,000	[REDACTED]
H Shares to be [REDACTED] pursuant to the [REDACTED]	[REDACTED]	[REDACTED]
Total	[REDACTED]	100.00

Immediately following the completion of the [REDACTED], assuming that the [REDACTED] is fully exercised, the issued share capital of our Company will be as follows:

Description of Shares	Number of Shares	Approximate percentage to the total share capital of our Company (%)
A Shares in issue	401,000,000	[REDACTED]
H Shares to be [REDACTED] pursuant to the [REDACTED]	[REDACTED]	[REDACTED]
Total	[REDACTED]	100.00

SHARE CAPITAL

SHARES OF OUR COMPANY

Upon completion of the [REDACTED], H Shares in issue and A Shares are ordinary Shares in the share capital of our Company and are considered as one class of Shares. Apart from certain qualified domestic institutional [REDACTED] in mainland China, the qualified [REDACTED] in mainland China under the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect (if our H Shares are eligible securities for that purpose) and other persons who are entitled to hold our H Shares pursuant to relevant PRC law or upon approvals of any competent authorities, H Shares generally cannot be subscribed for by or traded between legal or natural persons in mainland China.

Shanghai-Hong Kong Stock Connect has established a stock connect mechanism between mainland China and Hong Kong. Our A Shares can be subscribed for and traded by investors in mainland China, qualified foreign institutional investors or qualified foreign strategic investors and must be traded in Renminbi. As our A Shares are eligible securities under the Northbound Trading Link, they can also be subscribed for and traded by Hong Kong and other overseas investors pursuant to the rules and limits of Shanghai-Hong Kong Stock Connect. If our H Shares are eligible securities under the Southbound Trading Link, they can also be [REDACTED] for and traded by [REDACTED] in mainland China in accordance with the rules and limits of Shanghai-Hong Kong Stock Connect or Shenzhen-Hong Kong Stock Connect.

RANKING

Except for the differences set out in “— Shares of Our Company” above, our H Shares and our A 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. All dividends in respect of our H Shares are to be paid by us in Hong Kong dollars whereas all dividends in respect of our A Shares are to be paid by us in Renminbi. In addition to cash, dividends may also be distributed in the form of Shares. Holders of our H Shares will receive share dividends in the form of H Shares, and holders of our A Shares will receive share dividends in the form of A Shares.

NO CONVERSION OF OUR A SHARES INTO H SHARES FOR [REDACTED] AND [REDACTED] ON THE HONG KONG STOCK EXCHANGE

Our A Shares and our H Shares are generally neither interchangeable nor fungible, and the market prices of our A Shares and our H Shares may be different after the [REDACTED]. The Guidelines on Application for “Full Circulation” of Domestic Unlisted Shares of H-share 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 are not applicable to companies dual listed in the PRC and on the Hong Kong Stock Exchange. As of the Latest Practicable Date, there were no relevant rules or guidelines from the CSRC providing that A Shareholders may convert A shares held by them into H shares for [REDACTED] and [REDACTED] on the Hong Kong Stock Exchange.

SHARE CAPITAL

APPROVAL FROM HOLDERS OF A SHARES REGARDING THE [REDACTED]

Approval from holders of A Shares is required for our Company to [REDACTED] H Shares and seek the [REDACTED] of H Shares on the Hong Kong Stock Exchange. Such approval was obtained by us at the shareholders’ general meeting of our Company held on July 8, 2024 and is subject to the following conditions:

(i) **Size of the [REDACTED]**

The proposed number of H Shares to be [REDACTED] initially shall not exceed [REDACTED]% of the total issued share capital as enlarged by the H Shares to be [REDACTED] pursuant to the [REDACTED] (before the exercise of the [REDACTED]). The number of H Shares to be [REDACTED] pursuant to the full exercise of the [REDACTED] shall not exceed [REDACTED]% of the total number of H Shares to be [REDACTED] initially under the [REDACTED].

(ii) **Method of [REDACTED]**

The method of [REDACTED] shall be by way of an [REDACTED] to institutional investors and a [REDACTED] for subscription in Hong Kong.

(iii) **Target investors**

The H Shares shall be [REDACTED] to professional organizations, institutions individual [REDACTED] and the [REDACTED].

(iv) **[REDACTED] basis**

The [REDACTED] of the H Shares will be determined, among others, after due consideration of the interests of existing Shareholders of our Company, acceptance of [REDACTED] and [REDACTED] risks and in accordance with international practices through the demands for [REDACTED] and [REDACTED], subject to the domestic and overseas capital market conditions and by reference to the valuation level of comparable companies in domestic and overseas markets.

(v) **Validity period**

The [REDACTED] of H Shares and [REDACTED] of H Shares on the Hong Kong Stock Exchange shall be completed within 18 months from the date when the shareholders’ meeting was held on July 8, 2024.

There is no other approved [REDACTED] plans for our Shares except the [REDACTED].

SHAREHOLDERS’ GENERAL MEETING

For details of circumstance under which our shareholders’ general meeting is required, see “Appendix V — Summary of Articles of Association — Shareholders and General Meetings.”

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board of Directors currently consists of ten Directors, including five executive Directors, one non-executive Director and four independent non-executive Directors. The Directors serve for a term of three years and may be re-elected for successive reappointments.

The following table sets forth the key information in respect of our Directors:

Name	Age	Position	Time of joining our Group	Time of appointment as Director ⁽¹⁾	Roles and Responsibilities
Dr. Zhu Yi (朱義) ⁽²⁾	61	Executive Director, chairman of the Board, general manager and Chief Scientific Officer	August 1996	November 2010	Overall strategic planning, research and development and business management of our Group
Ms. Zhang Suyu (張蘇婭)	69	Executive Director, executive deputy general manager and chief financial officer	July 1997	August 2006	Overall strategic planning, formulation of financial strategies and overseeing the overall financial management of our Group
Mr. Kang Jian (康健)	56	Executive Director and deputy general manager	October 2000	November 2011	Major operational decisions and direct day-to-day management of our Group
Mr. Zhuo Shi (卓識)	40	Executive Director	June 2011	March 2021	Major operational decisions and direct day-to-day management of our Group

Notes:

(1) Denotes the date of appointment as a Director of the Company or its predecessor.

(2) Dr. Zhu Yi is the father of Dr. Zhu Hai.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Position	Time of joining our Group	Time of appointment as Director ⁽¹⁾	Roles and Responsibilities
Dr. Zhu Hai (朱海) ⁽³⁾	36	Executive Director	October 2019	February 2024	Major operational decisions and direct day-to-day management of our Group
Dr. David Guowei Wang	63	Non-executive Director	August 2017	August 2017	Providing professional advice to the Board
Mr. Li Mingyuan (李明遠)	70	Independent non-executive Director	November 2020	November 2020	Providing independent opinion and judgement to the Board
Mr. Yu Xiong (俞雄)	64	Independent non-executive Director	September 2019	September 2019	Providing independent opinion and judgement to the Board
Mr. Yang Min (楊敏)	53	Independent non-executive Director	September 2019	September 2019	Providing independent opinion and judgement to the Board
Dr. Xiao Geng (肖耿)	61	Independent non-executive Director	July 2024	July 2024	Providing independent opinion and judgement to the Board

Notes:

(1) Denotes the date of appointment as a Director of the Company or its predecessor.

(3) Dr. Zhu Hai is the son of Dr. Zhu Yi.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Executive Directors

Dr. Zhu Yi (朱義), aged 61, founded our Group in August 1996 and was appointed as our Director in November 2010. Dr. Zhu has been serving as the chairman of the Board and the general manager of our Company since November 2010, and as the Chief Scientific Officer since March 2021. He is responsible for the overall strategic planning, research and development and business management of our Group. Dr. Zhu is currently the chairman of the board of directors of Baili Pharmaceutical, an executive director and the manager of Baili-Bio, an executive director of Panku Capital, and an executive director and the general manager of SystImmune. With support of our R&D team, Dr. Zhu is responsible for overall strategic planning, research and development and management of SystImmune, which is a subsidiary principally engaged in research and development of pharmaceutical products, including innovative drug discovery and development.

Dr. Zhu has over 30 years of experience in the healthcare industry. He founded Baili Pharmaceutical in August 1996 and has been successively serving as its chairman of the board and general manager since then. Prior to founding our Group, Dr. Zhu taught at the department of microbiology and immunology of West China University of Medical Sciences (華西醫科大學) (currently known as West China Medical Center of Sichuan University (四川大學華西醫學中心)) from 1987 to 1990.

Dr. Zhu obtained a bachelor’s degree in radio physics from Sichuan University (四川大學) in the PRC in July 1984, a master’s degree in biology from Fudan University (復旦大學) in the PRC in July 1987 and a doctoral degree in management from Sichuan University (四川大學) in the PRC in June 2008.

Ms. Zhang Suya (張蘇姪), aged 69, joined our Group in July 1997 and was appointed as our Director in August 2006. Ms. Zhang has been serving as a Director and the executive deputy general manager of our Company since August 2006 and as the chief financial officer of our Company since October 2012. She is responsible for the overall strategic planning, formulation of financial strategies and overseeing the overall financial management of our Group. Ms. Zhang is currently a director of Baili Pharmaceutical.

Ms. Zhang has extensive experience in corporate and financial management. She joined Baili Pharmaceutical in July 1997 and has been successively serving as its financial manager, deputy general manager and director since then. She served as the secretary of the Board from May 2014 to June 2024. Since July 1997, Ms. Zhang has been holding several positions at Baili Pharmaceutical, including a financial manager, the deputy general manager and a director.

Ms. Zhang graduated with a major in Chinese language and literature from Sichuan Radio and Television University (四川廣播電視大學) (currently known as Open University of Sichuan (四川開放大學)) in the PRC in December 1988.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Kang Jian (康健), aged 56, joined our Group in October 2000 and has been serving as our Director and the deputy general manager of our Company since November 2011. He is responsible for the major operational decisions and direct day-to-day management of the Group. Mr. Kang currently holds various positions in our Group, including the general manager of Baili Pharmaceutical (one of our key subsidiaries), an executive director and the general manager of Jingxi Pharmaceutical, Hiatt Technology, Tianze Pharmaceutical and Guorui Pharmaceutical, and the legal representative of Lhasa Xinbo.

Mr. Kang has extensive experience in the biopharmaceutical industry. He joined Baili Pharmaceutical in October 2000 and has been successively serving as its vice factory director of production, director of biotechnology department, factory director, quality director and general manager since then.

Mr. Kang obtained a bachelor’s degree in chemical engineering from Chengdu University of Science and Technology (成都科學技術大學) in the PRC in July 1990 and a part-time master’s degree in economics from Sichuan University (四川大學) in the PRC in December 2000. Mr. Kang has been admitted as a licensed pharmacist in the PRC by Sichuan Provincial Department of Human Resources since October 1997 and obtained the qualification of senior engineer in the PRC issued by Chengdu Title Reform Leading Group in December 2001.

Mr. Zhuo Shi (卓識), aged 40, joined our Group in June 2011 and was appointed as our Director in March 2021. He is responsible for the major operational decisions and direct day-to-day management of our Group. Mr. Zhuo is currently the general manager of Baili-Bio.

Mr. Zhuo has over 13 years of experience in the biopharmaceutical industry. He joined Baili Pharmaceutical on June 13, 2011 and has been successively serving as its researcher at research and development center, project manager, director and the deputy general manager at the research and development center since then to July 2019. He then has been successively serving as the deputy general manager and general manager of Baili-Bio since August 2019. Mr. Zhuo has been serving as the deputy general manager of the Group since July 2023.

Mr. Zhuo obtained a bachelor’s degree in biotechnology from Peking University (北京大學) in the PRC in July 2008 and a master’s degree in ecology from Indiana University Bloomington in the United States in December 2010.

Dr. Zhu Hai (朱海), aged 36, joined our Group in October 2019 and was appointed as our Director in February 2024. He is responsible for the major operational decisions and direct day-to-day management of our Group.

Dr. Zhu Hai joined SystImmune in October 2019 and has been successively serving as its biostatistician, senior biostatistician, principal biostatistician, head of biometrics, vice president of biometrics, and special assistant to the CEO. Dr. Zhu Hai has been appointed to the Chief Technology & Data Officer of SystImmune since April 2024. With support of our R&D team, Dr. Zhu Hai is deeply involved in research and development and management of SystImmune, which is a subsidiary principally engaged in research and development of

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

pharmaceutical products, including innovative drug discovery and development. Prior to joining our Group, Dr. Zhu Hai served as a researcher at the Center of Drug Evaluation and Research of FDA from June 2019 to August 2019.

Dr. Zhu Hai obtained a bachelor’s degree in astronomy and space science from Nanjing University (南京大學) in the PRC in June 2011, a master’s degree in mathematics and statistics from Georgetown University in the United States in May 2013 and a doctoral degree in biostatistics from the University of Texas Health Science Center at Houston in the United States in December 2019.

Non-executive Director

Dr. David Guowei Wang, aged 63, was appointed as our Director in August 2017. He is responsible for providing professional advice to the Board.

Dr. Wang has over 26 years of experience in the medical industry. Dr. Wang is a partner and senior managing director of OrbiMed Advisors LLC and a director of OrbiMed Advisors III Limited, each an investment fund with a focus on the healthcare industry, where he has worked since August 2011. Dr. Wang served as the managing director at WI Harper Group from April 2006 to July 2011. From March 2010 to July 2012, he served on the board of directors of Edan Instruments, Inc. (深圳市理邦精密儀器股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 300206), a provider of advanced electronic medical equipment, where he also served on both the audit committee and strategic committee. He was a director of Suzhou Medical System Technology Co., Ltd. (蘇州麥迪斯頓醫療科技股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 603990) from October 2012 to May 2019, a non-executive director of EC Healthcare (醫思健康) (formerly known as Union Medical Healthcare Limited (香港醫思醫療集團有限公司)) (a company listed on the Stock Exchange, stock code: 2138) from August 2018 to April 2020, a director of Amoy Diagnostics Co., Ltd. (廈門艾德生物醫藥科技股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 300685) from June 2015 to August 2021 and a director of Gracell Biotechnologies Inc., a company previously listed on NASDAQ Global Market (previous stock code: GRCL), which was delisted in February 2024 following its acquisition by AstraZeneca, from March 2020 to February 2024. Further, he has been a director of SHANGHAI UPPER BIO-TECH PHARMA CO., LTD. (上海奧普生物醫藥股份有限公司) (a company listed on the National Equities Exchange and Quotations, stock code: 873758) since January 2016, a non-executive director of AK Medical Holdings Limited (愛康醫療控股有限公司) (a company listed on the Stock Exchange, stock code: 1789) since February 2016, a non-executive director of Gaush Meditech Ltd (高視醫療科技有限公司) (a company listed on the Stock Exchange, stock code: 2407) since December 2017 and a non-executive director of Laekna Inc. (來凱醫藥有限公司) (a company listed on the Stock Exchange, stock code: 2105) since July 2019, respectively.

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Dr. Wang obtained a bachelor’s degree in medicine from Beijing Medical University (北京醫科大學) (currently known as Peking University Health Science Center (北京大學醫學部)) in the PRC in July 1986 and a Doctor of Philosophy degree in developmental biology from California Institute of Technology in the United States in June 1995.

Independent Non-executive Directors

Mr. Li Mingyuan (李明遠), aged 70, was appointed as an independent non-executive Director of our company in November 2020. He is responsible for providing independent opinion and judgement to the Board.

Mr. Li has over 41 years of experience in the medical industry. He successively served as a teaching assistant at the teaching and research section of microbiology and immunology and a lecturer, an associate professor and a master advisor at the teaching and research section of microbiology of West China University of Medical Sciences (華西醫科大學) (currently known as West China Medical Center of Sichuan University (四川大學華西醫學中心)) from December 1982 to August 2000. Mr. Li also served as a professor and a doctoral at the teaching and research section of microbiology of West China School of Basic Medical Sciences & Forensic Medicine of Sichuan University (四川大學華西基礎醫學與法醫學院) from September 2000 to September 2019.

Mr. Li obtained a bachelor’s degree in clinical medicine and a part-time master’s degree in basic medicine from Sichuan Medical College (四川醫學院) and West China University of Medical Sciences (華西醫科大學) (each currently known as West China Medical Center of Sichuan University (四川大學華西醫學中心)) in the PRC in November 1982 and May 1990, respectively. He obtained the teacher qualification certificate in higher education issued by the State Education Commission of the PRC (currently known as the Ministry of Education of the PRC) in December 1996.

Mr. Yu Xiong (俞雄), aged 64, was appointed as an independent non-executive Director of our Company in September 2019. He is responsible for providing independent opinion and judgement to the Board.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Yu has decades of experience in the pharmaceutical industry. He started his career at Shanghai Institute of Pharmaceutical Industry Co., Ltd. (上海醫藥工業研究院有限公司) from July 1984, and then worked at China State Institute of Pharmaceutical Industry Co., Ltd. (中國醫藥工業研究總院有限公司). Later, Mr. Yu held or holds working experience or directorship in various companies, information of which is set forth in the following table:

Company name	Position	Period
Novastage Pharmaceuticals (Shenzhen), Ltd. (新領醫藥技術(深圳)有限公司)	Chairman of the board of directors	From July 2020 to January 2022
Jinyao Pharmaceutical Co., Ltd. (津藥藥業股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 600488)	Independent director	From December 2016 to February 2023
Shanghai Huatai Investment Development Co., Ltd. (上海華太投資發展有限公司)	Director	Since May 2018
Shanghai Fangyu Health Medicine Technology Co., Ltd. (上海方予健康醫藥科技有限公司)	Chairman of the board of directors	Since November 2018
Livzon Pharmaceutical Group Inc. (麗珠醫藥集團股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 000513)	Non-executive director	From June 2020 to October 2024
Guangzhou Respiratory Medicine Engineering Technology Co., Ltd. (廣州呼吸藥物工程技術有限公司) (formerly known as Guangzhou Jiankangyuan Respiratory Medicine Engineering Technology Co., Ltd. (廣州健康元呼吸藥物工程技術有限公司))	Executive director	From December 2020 to October 2024
Joincare Pharmaceutical Group Industry Co., Ltd. (健康元藥業集團股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 600380)	Vice president; President; and Director	From October 2016 to November 2020; from November 2020 to August 2024; and from August 2021 to August 2024
Shenzhen Haibin Pharmaceutical Co., Ltd. (深圳市海濱製藥有限公司)	Chairman of the board of directors	Since November 2021

Mr. Yu obtained a bachelor’s degree in chemistry from Fudan University (復旦大學) in the PRC in July 1984. He currently serves as the honorary chairman of the Pharmaceutical Engineering Professional Committee of the Chinese Pharmaceutical Association (中國藥學會製藥工程專業委員會).

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Yang Min (楊敏), aged 53, was appointed as an independent non-executive Director of our Company in September 2019. He is responsible for providing independent opinion and judgement to the Board.

Mr. Yang has over 33 years of experience in accounting and financial management. He successively served as an accountant of the finance department, a deputy manager of the social insurance department and the manager of the finance department at Jiajiang Hydraulic Machinery Company Limited of Power Construction Corporation of China (中國電建集團夾江水工機械有限公司) (currently known as Sinohydro Jiajiang Hydraulic Machinery Company Limited (中國水利水電夾江水工機械有限公司)) from July 1991 to December 2001. Further, Mr. Yang served as the manager of audit department II at Sichuan Zhongfa Accounting Firm Co., Ltd. (四川中砧會計師事務所有限公司) from 2002 to July 2003, the deputy director of Sichuan Xingchengxin United Accounting Firm (四川興誠信聯合會計事務所) from August 2003 to July 2005. Since August 2005, he has been serving as the director of Sichuan Branch of Jonten Certified Public Accountants (Limited Liability Partnership) (中天運會計師事務所(特殊普通合伙)), the executive partner of the firm, the chairman of its human resources and administrative management committee and a member of its risk management and technology support committee. Mr. Yang has also been serving as a director and the general manager of Chengdu Zhongtiancheng Engineering Cost Consulting Co., Ltd. (成都中天誠工程造價諮詢有限公司) since January 2009 and an independent director of Chengdu Tianao Electronics Co., Ltd. (成都天奧電子股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 002935) since April 2023.

Mr. Yang graduated with a major in accounting from Southwestern University of Finance and Economics (西南財經大學) in the PRC in December 1993.

Mr. Yang has been admitted as a member of the Chinese Institute of Certified Public Accountants since October 2003 and currently serves as the executive director of Sichuan Certified Public Accountant Association (四川省註冊會計師協會). Mr. Yang possesses appropriate professional accounting or related financial management expertise required under Rule 3.10(2) of the Listing Rules and confirms that he has gained such expertise through his experiences.

Dr. Xiao Geng (肖耿), aged 61, was appointed as an independent non-executive Director of our Company in July 2024. He is responsible for providing independent opinion and judgement to the Board.

Dr. Xiao has extensive experience in economics, financial and policy research industry. Dr. Xiao served as a director at Columbia University Global Center in Beijing (哥倫比亞大學北京全球中心) and a director at Brookings-Tsinghua Center for Public Policy (清華-布魯金斯公共政策研究中心). He served as the vice president of the Fung Global Institute (經綸國際經濟研究院) from August 2011 to July 2015. Dr. Xiao also served as a professor and a director at Peking University HSBC Business School (北大滙豐商學院) from August 2018 to July 2021. From August 2021 to October 2024, Dr. Xiao served as a professor of practice at the Chinese University of Hong Kong, Shenzhen and the director of the Institute of Policy and Practice at

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Shenzhen Finance Institute (深圳高等金融研究院). Since October 2024 and December 2024 respectively, he has been serving as a professor of practice and the associate dean at the School of Public Policy of the Chinese University of Hong Kong, Shenzhen. Further, Dr. Xiao has been serving as an independent non-executive director of Tsingtao Brewery Company Limited (青島啤酒股份有限公司), a company dually listed on the Stock Exchange (stock code: 168) and the Shanghai Stock Exchange (stock code: 600600) since June 2020, and an independent director of Midea Group Co., Ltd. (美的集團股份有限公司), a company dually listed on the Stock Exchange (stock code: 0300) and the Shenzhen Stock Exchange (stock code: 000333) since July 2024, respectively. He also served as an independent non-executive director of Bank of Jinzhou Co., Ltd. (錦州銀行股份有限公司), a company previously listed on the Stock Exchange (previous stock code: 416), which withdrew listing by way of privatisation in April 2024, from January 2020 to April 2024.

Dr. Xiao obtained a bachelor’s degree in system science and management science from University of Science and Technology of China (中國科學技術大學) in the PRC in 1985. He obtained his master’s degree and doctoral degree in economics from University of California, Los Angeles in the United States in 1987 and 1991, respectively.

SUPERVISORY COMMITTEE

Our Supervisory Committee currently consists of three members. The Supervisors serve for a term of three years and may be re-elected for successive reappointments.

The following table sets forth the key information in respect of our Supervisors:

Name	Age	Position	Time of joining our Group	Time of appointment as Supervisor	Roles and Responsibilities
Ms. Wang Jie (汪捷)	44	Chairwoman of the Supervisory Committee	June 2004	March 2023	Supervising the performance of our Directors and members of senior management and performing other supervisory duties as a member of the Supervisory Committee

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Position	Time of joining our Group	Time of appointment as Supervisor	Roles and Responsibilities
Mr. Liu Liang (劉亮)	44	Supervisor	October 2003	October 2012	Supervising the performance of our Directors and members of senior management and performing other supervisory duties as a member of the Supervisory Committee
Ms. Fu Ting (付婷)	29	Supervisor	January 2021	March 2023	Supervising the performance of our Directors and members of senior management and performing other supervisory duties as a member of the Supervisory Committee

Ms. Wang Jie (汪捷), aged 44, joined our Group in June 2004 and was appointed as our Supervisor in March 2023 and has been serving as the chairwoman of the Supervisory Committee since then. She is responsible for supervising the performance of our Directors and members of senior management and performing other supervisory duties as a member of the Supervisory Committee. Ms. Wang is currently the financial manager of Lhasa Xinbo.

Ms. Wang joined our Company as a financial accountant in June 2004 and was later promoted to the financial manager of our Company until April 2014. She has been serving as the financial manager of Lhasa Xinbo since April 2014.

Ms. Wang graduated with a major in computerized accounting from Chengdu University of Information Technology (成都信息工程大學) in the PRC in July 2002. Ms. Wang also obtained the professional qualification as an intermediate accountant in the PRC issued by the Ministry of Finance of the PRC and the Ministry of Human Resources and Social Security of the PRC in September 2021.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Liu Liang (劉亮), aged 44, joined our Group in October 2003 and was appointed as our Supervisor in October 2012. He is responsible for supervising the performance of our Directors and members of senior management and performing other supervisory duties as a member of the Supervisory Committee.

Mr. Liu joined our Company in October 2003 as an accountant at the financial department and worked as a specialist at the information technology department from November 2005 to February 2013 and a sales information director at the information technology department from March 2013 to November 2023. Mr. Liu has been serving as a research and development IT manager at the information technology department and the IT assistant to the chairman of the Board since November 2023.

Mr. Liu obtained his bachelor’s degree in accounting from Southwest Jiaotong University (西南交通大學) in the PRC in July 2003. Mr. Liu also obtained the professional qualification as an intermediate accountant in the PRC issued by Sichuan Provincial Department of Human Resources in October 2009.

Ms. Fu Ting (付婷), aged 29, joined our Group in January 2021 and was appointed as our Supervisor in March 2023. She is responsible for supervising the performance of our Directors and members of senior management and performing other supervisory duties as a member of the Supervisory Committee.

Ms. Fu joined our Company in January 2021 as a tax specialist, was promoted to a senior tax specialist in January 2022, and was promoted to the head of taxation in June 2024. Prior to joining our Group, she worked at Chengdu Dongxiang Property Service Co., Ltd. (成都東祥物業服務有限公司) from July 2018 to 2019 and Chengdu Dongfang Hope Enterprise Management Service Co., Ltd. (成都東方希望企業管理服務有限公司) from 2019 to December 2020.

Ms. Fu obtained her bachelor’s degree in accounting from Changchun University of Science and Technology (長春理工大學) in the PRC in June 2018. Ms. Fu also obtained the professional qualification as an intermediate accountant in the PRC issued by the Ministry of Finance of the PRC and the Ministry of Human Resources and Social Security of the PRC in September 2023.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

SENIOR MANAGEMENT

The following table sets forth the key information in respect of the members of our senior management:

Name	Age	Position	Time of joining our Group	Time of appointment as senior management ⁽¹⁾	Roles and Responsibilities
Dr. Zhu Yi (朱義)	60	Executive Director, chairman of the Board, general manager and Chief Scientific Officer	August 1996	November 2010	Overall strategic planning, research and development and business management of our Group
Ms. Zhang Suyu (張蘇婭)	68	Executive director, executive deputy general manager and chief financial officer	July 1997	August 2006	Overall strategic planning, formulation of financial strategies and overseeing the overall financial management of our Group
Mr. Kang Jian (康健)	55	Executive Director and deputy general manager	October 2000	November 2011	Major operational decisions and direct day-to-day management of our Group
Ms. Chen Yingge (陳英格)	33	Secretary of the Board	April 2024	June 2024	Board related matters, corporate governance and investor relations

Note:

(1) Denotes the date of appointment as a member of senior management of the Company or its predecessor.

For the biographical details of Dr. Zhu, Ms. Zhang Suyu and Mr. Kang Jian, see “— Board of Directors” in this section.

Ms. Chen Yingge (陳英格), aged 33, joined our Group in April, 2024 and was appointed as our secretary of the Board in June 2024. She is responsible for Board related matters, corporate governance and investor relations.

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Ms. Chen has over seven years of experience in securities and board related matters. Prior to joining our Group, she successively served as a securities affairs representative, and the secretary of the board of directors, company secretary and authorized representative of Shanghai Junshi Biosciences Co., Ltd. (上海君實生物醫藥科技股份有限公司), a company dually listed on the Stock Exchange (stock code: 1877) and the Shanghai Stock Exchange (stock code: 688180), from April 2017 to January 2018 and from January 2018 to April 2024, respectively.

Ms. Chen obtained a bachelor’s degree in pharmacy from Shanghai University of Traditional Chinese Medicine (上海中醫藥大學) in the PRC in July 2014 and a master’s degree in drug design from University College London in the United Kingdom in November 2015. Ms. Chen has obtained the qualification of secretary of the board of directors of the National Equities Exchange and Quotations and the qualification of secretary of the board of directors of the Shanghai Stock Exchange STAR Market since November 2017 and October 2019, respectively.

GENERAL

Save as disclosed above, none of the Directors, Supervisors or members of our senior management has held any directorship in any public company the securities of which are listed on any securities market in Hong Kong or overseas in the three years immediately preceding the date of this document.

Save as disclosed above, none of the Directors, Supervisors or members of our senior management was related to any other Directors, Supervisors and members of the senior management.

Save as disclosed in the sections headed “Relationship with our Controlling Shareholder,” “Substantial Shareholders” and “Appendix VI — Statutory and General Information — C. Further Information about Directors, Supervisors, Senior Management and Substantial Shareholders — 1. Disclosure of Interests” to this document, as of the Latest Practicable Date, none of the Directors, Supervisors or general manager of the Company held any interest in the securities within the meaning of Part XV of the SFO.

Save as disclosed herein, to the best knowledge, information and belief of our Directors and Supervisors having made all reasonable enquiries, there was no other matter with respect to the appointment of our Directors and Supervisors that needs to be brought to the attention of the Shareholders, and there was no information relating to our Directors and Supervisors that is required to be disclosed pursuant to Rule 13.51(2)(h) to (v) of the Listing Rules as of the Latest Practicable Date.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

CONFIRMATION FROM OUR DIRECTORS

Rule 8.10 of the Listing Rules

Each of our Directors confirms that as of the Latest Practicable Date, he or she did not have any interest in a business which competes or is likely to compete, directly or indirectly, with our Group’s business, which would require disclosure under Rule 8.10 of the Listing Rules.

From time to time our non-executive Director and independent non-executive Directors may serve on the boards of both private and public companies within the broader healthcare and biopharmaceutical industries. However, as these Directors are not members of our executive management team, we do not believe that his interests in such companies as a director would render us incapable of carrying on our business independently from the other companies in which such Directors may hold directorships from time to time.

Rule 3.09D of the Listing Rules

Each of our Directors confirms that he or she (i) has obtained the legal advice referred to under Rule 3.09D of the Listing Rules on June 26, 2024, and (ii) understands his or her obligations as a director of a [REDACTED] issuer on the Stock Exchange under the Listing Rules.

Rule 3.13 of the Listing Rules

Each of our independent non-executive Directors has confirmed (i) his or her independence as regards each of the factors referred to in Rules 3.13(1) to (8) of the Listing Rules; (ii) that he or she had no past or present financial or other interest in the business of the Company or its subsidiaries or any connection with any core connected person of the Company under the Listing Rules as of the Latest Practicable Date; and (iii) that there are no other factors that may affect his or her independence at the time of his or her appointment.

COMPANY SECRETARY

Mr. Lee Chung Shing (李忠成) has been appointed as the company secretary of our Company with effect from the [REDACTED]. Mr. Lee has over 25 years of experiences in providing services to listed companies in the areas of auditing, financial management, company secretarial services, investors relations and risk management. He is currently a vice president in the governance services department of an external service provider.

Mr. Lee is a member of the Hong Kong Institute of Certified Public Accountants and a fellow member of the Association of Chartered Certified Accountants. He obtained a bachelor’s degree in accountancy from the City University of Hong Kong and a master’s degree in business administration (financial services) from The Hong Kong Polytechnic University.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD COMMITTEES

Our Board delegates certain responsibilities to various committees. In accordance with the relevant PRC laws and regulations and the Corporate Governance Code, our Company has established four Board committees, namely the Audit Committee, the Nomination Committee, the Remuneration and Appraisal Committee and the Strategy and Development Committee.

Audit Committee

We have established the Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraph C.4 and paragraph D.3 of Part 2 of the Corporate Governance Code. The Audit Committee consists of three Directors, namely Mr. Yang Min, Mr. Li Mingyuan and Mr. Yu Xiong. Mr. Yang Min who holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules, serves as the chairperson of the Audit Committee. The primary duties of the Audit Committee include, but are not limited to, the following:

- proposing the appointment or change of external auditors to our Board, and monitoring the independence of external auditors and evaluating their performance;
- guiding internal audit work;
- examining the financial information of our Company, reviewing financial reports and statements of our Company and giving comments on relevant matters;
- assessing the effectiveness of internal control;
- coordinating the communication among management, internal audit department, related departments and external audit agency; and
- dealing with other matters that are authorized by the Board or involved in relevant laws and regulations.

Nomination Committee

We have established the Nomination Committee with written terms of reference in compliance with Rule 3.27A of the Listing Rules and paragraph B.3 of Part 2 of the Corporate Governance Code. The Nomination Committee consists of three Directors, namely Mr. Li Mingyuan, Dr. Zhu and Mr. Yu Xiong. Mr. Li Mingyuan serves as the chairperson of the Nomination Committee. The primary duties of the Nomination Committee include, but are not limited to, the following:

- making recommendations to our Board with regards to the size and composition of our Board based on our Company’s business operation, asset scale and equity structure;

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

- researching and developing standards and procedures for the election of our Board members, general managers and members of the senior management, and making recommendations to our Board;
- conducting extensive search and providing our Board with suitable candidates for our Directors, general managers and other members of the senior management;
- examining our Board candidates, general manager and members of the senior management and making recommendations to our Board;
- assessing and reviewing the independence of the independent non-executive Directors; and
- dealing with other matters that are authorized by the Board.

Remuneration and Appraisal Committee

We have established the Remuneration and Appraisal Committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and paragraph E.1 of Part 2 of the Corporate Governance Code. The Remuneration and Appraisal Committee consists of three Directors, namely Mr. Yu Xiong, Ms. Zhang Suyu and Mr. Yang Min. Mr. Yu Xiong serves as the chairperson of the Remuneration and Appraisal Committee. The primary duties of the Remuneration and Appraisal Committee include, but are not limited to, the following:

- making recommendations to the Board on the Company’s policy and structure for all Directors’ and senior management remuneration and on the establishment of a formal and transparent procedure for developing remuneration policy;
- reviewing and approving the senior management’s remuneration proposals with reference to the Board’s corporate goals and objectives;
- making recommendations to the Board on the remuneration packages of individual executive Directors, non-executive Director(s) and senior management;
- reviewing and/or approving matters relating to share schemes under Chapter 17 of the Listing Rules; and
- dealing with other matters that are authorized by the Board.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Strategy and Development Committee

We have established the Strategy and Development Committee with written terms of reference. The Strategy and Development Committee consists of three Directors, namely Dr. Zhu, Mr. Li Mingyuan and Mr. Yu Xiong. Dr. Zhu serves as the chairperson of the Strategy and Development Committee. The primary duties of the Strategy and Development Committee include, but are not limited to, the following:

- researching and making recommendations relating to the Company’s mid-term and long-term development strategies, major investment decisions and other important matters affecting the Company’s development;
- providing recommendations with respect to key strategic initiatives;
- examining the implementation of the abovementioned matters relating to Company’s strategy and development; and
- dealing with other matters that are authorized by our Board.

REMUNERATION OF DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Our Directors and Supervisors, certain of whom are also employees of our Company, receive remuneration in the form of fees, basic salaries, performance related bonuses, retirement benefits and share-based payments (if applicable). Independent non-executive Directors receive independent non-executive Directors’ allowances from the Company. The remuneration of the Directors, Supervisors and members of our senior management is determined with reference to the achievement of major operating indicators of the Company, the remuneration paid by relevant companies in the PRC pharmaceutical industry and in the relevant regions. For details of the service contracts and appointment letters entered into between the Company and our Directors and Supervisors, see “Appendix VI — Statutory and General Information — C. Further Information about Our Directors, Supervisors, Senior Management and Substantial Shareholders — 2. Particulars of Directors’ and Supervisors’ Service Contracts or Appointment Letters.”

In 2021, 2022 and 2023 and for the nine months ended September 30, 2024, the aggregate amount of remuneration of our Directors (excluding share-based payments) amounted to approximately RMB4.74 million, RMB4.99 million, RMB6.92 million and RMB9.18 million, respectively. For details of the share-based payments received by the Directors, see Note 14 to the Accountants’ Report in Appendix I to this document.

In 2021, 2022 and 2023 and for the nine months ended September 30, 2024, the aggregate amount of remuneration of our Supervisors amounted to approximately RMB0.48 million, RMB0.40 million, RMB0.47 million and RMB0.40 million, respectively.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Under the arrangement currently in force, we estimate the total remuneration before taxation to be accrued to our Directors and our Supervisors for the year ending December 31, 2025 to be approximately RMB17.00 million. The actual remuneration of Directors and Supervisors for 2025 may be different from the expected remuneration.

In 2021, 2022 and 2023 and for the nine months ended September 30, 2024, there were one, one, one and two Directors among the five highest paid individuals, respectively. The total emoluments for the remaining individuals among the five highest paid individuals in 2021, 2022 and 2023 and the nine months ended September 30, 2024 amounted to approximately RMB4.86 million, RMB7.54 million, RMB13.07 million and RMB9.09 million, respectively.

We confirmed that during the Track Record Period, no remuneration was paid by the Company to, or receivable by, our Directors, Supervisors or the five highest paid individuals as an inducement to join or upon joining the Company or as compensation for loss of office in connection with the management positions of the Company or any subsidiary of the Company.

Save as disclosed in Note 14 to the Accountants’ Report in Appendix I to this document, during the Track Record Period, none of our Directors or Supervisors waived any remuneration. Save as disclosed above, no other payments have been paid, or are payable, by the Company or our subsidiaries to our Directors, Supervisors or the five highest paid individuals during the Track Record Period.

CORPORATE GOVERNANCE

The Company is committed to achieving a high standard of corporate governance with a view to safeguarding the interests of our Shareholders. To accomplish this, the Company intends to comply with the Corporate Governance Code set out in Appendix C1 to the Listing Rules and the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix C3 to the Listing Rules after the [REDACTED].

Pursuant to code provision C.2.1 of Part 2 of the Corporate Governance Code, companies listed on the Stock Exchange are expected to comply with, but may choose to deviate from the requirement that the responsibilities between the chairperson and the chief executive should be segregated and should not be performed by the same individual. We do not have a separate chairperson and general manager and Dr. Zhu currently performs these two roles. Our Board believes that, in view of his experience, personal profile and his roles in our Company as mentioned above, Dr. Zhu is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our general manager. The Board also believes that vesting the roles of both the chairperson and general manager in the same person has the benefit of (i) ensuring consistent leadership within the Group, (ii) enabling more effective and efficient overall strategic planning and execution of strategic initiatives of the Board, and (iii) facilitating the flow of information between the management and the Board for our Group. The Board considers that the balance of power and authority for the present arrangement will not be impaired and this structure will enable the Company to make and implement decisions promptly and effectively.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD DIVERSITY POLICY

We are committed to promoting the culture of diversity in the Company. We have strived to promote diversity to the extent practicable by taking into consideration a number of factors in our corporate governance structure.

In order to enhance the effectiveness of our Board and to maintain the high standard of corporate governance, we [have adopted] the board diversity policy which sets out the objective and approach to achieve and maintain diversity of our Board. Pursuant to the board diversity policy, we seek to achieve board diversity through the consideration of a number of factors when selecting the candidates to our Board, including but not limited to gender, skills, age, professional experience, knowledge, cultural and educational background, nationality, ethnicity and length of service. The ultimate decision of the appointment will be based on merit and the contribution which the selected candidates will bring to our Board.

Our Directors have a balanced mix of knowledge and skills, including accounting, corporate and financial management in addition to industry experience in the pharmaceutical and medical industry. They obtained degrees in various majors including radio physics, biology, management, Chinese language and literature, business administration, chemical engineering, economics, biotechnology, ecology, astronomy and space science, mathematics and statistics, biostatistics, medicine, developmental biology, clinical medicine, basic medicine, chemistry, accounting, management science and economics. We have four independent non-executive Directors with different industry backgrounds, representing one third of the members of our Board. Further, as of the date of this document, our Board has a relatively wide range of ages ranging from 36 years old to 70 years old. Our Company has reviewed the membership, structure and composition of our Board, and is of the opinion that the structure of our Board is reasonable, and the experience and skills of the Directors in various aspects and fields can enable our Company to maintain a high standard of operation.

Besides, we recognize the particular importance of gender diversity. We have taken, and will continue to take, steps to promote gender diversity at all levels of our Company, including but without limitation at our Board and senior management levels. Currently, we have one female Director, namely, Ms. Zhang Suyu, who is also our executive deputy general manager and chief financial officer. Going forward, we will continue to work to enhance gender diversity of our Board when selecting and recommending suitable candidates for Board appointments to help achieve greater gender diversity in accordance with stakeholder expectations and recommended best practices. Our Company also intends to promote gender diversity at the mid to senior level so that our Company can maintain a balanced gender ratio at different levels. Taking into account our existing business model and specific needs as well as the different background of our Directors, the composition of our Board satisfies our board diversity policy.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Our Nomination Committee is responsible for ensuring the diversity of our Board members. After the [REDACTED], our Nomination Committee will review the board diversity policy from time to time to ensure its continued effectiveness and we will disclose in our corporate governance report about the implementation of the board diversity policy on an annual basis.

SYSTIMMUNE INCENTIVE PLANS

SystImmune adopted the SystImmune Incentive Plans to, motivate and retain employees within the Group or consultants to contribute to the growth of SystImmune. For further details of the SystImmune Incentive Plans, see “Statutory and General Information — D. SystImmune Incentive Plans” in Appendix VI to this Document.

COMPLIANCE ADVISER

We have appointed Messis Capital Limited as our Compliance Adviser in compliance with Rule 3A.19 of the Listing Rules. The Compliance Adviser will provide us with guidance and advice as to compliance with the Listing Rules and other applicable laws, rules, codes and guidelines. Pursuant to Rule 3A.23 of the Listing Rules, the Compliance Adviser will advise the Company in certain circumstances including:

- (i) before the publication of any regulatory announcement, circular or financial report;
- (ii) where a transaction, which might be a notifiable or connected transaction, is contemplated, including share issues, sales or transfers of treasury shares and share repurchases;
- (iii) where we propose to use the [REDACTED] from the [REDACTED] in a manner different from that detailed in this document or where our business activities, developments or results deviate from any forecast, estimate or other information in this document; and
- (iv) where the Stock Exchange makes an inquiry to the Company regarding unusual movements in the price or [REDACTED] volume of its [REDACTED] securities or any other matters in accordance with Rule 13.10 of the Listing Rules.

Pursuant to Rule 3A.24 of the Listing Rules, the Compliance Adviser will, on a timely basis, inform our Company of any amendment or supplement to the Listing Rules that are announced by the Stock Exchange. The Compliance Adviser will also inform our Company of any new or amended law, regulation or code in Hong Kong applicable to us, and advise us on the continuing requirements under the Listing Rules and applicable laws and regulations.

The term of the appointment will commence on the [REDACTED] and is expected to end on the date on which the Company complies with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED].

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You should read the following discussion and analysis in conjunction with our audited consolidated financial information and the respective accompanying notes thereto included in the Accountants’ Report set out in Appendix I to this document which have been prepared in accordance with IFRS. Our historical results do not necessarily indicate results expected for any future periods. The following discussion and analysis contain forward-looking statements that involve risks and uncertainties. Our actual results may differ from those anticipated in these forward-looking statements as a result of any number of factors, including those set forth in “Forward-looking Statements” and “Risk Factors.” In evaluating our business, you should carefully consider the information provided in this document including but not limited to the sections headed “Risk Factors” and “Business” in this document.

OVERVIEW

Our history can be traced back to 1996, when Dr. Zhu Yi, our chairman of the Board, general manager and Chief Scientific Officer, established Baili Pharmaceutical, which is the predecessor of our Company and currently one of our key subsidiaries. Through years of dedicated effort, we have cultivated expertise in complex generics and traditional Chinese medicine. More importantly, we have grown into an integrated pharmaceutical corporate group with capabilities spanning early-stage research, clinical development, manufacturing, and commercialization.

In 2010, we made the strategic move into the innovative drug business. To support this shift, we reinvested most of our revenue from our generic drug and traditional Chinese medicine business into innovative drug research and development. In 2014, we established SystImmune in Seattle, the U.S., to lead the 0-to-1 innovation of therapeutic modalities and discovery of novel drug pipelines. SystImmune also spearheads our global clinical development and future commercialization in global markets.

Our endeavors over the past decade have led to the creation of (i) an innovative ADC drug development platform, from which we have successfully advanced eight clinical-stage, innovative ADC candidates, including BL-B01D1, into approximately 50 clinical studies, including eight Phase III clinical trials for late-line cancer treatment and 12 Phase II clinical trials for 1L cancer treatment; and (ii) a multi-specific T cell engager platform, from which we have successfully advanced four innovative GNC multi-specific antibodies, including GNC-077, to clinical stage, which have been evaluated in 13 clinical studies.

With the clinical and commercial prospects of BL-B01D1, we entered into a global strategic license and collaboration agreement with BMS in December 2023 to co-develop and co-commercialize BL-B01D1, with a non-refundable and non-creditable upfront payment of US\$800.0 million (equivalent to approximately RMB5,679.7 million) (the “Upfront Payment”) and a total deal value worth up to US\$8.4 billion. Under this agreement, we will jointly develop and commercialize BL-B01D1 in the U.S. with BMS. In addition, we have retained exclusive

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rights for the development and commercialization of BL-B01D1 in mainland China, while we have granted BMS an exclusive license to develop and commercialize BL-B01D1 in the rest of the world. On March 7, 2024, we received the Upfront Payment from BMS. See “Business — License and Collaboration Agreement with Bristol-Myers Squibb Company” for more details.

In addition to our biologics portfolio at the development stage, we have a marketed product portfolio which includes generics (covering a wide range of therapeutic areas such as anesthesia, parenteral nutrition, anti-infective and pediatric drugs) and traditional Chinese medicine products.

During the Track Record Period, our revenue was RMB795.0 million, RMB701.8 million, RMB560.4 million and RMB5,661.2 million in 2021, 2022 and 2023 and in the nine months ended September 30, 2024, respectively. Revenue generated from the sale of pharmaceutical products was RMB795.0 million, RMB701.8 million, RMB560.4 million and RMB326.9 million in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively. Sales of pharmaceutical products decreased over the Track Record Period as certain of our major marketed products are generic drugs that were impacted by the VBP schemes, which resulted in decreases in both prices and sales volume of relevant products during the Track Record Period. In the nine months ended September 30, 2024, we also generated license fee income of RMB5,331.7 million, representing part of the Upfront Payment received from BMS in March 2024 under the BMS Agreement. We incurred net loss of RMB107.6 million, RMB282.4 million and RMB780.5 million in 2021, 2022 and 2023, respectively, and achieved a profit of RMB4,065.4 million in the nine months ended September 30, 2024. Our net losses recorded in the first three years of the Track Record Period were primarily in relation to: (i) our substantial investment in R&D activities for innovative drug candidates, and (ii) the reduction of revenue from the sale of pharmaceutical products. Our net profit achieved in the nine months ended September 30, 2024 was primarily due to the recognition of the license fee income generated under our license and collaboration agreement with BMS. In addition, we experienced net operating cash outflow of RMB137.5 million, RMB256.6 million and RMB618.0 million in 2021, 2022 and 2023, respectively, which was primarily due to our losses before tax, while we generated net operating cash inflow of RMB4,430.6 million in the nine months ended September 30, 2024, primarily due to our profit before tax.

BASIS OF PREPARATION

The historical financial information has been prepared based on the accounting policies set out in Note 3 to the Accountants’ Report in Appendix I to this document which conform with the International Financial Reporting Standards, or IFRSs, issued by International Accounting Standards Board, or IASB. All IFRSs effective for the accounting period commencing from January 1, 2024, together with the relevant transitional provisions, have been early adopted by us in the preparation of the historical financial information throughout the Track Record Period. The historical financial information has been prepared on the historical cost basis except for certain financial instruments that are measured at fair values at the end of each of the Track Record Period.

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MAJOR FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our business, results of operations and financial condition have been, and are expected to continue to be, affected by a number of factors, which primarily include the following:

Our Ability to Successfully Develop and Commercialize Drug Candidates in Our Biologics Portfolio

Our business and results of operations will be dependent on our receipt of regulatory approval for and successful commercialization of our drug candidates in our biologics portfolio. As of the Latest Practicable Date, our innovative drug pipeline featured 14 clinical-stage drug candidates, led by our BL-B01D1, an EGFR × HER3 bispecific ADC currently in Phase III clinical trials, which we believe has the potential to be a backbone pan-tumor treatment. Our pipeline also includes two other candidates in Phase III clinical trials: BL-M07D1, an innovative HER2-specific ADC, and SI-B001, a potential first-in-class EGFR × HER3 bispecific antibody. See “Business — Our Technology Platforms and Biologics Portfolio” for more information on the development status of our drug candidates.

We have not generated any revenue from the sales of drugs in our biologics portfolio. Our business and results of operations depend on our ability to continuously advance preclinical and clinical development of, and obtain the requisite regulatory approvals for, our drug candidates in biologics portfolio. Once our drug candidates are commercialized, our business and results of operations will be driven by the market acceptance and supply of our commercialized drugs. We have a proven track record in developing, commercializing and manufacturing pharmaceuticals that have gained market acceptance in China. See “Business — Our Marketed Products” for more details. To successfully develop and launch drug candidates in our biologics portfolio, we intend to continue investing in our R&D and clinical development of our pipeline products, and leveraging our commercialization-ready manufacturing facilities and cumulative front-line sales and marketing experience in China market. For the international markets, we plan to pursue and leverage our strategic partnership with leading pharmaceutical companies, and also expand our global manufacturing, commercialization and operational capabilities. For more details, see “Business — Our Journey.”

Our Collaboration with BMS

In December 2023, we entered into the BMS Agreement, effective as of February 8, 2024, under which we and BMS will conduct a global strategic license and collaboration to co-develop and co-commercialize BL-B01D1. Under the BMS Agreement, we and BMS will jointly develop and commercialize BL-B01D1 in the U.S., and we have retained exclusive rights to develop and commercialize BL-B01D1 in mainland China, and we granted BMS an exclusive license to develop and commercialize BL-B01D1 in the rest of the world, subject to certain specified conditions and limitations.

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Pursuant to the BMS Agreement, in March 2024, we received a non-refundable and non-creditable upfront payment of US\$800 million from BMS, which is not subject to any further conditions, and BMS is required to pay up to US\$500 million in contingent near-term payments. We are also eligible to receive up to an aggregate of US\$7.1 billion contingent upon the achievement of certain specified regulatory and sales performance milestones for a total potential consideration of up to US\$8.4 billion. BMS is also required to pay us tiered royalties based on a percentage of aggregate annual net sales of BL-B01D1 in the world excluding the U.S. and the mainland China ranging from high single-digit to low double-digits, subject to certain customary reductions and a royalty floor. We are required to pay BMS a single-tier royalty of a mid-single-digit percentage of aggregate annual net sales of BL-B01D1 in mainland China. Further, under the BMS Agreement, we and BMS will share the relevant development costs of and the net profits/losses related to the sales of BL-B01D1 in the U.S. according to certain agreed-upon percentages. See “Business — License and Collaboration Agreement with Bristol-Myers Squibb Company” for more details.

The Upfront Payment from BMS to us contributed a substantial majority of our revenue in the nine months ended September 30, 2024. We may in the future depend to a certain degree on the milestone payments from BMS to support our future development plan, and the milestone payments in the BMS Agreement are generally dependent on the accomplishment of various development, regulatory and sales milestones. The successful or timely achievement of many of these milestones relies on the performance of both parties without early termination. In addition, clinical development, regulatory approval and market acceptance are uncertain in nature and not within our full control. See “Risk Factors — Key Risks Relating to Our Business and Industry — If we or BMS do not achieve our product development or commercialization objectives in the time frames we expect, we may not receive milestone or royalty payments or make profits to support our future development plan.”

Our Ability to Compete in the Centralized Tender Process for Pharmaceutical Procurement by Public Medical Institutions in China

In addition to our biologics portfolio at the development stage, we have a marketed product portfolio which includes generics (covering a wide range of therapeutic areas such as anesthesia, parenteral nutrition, anti-infectives, pediatric drugs) and traditional Chinese medicine products. A substantial portion of the products we sell to distributors are then sold to public hospitals and other medical institutions in China. Public medical institutions in China are required to implement a centralized tender process for the procurement of pharmaceuticals listed in the medical insurance catalogs or consumed in large volumes and commonly prescribed for clinical uses. We are required to submit our bids in a centralized tender process in order to supply our products to these public medical institutions. These bids are generally considered based on, among other things, price competitiveness, product quality, clinical effectiveness, as well as qualifications and reputation of the manufacturer. If we are successful in winning bids in a centralized tender process, the relevant products will be sold to the public medical institutions at the bid prices, which is the primary determinant of prices at which we sell our products to our distributors. The centralized tender process has created pricing pressure among substitute products or products that are perceived to be substitute products.

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Our bidding strategy generally focuses on differentiating our products from those of our competitors instead of competing solely based on pricing. Therefore, our sales volumes and profitability depend on our ability to successfully differentiate our products from competing products and price our bids in a manner that enables us to succeed in the centralized tender processes at profitable levels. We believe each of our major products had competitive advantages in the centralized tender processes during the Track Record Period as a result of their nationwide recognition, or their passing of the quality and efficacy consistency evaluations. If we are unable to differentiate our products or are otherwise not successful in winning bids in the centralized tender processes at profitable levels, we will lose the revenue associated with the sale of the affected products to the relevant public medical institutions. See “Risk Factors — Other Risks Relating to Our Operations — If we are unable to succeed in tender processes to sell our products to PRC public hospitals and other medical institutions, we may lose market share and our revenue and profitability could be adversely affected.”

The Implementation and Expansion of the VBP Scheme for Sales of Drugs to PRC Public Medical Institutions

Certain pharmaceutical products in our marketed product portfolio are subject to the VBP scheme in China. The VBP scheme aims to achieve a lower price for pharmaceuticals with mature, high-volume clinical usage and sufficient market competition through a competitive bidding process for large-volume procurement. Such policy embodies a PRC regulatory aim to significantly reduce drug prices the burden of pharmaceutical costs on patients. The VBP scheme has been rolled out at both the national and regional levels. For pharmaceuticals, the national VBP scheme primarily includes generics that have met the consistency evaluation criteria. The manufacturers and importers of the drugs included in each VBP scheme are invited to bid to supply the drugs to public medical institutions. Most of the successful bidders in the VBP scheme will experience substantial price cuts. Bidders who are unsuccessful or who chose not to participate in the VBP scheme will typically experience similar price cuts due to factors including reduced market share, intensified competition and regulatory requirements.

During the Track Record Period, a number of our products were subject to national or provincial VBP schemes. For example, propofol medium and long chain fat emulsion injection and dexmedetomidine hydrochloride injection were subject to the national VBP scheme; Lewejing (propofol injectable emulsion) participated in provincial VBP schemes and later the national VBP scheme; Tianze (medium and long chain fat emulsion injection) and Xinbolin (ribavirin granule) participated in provincial VBP schemes. As the number of compounds included in the VBP schemes continues to increase, our marketed drugs that have passed the consistency evaluation may be included in the national VBP scheme. In addition, certain of our drugs that have passed or not passed the consistency evaluation may be tendered and procured in the provincial VBP scheme. While the sales volumes of our drug products may increase if we succeed in the bidding process under the VBP scheme, the inclusion in the VBP scheme typically exerts downward pressure on the prices of our products, thus impacting our revenue, gross profits and gross profit margins. See “Risk Factors — Key Risks Relating to Our Business and Industry — We may experience difficulties in our sales efforts as a result of pricing regulations or other policies that are intended to reduce healthcare costs, which could adversely affect our operations, revenue and profitability.”

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Our Cost Structure

Our results of operations are significantly affected by our cost structure, which primarily consists of cost of sales, research and development expenses, and distribution and selling expenses. During the Track Record Period, our cost of sales related to the sale of the pharmaceutical products, which primarily consisted of cost of materials, manufacturing costs, direct labor costs and delivery costs. Our cost of sales as a percentage of revenue from the sale of pharmaceutical products was 26.8%, 35.2%, 45.2% and 58.4% in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively. The increase of our cost of sales as a percentage of revenue from the sale of pharmaceutical products during the Track Record Period was primarily due to the decrease of our revenue from sale of pharmaceutical products, mainly affected by the implementation of the VBP scheme. For details, see “— Period to Period Comparison of Results of Operations.”

Research and development expenses have been and are expected to continue to be a major component in our cost structure, considering our strategic focus on the innovative drug business. Our research and development expenses primarily consist of (i) testing and examination costs including clinical trial expenses, (ii) staff costs, (ii) costs of materials, and (iv) depreciation expenses for right-of-use assets, property and equipment used for research and development purposes. Our research and development expenses amounted to RMB278.6 million, RMB375.0 million, RMB746.2 million and RMB931.7 million in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively. For details, see “— Description of Key Statements of Profit or Loss Items — Research and Development Expenses.”

During the Track Record Period, we incurred distribution and selling expenses in relation to our sale of marketed pharmaceutical products. Our distribution and selling expenses primarily consist of (i) marketing and promotion expenses, (ii) staff costs, and (iii) travelling expenses. Our distribution and selling expenses amounted to RMB391.3 million, RMB324.3 million, RMB251.2 million and RMB156.0 million in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively, in line with our business scale of the sale of pharmaceutical products. For details, see “— Description of Key Statements of Profit or Loss Items — Distribution and Selling Expenses.”

We expect our cost structure to evolve as we continue to develop and expand our business. In light of our strategic focus on the innovative drug business, as the preclinical studies and clinical trials of our drug candidates continue to progress, we expect to incur additional costs in relation to, among other things, testing and experiment fees, R&D staff costs, and raw materials procurement. Additionally, we anticipate increasing legal, compliance, accounting, insurance and investor and public relations expenses associated with being a [REDACTED] in Hong Kong.

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MATERIAL ACCOUNTING POLICY INFORMATION

The historical financial information has been prepared in accordance with the following accounting policies which conform with IFRSs issued by the IASB. For the purpose of preparation and presentation of the historical financial information, information is considered material if such information is reasonably expected to influence decisions made by primary users. In addition, the historical financial information includes the applicable disclosures required by the Listing Rules and by the Hong Kong Companies Ordinance. The historical financial information has been prepared on the historical cost basis, except for certain financial instruments that are measured at fair values at the end of each reporting period, as explained in the accounting policies set out below.

Revenue from Contracts with Customers

Sale of pharmaceutical products

Revenue from the sale of pharmaceutical products is recognized at point in time when control of the goods has transferred, being when the goods have been shipped to the specific location and accepted, the customers have the primary responsibility for the risks of obsolescence and loss in relation to the goods while it can request return or refund only if the goods delivered do not meet the required quality standards.

At the point of sale, a corresponding adjustment to revenue is made for those products expected to be returned. We estimate the future sales return of the products sold based on the historical experience. A refund liability is recognized for sales in which revenue has yet to be recognized. Right to returned goods asset (and corresponding adjustment to cost of sales) is recognized for right to recover products from customers on settling the refund liability.

The credit period granted to customers by us is determined based on the characteristics of customers' credit risk and there is no significant financing component. For customers with long-term relationships, the normal credit term granted ranges from 30 to 120 days upon delivery.

A contract liability represents our obligation to transfer goods or services to a customer for which we have received consideration (or an amount of consideration is due) from the customer. All the contracts that are unsatisfied are for periods of one year or less. As we apply the practical expedient in IFRS 15, the transaction price allocated to these unsatisfied contracts is not disclosed.

Under the standard contract terms, customers have a right to receive rebates. We use our accumulated historical experience to estimate the amount of consideration to which it will be entitled using the most likely amount.

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License fee income

In December 2023, we entered into an exclusive license and collaboration agreement with BMS. Under the agreement, we and BMS will jointly develop and commercialize BL-B01D1 in the U.S. We and BMS will share net profits/losses related to the sales of BL-B01D1 in the U.S. according to certain agreed-upon percentages. In addition, we granted BMS an exclusive license to develop and commercialize BL-B01D1 in the rest of the world, subject to certain specified conditions and limitations. In the opinion of the management, the collaboration arrangement constitutes a joint arrangement under which we share the risks and benefits associated with such activities in U.S.

BL-B01D1, internally discovered and developed, is a clinical-stage EGFR × HER3 bispecific ADC intended for the treatment of various solid tumors. The consideration for the agreement comprises a fixed element (a non-refundable and non-creditable upfront payment of US\$800.0 million (equivalent to approximately RMB5,679.7 million), several variable elements (i.e. further payments according to timing in achievements of various clinical trial milestones, regulatory milestones, sales milestones and sales-based royalties).

We determined that the consideration for the Upfront Payment relates to two performance obligations: (1) the grant of license and (2) the transfer of manufacturing technology relating to the process for the manufacture of BL-B01D1 and its related products. We allocate the total transaction price of the Upfront Payment into two performance obligations based on estimation of the standalone selling price for the transfer of manufacturing technology, which a customer in the market would be willing to pay, and then applying residual approach in the estimation of standalone selling price for the grant of license.

The revenue, for grant of license which represents a right to use our intellectual property, is recognized at a point in time at which the license transfers. During the nine months ended September 30, 2024, the transfer of license to the customer was completed and we recognized revenue of US\$751.0 million (equivalent to approximately RMB5,331.7 million) in relation to the grant of license. The remaining transaction price of US\$49.0 million (equivalent to approximately RMB348.0 million) is allocated to the performance obligation of transferring manufacturing technology, which is recorded in contract liability and the timing of transfer is at the discretion of the customer.

For more details about the contractual arrangement, see “Business — License and Collaboration Agreement with Bristol-Myers Squibb Company.”

Leases

Definition of a Lease

A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

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As a lessee

Short-term leases

We apply the short-term lease recognition exemption to leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option.

Right-of-use assets

The cost of right-of-use assets includes:

- the amount of the initial measurement of the lease liability;
- any lease payments made at or before the commencement date; and
- any initial direct costs incurred by us.

Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities.

Right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term.

We present right-of-use assets as a separate line item on the consolidated statements of financial position.

Lease liabilities

At the commencement date of a lease, we recognize and measure the lease liability at the present value of lease payments that are unpaid at that date. In calculating the present value of lease payments, we use the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable.

The lease payments include fixed payments (including in-substance fixed payments).

After the commencement date, lease liabilities are adjusted by interest accretion and lease payments.

We present lease liabilities as a separate line item on the consolidated statements of financial position.

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Lease modifications

We account for a lease modification as a separate lease if:

- the modification increases the scope of the lease by adding the right to use one or more underlying assets; and
- the consideration for the leases increases by an amount commensurate with the stand-alone price for the increase in scope and any appropriate adjustments to that stand-alone price to reflect the circumstances of the particular contract.

For a lease modification that is not accounted for as a separate lease, we remeasure the lease liability based on the lease term of the modified lease by discounting the revised lease payments using a revised discount rate at the effective date of the modification.

We account for the remeasurement of lease liabilities by making corresponding adjustments to the relevant right-of-use assets.

As a lessor

Classification and measurement of leases

Leases for which we are a lessor are classified as finance or operating leases. Whenever the terms of the lease transfer substantially all the risks and rewards incidental to ownership of an underlying asset to the lessee, the contract is classified as a finance lease. All other leases are classified as operating leases.

Rental income from operating leases is recognized in profit or loss on a straight-line basis over the term of the relevant lease.

Sale and leaseback transactions

We apply the requirements of IFRS 15 “Revenue from Contracts with Customers” to assess whether sale and leaseback transaction constitutes a sale by us.

As a seller-lessee

For a transfer that does not satisfy the requirements as a sale, we as a seller-lessee continue to recognize the assets and accounts for the transfer proceeds as sale and leaseback payable within the scope of IFRS 9 “Financial Instruments”.

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Government Grants

Government grants are not recognized until there is reasonable assurance that we will comply with the conditions attached to them and that the grants will be received.

Government grants are recognized in profit or loss on a systematic basis over the periods in which we recognize as expenses the related costs for which the grants are intended to compensate. Specifically, government grants whose primary condition is that we should purchase, construct or otherwise acquire non-current assets are recognized as deferred income in the consolidated statement of financial position and transferred to profit or loss on a systematic basis over the useful lives of the related assets.

Government grants related to income that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to us with no future related costs are recognized in profit or loss in the period in which they become receivable. Such grants are presented under “other income”.

Property, Plant and Equipment

Property, plant and equipment are tangible assets that are held for use in the production or supply of goods or services, or for administrative purposes other than construction in progress as described below. Property, plant and equipment are stated in the consolidated statements of financial position at cost less subsequent accumulated depreciation and subsequent accumulated impairment losses, if any.

Properties in the course of construction for production, supply or administrative purposes are carried at cost, less any recognized impairment loss. Costs include any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Depreciation of these assets, on the same basis as other property assets, commences when the assets are ready for their intended use.

Depreciation is recognized so as to write off the cost of assets other than construction in progress less their residual values over their estimated useful lives, using the straight-line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each reporting period, with the effect of any changes in estimate accounted for on a prospective basis.

An item of property, plant and equipment is derecognized upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property, plant and equipment is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognized in profit or loss.

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Intangible Assets

Intangible assets acquired separately

Intangible assets with finite useful lives that are acquired separately are carried at costs less accumulated amortization and any accumulated impairment losses. Amortization for intangible assets with finite useful lives is recognized on a straight-line basis over their estimated useful lives. The estimated useful life and amortization method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis.

Internally-generated intangible assets — research and development expenditure

Expenditure on research activities is recognized as an expense in the period in which it is incurred.

An internally-generated intangible asset arising from development activities is recognized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. Where no internally-generated intangible asset can be recognized, development expenditure is recognized in profit or loss in the period in which it is incurred.

Subsequent to initial recognition, internally-generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses (if any), on the same basis as intangible assets that are acquired separately.

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Impairment on Property, Plant and Equipment, Right-of-use Assets, Investment Properties and Intangible Assets

At the end of each reporting period, we review the carrying amounts of its property, plant and equipment, right-of-use assets, investment properties and intangible assets with finite useful lives to determine whether there is any indication that these assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the relevant asset is estimated in order to determine the extent of the impairment loss (if any).

The recoverable amount of property, plant and equipment, right-of-use assets, investment properties and intangible assets are estimated individually. When it is not possible to estimate the recoverable amount individually, we estimate the recoverable amount of the cash-generating unit to which the asset belongs.

In testing a cash-generating unit for impairment, corporate assets are allocated to the relevant cash-generating unit when a reasonable and consistent basis of allocation can be established, or otherwise they are allocated to the smallest group of cash-generating units for which a reasonable and consistent allocation basis can be established. The recoverable amount is determined for the cash-generating unit or group of cash-generating units to which the corporate asset belongs, and is compared with the carrying amount of the relevant cash-generating unit or group of cash-generating units.

Recoverable amount is the higher of fair value less costs of disposal and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset (or a cash-generating unit) for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or a cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or a cash-generating unit) is reduced to its recoverable amount. For corporate assets or portion of corporate assets which cannot be allocated on a reasonable and consistent basis to a cash-generating unit, we compare the carrying amount of a group of cash-generating units, including the carrying amounts of the corporate assets or portion of corporate assets allocated to that group of cash-generating units, with the recoverable amount of the group of cash-generating units. In allocating the impairment loss, the impairment loss is allocated first to reduce the carrying amount of any goodwill (if applicable) and then to the other assets on a pro-rata basis based on the carrying amount of each asset in the unit or the group of cash-generating units. The carrying amount of an asset is not reduced below the highest of its fair value less costs of disposal (if measurable), its value in use (if determinable) and zero. The amount of the impairment loss that would otherwise have been allocated to the asset is allocated pro rata to the other assets of the unit or the group of cash-generating units. An impairment loss is recognized immediately in profit or loss.

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Where an impairment loss subsequently reverses, the carrying amount of the asset (or cash-generating unit or a group of cash-generating units) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset (or a cash-generating unit or a group of cash-generating units) in prior years. A reversal of an impairment loss is recognized immediately in profit or loss.

During the Track Record Period, no indications of the impairment for the non-financial assets were identified, given that (i) the assets’ value have not declined significantly, (ii) assets are not obsolete or physically damaged, and (iii) none of the indications listed in paragraph 14 of International Accounting Standard 36 “Impairment of Assets” were noticed or identified by us.

KEY SOURCES OF ESTIMATION UNCERTAINTY

In the application of our accounting policies, our Directors are required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are 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.

The following are the key sources of estimation uncertainty at the end of each year/period of the Track Record Period that may have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next twelve months.

Key Sources of Estimation Uncertainties

Recognition of deferred tax assets

Deferred tax assets in respect of unused tax losses carried forward and deductible temporary differences are recognized and measured based on the expected manner of realization or settlement of the carrying amounts of the relevant assets and liabilities, using tax rates enacted or substantively enacted at the end of each reporting period. In determining the carrying amounts of deferred tax assets, expected taxable profits are estimated which involves several assumptions relating to the operating environment of us and require a significant level of judgement exercised by the directors of our Company. Any change in such assumptions and judgement would affect the carrying amounts of deferred tax assets to be recognized and hence the net profit or loss in the future periods. The information about our deferred tax assets is disclosed in Note 20 to the Accountants’ Report in Appendix I to this document.

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Estimated impairment of trade receivables

Trade receivables which considered credit-impaired are assessed on individual basis. In addition, we use collective assessment to calculate ECL for trade receivables balances which are not assessed individually at the end of each reporting period. The ECL rates are based on internal credit ratings as groupings of various debtors that have similar loss patterns. The collective assessment is based on our historical default rates taking into consideration forward-looking information that is reasonable and supportable available without undue costs or effort.

At every reporting date, the historical observed default rates are reassessed and changes in the forward-looking information are considered.

The provision of ECL is sensitive to changes in estimates. The information about our trade receivables and the related ECL disclosures is disclosed in Notes 23 and 42 to the Accountants’ Report in Appendix I to this document, respectively.

DESCRIPTION OF KEY STATEMENTS OF PROFIT OR LOSS ITEMS

The following table sets forth selected consolidated statements of profit or loss with line items in absolute amounts and as percentages of our revenue for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	% of		% of		% of		% of		% of	
	Amount	revenue	Amount	revenue	Amount	revenue	Amount	revenue	Amount	revenue
<i>(RMB in thousands, except for percentages)</i>										
<i>(Unaudited)</i>										
Revenue	794,955	100.0	701,833	100.0	560,416	100.0	376,599	100.0	5,661,227	100.0
Cost of sales	(212,735)	(26.8)	(246,844)	(35.2)	(253,401)	(45.2)	(161,031)	(42.8)	(190,920)	(3.4)
Gross profit	582,220	73.2	454,989	64.8	307,015	54.8	215,568	57.2	5,470,307	96.6
Other income	70,311	8.8	70,489	10.0	59,249	10.6	42,906	11.4	163,819	2.9
Other gains and losses, net	2,434	0.3	(563)	(0.1)	(1,248)	(0.2)	(733)	(0.2)	(46,296)	(0.8)
Impairment losses under expected credit loss ("ECL") model, net of reversal	2,998	0.4	(7,686)	(1.1)	6,442	1.1	6,224	1.7	1,477	0.0
Research and development expenses	(278,603)	(35.0)	(375,020)	(53.4)	(746,232)	(133.2)	(509,799)	(135.4)	(931,701)	(16.5)
Distribution and selling expenses	(391,296)	(49.2)	(324,297)	(46.2)	(251,193)	(44.8)	(179,718)	(47.7)	(156,046)	(2.8)

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	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	% of		% of		% of		% of		% of	
	Amount	revenue	Amount	revenue	Amount	revenue	Amount	revenue	Amount	revenue
(RMB in thousands, except for percentages)										
(Unaudited)										
Administrative expenses	(79,869)	(10.0)	(82,194)	(11.7)	(115,397)	(20.6)	(87,211)	(23.2)	(122,322)	(2.2)
Other expenses	(3,939)	(0.5)	(2,311)	(0.3)	(2,970)	(0.5)	(2,441)	(0.6)	(1,748)	(0.0)
Finance costs	(16,343)	(2.1)	(22,481)	(3.2)	(24,679)	(4.4)	(18,492)	(4.9)	(27,798)	(0.5)
(Loss) Profit before tax	(112,087)	(14.1)	(289,074)	(41.2)	(769,013)	(137.2)	(533,696)	(141.7)	4,349,692	76.8
Income tax credit/(expense)	4,445	0.6	6,695	1.0	(11,486)	(2.0)	18,590	4.9	(284,324)	(5.0)
(Loss) Profit for the year/period	(107,642)	(13.5)	(282,379)	(40.2)	(780,499)	(139.3)	(515,106)	(136.8)	4,065,368	71.8

Revenue

Revenue by Nature

During the Track Record Period, we generated revenue primarily from the sale of pharmaceutical products in China and the license fee income in the United States. The following table sets forth a breakdown of our revenue by nature in both absolute amounts and as percentages of our revenue for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	% of		% of		% of		% of		% of	
	Amount	revenue	Amount	revenue	Amount	revenue	Amount	revenue	Amount	revenue
(RMB in thousands, except for percentages)										
(Unaudited)										
Sale of pharmaceutical products	794,955	100.0	701,833	100.0	560,416	100.0	376,599	100.0	326,936	5.8
License fee income	–	–	–	–	–	–	–	–	5,331,724	94.2
Others ⁽¹⁾	–	–	–	–	–	–	–	–	2,567	0.0
Total	794,955	100.0	701,833	100.0	560,416	100.0	376,599	100.0	5,661,227	100.0

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Note:

- (1) Representing revenue generated from the sale of clinical trial supplies relating to BL-B01D1 to BMS pursuant to a clinical supply agreement entered between us and BMS. See “Business – License and Collaboration Agreement with Bristol – Myers Squibb Company” for more details.

Revenue from the sale of pharmaceutical products

In 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, our revenue from the sale of pharmaceutical products was RMB795.0 million, RMB701.8 million, RMB560.4 million, RMB376.6 million and RMB326.9 million, respectively. Revenue from the sale of pharmaceutical products is recognized at a point in time when control of the goods has transferred, being when the goods have been shipped to the specific location and accepted.

Revenue from the license fee income

In the nine months ended September 30, 2024, we also generated revenue from the license fee income, representing part of the Upfront Payment under the BMS Agreement. Pursuant to the BMS Agreement, in March 2024, we received a non-refundable and non-creditable Upfront Payment of US\$800 million (equivalent to approximately RMB5,679.7 million) from BMS. We recognized revenue of US\$751.0 million (equivalent to approximately RMB5,331.7 million) in relation to our performance of the grant of license to BMS in the nine months ended September 30, 2024. The revenue for grant of license which represents a right to use the Group’s intellectual property is recognized at a point in time at which the license transfers. The remaining Upfront Payment of US\$49.0 million (equivalent to approximately RMB348.0 million) is allocated to the performance obligation of transferring manufacturing technology, which is recorded as contract liability and the timing of transfer is at the discretion of BMS.

Revenue from the Sale of Pharmaceutical Products by Product

The following table sets forth our revenue from the sale of our pharmaceutical products by product for the periods indicated:

Year ended December 31,						Nine months ended September 30,			
2021		2022		2023		2023		2024	
Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
(RMB in thousands, except for percentages)									
(Unaudited)									

Anesthesia

Leweijing	258,356	32.5	313,652	44.7	212,429	37.9	149,888	39.8	96,801	29.6
Leweitai	116,805	14.7	28,414	4.0	19,636	3.5	14,464	3.8	18,549	5.7
Youmeining	26,729	3.4	23,272	3.3	11,400	2.0	8,655	2.3	12,240	3.7

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	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
(RMB in thousands, except for percentages)										
(Unaudited)										
Parenteral nutrition										
Tianze	115,555	14.5	61,554	8.8	39,864	7.1	30,874	8.2	19,159	5.9
Anti-infectives										
Xinbolin	34,500	4.3	58,724	8.4	33,492	6.0	13,336	3.5	10,461	3.2
Aobolin	10,408	1.3	8,427	1.2	1,988	0.4	1,516	0.4	1,632	0.5
Pediatric drugs										
Dulabao	14,058	1.8	8,590	1.2	13,877	2.5	11,346	3.0	6,819	2.1
Leyeping and Pujikang	15,593	2.0	19,623	2.8	31,407	5.6	23,071	6.1	14,907	4.6
Traditional Chinese medicine										
Astragalus granule	160,988	20.3	134,148	19.1	155,696	27.8	97,953	26.0	92,331	28.2
Chaihuang granule	24,303	3.1	28,870	4.1	21,317	3.8	15,251	4.0	9,685	3.0
Other chemical drugs and traditional Chinese medicines										
	17,660	2.1	16,559	2.4	19,310	3.4	10,246	2.7	44,352	13.6
Total	<u>794,955</u>	<u>100.0</u>	<u>701,833</u>	<u>100.0</u>	<u>560,416</u>	<u>100.0</u>	<u>376,599</u>	<u>100.0</u>	<u>326,936</u>	<u>100.0</u>

Cost of Sales

During the Track Record Period, our cost of sales related to the sale of the pharmaceutical products, which primarily consisted of cost of materials, manufacturing and delivery costs, and direct labor costs. In 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, our cost of sales was RMB212.7 million, RMB246.8 million, RMB253.4 million, RMB161.0 million and RMB190.9 million, respectively.

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The table below sets forth a breakdown of our cost of sales for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
	(RMB in thousands, except for percentages)									
	(Unaudited)									
Cost of materials	117,194	55.1	139,476	56.5	139,831	55.2	87,737	54.5	105,253	55.1
Manufacturing and delivery costs	60,639	28.5	72,470	29.4	69,067	27.3	44,337	27.5	53,661	28.1
Direct labor costs	18,503	8.7	19,495	7.9	19,063	7.5	12,163	7.6	15,621	8.2
Others ⁽¹⁾	16,399	7.7	15,403	6.2	25,440	10.0	16,793	10.4	16,385	8.6
Total	212,735	100.0	246,844	100.0	253,401	100.0	161,031	100.0	190,920	100.0

Note:

(1) Other cost of sales primarily includes impairment and write-off losses related to inventory.

The following table sets forth a breakdown of our cost of sales by product in absolute amounts and as percentages of our total cost of sales for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
	(RMB in thousands, except for percentages)									
	(Unaudited)									
Anesthesia										
Leweijing	42,944	20.2	72,874	29.5	61,372	24.2	42,552	26.4	61,629	32.3
Loweitai	5,687	2.7	3,604	1.5	5,533	2.2	3,813	2.4	5,893	3.1
Youmeining	669	0.3	891	0.4	636	0.3	498	0.3	587	0.3
Parenteral nutrition										
Tianze	32,844	15.4	22,673	9.2	16,217	6.4	12,641	7.8	8,289	4.3
Anti-infectives										
Xinbolin	7,966	3.7	17,912	7.3	11,429	4.5	3,929	2.4	4,449	2.3
Aobolin	4,020	1.9	3,634	1.5	840	0.3	613	0.4	961	0.5
Pediatric drugs										
Dulabao	1,779	0.8	1,151	0.5	1,769	0.7	1,420	0.9	1,111	0.6
Leyeping and Pujikang	4,293	2.0	7,033	2.8	9,071	3.6	6,790	4.2	4,573	2.4

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	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
(RMB in thousands, except for percentages)										
(Unaudited)										
Traditional Chinese medicine										
Astragalus granule	76,591	36.0	80,663	32.7	98,922	39.0	59,578	37.0	61,766	32.4
Chaihuang granule	11,834	5.6	14,833	6.0	11,377	4.5	7,922	4.9	6,314	3.3
Other chemical drugs and traditional Chinese medicines										
Chinese medicines	7,709	3.7	6,173	2.4	10,795	4.3	4,482	2.8	18,963	9.9
Add: Others⁽¹⁾	16,399	7.7	15,403	6.2	25,440	10.0	16,793	10.4	16,385	8.6
Total	212,735	100.0	246,844	100.0	253,401	100.0	161,031	100.0	190,920	100.0

Note:

- (1) Represent the add-back of other cost of sales primarily including impairment and write-off losses related to inventory.

Gross Profit and Gross Profit Margin

Our gross profit represents our revenue less cost of sales. Gross profit margin represents our gross profit as a percentage of our revenue. In 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, our gross profit was RMB582.2 million, RMB455.0 million, RMB307.0 million, RMB215.6 million and RMB5,470.3 million, representing a gross profit margin of 73.2%, 64.8%, 54.8%, 57.2% and 96.6%, respectively.

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The following table sets forth a breakdown of our gross profit and gross profit margin by business for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Gross profit		Gross profit		Gross profit		Gross profit		Gross profit	
	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %
(RMB in thousands, except for percentages)										
(Unaudited)										
Sale of pharmaceutical products	582,220	73.2	454,989	64.8	307,015	54.8	215,568	57.2	136,016	41.6
License fee income	–	–	–	–	–	–	–	–	5,331,724	100.0
Others	–	–	–	–	–	–	–	–	2,567	100.0
Total	582,220	73.2	454,989	64.8	307,015	54.8	215,568	57.2	5,470,307	96.6

The following table sets forth a breakdown of our gross profit and gross profit margin by product for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Gross profit		Gross profit		Gross profit		Gross profit		Gross profit	
	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %
(RMB in thousands, except for percentages)										
(Unaudited)										
Anesthesia										
Leweijing	215,412	83.4	240,778	76.8	151,057	71.1	107,336	71.6	35,172	36.3
Leweitai	111,118	95.1	24,810	87.3	14,103	71.8	10,651	73.6	12,655	68.2
Youmeining	26,060	97.5	22,381	96.2	10,764	94.4	8,157	94.2	11,653	95.2
Parenteral nutrition										
Tianze	82,711	71.6	38,881	63.2	23,647	59.3	18,233	59.1	10,870	56.7
Anti-infectives										
Xinbolin	26,534	76.9	40,812	69.5	22,063	65.9	9,407	70.5	6,012	57.5
Aobolin	6,388	61.4	4,793	56.9	1,148	57.7	903	59.6	672	41.1

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	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Gross profit		Gross profit		Gross profit		Gross profit		Gross profit	
	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %	Gross profit	margin %
(RMB in thousands, except for percentages)										
(Unaudited)										
Pediatric drugs										
Dulabao	12,279	87.3	7,439	86.6	12,108	87.3	9,925	87.5	5,708	83.7
Leyeping and Pujikang	11,300	72.5	12,590	64.2	22,336	71.1	16,281	70.6	10,334	69.3
Traditional Chinese medicine										
Astragalus granule	84,397	52.4	53,485	39.9	56,774	36.5	38,375	39.2	30,564	33.1
Chaihuang granule	12,469	51.3	14,037	48.6	9,940	46.6	7,329	48.1	3,371	34.8
Other chemical drugs and traditional Chinese medicines	9,951	56.3	10,386	62.7	8,515	44.1	5,764	56.3	25,390	57.2
Add: Others⁽¹⁾	(16,399)	–	(15,403)	–	(25,440)	–	(16,793)	–	(16,385)	–
Total	582,220	73.2	454,989	64.8	307,015	54.8	215,568	57.2	136,016	41.6

Note:

- (1) Represent the add-back of other cost of sales primarily including impairment and write-off losses related to inventory.

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Other Income

Our other income consists of government grants, interest income on bank deposits, release of expense-related government subsidies, rental income, release of assets-related government subsidies, and others. The following table sets forth a breakdown of our other income for the periods indicated:

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
<i>(RMB in thousands)</i>					
<i>(Unaudited)</i>					
Other Income					
Government grants ⁽¹⁾	61,935	49,441	49,329	35,027	27,713
Interest income on bank deposits	475	767	5,703	4,373	130,176
Release of expense- related government subsidies ⁽²⁾	5,419	17,970	1,600	1,600	2,843
Rental and rental- related income	1,601	1,403	1,429	1,083	1,333
Release of assets- related government subsidies ⁽²⁾	558	801	1,060	719	1,196
Others	323	107	128	104	558
Total	70,311	70,489	59,249	42,906	163,819

Notes:

- (1) Government grants mainly represent unconditional subsidies granted by the PRC local authorities to support the operation activities/technology innovation and contribution of us, which no future related cost is expected to be incurred in and were recognized in our statement of profit or loss when payments were received or receivable.
- (2) Expense-related government subsidies represent conditional government subsidies that related to our research and development activities, which were recognized as deferred income and released to statement of profit or loss upon completion of the activities. Assets-related government subsidies represent conditional government subsidies that related to the construction of our production facilities, which were recognized as deferred income and released to statement of profit or loss when assets were amortized over the estimated useful lives.

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Other Gains and Losses, Net

Our other gains and losses, net primarily consist of gain on fair value change of financial assets at FVTPL, net foreign exchange loss or gain, and loss on disposal or written-off of property, plant and equipment. The following table sets forth a breakdown of our other gains and losses, net for the periods indicated:

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
<i>(RMB in thousands)</i>					
<i>(Unaudited)</i>					
Gain on fair value change of financial assets at FVTPL	3,140	–	4	4	30,675
Net foreign exchange loss	(140)	(55)	(1,107)	(632)	(76,807)
Loss on disposal/ written-off of property, plant and equipment	(447)	(465)	(254)	(216)	(134)
Others	(119)	(43)	109	111	(30)
Total	2,434	(563)	(1,248)	(733)	(46,296)

Research and Development Expenses

Our research and development expenses primarily consist of testing and examination costs, staff costs, cost of materials, depreciation expenses, licensing fees and office expenses. The table below sets forth a breakdown of our research and development expenses for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
<i>(RMB in thousands, except for percentages)</i>										
<i>(Unaudited)</i>										
Testing and examination costs	81,282	29.2	137,367	36.6	356,381	47.8	250,666	49.2	513,111	55.1
Staff costs	69,167	24.8	104,814	27.9	169,488	22.7	112,544	22.1	208,948	22.4

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	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
(RMB in thousands, except for percentages)										
(Unaudited)										
Cost of materials	63,947	23.0	60,998	16.3	87,190	11.7	57,621	11.3	95,267	10.2
Depreciation expenses	28,243	10.1	32,532	8.7	33,695	4.5	24,997	4.9	35,878	3.9
Licensing fees	9,979	3.6	6,875	1.8	29,315	3.9	25,275	5.0	13,914	1.5
Office expenses	9,487	3.4	10,443	2.8	19,768	2.6	15,268	3.0	22,779	2.4
Others	16,498	5.9	21,991	5.9	50,395	6.8	23,428	4.6	41,803	4.5
Total	278,603	100.0	375,020	100.0	746,232	100.0	509,799	100.0	931,701	100.0

Cost of materials mainly comprises the consumption of raw materials, consumables, chemical reagents, biological products, and reference drugs. Staff costs mainly consist of salaries, bonuses, and other benefits and welfare of our research and development personnel. Testing and examination costs mainly consist of clinical trials expenses and preclinical studies expenses. Depreciation expenses mainly comprise depreciation expenses for right-of-use assets, property, plant and equipment for research and development purposes. Office expenses mainly comprise office-related expenditure for R&D purposes. Licensing fees mainly relate to our patent and other intellectual property application fees. Others mainly comprise utilities, travel expenses and other miscellaneous expenses.

The table below sets forth a breakdown of our research and development expenses incurred on (i) BL-B01D1, (ii) other innovative drug candidates and (iii) generic drug candidates, respectively, for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
(RMB in thousands, except for percentages)										
(Unaudited)										
BL-B01D1	20,515	7.4	58,683	15.7	243,837	32.7	158,309	31.1	388,812	41.7
Other innovative										
drug candidates	178,554	64.1	263,329	70.2	449,428	60.2	308,525	60.5	508,840	54.6
Generic drug candidates	79,534	28.5	53,008	14.1	52,967	7.1	42,965	8.4	34,049	3.7
Total	278,603	100.0	375,020	100.0	746,232	100.0	509,799	100.0	931,701	100.0

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Distribution and Selling Expenses

Our distribution and selling expenses primarily consist of marketing and promotion expenses, staff costs and travelling expenses. The following table sets forth a breakdown of our distribution and selling expenses for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
<i>(RMB in thousands, except for percentages)</i>										
<i>(Unaudited)</i>										
Marketing and										
promotion expenses	313,618	80.1	248,540	76.6	160,505	63.9	114,429	63.7	77,955	50.0
Staff costs	50,897	13.0	51,868	16.0	58,538	23.3	41,388	23.0	51,702	33.1
Travelling expenses	15,147	3.9	13,909	4.3	19,202	7.6	13,592	7.6	8,463	5.4
Others	11,634	3.0	9,980	3.1	12,948	5.2	10,309	5.7	17,926	11.5
Total	391,296	100.0	324,297	100.0	251,193	100.0	179,718	100.0	156,046	100.0

Marketing and promotion expenses primarily comprise (i) expenses associated with organizing and participating in various academic conferences, seminars and symposia, which amounted to RMB174.4 million, RMB114.3 million, RMB43.6 million and RMB1.3 million in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively; (ii) expenses related to various marketing and promotional services, including market research and business development, which amounted to RMB62.5 million, RMB59.4 million, RMB59.7 million and RMB41.6 million in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively; and (iii) expenses related to product demonstration, feedback collection, and scientific communication and education sessions conducted with healthcare professionals, which amounted to RMB76.8 million, RMB74.9 million, RMB57.2 million and RMB35.1 million in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively.

Staff costs mainly consist of salaries, bonuses, and other benefits and welfare of our sales and marketing personnel. Travelling expenses mainly consist of travel and accommodation expenses of our in-house sales and marketing personnel for the promotion of our products. Other distribution and selling expenses mainly consist of office expenses and certain other expenses directly related to our marketing and promotion activities.

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Administrative Expenses

Our administrative expenses primarily consist of staff costs, depreciation and amortization, office expenses, professional services fee and travelling expenses. The table below sets forth a breakdown of our administrative expenses for the periods indicated:

	Year ended December 31,						Nine months ended September 30,			
	2021		2022		2023		2023		2024	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
<i>(RMB in thousands, except for percentages)</i>										
<i>(Unaudited)</i>										
Staff costs	43,999	55.1	48,420	58.9	60,601	52.5	45,274	51.9	76,041	62.2
Depreciation and amortization	9,071	11.4	10,251	12.5	10,208	8.8	8,556	9.8	7,018	5.7
Office expenses	7,794	9.8	7,820	9.5	9,568	8.3	7,786	8.9	10,013	8.2
Professional services fee	6,012	7.5	3,907	4.8	13,060	11.3	10,362	11.9	7,637	6.2
Travelling expenses	3,005	3.8	2,181	2.7	4,503	3.9	3,062	3.5	7,844	6.4
Others	9,988	12.5	9,615	11.7	17,457	15.1	12,171	14.0	13,769	11.3
Total	79,869	100.0	82,194	100.0	115,397	100.0	87,211	100.0	122,322	100.0

Staff costs mainly consist of salaries, bonuses, and other benefits and welfare of our Directors, senior management and administrative personnel and staff recruitment expenses. Depreciation and amortization are mainly related to property and equipment for office and other administrative functions. Office expenses are mainly related to office expenditure for administrative purposes. Professional service fees mainly comprise service fees to auditors, legal counsel and other professional service providers. Travelling expenses are mainly related to travel and accommodation expenses of our administrative personnel. Other administrative expenses mainly consist of other taxes, bank charges and other miscellaneous administrative expenses.

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Other Expenses

Our other expenses comprise (i) depreciation of investment properties, representing depreciation recognized so as to write off the cost of investment properties over their estimated useful lives and after taking into account of their estimated residual value, using the straight-line method; (ii) donations we made to promote the development of medical and healthcare services; and (iii) enterprise income tax penalties and overdue fine. The following table sets forth a breakdown of our other expenses for the periods indicated:

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	(RMB in thousands)			(Unaudited)	
Depreciation of investment properties	1,389	1,297	1,323	966	1,260
Donations	1,603	143	246	146	450
Penalties and overdue fine ⁽¹⁾	947	871	1,401	1,329	38
Total	3,939	2,311	2,970	2,441	1,748

Note:

- (1) It occurred as our Company, acting as a bona fide third party, obtained VAT invoices and, upon self-review, proactively made tax adjustments and paid the corresponding taxes and overdue fines.

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Finance Costs

Our finance costs consist of interest expenses on bank borrowings, sale and leaseback payable, lease liabilities, and redeemable shares. The following table sets forth a breakdown of our finance costs for the periods indicated:

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	<i>(RMB in thousands)</i>				
	<i>(Unaudited)</i>				
Interest expense on:					
– bank borrowings	6,806	12,494	18,500	13,645	26,154
– sale and leaseback payable ⁽¹⁾	1,474	9,390	5,733	4,429	1,222
– lease liabilities	412	597	446	418	422
– redeemable shares	7,651	–	–	–	–
Total	16,343	22,481	24,679	18,492	27,798

Note:

- (1) Sale and leaseback payable arose from the transaction where we sold and leased back certain equipment from financing institutions. We continue to recognize the assets and accounts for the transfer proceeds as borrowings, as the transfer does not qualify as a sale.

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Income Tax (Credit) Expense

The income tax (credit) expense consists of current tax and deferred tax. The following table sets forth a breakdown of our income tax (credit) expense for the periods indicated:

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	(RMB in thousands)			(Unaudited)	
PRC Enterprise					
Income Tax					
(“EIT”)					
– current tax	11,306	7,380	854	3,581	171,010
– under-provision					
in prior					
years/periods ⁽¹⁾	1,992	3,323	3,703	681	51
U.S. Income Tax	–	–	–	–	259,160
Deferred tax	(17,743)	(17,398)	6,929	(22,852)	(145,897)
Total income tax					
(credit)/expense	(4,445)	(6,695)	11,486	(18,590)	284,324

Note:

- (1) Under-provision of EIT in prior years/periods occurred because certain tax invoices provided by certain suppliers and received by the Group, as a bona fide third party, were later disallowed by the relevant tax authorities. Consequently, the Group was notified to pay additional taxes, including overdue payment for previous years/periods, based on the amounts of these invoices that should have reduced profit before tax. As of the Latest Practicable Date, the Group has not been subject to any penalties or fines from the relevant tax authorities regarding this matter.

China

Under the Law of the PRC on Enterprise Income Tax (the “EIT Law”) and Implementation Regulation of the EIT Law, the EIT rate of our entities established in the PRC is 25% for the Track Record Period.

The subsidiary of our Company, namely Lhasa Xinbo, that is engaged in the Encouraged Industries in the Western Region (西部地區鼓勵類產業) are eligible for the preferential EIT rate at 15% during the Track Record Period.

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In November 2019, the Certificate of New Hi-tech Enterprise was granted to one subsidiary of our Company, namely Baili Pharmaceutical, which was expired in 2021 and renewed in December 2023 with a valid period of three years. As such, Baili Pharmaceutical is eligible for the preferential EIT rate of 15% in 2021 and 2023 and the nine months ended September 30, 2024. In 2022, Baili Pharmaceutical was engaged in the Encouraged Industries in the Western Region and was eligible for the preferential EIT rate at 15%.

In December 2020, one subsidiary of our Company, namely Guorui Pharmaceutical, has been accredited as a New Hi-tech Enterprise, which was renewed in December 2023 with a valid period of three years, and Guorui Pharmaceutical is eligible for the preferential EIT rate of 15% during the Track Record Period.

Since 2023, two subsidiaries of our Company, namely Hiatt Technology and Tianze Pharmaceutical, are qualified as small and micro enterprises and are eligible for the preferential EIT rate at 20%.

Since 2024, one subsidiary of our Company, namely Baili-Bio, that is engaged in the Encouraged Industries in the Western Region, is eligible for the preferential EIT rate at 15%.

United States

Our U.S. subsidiary is subject to U.S. EIT representing 21% of the applicable U.S. Federal Income Tax rate and blended average rate of 3.52% of the State Income Tax arising from applicable State in the U.S.

During the Track Record Period and up to the Latest Practicable Date, we paid all relevant taxes that were applicable to us and due and had no disputes or unresolved tax issues with relevant tax authorities.

BUSINESS SUSTAINABILITY

To realize long-term growth and enhance patient outcomes, we made the strategic move into the innovative drug business in 2010 and has focused on discovering and developing breakthrough oncology therapies since 2014. Leveraging our proprietary technology platforms, we have systematically built a pipeline of potential first- and best-in-class treatments across multiple modalities that target major tumor types. As of the Latest Practicable Date, our innovative drug pipeline featured 14 clinical-stage drug candidates, led by our BL-B01D1, which we believe has the potential to become a backbone pan-tumor treatment.

We recorded net losses of RMB107.6 million, RMB282.4 million and RMB780.5 million in 2021, 2022 and 2023, respectively. Our net losses recorded during the Track Record Period were primarily in relation to: (i) our substantial investment in R&D activities for the development of ADC, bispecific as well as multi-specific antibody drugs, and (ii) the reduction of revenue from the sale of pharmaceutical products mainly because certain of our major marketed products are generic drugs subject to the impact of the VBP schemes, which resulted in decreases in both prices and sales volumes of relevant products during the Track Record

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Period. The profitability of our generics and traditional Chinese medicine business was negatively impacted in 2023 and the nine months ended September 30, 2024, mainly because some of our major marketed products were included in national or provincial VBP schemes. We recorded a net profit of RMB4,065.4 million in the nine months ended September 30, 2024, mainly attributable to the license fee we received as part of the Upfront Payment in connection with the licenses and other rights granted to BMS by us pursuant to the BMS Agreement. Our strategic collaboration with BMS is the culmination of years of dedication to innovative drug development and first step toward generating revenue from our innovative oncology drug portfolio.

Going forward, we aim to continue to make substantial investments in discovering and developing innovative drugs with blockbuster potential while realizing the commercial value of our pipeline assets. Over the next decade, we plan to unlock this potential through a combination of sales of innovative drugs and revenue from collaborations and licensing. During this period, we will continue to strengthen our competitive R&D capabilities and expand our market entry and commercialization efforts globally. These steps will support our ambition to emerge as a leading multinational pharmaceutical company. Specifically:

Expedite the clinical development and commercialization of our lead asset BL-B01D1

Our internally discovered and developed BL-B01D1 is the world’s first and only clinical-stage EGFR × HER3 bispecific ADC intended for the treatment of various solid tumors. It is also the first bispecific ADC to have advanced into Phase III trials in the world and one of the most investigated clinical-stage ADCs, as it has been studied in over 2,000 patients across various cancer types. As of the Latest Practicable Date, we had conducted approximately 30 clinical trials for BL-B01D1, including seven Phase III clinical trials evaluating BL-B01D1 as monotherapy for late-line treatment of various cancers, including two NSCLC indications, SCLC, two BC indications, ESCC, and NPC. Based on the clinical data, we believe BL-B01D1 has the potential to be a backbone pan-tumor treatment.

Our near-term priority is to further accelerate the clinical development for BL-B01D1 both in China and around the globe by leveraging our global strategic collaboration with BMS.

BL-B01D1 holds significant potential to drive our near-term revenue growth. In addition to the Upfront Payment, we are eligible to receive a nonrefundable milestone payment of US\$250 million upon the initiation of the first Phase II or Phase III trial of the Licensed Product as 1L or 2L treatment in the U.S. on or before December 31, 2025, and another nonrefundable milestone payment of US\$250 million upon the initiation of the first Phase III trial of the Licensed Product as 1L treatment in the U.S. on or before December 31, 2026. Such milestones were established through mutual agreement. We expect the first BLA submission to the FDA in as early as 2028. We reasonably anticipate that we will be eligible to receive the contingent near-term payments based on the current pace of clinical progress for BL-B01D1 and the anticipated market entry timetable. We are also eligible to receive up to an aggregate of US\$7.1 billion contingent upon the achievement of certain specified regulatory and sales performance milestones for a total potential consideration of up to US\$8.4 billion.

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Under our global license and collaboration agreement with BMS, we and BMS plan to initiate multiple late-stage clinical trials of BL-B01D1 globally for various solid tumors in the next few years. We will (i) proactively advance BL-B01D1’s development in combination with PD-(L)1 therapies, aiming to replace the chemotherapy component in 1L treatment for solid tumors where PD-(L)1 combo therapies are the current standard of care; (ii) proactively advance BL-B01D1’s development in combination with TKIs as the new standard of care for cancer indications currently treated with TKI monotherapy in 1L settings; and (iii) continue to develop BL-B01D1 in late-line settings, as well as in neoadjuvant and adjuvant settings across over ten epithelial cancers where BL-B01D1 has shown promising efficacy and manageable safety. We expect NDA submission to the NMPA for BL-B01D1 in its first indication by 2026, and the first BLA submission to the FDA in as early as 2028. Over the next three to five years, BL-B01D1 is anticipated to have multiple regulatory approval applications submitted for various indications in China, the U.S., Europe and other regulatory regions.

In the meantime, we are strengthening our commercialization capabilities, including scaling up our manufacturing processes to ensure we can meet market demand upon approval, and building a robust sales and marketing team.

Maintaining financial stability through generics and traditional Chinese medicine business

In addition to our innovative drug business, we have built a strong business in the space of generic drugs and traditional Chinese medicines in the past 28 years. Over the decades, we built a portfolio of marketed products comprising 19 generic products and three traditional Chinese medicine products as well as over 20 generic drug candidates under development. We established numerous areas of focus within this space, including anesthesia, parenteral nutrition, anti-infectives and pediatrics. Our rich pipeline of products, across a broad range of therapeutic areas, and at staggered development and commercialization stages, not only allows for sustained commercial success, but also facilitates our accumulation of technologies in complex generics development and manufacture as well as the build-up of our marketing and commercial capabilities.

Our Directors believe that our business of selling generic drugs and traditional Chinese medicine is sustainable in the foreseeable future due to the following reasons:

Business

- (i) *Market position:* The generics and traditional Chinese medicine market in China is vast. Our established leadership, both in our focused areas and in the drug market generally, in and of itself forms a virtuous circle and allows us to compete at an advantage and hold on to leading market positions (and substantial market shares) for our products, especially those large revenue contributors. For details, see “Business — Our Marketed Products.”

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- (ii) *Product portfolio:* We have established product portfolio in our focused therapeutic areas at staggered development and commercialization stages. Our multiple major marketed products continue to hold a leading market position. By leveraging our technological advantages in the fields of generics and complex formulations, we also strategically select and develop new products with competitive edges in light of the policy environment and competitive landscape.
- (iii) *Regulatory landscape:* Overall, we have demonstrated the potential to sustain operations under the VBP and centralized tender regime. For our major products subject to centralized procurement, we believe in most cases their prices have bottomed out and stabilized now under a policy framework that is expected to be stable. According to CIC, this trend aligns with industry observations for generic products that were among the first batch to be included in the national VBP scheme, for which the effects of the scheme have largely materialized. Once a product is included in national or provincial VBP schemes, these products enjoy priority sales into hospitals, achieving coverage efficiently and cost-effectively. This not only increases the market recognition of our VBP-included products but also enhances our brand reputation in general. As our brand reputation grows, a synergistic effect is created for our other products. We can leverage the brand recognition and hospital coverage achieved by our VBP-included products to achieve more effective market penetration and reduced promotional costs. Further, as the VBP policies settled in the past few years, we have timely adjusted our sales and product development strategies in response to such policies, and shifted our focus towards products that are less likely to be adversely affected, or that may even benefit from the VBP schemes. While profitability remains achievable, the VBP policies may reduce the profit margin of the procured products, which could deter new market entrants and help stabilize our market position in the long term. Additionally, multiple of our products are sold through both in-hospital and outside-of-hospital channels. In the outside-of-hospital drug market, prices are less affected by the bidding prices of VBP or centralized tender process.
- (iv) *Integrated capabilities:* We have an integrated system that encompasses drug R&D, manufacture, supply and marketing capabilities and has advantages in costs as a result of our integrated production of both API and finished drug products, ensuring our cost control and quality control capabilities. We also possess strong management capabilities, enabling us to leverage operational efficiency and economies of scale. These capabilities help us effectively avoid reliance on API suppliers, and also provide very strong support for the Company’s marketed and pipeline products to capture market share.
- (v) *Commercialization:* We are a large pharmaceutical company with a stable sales network across the country including over 1,600 distributors during the Track Record Period. Our established sales network and team, as well as insights in the market trends and customer needs, allow us to continue to achieve market coverage and penetration of our marketed and future products.

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(i) As of the Latest Practicable Date, the drug classes of six of our marketed products that accounted for over 50% of our revenue from the sale of pharmaceutical products during the Track Record Period were subject to national and/or provincial VBP schemes, leading to significant variability in both pricing and sales volumes of these products. See “Business — Our Marketed Products — Generic Drugs” for further details. Over the past few years, we have adapted our sales and marketing strategies to align with the evolving regulatory environment as VBP policies became settled. The primary financial impact of the VBP schemes has already been reflected in our financial results during the Track Record Period. Looking forward, we anticipate that the aggregate sales of these products to stabilize, with a potential for modest growth, in the foreseeable future:

- ***Our product in national VBP:*** Lewejing is currently our only bid winning product in an ongoing national VBP scheme. It generated revenue of RMB258.4 million, RMB313.7 million, RMB212.4 million and RMB96.8 million, accounting for 32.5%, 44.7%, 37.9% and 29.6% of our revenue from the sale of pharmaceutical products, in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively. Lewejing was previously included in several provincial VBP schemes, all of which concluded in March 2024 when the largest specification (50ml:0.5g) of Lewejing was included into the ninth batch of the national VBP scheme. Under the national VBP, we will be the primary supplier for the largest specification of Lewejing in seven provinces for a period from March 2024 to December 2027, with a guaranteed minimum annual sales volume. The inclusion into the national VBP is expected to lead to an increase in the sales volume of the largest specification of Lewejing, while leading to a significant reduction in its price. Further, since the largest specification is prioritized in channels subject to national VBP, the sales volumes of the two smaller specifications are adversely affected. Their prices are to be reduced as recommended by the national VBP policy to remain competitive in the market. Lewejing only participated in the national VBP scheme in March 2024. In 2024, the average selling price of Lewejing remained stable compared to the nine months ended September 30, 2024, and the period-to-period decline in its sales revenue during this period remained stable compared to the decline experienced in the nine months ended September 30, 2024. As a result, the impact of this inclusion on its sales revenue has been gradually reflected in our financial results since March 2024, although such impact may not have been fully reflected so far. Once the impact of inclusion in the national VBP scheme is realized, we expect Lewejing’s sales to stabilize for the remainder of the national VBP scheme’s duration.

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- ***Our products in provincial VBP post national VBP:*** Leweitai generated revenue of RMB116.8 million, RMB28.4 million, RMB19.6 million, and RMB18.5 million, accounting for 14.7%, 4.0%, 3.5% and 5.7% of our revenue from the sale of pharmaceutical products in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively. The drug class of Leweitai, i.e. propofol medium and long chain fat emulsion injection, was included in the fourth batch of national VBP scheme in February 2021. Our product Leweitai was not included as it was still awaiting the consistency evaluation required for participation in the bidding process at that time. The winning bidders of this scheme obtained a significant share of the national market for propofol medium and long chain fat emulsion injection at a substantially reduced selling price. Although not participating in the national VBP scheme, Leweitai also experienced substantial downward adjustment of its selling price under the centralized tender process. This product, which previously held a significant market share, saw a large decline of sales volume from 2021 to 2022. After the expiry of the national VBP scheme, this drug class entered a phase of continuation procurement at provincial and regional levels, with guaranteed regional sales volumes. As it had lost substantial market share post to the national VBP, its inclusion in provincial continuation procurements schemes across 22 provinces and municipalities led to a recovery in sales volume from 2022 through the nine months ended September 30, 2024, along with a further price reduction in general. For those provincial schemes expiring in 2024 or early 2025, we have won the bids to renew in several of those provinces, and are also actively preparing for the renewal process in the remaining provinces. Based on the current procurement rules in the relevant provinces, we expect that our likelihood of securing continued procurement contracts there remains relatively high. Moreover, according to CIC, prices for the renewal of provincial continuation procurements are typically in line with the bid-winning prices in the initial contract term for products that are already included in the initial term. As a result, we expect Leweitai’s price to remain stable in the coming years. With a high probability of securing stable pricing in upcoming procurement rounds based on past procurement practices, we expect our sales revenue of this product to stabilize as we continue to enhance our market penetration in the provinces where it is part of the VBP schemes.

Youmeining generated revenue of RMB26.7 million, RMB23.3 million, RMB11.4 million, and RMB12.2 million, accounting for 3.4%, 3.3%, 2.0% and 3.7% of our revenue from the sale of pharmaceutical products, in 2021, 2022 and 2023 and the nine months ended September 30, 2024, respectively. The drug class of Youmeining, i.e. dexmedetomidine hydrochloride injection, was included in the national VBP scheme from December 2018 to early 2021. Similar to Leweitai, Youmeining experienced a significant decline in market share due to non-participation in the national VBP bidding process, but successfully regained certain sales volume through participation in the provincial continuation procurement in nine provinces and municipalities. We

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have already won the bids in the renewal schemes of two provinces starting from mid-2024, and based on the current procurement rules in the relevant provinces, we expect that the likelihood of securing continued procurement contracts for the other six provinces to be relatively high. In terms of pricing, this product is also expected to remain stable in the renewal of continuation procurement schemes in which it is already included in the initial term. From 2023 through the nine months ended September 30, 2024, this product’s sales volume and average selling price only marginally fluctuated. Given the stability in procurement schemes and pricing, we expect its sales revenue to stabilize as we continue to enhance our market penetration in the provinces where it is part of the VBP schemes.

- ***Our products in provincial VBP:*** Tianze generated revenue of RMB115.6 million, RMB61.6 million, RMB39.9 million, and RMB19.2 million accounted for 14.5%, 8.8%, 7.1% and 5.9% of our revenue from the sale of pharmaceutical products in 2021, 2022 and 2023 and the nine months ended September 30, 2024. In June 2021, a competing drug class of Tianze was included in the national VBP scheme for a duration of two years and gained market share, which largely affected the market demand for our product from the second half of 2021 through 2023. Its sales volume declined further in 2023 as Tianze did not obtain the consistency evaluation certification for participation in centralized tender process in certain provinces in the same year. We believe the impact of the inclusion of Tianze’s competing drug class in the national VBP scheme has been largely reflected during the Track Record Period and expect limited effects going forward. Further, in January 2024, two of the four specifications of Tianze successfully passed the consistency evaluation, making it eligible to participate in the centralized tender process of additional provinces. This presents an opportunity to regain market share in those provinces after a phase-in period. In addition, the drug class of Tianze is listed in the NEDL, an official list of selected medications deemed essential for addressing the primary healthcare needs of the population, and therefore prioritized for availability, affordability, and accessibility across the national healthcare system. Although Tianze’s sales volume further declined in 2024 following the expiry of a provincial VBP scheme in early 2024, we expect that its revenue to stabilize in the years after 2024.

Xinbolin generated revenue of RMB34.5 million, RMB58.7 million, RMB33.5 million, and RMB10.5 million, accounting for 4.3%, 8.4%, 6.0%, and 3.2% of our revenue from the sale of pharmaceutical products in 2021, 2022 and 2023 and the nine months ended September 30, 2024. The fluctuations in Xinbolin’s revenue during the Track Record Period were largely influenced by the COVID-19 pandemic. The drug class of Xinbolin, i.e. ribavirin, has not been included in the national VBP. According to CIC, based on the outcomes of the tenth national VBP, one of the prerequisites to be included in the national VBP scheme is that a drug class has at least six generics that passed the consistency

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evaluation. According to the same source, none of the products in the same drug class as Xinbolin had passed the consistency evaluation as of the Latest Practicable Date. Therefore, it is less likely that this drug class will be included in the national VBP scheme in the near future. As an anti-infective granule drug, while Xinbolin is included in some provincial VBP schemes, its primary retail sales channel is retail pharmacies and clinics rather than hospitals. The likelihood that the price of Xinbolin will be significantly impacted by VBP schemes is low. Going forward, we expect its sales revenue to remain stable in the coming years.

- (ii) Our other four major products, including two traditional Chinese medicine products and two generic drugs, are currently not included in either national or provincial VBP schemes. The revenue fluctuations of these marketed products during the Track Record Period were primarily due to the impact of the COVID-19 pandemic. These products have neither passed nor are currently undergoing consistency evaluation. According to CIC, the drug classes of these products currently do not meet the prerequisite requirements for national VBP schemes. Therefore, the likelihood of an immediate significant nationwide price reduction is low. In the foreseeable future, we expect revenue from these products to stabilize in line with industry trends.
- (iii) We anticipate that other approved drugs in our generics drug portfolio will drive the increase of our sales revenue. Our sales from other chemical and Chinese medicine products increased by RMB2.8 million from RMB16.6 million in 2022 to RMB19.3 million in 2023, and further increased by RMB34.1 million from RMB10.2 million for the nine months ended September 30, 2023 to RMB44.4 million for the nine months ended September 30, 2024 primarily due to the launch of new generic products. The following products are expected to contribute more revenue in the next few years:
 - *Sevoflurane for inhalation*: Our sevoflurane product, an inhalation anesthetic drug, was approved in May 2023. According to CIC, the market size of sevoflurane for inhalation in China’s public medical institutions in 2023 amounted to RMB3,045.6 million. Our sevoflurane product has been included in the provincial VBP scheme of Fujian since December 2023, which is expected to increase our market share in Fujian. We plan to promote this product as a key product in our anesthetic product line and continue to expand the sales channels of this product. We expect it to be a growth driver of our generics and traditional Chinese medicine business.
 - *Structural fat emulsion injection*: Our structural fat emulsion injection product, a parenteral nutrition drug, was approved in June 2024. According to CIC, the market size of structural fat emulsion injection (C6-24) in China’s public medical institutions in 2023 amounted to RMB1,038.7 million. As of the Latest Practicable Date, only one other structural fat emulsion injection had passed consistency evaluation and was being sold in China. Since drugs selected for

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national VBP must have one originator and at least six manufactures of generic versions that pass consistency evaluation, the likelihood that this drug class will be included in the national VBP scheme in the near future is low. The drug class of this product has been included in Fujian’s centralized procurement catalog and based on the current procurement rules, we expect that our product is likely to secure a two-year bid. We plan to promote this product as a key product in our parenteral nutrition product line and expect it to be a growth driver of our generics and traditional Chinese medicine business.

- *Dexmedetomidine hydrochloride and sodium chloride injection*: Our dexmedetomidine hydrochloride and sodium chloride injection, a sedative medication, was approved in June 2023. This product is listed in the NRDL and has priority access to public hospitals. We currently enjoy a relatively favorable market share and hospital coverage.
- *Nifekalant hydrochloride*: Our nifekalant hydrochloride product, an antiarrhythmic drug, was approved in 2014. According to CIC, we are currently the sole manufacturer of this drug class in China, which gives us substantial competitive advantages. We believe that our ongoing market education efforts for this product will drive an increase in its future demand.

Further, we expect approvals of additional generic drug products with commercial potential, such as etomidate medium/long chain fat emulsion injection and gadopentetate dimeglumine injection products.

- (iv) The inclusion of a majority of our major generic drug products in the VBP schemes is expected to reduce the need for distributor management and product promotional activities. The VBP schemes typically involve bulk purchasing agreements, which in turn can reduce the need for extensive promotional and sales efforts. Once a product is included in national or provincial VBP schemes, these products enjoy priority sales into hospitals, achieving coverage efficiently and cost-effectively. Our marketing and promotion expenses gradually decreased in the Track Record Period from RMB313.6 million in 2021 to RMB160.5 million in 2023, and further from RMB114.4 million in the nine months ended September 30, 2023 to RMB78.0 million in the corresponding period in 2024. According to CIC, products included in national or provincial VBP schemes have typically seen a noticeable reduction in distribution and selling expenses.

Further, in line with our strategic shift to innovative drug business, we expect research and development expenses as well as general and administrative expenses related to our generics and traditional Chinese medicine business as a percentage of revenue to decrease, which, according to CIC, is in line with industry trend. CIC has advised that when a company shifts its business focus away from generic drugs, it likely will reduce its investment in developing new generic drugs. Since VBP inclusion generally leads to reduced profit margins for the covered products,

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companies tend to focus on enhancing efficiency to maintain profitability level. The inclusion of generic products in the VBP schemes is expected to reduce the need for distributor management and product promotional activities, and management resources can be redirected to improving administrative efficiency. Therefore, the inclusion of major generics in VBP schemes is likely to result in a reduction of both research and development expenses as well as general and administrative expenses as companies shift their attention to maximizing operational efficiency.

Having reviewed the basis of the Directors’ view and based on the independent due diligence work performed by the Joint Sponsors, nothing material has come to the attention of the Joint Sponsors, that would reasonably cause them to cast doubt on the Directors’ view above with respect to the sustainability of the Group’s generics and traditional Chinese medicine businesses.

Continue to advance our diverse portfolio of innovative drugs

In addition to BL-B01D1, leveraging our proprietary technology platforms, we have systematically built a pipeline of potential first- and best-in-class treatments across multiple modalities that target major tumor types. As of the Latest Practicable Date, our innovative drug pipeline featured 14 clinical-stage drug candidates. In addition to BL-B01D1, our pipeline includes two other candidates in Phase III clinical trials: BL-M07D1, an innovative HER2-specific ADC, and SI-B001, a potential first-in-class EGFR × HER3 bispecific antibody. In addition, we have successfully advanced four innovative GNC multi-specific antibodies, including GNC-077, to clinical stage. GNC-038, GNC-035 and GNC-039, all at Phase Ib stage, are the world’s first and only tetra-specific antibodies in clinical development. We believe ADCs, as “targeted chemotherapy,” and GNCs, as “targeted immunotherapy,” will become two of the most crucial types of weapons in our arsenal against cancer. Recognizing the significant uncertainty that accompanies the commercialization of innovative drug candidates, we are committed to maintaining a diverse portfolio of drugs at various stages of development. This diversification is designed to spread risk and provide multiple avenues for revenue generation. We will leverage the experience and capabilities to be gained from developing and commercializing BL-B01D1 to accelerate the advancement of our other drug candidates.

Drive revenue growth through product sales and collaborations

To build a sustainable revenue model, we plan to develop a combination of revenue streams from our innovative drug portfolio. Sales of innovative drugs are expected to be an increasingly significant source of revenue in the next decade as our lead asset, BL-B01D1, and other key candidates receive market approvals. We believe our co-development and co-commercialization arrangement with BMS will contribute to fully realizing the commercial potential of BL-B01D1. Under our global strategic collaboration with BMS, (i) we expect to generate revenue from the sales of BL-B01D1 in mainland China, where we have the exclusive right to commercialize BL-B01D1, while paying BMS a royalty of a mid-single-digit percentage of aggregate annual net sales; (ii) we and BMS will share the net profits/losses related to its sales in the U.S. according to certain agreed-upon percentages; (iii) BMS is

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required to pay us tiered royalties based on a percentage of aggregate annual net sales of BL-B01D1 in the rest of the world, excluding the U.S. and mainland China, subject to certain customary reductions and a royalty floor; and (iv) for commercialization in the U.S. and the rest of the world, we will take on certain manufacturing responsibilities, which provides an additional source of revenue.

In addition, we will strategically explore out-licensing deals, partnerships, and co-development and co-commercialization agreements based on the unique circumstances surrounding each asset to seek additional revenue opportunities. We have a robust, highly innovative and diverse pipeline of potential first- and best-in-class drug candidates across multiple modalities that target major tumor types. By leveraging our dual-location expertise in the U.S. and China, we efficiently implement proof-of-concept clinical development strategies that accelerate the time-to-market for our drug candidates. We believe our pipeline has the potential to generate significant revenue through out-licensing, partnerships, and co-development and co-commercialization agreements. This approach allows us to maximize the value of our innovative drug candidate pipeline while managing risks associated with bringing new drugs to market. We believe that through our global strategic collaboration with BMS, we have gained deep insights into market dynamics and competitive positioning, equipping us with the knowledge to identify and capitalize on future opportunities.

In our pursuit of becoming the next multinational pharmaceutical company, licensing-out collaborations allow us to work alongside industry pioneers and accelerate the enhancement of our commercialization capabilities.

PERIOD TO PERIOD COMPARISON OF RESULTS OF OPERATIONS

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

Revenue

Our revenue increased significantly from RMB376.6 million in the nine months ended September 30, 2023 to RMB5,661.2 million in the nine months ended September 30, 2024, which was primarily due to the increase of license fee income from nil in the nine months ended September 30, 2023 to RMB5,331.7 million in the nine months ended September 30, 2024. The license fee received in the nine months ended September 30, 2024 was part of the Upfront Payment in connection with the licenses and other rights granted to BMS by us pursuant to the BMS Agreement. See “— Description of Key Statements of Profit or Loss Items — Revenue” for more details.

Outside of our license fee income, our revenue from the sale of pharmaceutical products decreased by RMB49.7 million, or 13.2%, from RMB376.6 million in the nine months ended September 30, 2023 to RMB326.9 million in the nine months ended September 30, 2024, which

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was mainly attributable to a decrease of revenue from the sales of Lewejing (propofol injectable emulsion), Tianze (medium and long chain fat emulsion injection) and astragalus granule, partially offset by an increase in revenue from the sales of other chemical drugs and Chinese medicines.

- *Lewejing (propofol injectable emulsion).* Our revenue generated from Lewejing decreased by RMB53.1 million, or 35.4%, from RMB149.9 million in the nine months ended September 30, 2023 to RMB96.8 million in the nine months ended September 30, 2024, which was primarily due to (i) a decrease of the average selling price of Lewejing per unit from RMB11.9 in the nine months ended September 30, 2023 to RMB9.0 in the nine months ended September 30, 2024; and (ii) a decrease of the sales volume of Lewejing from 12.6 million units in the nine months ended September 30, 2023 to 10.8 million units in the nine months ended September 30, 2024. The decrease in the average selling price of Lewejing was largely due to a significant price reduction of a large specification (50 ml:0.5g) of Lewejing included in the ninth batch of the national VBP scheme starting in March 2024. Before winning the bids in the national VBP scheme, the sales revenue of Lewejing ranked 4th nationally in 2023 with a market share of 12.1% of the propofol emulsion injection market in China, according to CIC. Under the national VBP, each winning bidder will mainly supply the products for certain designated provinces. Therefore, Lewejing’s sales volume outside of the seven provinces for which it is the primary supplier declined after the implementation of the national VBP. Additionally, smaller specification products (10ml:0.1g, 20ml:0.2g) contributed to a majority of sales volume of Lewejing in the past, and post national VBP, larger specification products (50ml:0.5g) became more mainstream than smaller ones, leading to further decrease of the total number of units sold, regardless of specifications.
- *Tianze (medium/long chain fat emulsion injection).* Our revenue generated from Tianze decreased by RMB11.7 million, or 37.9%, from RMB30.9 million in the nine months ended September 30, 2023 to RMB19.2 million in the nine months ended September 30, 2024, which was primarily due to a decrease of sales volume of Tianze from 1.1 million units in the nine months ended September 30, 2023 to 0.7 million units in the nine months ended September 30, 2024. This decrease was primarily because (i) the provincial VBP scheme J in which Tianze participated expired in early 2024, (ii) the competing drug class of Tianze continued to occupy the market by participating various provincial VBP schemes and procurement continuation following the expiry of national VBP scheme, while Tianze still losing its market share in certain provinces that require certification of consistency evaluation for participation in centralized tender process in those provinces. With two of the four specifications of Tianze passing the consistency evaluation in January 2024, we expect to regain the market share by participating in the centralized tender process of additional provinces.

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- *Astragalus granule.* Our revenue generated from astragalus granule decreased by RMB5.6 million, or 5.7%, from RMB98.0 million in the nine months ended September 30, 2023 to RMB92.3 million in the nine months ended September 30, 2024. The sales volume of astragalus granule decreased from 4.0 million units in the nine months ended September 30, 2023 to 3.4 million units in the nine months ended September 30, 2024, which was primarily due to the increased market demand of and sales for astragalus granule as immune-supporting supplement in light of the increased COVID-19 cases in the first few months of 2023.
- *Sales of other chemical drugs and Chinese medicines.* Our sales from other chemical and Chinese medicine products increased by RMB34.1 million from RMB10.2 million in the nine months ended September 30, 2023 to RMB44.4 million in the nine months ended September 30, 2024, primarily due to the launch of new generic products including sevoflurane for inhalation. Our sevoflurane product, an inhalation anesthetic drug, was approved in May 2023 and contributed revenue of approximately RMB27.2 million in the nine months ended September 30, 2024.

Cost of sales

Our cost of sales increased by 18.6% from RMB161.0 million in the nine months ended September 30, 2023 to RMB190.9 million in the nine months ended September 30, 2024, which was mainly driven by our increased sales volumes of higher-cost larger specification products (50ml:0.5g) of Lewejing (propofol injectable emulsion) compared to smaller ones (10ml:0.1g, 20ml:0.2g) post national VBP, and our increased sales of other chemical drugs and Chinese medicines.

Gross profit and gross profit margin

As a result of foregoing, our overall gross profit increased significantly from RMB215.6 million in the nine months ended September 30, 2023 to RMB5,470.3 million in the nine months ended September 30, 2024. Our gross profit margin increased from 57.2% in the nine months ended September 30, 2023 to 96.6% in the nine months ended September 30, 2024.

Our gross profit of the sale of pharmaceutical products decreased by RMB79.6 million, or 36.9%, from RMB215.6 million in the nine months ended September 30, 2023 to RMB136.0 million in the nine months ended September 30, 2024. Our gross profit margin of the sale of pharmaceutical products decreased from 57.2% in the nine months ended September 30, 2023 to 41.6% in the nine months ended September 30, 2024, primarily because of the following products:

- *Lweijing (propofol injectable emulsion).* Gross profit margin of Lewejing decreased from 71.6% in the nine months ended September 30, 2023 to 36.3% in the nine months ended September 30, 2024, primarily because of (i) a decrease in its average selling price by 24.4% from RMB11.9 per unit in the nine months ended September 30, 2023 to RMB9.0 per unit in the nine months ended September 30,

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2024 due to a downward adjust of its selling price as this product participated in the ninth batch of the national VBP scheme starting in March 2024; and (ii) an increase in its cost of sales per unit by 69.0% from RMB3.4 in the nine months ended September 30, 2023 to RMB5.7 in the nine months ended September 30, 2024, which was largely due to (a) an increase in higher-costed large volume injection products as this product participated in the ninth batch of the national VBP scheme starting in March 2024; and (b) fixed production costs such as equipment depreciation and other expenses allocating to fewer units as the sales volume of Lewejing decreased from 12.6 million units in the nine months ended September 30, 2023 to 10.8 million units in the nine months ended September 30, 2024.

- *Leweitai (propofol medium and long chain fat emulsion injection)*. Gross profit margin of Leweitai decreased from 73.6% in the nine months ended September 30, 2023 to 68.2% in the nine months ended September 30, 2024, primarily because of a decrease in its average selling price by 18.9% from RMB12.2 per unit in the nine months ended September 30, 2023 to RMB9.9 per unit in the nine months ended September 30, 2024 following its participation in the provincial procurement continuation schemes in certain markets beginning from April 2023 following the expiry of the fourth batch of national VBP scheme.
- *Astragalus granule*. Gross profit margin of astragalus granule decreased from 39.2% in the nine months ended September 30, 2023 to 33.1% in the nine months ended September 30, 2024, primarily because of an increase in its cost of sales per unit by 21.8% from RMB14.8 in the nine months ended September 30, 2023 to RMB18.0 in the nine months ended September 30, 2024. This increase was largely due to a rise in the prices of raw material astragalus used in the production of astragalus granules. The cost of these raw materials surged because of increased demand for astragalus, which is widely used for its medicinal properties.
- *Xinbolin (ribavirin granule)*. Gross profit margin of Xinbolin decreased from 70.5% in the nine months ended September 30, 2023 to 57.5% in the nine months ended September 30, 2024, primarily because of an increase in its cost of sales per unit by 40.7% from RMB1.8 in the nine months ended September 30, 2023 to RMB2.6 in the nine months ended September 30, 2024. This increase was largely due to (i) a rise in the prices of raw material ribavirin used in the production of ribavirin granules; and (ii) fixed production costs such as equipment depreciation and other expenses allocating to fewer units as the sales volume of Xinbolin decreased from 2.1 million units in the nine months ended September 30, 2023 to 1.7 million units in the nine months ended September 30, 2024.

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Other income

Our other income increased significantly from RMB42.9 million in the nine months ended September 30, 2023 to RMB163.8 million in the nine months ended September 30, 2024, primarily due to an increase in interest income on bank deposits of RMB125.8 million attributable to an increase in bank deposits and the average interest rate, which was partially offset by a decrease in government grants of RMB7.3 million.

Other gains and losses, net

We recorded net other losses of RMB0.7 million and RMB46.3 million in the nine months ended September 30, 2023 and 2024, respectively. The increase was primarily due to the net foreign exchange loss of RMB76.8 million in the nine months ended September 30, 2024 mainly attributable to the foreign exchange loss relating to the Upfront Payment of US\$800 million we received from BMS in March 2024. Such increase was partially offset by our gain on fair value change of financial assets at FVTPL of RMB30.7 million in the nine months ended September 30, 2024.

Research and development expenses

Our research and development expenses increased by 82.8% from RMB509.8 million in the nine months ended September 30, 2023 to RMB931.7 million in the nine months ended September 30, 2024, primarily due to (i) an increase in testing and examination costs of RMB262.4 million; (ii) an increase in staff costs of RMB96.4 million mainly attributable to the increase in the compensation of our research and development personnel; and (iii) an increase in cost of materials of RMB37.6 million. The increases in testing and examination costs and cost of materials were mainly attributable to our continued R&D efforts on innovative biologics drug candidates in the nine months ended September 30, 2024. The increase was partially offset by a decrease in licensing fees of RMB11.4 million.

Distribution and selling expenses

Our distribution and selling expenses decreased by 13.2% from RMB179.7 million in the nine months ended September 30, 2023 to RMB156.0 million in the nine months ended September 30, 2024, resulting from a decrease in our marketing and promotion expenses of RMB36.5 million, which was in line with our business scale of the sale of pharmaceutical products.

Administrative expenses

Our administrative expenses increased by 40.3% from RMB87.2 million for the nine months ended September 30, 2023 to RMB122.3 million in the nine months ended September 30, 2024, primarily due to (i) an increase in staff costs of RMB30.8 million as we offered higher compensation packages to our administrative personnel for the development of our innovative drug business, which was in line with our substantial investment in the innovative drug business; and (ii) an increase in travelling expenses of RMB4.8 million mainly attributable to increased travelling activities to support the growth of our innovative drug business, partially offset by a decrease in professional service fees of RMB2.7 million.

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Other expenses

Our other expenses remained relatively stable at RMB2.4 million and RMB1.7 million in the nine months ended September 30, 2023 and 2024, respectively.

Finance costs

Our finance costs increased by 50.3% from RMB18.5 million for the nine months ended September 30, 2023 to RMB27.8 million for the nine months ended September 30, 2024, primarily due to an increase in interest expenses on bank borrowings of RMB12.5 million mainly attributable to an increase in average bank borrowing balance.

Income tax (credit) expense

We recorded income tax expense of RMB284.3 million in the nine months ended September 30, 2024 as compared to the income tax credit of RMB18.6 million in the nine months ended September 30, 2023, primarily due to an increase in taxable income in the nine months ended September 30, 2024 in relation to us receiving the Upfront Payment under the BMS Agreement in March 2024.

Profit (loss) for the period

As a result of the foregoing, we recorded profit for the period of RMB4,065.4 million in the nine months ended September 30, 2024, as compared to loss for the period of RMB515.1 million in the nine months ended September 30, 2023.

Year Ended December 31, 2023 Compared to Year Ended December 31, 2022

Revenue

Our revenue decreased by RMB141.4 million, or 20.1%, from RMB701.8 million in 2022 to RMB560.4 million in 2023, primarily due to the decrease in revenue from the sale of pharmaceutical products, which was mainly attributable to a decrease of revenue from the sales of Leweijing (propofol injectable emulsion), Leweitai (propofol medium and long chain fat emulsion injection), Youmeining (dexmedetomidine hydrochloride injection), Tianze (medium/long chain fat emulsion injection) and Xinbolin (ribavirin granule), partially offset by an increase in revenue from the sales of astragalus granule.

- *Leweijing (propofol injectable emulsion).* Our revenue generated from Leweijing decreased by RMB101.2 million, or 32.3%, from RMB313.7 million in 2022 to RMB212.4 million in 2023, which was primarily due to (i) a decrease of the average selling price of Leweijing per unit from RMB13.7 in 2022 to RMB12.0 in 2023; and (ii) a decrease of the sales volume of Leweijing from 22.9 million units in 2022 to 17.7 million units in 2023. The decrease of the average selling price of Leweijing was because of its participation in several provincial VBP schemes since mid-2022.

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The decrease of the sales volume of Lewejing was primarily because (i) due to Lewejing’s inclusion in a provincial alliance VBP scheme covering six provinces which began in December 2022, as a market practice, distributors increased their purchases of Lewejing in late 2022, and reduced their orders in the subsequent period as these pre-stocked products were gradually sold off in 2023; according to CIC, it is common for distributors to increase their purchases of a product that has won bids in the VBP scheme before its implementation; (ii) hospitals in the provinces that implemented the new VBP scheme purchased this product primarily through the VBP scheme, leading to a decline in sales volume to hospitals outside of VBP; and (iii) its sales volume in several provinces declined due to increased competition and changes in market conditions. See “Business — Our Marketed Products — Generic Drugs — Anesthesia Drugs — Lewejing” for more details of Lewejing’s participation in relevant VBP schemes during the Track Record Period.

- *Leweitai (propofol medium and long chain fat emulsion injection)*. Our revenue generated from Leweitai decreased by RMB8.8 million, or 30.9%, from RMB28.4 million in 2022 to RMB19.6 million in 2023, which was primarily due to a decrease of the average selling price of Leweitai per unit from RMB26.4 in 2022 to RMB11.4 in 2023 following its participation in the provincial procurement continuation schemes in certain markets beginning from July 2022 following the expiry of the fourth batch of national VBP scheme. Such decrease was partially offset by an increase of sales volume of Leweitai from 1.1 million units in 2022 to 1.7 million units in 2023 as Leweitai regained some market share by participating in those provincial procurement schemes after the national scheme ended. See “Business — Our Marketed Products — Generic Drugs — Anesthesia Drugs — Leweitai” for more details of Leweitai’s participation in relevant VBP schemes during the Track Record Period.
- *Youmeining (dexmedetomidine hydrochloride injection)*. Our revenue generated from Youmeining decreased by RMB11.9 million, or 51.0%, from RMB23.3 million in 2022 to RMB11.4 million in 2023, which was primarily due to (i) a decrease of the average selling price of Youmeining per unit from RMB38.8 in 2022 to RMB26.3 in 2023 following its participation in the procurement continuation scheme in certain markets in 2022 and 2023 following the expiry of the national VBP scheme; and (ii) a decrease of the sales volume of Youmeining from 0.6 million units in 2022 to 0.4 million units in 2023 as this product lost its market share in certain provinces that implemented provincial VBP schemes, of which we did not win in the bidding process. See “Business — Our Marketed Products — Generic Drugs — Anesthesia Drugs — Youmeining” for more details of Youmeining’s participation in relevant VBP schemes during the Track Record Period.
- *Tianze (medium/long chain fat emulsion injection)*. Our revenue generated from Tianze decreased by RMB21.7 million, or 35.2%, from RMB61.6 million in 2022 to RMB39.9 million in 2023, which was primarily due to a decrease of sales volume of Tianze from 2.2 million units in 2022 to 1.5 million units in 2023. This decrease

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was primarily because of (i) this product losing its market share in certain provinces as Tianze did not obtain the certification of consistency evaluation for participation in centralized tender process in those provinces in 2023; and (ii) the prolonged period for the market to fully consume the volume of its competing drug class included in the fifth batch of national VBP scheme in June 2021. The VBP cycle duration of the fifth batch of national VBP scheme lasted normally two years and continued to affect the market demand for Tianze in 2023. In January 2024, specifications of Tianze at 100ml:20% and 250ml:20% have successfully passed the consistency evaluation. See “Business — Our Marketed Products — Generic Drugs — Parenteral Nutrition Drugs — Tianze” for more details of Tianze’s consistency evaluation.

- *Xinbolin (ribavirin granule)*. Our revenue generated from Xinbolin decreased by RMB25.2 million, or 43.0%, from RMB58.7 million in 2022 to RMB33.5 million in 2023, which was primarily because distributors increased their purchases of Xinbolin in late 2022, anticipating increased market demand in light of the increased COVID-19 cases in late 2022 and the first few months of 2023. In 2022, the sales volume of Xinbolin amounted to 11.8 million units, as compared to 5.9 million units in 2023.
- *Astragalus granule*. Our revenue generated from astragalus granule increased by RMB21.5 million, or 16.1%, from RMB134.1 million in 2022 to RMB155.7 million in 2023, as we intensified promotion efforts to large pharmaceutical retail chains after the COVID-19 pandemic eased in 2023, leading to an increase in foot traffic and market demand at pharmacies for our astragalus granule.

Cost of sales

Our cost of sales remained relatively stable at RMB246.8 million in 2022 and RMB253.4 million in 2023.

Gross profit and gross profit margin

Our gross profit decreased by RMB148.0 million, or 32.5%, from RMB455.0 million in 2022 to RMB307.0 million in 2023. Our gross profit margin decreased from 64.8% in 2022 to 54.8% in 2023, primarily because of the following products:

- *Leweijing (propofol injectable emulsion)*. Gross profit margin of Leweijing decreased from 76.8% in 2022 to 71.1% in 2023, primarily because of a decrease in its average selling price by 12.1% from RMB13.7 per unit in 2022 to RMB12.0 per unit in 2023 due to an increase in sales volume of lower-priced products as this product newly participated in several provincial VBP schemes since mid-2022.

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- *Leweitai (propofol medium and long chain fat emulsion injection)*. Gross profit margin of Leweitai decreased from 87.3% in 2022 to 71.8% in 2023, primarily because of a decrease in its average selling price by 56.7% from RMB26.4 per unit in 2022 to RMB11.4 per unit in 2023 following its participation in the provincial procurement continuation schemes in certain markets beginning from July 2022 following the expiry of the fourth batch of national VBP scheme.
- *Youmeining (dexmedetomidine hydrochloride injection)*. Gross profit margin of Youmeining decreased from 96.2% in 2022 to 94.4% in 2023, primarily because of a decrease in its average selling price by 32.1% from RMB38.8 per unit in 2022 to RMB26.3 per unit in 2023 following its participation in the procurement continuation scheme in certain markets in 2022 and 2023 following the expiry of the national VBP scheme.
- *Astragalus granule*. Gross profit margin of astragalus granule decreased from 39.9% in 2022 to 36.5% in 2023, primarily because of an increase in its cost of sales per unit by 9.0% from RMB14.9 in 2022 to RMB16.2 in 2023. This increase was largely due to a rise in the prices of raw material astragalus used in the production of astragalus granules. The cost of these raw materials surged because of increased demand for astragalus, which is widely used for its medicinal properties.
- *Tianze (medium/long chain fat emulsion injection)*. Gross profit margin of Tianze decreased from 63.2% in 2022 to 59.3% in 2023, primarily because of an increase in its cost of sales per unit by 5.8% from RMB10.3 in 2022 to RMB10.9 in 2023. This increase was largely due to fixed production costs such as equipment depreciation and other expenses allocating to fewer units as the sales volume of Tianze decreased from 2.2 million units in 2022 to 1.5 million units in 2023.
- *Xinbolin (ribavirin granule)*. Gross profit margin of Xinbolin decreased from 69.5% in 2022 to 65.9% in 2023, primarily because of an increase in its cost of sales per unit by 27.5% from RMB1.5 in 2022 to RMB1.9 in 2023. This increase was largely due to (i) a rise in the prices of raw material ribavirin used in the production of ribavirin granules; and (ii) fixed production costs such as equipment depreciation and other expenses allocating to fewer units as the sales volume of Xinbolin decreased from 11.8 million units in 2022 to 5.9 million units in 2023.

Other income

Our other income decreased by 15.9% from RMB70.5 million in 2022 to RMB59.2 million in 2023, primarily due to a decrease in release of expense-related government subsidies of RMB16.4 million as we recognized expense-related government subsidies of RMB18.0 million in 2022 for our drug candidate R&D activities, which was partially offset by an increase in interest income on bank deposits of RMB4.9 million mainly attributable to an increase in our cash balances through proceeds raised from our A-share initial public offering in December 2022.

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Other gains and losses, net

Our other gains and losses, net increased from net other losses of RMB0.6 million in 2022 to net other losses of RMB1.2 million in 2023, primarily due to an increase in net foreign exchange loss of RMB1.1 million mainly attributable to fluctuations in exchange rates of US dollars against Renminbi.

Research and development expenses

Our research and development expenses increased by 99.0% from RMB375.0 million in 2022 to RMB746.2 million in 2023, primarily due to (i) an increase in testing and examination costs of RMB219.0 million; (ii) an increase in staff costs of RMB64.7 million mainly attributable to the increase in the compensation of our research and development personnel; (iii) an increase in cost of materials of RMB26.2 million; and (iv) an increase in licensing fees of RMB22.4 million mainly due to the increase in patent fees in relation to the growing number of innovative drug projects and the advancement of these projects. The increases in testing and examination costs and cost of materials were mainly attributable to our continued R&D efforts on innovative biologics drug candidates in 2023.

Distribution and selling expenses

Our distribution and selling expenses decreased by 22.5% from RMB324.3 million in 2022 to RMB251.2 million in 2023, resulting from a decrease in our marketing and promotion activities of RMB88.0 million, which was in line with our decrease in revenue.

Administrative expenses

Our administrative expenses increased by 40.4% from RMB82.2 million in 2022 to RMB115.4 million in 2023, primarily due to (i) an increase in staff costs of RMB12.2 million mainly attributable to the increase in our staff headcount and the compensation of our administrative personnel for the development of our innovative drug business, which was in line with our substantial investment in the innovative drug business; (ii) an increase in professional service fees of RMB9.2 million for legal and accounting professional services incurred as a result of our A-share listing and business development activities; and (iii) an increase in travelling expenses of RMB2.3 million mainly due to reduced travelling activities in 2022 as a result of travelling restrictions during the COVID-19 pandemic.

Other expenses

Our other expenses remained relatively stable at RMB2.3 million in 2022 and RMB3.0 million in 2023.

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Finance costs

Our finance costs increased by 9.8% from RMB22.5 million in 2022 to RMB24.7 million in 2023, primarily due to an increase in interest expenses on bank borrowings of RMB6.0 million mainly attributable to an increase in average bank borrowing balance.

Income tax (credit) expense

We recorded income tax credit of RMB6.7 million in 2022 and income tax expense of RMB11.5 million in 2023, primarily due to the tax effect of tax losses or deductible temporary differences not recognized in 2023 leading to higher tax expenses.

Loss for the year

As a result of the foregoing, we recorded loss for the year of RMB780.5 million in 2023 as compared to that of RMB282.4 million in 2022.

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

Revenue

Our revenue decreased by RMB93.1 million, or 11.7%, from RMB795.0 million in 2021 to RMB701.8 million in 2022, which was primarily due to a decrease in revenue from the sales of Leweitai (propofol medium/long chain fat emulsion injection), Tianze (medium/long chain fat emulsion injection) and astragalus granule, partially offset by an increase in revenue from the sales of Lewejing (propofol injectable emulsion).

- *Leweitai (propofol medium and long chain fat emulsion injection).* Our revenue generated from Leweitai decreased by RMB88.4 million, or 75.7%, from RMB116.8 million in 2021 to RMB28.4 million in 2022, which was primarily due to (i) a decrease of the sales volume of Leweitai from 2.5 million units in 2021 to 1.1 million units in 2022, and (ii) a decrease of the average selling price of Leweitai per unit from RMB47.5 in 2021 to RMB26.4 in 2022. The decrease in sales volume was primarily due to the inclusion of propofol medium and long chain fat emulsion injection in the fourth batch of national VBP scheme in February 2021, in which Leweitai did not participate as it was still waiting certification documents from consistency evaluation required for participation in the bidding process at that time. As Leweitai held a sizable market size prior to the national VBP, its exclusion from the scheme resulted in a significant loss of market share as the VBP-winning bidders captured a significant portion of the market. Furthermore, the average selling prices of Leweitai were also substantially reduced since it was included in the multiple continuation procurement schemes in 2022, and its prices under the centralized tender process in certain provinces were adjusted to align with the lowest prices under the centralized tender process across various provinces.

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- *Tianze (medium/long chain fat emulsion injection)*. Our revenue generated from Tianze decreased by RMB54.0 million, or 46.7%, from RMB115.6 million in 2021 to RMB61.6 million in 2022, which was primarily due to (i) a decrease of the sales volume of Tianze from 3.5 million units in 2021 to 2.2 million units in 2022, and (ii) a decrease of the average selling price of Tianze per unit from RMB32.8 in 2021 to RMB28.0 in 2022. Both decreases were primarily due to the inclusion of the competing drug class of Tianze in the fifth batch of national VBP scheme in June 2021, which affected the market demand and resulted in the price pressure for our product.
- *Astragalus granule*. Our revenue generated from astragalus granule decreased by RMB26.8 million, or 16.7%, from RMB161.0 million in 2021 to RMB134.1 million in 2022, which was primarily due to a decrease of the sales volume of astragalus granule from 6.4 million units in 2021 to 5.4 million units in 2022 as a result of the reduced outpatient visits and customer traffic at pharmacies in light of the impact of the COVID-19 pandemic in 2022.
- *Leweijing (propofol injectable emulsion)*. Our revenue generated from Leweijing increased by RMB55.3 million, or 21.4%, from RMB258.4 million in 2021 to RMB313.7 million in 2022, which was primarily due to an increase of the sales volume of Leweijing from 17.6 million units in 2021 to 22.9 million units in 2022. This increase was primarily because (i) Leweijing entered four new provincial procurement schemes covering a total of six provinces in 2022, contributing to an increase of its sales volume in these provinces; (ii) the market demand for propofol injectable emulsion increased following inclusion of its competing drug class, propofol medium and long chain fat emulsion injection, in the fourth batch of national VBP scheme in February 2021, which experienced significant reduction in price and profit margin due to the inclusion into the national VBP scheme. This price and profit margin reduction led distributors to reduce their purchase of propofol medium and long chain fat emulsion injection for profitability considerations and turned to the embrace of propofol injectable emulsion. See “Business — Our Marketed Products — Generic Drugs — Anesthesia Drugs — Leweijing” for more details of Leweijing’s participation in relevant VBP schemes during the Track Record Period.

Cost of sales

Our cost of sales increased by 16.0% from RMB212.7 million in 2021 to RMB246.8 million in 2022, which was mainly driven by our increased sales volumes of Leweijing (propofol injectable emulsion) in 2022.

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Gross profit and gross profit margin

Our gross profit decreased by RMB127.2 million, or 21.9%, from RMB582.2 million in 2021 to RMB455.0 million in 2022. Our gross profit margin decreased from 73.2% in 2021 to 64.8% in 2022, primarily because of the following products:

- *Leweitai (propofol medium and long chain fat emulsion injection)*. Gross profit margin of Leweitai decreased from 95.1% in 2021 to 87.3% in 2022, primarily because of (i) a decrease in its average selling price by 44.4% from RMB47.5 per unit in 2021 to RMB26.4 per unit in 2022; and (ii) an increase in its cost of sales per unit by 44.8% from RMB2.3 in 2021 to RMB3.4 in 2022. This increase in cost of sales per unit was largely due to fixed production costs such as equipment depreciation and other expenses allocating to fewer units as the sales volume of Leweitai decreased from 2.5 million units in 2021 to 1.1 million units in 2022.
- *Leweijing (propofol injectable emulsion)*. Gross profit margin of Leweijing decreased from 83.4% in 2021 to 76.8% in 2022, primarily because of (i) an decrease of its average selling price by 7.0% from RMB14.7 per unit in 2021 to RMB13.7 per unit in 2022, and (ii) an increase in its cost of sales per unit by 30.0% from RMB2.4 in 2021 to RMB3.2 in 2022. The decrease in its average selling price was primarily due to its inclusion in several provincial VBP schemes. The increase in cost of sales per unit was largely due to an upgrade of production materials and process of Leweijing to meet consistency evaluation requirements. Leweijing passed the consistency evaluation in December 2021, leading to increased costs of production thereafter.
- *Tianze (medium/long chain fat emulsion injection)*. Gross profit margin of Tianze decreased from 71.6% in 2021 to 63.2% in 2022, primarily because of (i) a decrease in its average selling price by 14.5% from RMB32.8 per unit in 2021 to RMB28.0 per unit in 2022, and (ii) an increase in its cost of sales per unit by 17.5% from RMB9.3 in 2021 to RMB10.3 in 2022. The decrease in average selling price was primarily due to its inclusion in a provincial VBP scheme in mid-2021. The increase in its cost of sales was largely due to fixed production costs such as equipment depreciation and other expenses allocating to fewer units as the sales volume of Tianze decreased from 3.5 million units in 2021 to 2.2 million units in 2022.
- *Astragalus granule*. Gross profit margin of astragalus granule decreased from 52.4% in 2021 to 39.9% in 2022, primarily because of an increase in its cost of sales per unit by 24.8% from RMB11.9 in 2021 to RMB14.9 in 2022. This increase was largely due to (i) a rise in the prices of raw material astragalus used in the production of astragalus granules; and (ii) fixed production costs such as equipment depreciation and other expenses allocating to fewer units as the sales volume of astragalus granule decreased from 6.4 million units in 2021 to 5.4 million units in 2022.

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Other income

Our other income remained relatively stable at RMB70.3 million and RMB70.5 million in 2021 and 2022, respectively, among which, (i) our government grant decreased from RMB61.9 million in 2021 to RMB49.4 million in 2022, primarily due to the decrease of the development incentive funds from relevant government authorities; and (ii) our release of expense-related government subsidies increased from RMB5.4 million in 2021 to RMB18.0 million in 2022 as we recognized expense-related government subsidies of RMB18.0 million in 2022 for our drug candidate R&D activities.

Other gains and losses, net

Our other gains and losses, net decreased from net other gains of RMB2.4 million in 2021 to net other losses of RMB0.6 million in 2022, primarily because we subscribed for short-term structured deposit products in 2021 resulting in gain on such financial assets at FVTPL.

Research and development expenses

Our research and development expenses increased by 34.6% from RMB278.6 million in 2021 to RMB375.0 million in 2022, primarily due to (i) an increase in testing and examination costs of RMB56.1 million; and (ii) an increase in staff costs of RMB35.6 million mainly attributable to the increase in the compensation of our research and development personnel. The increases in testing and examination costs and cost of materials were mainly attributable to our continued R&D efforts on innovative biologics drug candidates in 2022.

Distribution and selling expenses

Our distribution and selling expenses decreased by 17.1% from RMB391.3 million in 2021 to RMB324.3 million in 2022, resulting from a decrease in our marketing and promotion activities of RMB65.1 million, which was in line with our decrease in revenue.

Administrative expenses

Our administrative expenses increased slightly by 2.9% from RMB79.9 million in 2021 to RMB82.2 million in 2022, primarily due to (i) an increase in staff costs of RMB4.4 million mainly attributable to the increase in the compensation of our administrative personnel; and (ii) an increase in depreciation and amortization of RMB1.2 million mainly attributable to increased office spaces to support our business, which was partially offset by a decrease in professional service fees of RMB2.1 million.

Other expenses

Our other expenses decreased from RMB3.9 million in 2021 to RMB2.3 million in 2022, primarily because we made donations of RMB1.6 million in 2021 to a local medical foundation to promote the development of medical and healthcare services.

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Finance costs

Our finance costs increased by 37.6% from RMB16.3 million in 2021 to RMB22.5 million in 2022, primarily due to an increase in interest expense on sale and leaseback payable of RMB7.9 million and an increase in interest expenses on bank borrowings of RMB5.7 million mainly attributable to an increase in average bank borrowing balance, partially offset by a decrease in interest expenses on redeemable shares of RMB7.7 million.

Income tax credit

Our income tax credit increased from RMB4.4 million in 2021 to RMB6.7 million in 2022, primarily due to (i) an increase in research and development expenses that were qualified for an additional 100% deduction for EIT purpose in accordance with the relevant PRC regulations; and (ii) an increase in tax credit at the PRC EIT rate of 25% due to the increase in loss before taxation, which was partially offset by an increase in the tax effect of tax losses or deductible temporary differences not recognized in 2022.

Loss for the year

As a result of the foregoing, we recorded a loss of RMB282.4 million in 2022 as compared to RMB107.6 million in 2021.

DISCUSSION OF SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The table below sets forth our current assets and current liabilities as of the dates indicated:

	As of December 31,			As of	As of
	2021	2022	2023	September 30,	November 30,
				2024	2024
	(RMB in thousands)				(Unaudited)
Current assets:					
Inventories	82,327	101,327	140,908	164,878	177,230
Right to returned goods assets	6,924	6,619	5,951	6,079	6,079
Trade and other receivables	173,508	293,077	205,016	282,943	293,874
Tax recoverable	–	–	268	–	–
Bills receivables at FVTOCI	6,831	20,581	19,714	12,344	16,338
Term deposits	–	–	–	698,790	2,165,699

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	As of December 31,			As of September 30,	As of November 30,
	2021	2022	2023	2024	2024
	(RMB in thousands)				(Unaudited)
Restricted bank balances	–	4,046	12,270	25,800	8,750
Cash and cash equivalents	154,222	1,000,695	391,693	4,950,699	3,624,571
Total current assets	423,812	1,426,345	775,820	6,141,533	6,292,541
Current liabilities:					
Borrowings	161,250	185,603	449,489	906,565	882,392
Trade and other payables	273,506	460,386	549,516	575,397	647,999
Amount due to a related party	14	14	14	12	–
Contract liabilities	10,783	17,416	8,672	350,375	360,641
Refund liabilities	15,813	14,053	11,193	10,228	10,526
Sale and leaseback payable	19,019	61,858	41,430	7,599	7,690
Lease liabilities	5,215	6,965	4,702	8,219	11,970
Tax payable	1,538	4,963	10	220,165	118,224
Deferred income	558	801	1,594	1,468	1,468
Total current liabilities	487,696	752,059	1,066,620	2,080,028	2,040,910
Net current (liabilities) assets	(63,884)	674,286	(290,800)	4,061,505	4,251,631

Our net current assets increased from RMB4,061.5 million as of September 30, 2024 to RMB4,251.6 million as of November 30, 2024, primarily due to (i) an increase in term deposits of RMB1,466.9 million; and (ii) a decrease in tax payable of RMB101.9 million, which was partially offset by a decrease in cash and cash equivalents of RMB1,326.1 million.

We recorded net current assets of RMB4,061.5 million as of September 30, 2024, as compared to net current liabilities of RMB290.8 million as of December 31, 2023, primarily due to an increase in cash and cash equivalents of RMB4,559.0 million and an increase in term deposits of RMB698.8 million as we received the Upfront Payment from BMS under the BMS Agreement, which was partially offset by (i) an increase in borrowings of RMB457.1 million; and (ii) an increase in contract liabilities of RMB341.7 million.

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We recorded net current liabilities of RMB290.8 million as of December 31, 2023, as compared to net current assets of RMB674.3 million as of December 31, 2022, primarily due to (i) a decrease in cash and cash equivalents of RMB609.0 million as a result of the operating costs associated with our R&D activities; and (ii) an increase in borrowings of RMB263.9 million.

We recorded net current assets of RMB674.3 million as of December 31, 2022, as compared to net current liabilities of RMB63.9 million as of December 31, 2021, primarily due to (i) an increase in cash and cash equivalents of RMB846.5 million as we received the proceeds raised from our A-share initial public offering in December 2022; and (ii) an increase in trade and other receivables of RMB119.6 million, which was partially offset by an increase in trade and other payables of RMB186.9 million.

Inventories

The following table sets forth a breakdown of our inventories as of the dates indicated:

	As of December 31,			As of September 30,
	2021	2022	2023	2024
	<i>(RMB in thousands)</i>			
Raw materials and consumables	34,323	46,453	64,109	80,208
Work in progress	22,378	25,989	22,000	27,746
Finished goods	29,489	21,196	56,611	58,942
Goods in transit	76	9,242	3,337	1,898
	86,266	102,880	146,057	168,794
Less: provision	(3,939)	(1,553)	(5,149)	(3,916)
Total	82,327	101,327	140,908	164,878

Our inventories increased by 23.1% from RMB82.3 million as of December 31, 2021 to RMB101.3 million as of December 31, 2022, primarily due to (i) an increase in raw materials and consumables of RMB12.1 million as we continued to advance our innovative drug research and development projects and increased the procurement of raw materials related to these projects; and (ii) an increase in goods in transit of RMB9.2 million, which was partially offset by a decrease in finished goods of RMB8.3 million.

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Our inventories increased by 39.1% from RMB101.3 million as of December 31, 2022 to RMB140.9 million as of December 31, 2023, primarily due to (i) an increase in finished goods of RMB35.4 million as (a) we maintained a higher inventory level at the year-end of 2023 in anticipation of increased sales volume of Lewejing (propofol injectable emulsion) following its winning in the bidding process under the ninth batch of the national centralized VBP scheme at the year-end of 2023; and (b) the inventory of Leyeping and Pujikang (glucose electrolyte effervescent tablets) and astragalus granules increased as we intensified our promotion efforts to large pharmaceutical retail chains, leading to an increase in foot traffic and market demand at pharmacies and prompting us to stockpile relevant products to meet the rising demand; and (ii) an increase in raw materials and consumables of RMB17.7 million as we continued to advance our innovative drug research and development projects and increased the procurement of raw materials related to these projects, which was partially offset by (i) a decrease in goods in transit of RMB5.9 million; and (ii) a decrease in work in progress of RMB4.0 million.

Our inventories increased by 17.0% from RMB140.9 million as of December 31, 2023 to RMB164.9 million as of September 30, 2024, primarily due to (i) an increase in raw materials and consumables of RMB16.1 million as we increased procurement of raw materials to advance our innovative drug research and development projects; and (ii) an increase in work in progress of RMB5.7 million.

In 2021, 2022 and 2023 and the nine months ended September 30, 2024, our inventory turnover days were 127 days, 136 days, 175 days and 216 days, respectively. We calculate the inventory turnover days using the average of the opening and ending inventory balances for the period, net of write down of inventories, divided by cost of sales for the relevant period, multiplied by the number of days for the relevant period (365 days for 2021, 2022 and 2023 and 270 days for the nine months ended September 30, 2024). Inventory turnover days remained relatively stable at 127 days in 2021 and 136 days in 2022, and increased to 175 days in 2023 and to 216 days in the nine months ended September 30, 2024, primarily because we maintained a higher inventory level at the year-end of 2023 in anticipation of increased sales volume of Lewejing (propofol injectable emulsion) following its winning in the bidding process under the ninth batch of the national centralized VBP scheme at the year-end of 2023.

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The following table sets forth an aging analysis of our inventories as of the dates indicated:

	As of December 31,			As of September 30,
	2021	2022	2023	2024
	<i>(RMB in thousands)</i>			
Less than 1 year	67,106	88,448	123,228	142,695
1-2 years	11,272	6,175	14,928	15,443
2-3 years	6,777	2,749	2,489	3,923
Over 3 years	1,111	5,508	5,412	6,733
Less: provision	(3,939)	(1,553)	(5,149)	(3,916)
Total	82,327	101,327	140,908	164,878

As of November 30, 2024, approximately RMB81.1 million or approximately 49.2% of our inventories as of September 30, 2024, were subsequently consumed. We believe there are no material recoverability issues for our inventories, given that (i) the stable nature of current market demand for our marketed products provides a solid basis for our outlook on the recoverability of our inventory. For example, according to CIC, the anesthetic drug market in China is projected to reach RMB34.1 billion in 2033 at a CAGR of 5.3% from 2023, the anti-infective drug market in China is projected to reach RMB53.3 billion in 2033 at a CAGR of 7.0% from 2023, and the traditional Chinese medicine market in China is projected to reach RMB563.8 billion in 2033 at a CAGR of 2.9% from 2023. See “Industry Overview — Other Segments” for more details; (ii) a substantial portion of the Company’s inventory feature a short inventory age, as they are usually sold within one year; (iii) we had not recognized any material impairment loss caused by the utilization of inventories that have materially and adversely affected our business operations during the Track Record Period; and (iv) we have implemented an effective inventory management system which monitors stages of the warehousing process, ensuring optimal oversight and control. We made provisions for our inventories to the net realizable value if their expected net realizable value is lower than the cost of the inventories. As of December 31, 2021, 2022 and 2023 and September 30, 2024, the balances of provision of inventory impairment were RMB3.9 million, RMB1.6 million, RMB5.1 million and RMB3.9 million, respectively, which we believe to be adequate by taking into account the factors including the expiry dates of the inventories and the expected future demand of relevant products.

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Trade and Other Receivables

The following table sets forth a breakdown of our trade and bills receivables as of the dates indicated:

	As of December 31,			As of September 30,
	2021	2022	2023	2024
	<i>(RMB in thousands)</i>			
Trade receivables – contract with customers	118,846	247,233	109,429	79,120
Less: allowance for credit losses	(13,664)	(18,730)	(11,034)	(9,657)
	105,182	228,503	98,395	69,463
Bills receivables	24,144	19,831	20,775	12,312
Less: allowance for credit losses	(1,207)	(992)	(1,039)	(615)
	22,937	18,839	19,736	11,697
Other receivables	3,877	6,379	5,305	25,444
Less: allowance for credit losses	(927)	(1,243)	(1,400)	(1,724)
	2,950	5,136	3,905	23,720
Prepayments to suppliers	22,916	29,845	57,199	92,306
Value added tax recoverable	17,240	7,708	25,237	60,114
Prepaid expenses	122	3,046	544	664
Deferred issue costs	2,161	–	–	24,979
Total	173,508	293,077	205,016	282,943

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Our trade receivables represent the outstanding amounts due from our customers for our pharmaceutical products. We typically grant our customers credit terms of 30 to 120 days. We seek to maintain strict credit control over our outstanding receivables, and overdue balances are reviewed regularly and actively monitored by senior management to minimize credit risk. Our bills receivable represents short-term bank acceptance notes received from our customers in lieu of cash payments. Prepayments to suppliers mainly comprise prepayment for research and development costs, prepayment for procurement of raw materials and prepayment for other operating costs and expenses. Value added tax recoverable represent value added taxes paid with respect to our procurement that can be credited against future value added tax payables. Other receivables primarily comprise staff advances, deposits and interest receivable.

Our trade and other receivables increased by 68.9% from RMB173.5 million as of December 31, 2021 to RMB293.1 million as of December 31, 2022, and decreased by 30.0% from RMB293.1 million as of December 31, 2022 to RMB205.0 million as of December 31, 2023, primarily due to (i) the increase in trade receivables in late 2022 as our sales of certain anti-infectives, pediatric drugs and traditional Chinese medicine increased in late 2022 in line with the increased market demand due to the COVID-19 outbreak; and (ii) the prolonged settlement of trade receivables by our customers in light of the COVID-19 outbreak. The decrease in our trade and other receivables as of December 2023 was partially offset by an increase in prepayments to suppliers from RMB29.8 million as of December 31, 2022 to RMB57.2 million as of December 31, 2023, as we increased prepayments to our supplier clinical sites and CROs in line with increasing number of and advancement of R&D projects for the innovative drug business. Our trade and other receivables increased by 38.0% from RMB205.0 million as of December 31, 2023 to RMB282.9 million as of September 30, 2024, primarily due to the increase in prepayments to suppliers of RMB35.1 million in line with the advancement of our innovative drug research and development projects, and the increase in value-added tax recoverable of RMB34.9 million.

The table below sets forth an aging analysis of our trade receivables and bills receivables (net of allowance for credit losses), based on the dates of goods delivery as of the dates indicated:

	As of December 31,			As of September 30,
	2021	2022	2023	2024
	<i>(RMB in thousands)</i>			
Within 1 year	124,912	243,275	115,701	79,327
1-2 years	980	3,080	1,171	1,014
2-3 years	1,358	417	1,023	328
Over 3 years	869	570	236	491
	<u>128,119</u>	<u>247,342</u>	<u>118,131</u>	<u>81,160</u>

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In 2021, 2022 and 2023 and the nine months ended September 30, 2024, our trade receivables turnover days were 62 days, 87 days, 107 days and 69 days, respectively. We calculate the trade receivables turnover days using the average of the opening and ending trade receivable balances for the period, net of loss allowance, divided by revenue for the relevant period, multiplied by the number of days for the relevant period (365 days for 2021, 2022 and 2023 and 270 days for the nine months ended September 30, 2024). Trade receivables turnover days increased from 62 days in 2021 to 87 days in 2022, and further increased to 107 days in 2023, primarily due to (i) the decrease in our revenue from the sale of pharmaceutical products from 2021 to 2022 and further to 2023; and (ii) the increase in trade receivables in late 2022 as our sales of certain anti-infectives, pediatric drugs and traditional Chinese medicine increased in late 2022 in line with the increased market demand due to the COVID-19 outbreak; and (iii) the prolonged settlement of trade receivables by our customers in light of the COVID-19 outbreak. Trade receivables turnover days decreased from 107 days in 2023 to 69 days for the nine months ended September 30, 2024 as we enhanced our collection efforts.

Given that the risk characteristics of the ECL of trade receivables, the corresponding historical credit losses, and the forward-looking information on macroeconomic factors remained largely consistent during the Track Record Period, we adopted consistent ECL loss rates as of December 31, 2021, 2022 and 2023 and September 30, 2024.

As of November 30, 2024, RMB41.8 million, or approximately 52.9% of our trade receivables as of September 30, 2024 had been subsequently settled. During the Track Record Period, in accordance with our accounting policies in relation to the expected credit losses, we made provisions on trade receivables of RMB13.7 million, RMB18.7 million, RMB11.0 million and RMB9.7 million as of December 31, 2021, 2022 and 2023 and September 30, 2024, respectively, which we believe to be adequate after considering the payment pattern of our customers with similar risk profiles and the corresponding historical credit loss experienced and forward-looking information that is available. Subject to the foregoing, we believe that there are no material recoverability issues for our trade receivables, given that (i) our customers are primarily large corporate entities with solid credit profiles and a history of settling receivables with us, (ii) our sales personnel maintain regular communication with these customers to monitor their business performance and financial position and to discuss settlement plans, and (iii) we have generally maintained good business relationships with these customers.

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Trade and Other Payables

The below table sets forth the breakdown of trade and other payables as of the dates indicated:

	As of December 31,			As of September 30,
	2021	2022	2023	2024
	<i>(RMB in thousands)</i>			
Trade payables	45,962	116,854	128,999	104,406
Trade payables settled with endorsed bills	22,059	13,719	11,176	9,913
Bills payables	–	11,993	31,170	104,560
Subtotal	68,021	142,566	171,345	218,879
Salaries and wages payables	27,585	39,996	44,292	53,598
Other tax payables	10,080	30,723	18,350	3,200
Accruals	11,584	44,275	110,078	146,228
Accrual for promotional cost	90,368	104,478	87,878	47,329
Consideration payable for acquisition of property, plant and equipment	15,005	24,020	68,821	31,915
Deposits from suppliers	46,224	44,503	43,762	55,884
Accrual for issue costs	–	25,140	–	8,760
Other payables	4,639	4,685	4,990	9,604
Subtotal	205,485	317,820	378,171	356,518
Total	273,506	460,386	549,516	575,397

Our trade payables primarily comprise the outstanding amounts due to our suppliers, including raw material suppliers. Credit terms granted by our suppliers vary. Our raw materials suppliers generally provide us credit terms of 30 to 180 days. Our bills payables represent short-term bank acceptance notes issued to our suppliers in lieu of cash payments, with maturity dates typically within one year. Payables for staff related costs mainly represent salary and wages payables to our employees. Accruals primarily comprise payables to CROs we engaged to support our preclinical research and clinical trials. Provision for promotional cost primarily comprise payables to service providers for provision of promotion services. Consideration payable for acquisition of property, plant and equipment primarily comprise payables for the construction of our production facilities.

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Our trade and other payables increased by 68.3% from RMB273.5 million as of December 31, 2021 to RMB460.4 million as of December 31, 2022, and further increased by 19.4% to RMB549.5 million as of December 31, 2023, which was primarily due to an increase in trade payables and accruals in line with our continued R&D efforts and investments. Our trade and other payables remained relatively stable at RMB549.5 million as of December 31, 2023 and RMB575.4 million as of September 30, 2024.

The below table sets forth an ageing analysis of the trade payables and bills payables as of the dates indicated, based on the invoice date:

	As of December 31,			As of September 30,
	2021	2022	2023	2024
	<i>(RMB in thousands)</i>			
Within 1 year	66,492	141,447	170,513	218,469
1-2 years	1,245	945	695	257
2-3 years	87	43	6	16
Over 3 years	197	131	131	137
Total	68,021	142,566	171,345	218,879

In 2021, 2022 and 2023 and the nine months ended September 30, 2024, our trade payables turnover days were 69 days, 120 days, 177 days and 165 days, respectively. We calculate the trade payables turnover days using the average of the opening and closing trade payable balances for the period, divided by cost of sales for the relevant period, multiplied by the number of days for the relevant period (365 days for 2021, 2022 and 2023 and 270 days for the nine months ended September 30, 2024). Trade payables turnover days increased from 69 days in 2021 to 120 days in 2022 primarily due to our efforts to request longer credit terms for trade payables from our suppliers in light of the COVID-19 pandemic in the fourth quarter of 2022, and further to 177 days in 2023, primarily due to increased purchases of raw materials towards the end of 2023 in line with our outlook of increased sales volume of certain products including Lewejing (propofol injectable emulsion), Leyeping and Pujikang (glucose electrolyte effervescent tablets), and astragalus granules. Trade payables turnover days remained relatively stable at 177 days in 2023 and 165 days in the nine months ended September 30, 2024.

As of November 30, 2024, approximately RMB48.2 million, or 46.2% of our trade payables as of September 30, 2024, had been settled.

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Contract Liabilities

Our contract liabilities comprise (i) the advance payments from customers for our sale of pharmaceutical products; (ii) the sales rebates that have been accrued but not yet paid to our distributors with whom we typically have standard sales rebate terms in our distribution agreements; and (iii) the transfer of manufacturing technology of BL-B01D1 from us to BMS pursuant to the BMS Agreement for which we have received the consideration from BMS as part of the Upfront Payment but not yet performed such obligation, the timing of which is at the discretion of BMS. For details, see “— Material Accounting Policy Information — Revenue from Contracts with Customers — License fee income.”

As of December 31, 2021, 2022 and 2023 and September 30, 2024, our contract liabilities was RMB10.8 million, RMB17.4 million, RMB8.7 million and RMB350.4 million, respectively. The fluctuation of our contract liabilities during the Track Record Period was primarily due to (i) the postponed fulfilment of the customer orders placed in late 2022 as a result of the COVID-19 outbreak in late 2022; and (ii) our recording of the transfer of manufacturing technology as contract liability in the nine months ended September 30, 2024 in relation to our performance obligations under the BMS Agreement.

As of November 30, 2024, approximately RMB2.5 million, or 0.7% of our contract liabilities as of September 30, 2024, had been subsequently recognized as revenue.

Right to Returned Goods Assets/Refund Liabilities

The right to returned goods assets represents our right to recover products from customers where customers exercise their right of return under the customary industry practice. We use our accumulated historical experience to estimate the number of returns on a portfolio level using the expected value method. As of December 31, 2021, 2022 and 2023 and September 30, 2024, our right to returned goods assets amounted to RMB6.9 million, RMB6.6 million, RMB6.0 million and RMB6.1 million, respectively.

The refund liabilities are related to customers’ right to return products under customary industry practice. At the point of sale, a refund liability and a corresponding adjustment to revenue is recognized for those products expected to be returned. We use our accumulated historical experience to estimate the number of returns on a portfolio level using the expected value method. As of December 31, 2021, 2022 and 2023 and September 30, 2024, our refund liabilities amounted to RMB15.8 million, RMB14.1 million, RMB11.2 million and RMB10.2 million, respectively.

Amount due to a Related Party

We had amount due to a related party of RMB12 thousand as of September 30, 2024, which were non-trade in nature and were unsecured, interest free and repayable on demand. As of the Latest Practicable Date, the non-trade balances had been settled.

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LIQUIDITY AND CAPITAL RESOURCES

Our primary use of cash is to fund our working capital requirements and other recurring expenses. During the Track Record Period, we financed our operations primarily through cash generated from our operating activities and bank borrowings. In the foreseeable future, we believe that our liquidity requirements will be satisfied with a combination of cash flow generated from our operating activities, the [REDACTED] received from the [REDACTED], and other funds raised from the capital markets from time to time. We will closely monitor the level of our working capital, and diligently review future cash flow requirements and adjust our operation and expansion plans, if necessary, to ensure that we maintain sufficient working capital to support our business operations. Our cash and cash equivalents were RMB154.2 million, RMB1,000.7 million, RMB391.7 million and RMB4,950.7 million as of December 31, 2021, 2022 and 2023 and September 30, 2024, respectively.

Cash Flows

The following table sets forth a summary of our consolidated statements of cash flows for the periods indicated:

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	<i>(RMB in thousands)</i>			<i>(Unaudited)</i>	
(Loss) profit before tax	(112,087)	(289,074)	(769,013)	(533,696)	4,349,692
Adjustment for cash flows from operating activities before movement of working capital	64,702	81,000	91,534	66,059	19,074
Changes in working capital	(67,992)	(41,288)	69,270	27,664	271,590
Income tax paid	(22,073)	(7,278)	(9,778)	(8,680)	(209,798)
Net cash flows (used in)/from operating activities	(137,450)	(256,640)	(617,987)	(448,653)	4,430,558
Net cash flows from/(used in) investing activities	158,345	(36,977)	(79,399)	(68,559)	(604,189)
Net cash flows from/(used in) financing activities	88,876	1,139,833	91,003	(97,502)	794,684

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	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	(RMB in thousands)			(Unaudited)	
Net increase (decrease) in cash and cash equivalents	109,771	846,216	(606,383)	(614,714)	4,621,053
Cash and cash equivalents at the beginning of the year/period	45,212	154,222	1,000,695	1,000,695	391,693
Effect of foreign exchange rate changes	(761)	257	(2,619)	(624)	(62,047)
Cash and cash equivalents at the end of the year/period	154,222	1,000,695	391,693	385,357	4,950,699

Operating activities

Our net cash flows from operating activities for the nine months ended September 30, 2024 was RMB4,430.6 million, primarily attributable to a profit before tax of RMB4,349.7 million, as adjusted by changes in working capital, which primarily consist of an increase in contract liabilities of RMB337.1 million, partially offset by (i) the adjustment for interest income on bank deposits of RMB130.2 million, (ii) a decrease in trade and other payables of RMB53.0 million, (iii) an increase in inventories of RMB35.9 million and (iv) the adjustment for gain on fair value change of financial assets at FVTPL of RMB30.7 million.

Our net cash flows used in operating activities in 2023 was RMB618.0 million, primarily attributable to a loss before tax RMB769.0 million, as adjusted by (i) certain non-cash items primarily consist of depreciation of property, plant and equipment of RMB57.2 million; and (ii) changes in working capital, which primarily consist of a decrease in trade and other receivables of RMB126.1 million, partially offset by an increase in inventories of RMB52.6 million.

Our net cash flows used in operating activities in 2022 was RMB256.6 million, primarily attributable to a loss before tax of RMB289.1 million, as adjusted by (i) the add-back of depreciation of property, plant and equipment of RMB56.1 million; and (ii) changes in working capital, which primarily consist of an increase in trade and other payables of RMB80.5 million, partially offset by an increase in trade and other receivables of RMB89.1 million.

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Our net cash flows used in operating activities in 2021 was RMB137.5 million, primarily attributable to a loss before tax of RMB112.1 million, as adjusted by (i) certain non-cash items primarily consist of release of expense-related government subsidies of RMB5.4 million; and (ii) changes in working capital, which primarily consist of a decrease in trade and other payables of RMB153.8 million, partially offset by a decrease in trade and other receivables of RMB102.9 million.

Investing activities

Our net cash flows used in investing activities for the nine months ended September 30, 2024 was RMB604.2 million, primarily attributable to (i) purchase of financial assets at FVTPL of RMB1,619.3 million and (ii) placement of term deposits of RMB697.3 million, partially offset by proceeds from disposal of financial assets at FVTPL of RMB1,649.9 million.

Our net cash flows used in investing activities in 2023 was RMB79.4 million, primarily attributable to purchase of property, plant and equipment and intangible assets of RMB81.9 million and placement of restricted bank balances of RMB45.4 million, partially offset by withdrawal from restricted bank balances of RMB37.2 million.

Our net cash flows used in investing activities in 2022 was RMB37.0 million, primarily attributable to purchase of property, plant and equipment and intangible assets of RMB34.6 million and placement of restricted bank balances of RMB14.0 million, partially offset by withdrawal from restricted bank balances of RMB10.0 million.

Our net cash flows generated from investing activities in 2021 was RMB158.3 million, primarily attributable to proceeds from disposal of financial assets at FVTPL of RMB479.9 million, partially offset by purchase of financial assets at FVTPL of RMB279.2 million.

Financing activities

Our net cash flows generated from financing activities for the nine months ended September 30, 2024 was RMB794.7 million, primarily attributable to new bank borrowings raised of RMB1,128.9 million, partially offset by repayment of bank borrowings of RMB243.0 million and repayment of sales and leaseback of equipment of RMB40.2 million.

Our net cash flows generated from financing activities in 2023 was RMB91.0 million, primarily attributable to new bank borrowings raised of RMB447.7 million, partially offset by repayment of bank borrowings of RMB239.7 million.

Our net cash flows generated from financing activities in 2022 was RMB1,139.8 million, primarily attributable to proceeds from issue of shares of RMB907.5 million in relation to our A-share initial public offering and new bank borrowings raised of RMB375.0 million, partially offset by repayment of bank borrowings of RMB161.0 million.

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Our net cash flows generated from financing activities in 2021 was RMB88.9 million, primarily attributable to new bank borrowings raised of RMB242.0 million, partially offset by repayment of bank borrowings of RMB181.0 million.

Working Capital Sufficiency

We intend to finance our future working capital requirements with cash generated from our operations, the net [REDACTED] from the [REDACTED] and other funds raised from the capital markets from time to time. Our future working capital requirements will depend on a number of factors, including, but not limited to, our operating income, our business expansion plan and hiring qualified employees for our business operations. Based on our available cash balance, the anticipated cash flow from operations, available banking facilities and the anticipated net [REDACTED] from the [REDACTED], our Directors are of the opinion that we will have sufficient funds to meet our working capital requirements and financial requirements for capital expenditure for at least the next 12 months from the date of this document.

Our Directors are of the view that we will have adequate working capital and sufficient cash balance to support our business growth until we achieve a net operating cash inflow position, without taking account of the estimated [REDACTED] from the [REDACTED], on the following grounds: (i) we had cash and cash equivalents of RMB4,950.7 million, which are all highly liquid assets, as of September 30, 2024; (ii) we have implemented and will in the future continue to implement a wide array of initiatives to improve our ability to generate profit and operating cash inflow and increase operational leverages, all of which are expected to help us generate continued cash flows from our operations. For more details regarding our initiatives to improve our ability to generate profit and operating cash inflow, see “— Business Sustainability”; (iii) we will continue to enhance our operating efficiencies by leveraging economies of scale, optimizing production processes, negotiating favorable supply agreements, and continuously seeking opportunities to reduce overhead; and (iv) we had unutilized banking facilities of RMB342.4 million as of November 30, 2024, and we may seek additional funding through public or private offerings, debt financing, or other sources, if needed.

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INDEBTEDNESS

The following table sets forth the details of our indebtedness as of the dates indicated:

	As of December 31,			As of September 30,	As of November 30,
	2021	2022	2023	2024	2024
	(RMB in thousands)				(Unaudited)
Current:					
Borrowings	161,250	185,603	449,489	906,565	882,392
Sale and leaseback payable	19,019	61,858	41,430	7,599	7,690
Lease liabilities	5,215	6,965	4,702	8,219	11,970
Non-current:					
Borrowings	50,000	239,960	183,920	613,830	1,011,017
Sale and leaseback payable	42,455	47,223	7,636	–	–
Lease liabilities	8,970	5,723	1,017	14,286	28,888
Total	286,909	547,332	688,194	1,550,499	1,941,957

Bank Borrowings

As of December 31, 2021, 2022 and 2023, September 30, 2024 and November 30, 2024, our current and non-current bank borrowings were RMB211.3 million, RMB425.6 million, RMB633.4 million, RMB1,520.4 million and RMB1,893.4 million. Our bank borrowings as of September 30, 2024 increased despite having ample cash and cash equivalents due to our strategic cash management approach. Most of our cash and cash equivalents were derived from the Upfront Payment from BMS under the BMS Agreement and were deposited in US dollars as they met our future business needs and provided a favorable interest rate. Meanwhile, to supplement our operational cash in Renminbi, we incurred bank borrowings in Renminbi at a lower interest rate than our interest income received in US dollars.

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The following table sets forth the details of our borrowings as of the dates indicated:

	As of December 31,			As of September 30,
	2021	2022	2023	2024
	<i>(RMB in thousands)</i>			
Bank borrowings				
– Secured	211,250	355,483	543,365	1,227,167
– Unsecured	–	70,080	90,044	293,228
	<u>211,250</u>	<u>425,563</u>	<u>633,409</u>	<u>1,520,395</u>
– Fixed-rate borrowings	161,232	155,133	275,117	651,465
– Floating-rate borrowings	<u>50,018</u>	<u>270,430</u>	<u>358,292</u>	<u>868,930</u>
	<u>211,250</u>	<u>425,563</u>	<u>633,409</u>	<u>1,520,395</u>
Carrying amount repayable: (based on scheduled payment terms)				
Within one year	161,250	185,603	449,489	906,565
More than one year, but not more than two years	–	170,040	183,920	380,900
More than two years, but not more than five years	50,000	69,920	–	232,930
Less: Amount due for settlement within 12 months shown under current liabilities	(161,250)	(185,603)	(449,489)	(906,565)
Amount due for settlement after 12 months shown under non-current liabilities	50,000	239,960	183,920	613,830

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The following table sets forth ranges of effective interest rate of our bank borrowings as of the dates indicated:

	As of December 31,			As of September 30,
	2021	2022	2023	2024
	<i>(RMB in thousands)</i>			
Effective interest rate per annum:				
	4.38%-	3.85%-	3.60%-	2.85%-
– Fixed-rate borrowings	4.90%	4.80%	3.90%	3.85%
		4.10%-	3.70%-	2.65%-
– Floating-rate borrowings	4.45%	4.65%	4.45%	4.45%

During the Track Record Period and up to the Latest Practicable Date, we had not been in violation of any of the material covenants pursuant to the respective loan agreements we entered into with the relevant banks, and there was no delay or default in the repayment of borrowings during the Track Record Period. Taking our financial position into consideration, we are able to abide by these covenants amid current market conditions and that our capital raising abilities were not materially affected as of the Latest Practicable Date.

As of November 30, 2024, we had unutilized banking facilities of RMB342.4 million.

Sale and Leaseback Payable

Our sale and leaseback payables related to our leases of certain properties and equipment. As of December 31, 2021, 2022 and 2023, September 30, 2024 and November 30, 2024, we had current and non-current sale and leaseback payables of RMB61.5 million, RMB109.1 million, RMB49.1 million, RMB7.6 million and RMB7.7 million, respectively.

Lease Liabilities

Our lease liabilities primarily comprise leases of offices with a term of one year or more. As of December 31, 2021, 2022 and 2023, September 30, 2024 and November 30, 2024, we had a total of current and non-current lease liabilities of RMB14.2 million, RMB12.7 million, RMB5.7 million, RMB22.5 million and RMB40.9 million, respectively.

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Indebtedness as of the Most Recent Practicable Date

As of November 30, 2024, being the most recent practicable date for determining our indebtedness, we have approximately RMB1,942.0 million outstanding indebtedness as set out below:

- bank borrowings of approximately RMB1,262.9 million which are secured by land use rights and property, plant and equipment and unguaranteed;
- bank borrowings of approximately RMB630.5 million which are unsecured and unguaranteed;
- sale and leaseback payable of approximately RMB7.7 million which are secured by property, plant and equipment and guaranteed by the shareholder of the Company;
- lease liabilities of approximately RMB40.9 million relating to right-of-use assets in respect of buildings which were secured by rental deposits and unguaranteed.

Indebtedness Statement

Except as disclosed in this document, as of November 30, 2024, we did not have any outstanding or authorized but unissued debt securities, term loans, other borrowings, liabilities under acceptance or other similar indebtedness, hire purchase commitments, mortgages and charges, guarantees or other material contingent liabilities.

Our Directors confirm that as of the Latest Practicable Date, there was no material covenant on any of our outstanding debt and there was no breach of any covenant during the Track Record Period and up to the Latest Practicable Date. Our Directors further confirm that we did not experience any difficulty in obtaining bank loans and other borrowings, default in payment of bank loans and other borrowings or breach of covenants during the Track Record Period and up to the Latest Practicable Date. Our Directors also confirm that there has been no material change in our indebtedness since November 30, 2024 and up to the date of this document.

CONTINGENT LIABILITIES

As of the Latest Practicable Date, we did not have any significant contingent liabilities.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into, nor we expect to enter into, any off-balance sheet arrangements. We also have not entered into any financial guarantees or other relevant commitments. In addition, we have not entered into any derivative contracts that are indexed to our equity interests and classified as owners' equity. We do not have any variable interest in any unconsolidated entity that provides financing, liquidity, market risk or credit support to us or engages in leasing or hedging with us.

FINANCIAL INFORMATION

RELATED PARTY TRANSACTIONS

During the Track Record Period, our Controlling Shareholder provided guarantees in respect of our certain bank facilities and lease agreements. As of the Latest Practicable Date, all such guarantees provided by our Controlling Shareholder were released. As of the Latest Practicable Date, the Controlling Shareholder or his close associates did not provide any loans, guarantees or pledges to our Group, and our Group did not provide any loans, guarantees or pledges to our Controlling Shareholder or his close associates. We also provided compensation to our key management personnel in the ordinary course of our business. For more details about our related party transactions, see Note 38 to the Accountants’ Report in Appendix I to this document.

Our Directors believe that each of the related party transactions set out in Note 38 to the Accountants’ Report in Appendix I to this document was conducted on an arm’s length basis and would not distort our track record results or make our historical results not reflective of our future performance.

CAPITAL EXPENDITURES

Our capital expenditures during the Track Record Period were primarily related to purchases of property, plant and equipment in relation to the construction and upgrade of our research and development and manufacturing facilities, as well as purchases of intangible assets. The following table sets forth the breakdown of our capital expenditures for the periods indicated. We expect to finance our planned capital expenditures through operating cash flows. We may adjust our capital expenditures for any given period according to our development plans or in light of market conditions and other factors we believe to be appropriate.

	As of December 31,			As of
	2021	2022	2023	September 30,
				2024
	<i>(RMB in thousands)</i>			
Additions of items of property, plant and equipment	59,085	74,246	178,313	47,287
Additions of intangible assets	1,290	1,588	1,645	1,390
Total	60,375	75,834	179,958	48,677

FINANCIAL INFORMATION

CAPITAL COMMITMENTS

The following table sets out our capital commitments as of the dates indicated:

	As of December 31,			As of September 30,
	2021	2022	2023	2024
	<i>(RMB in thousands)</i>			
Capital expenditure in respect of: the acquisition of property, plant and equipment and intangible assets contracted for but not provided	76,296	76,721	11,800	24,819

DIVIDEND

We do not currently have a formal dividend policy or a fixed dividend payout ratio. After the completion of the [REDACTED], we may distribute dividends in the form of cash or by other means permitted by our Articles of Association. A decision to declare or to pay dividends in the future and the amount of dividends will be at the discretion of our Board and will depend on a number of factors, including our results of operations, cash flows, financial condition, payments by our subsidiaries of cash dividends to us, business prospects, statutory, regulatory restrictions on our declaration and payment of dividends and other factors that our Board may consider important. Any declaration and payment as well as the amount of dividends will be subject to our constitutional documents and the relevant laws. Our Shareholders in a general meeting may approve any declaration of dividends.

According to the applicable PRC laws and our Articles of Association, we will pay dividends out of our profit after tax only after we have made the following allocations: recovery of the losses incurred in the previous year; allocations to the statutory reserve equivalent to 10% of our profit after tax; and allocations to a discretionary common reserve of certain percentage of our profit after tax that are approved by a Shareholders’ meeting.

Any distributable profits that are not distributed in any given year will be retained and become available for distribution in subsequent years. Pursuant to our Articles of Association, the amount of the cash dividend distributed should be at least 10% of our profits available for distribution generated in each financial year.

FINANCIAL INFORMATION

In 2021, we distributed dividends of RMB20.0 million, representing a dividend of RMB0.06 per Share. Other than the foregoing, no dividend has been proposed, paid or declared by us during the Track Record Period. Our future declarations of dividends may or may not reflect our historical declarations of dividends and will be at the discretion of our Directors and subject to the approval of the Shareholders’ meeting.

DISTRIBUTABLE RESERVES

As of September 30, 2024, we did not have any distributable reserves.

KEY FINANCIAL RATIOS

The following table sets forth certain of our key financial ratios as of the dates and for the periods indicated:

	As of/For the year December 31,			As of/ For the nine months ended September 30,
	2021	2022	2023	2024
Gross profit margin ⁽¹⁾	73.2%	64.8%	54.8%	96.6%
Current ratio ⁽²⁾	0.87	1.90	0.73	2.95
Quick ratio ⁽³⁾	0.70	1.76	0.60	2.87

Notes:

- (1) Gross profit margin is calculated based on gross profit divided by revenue for the year/period.
- (2) Current ratio is calculated based on total current assets divided by total current liabilities as of year/period end.
- (3) Quick ratio is calculated based current assets less inventories divided by current liabilities as of year/period end.

DISCLOSURE ABOUT FINANCIAL RISKS

Our activities are exposed to a variety of financial risks, including market risk (including currency risk, interest rate risk and other price risk), credit risk and liquidity risk. Our overall risk management strategy seeks to minimize the potential adverse effects on our financial performance. Our senior management is responsible for the risk management.

FINANCIAL INFORMATION

Market Risk

Foreign currency risk

Several subsidiaries of our Company have foreign currency bank balances, trade payables and intra-group balance which expose us to foreign currency risk. Please refer to Note 42 to the Accountants’ Report included in Appendix I to this document for further details of the foreign currency risk we face.

Interest rate risk

We are exposed to fair value interest rate risk in relation to certain interest-bearing bank balances, certificates of deposit and restricted bank balances, term deposits, bills receivables at FVTOCI, sale and leaseback payables, fixed-rate borrowings and lease liabilities, all bear fixed interest rates. We are mainly exposed to cash flow interest rate risk in relation to borrowings at floating interest rates (depends on the PRC loan prime rate). We currently do not have an interest rate hedging policy. There are no concentration on our interest rate risks. However, the management will consider hedging significant interest rate risk should the need arise. Please refer to Note 42 to the Accountants’ Report included in Appendix I to this document for further details of the interest rate risk we face.

Other price risk

We are exposed to other price risk arising from financial products, which is presented as financial assets at FVTPL. Please refer to Note 42 to the Accountants’ Report included in Appendix I to this document for further details of the other price risk we face.

Credit Risk

We are exposed to credit risk in relation to the cash and cash equivalents, term deposits, amounts due from related parties, trade and bills receivables and financial assets included in prepayments, other receivables and other assets. The carrying amounts of each class of the above financial assets represent our maximum exposure to credit risk in relation to financial assets. We trade mainly with recognized and creditworthy third parties. It is our policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an on-going basis.

Please refer to Note 42 to the Accountants’ Report included in Appendix I to this document for further details of the credit risk we face.

Liquidity Risk

In the management of the liquidity risk, we monitor and maintain a level of cash and cash equivalents deemed adequate by our management to finance the operations and mitigate the effects of fluctuations in cash flows. Please refer to Note 42 to the Accountants’ Report included in Appendix I to this document for further details of the liquidity risk we face.

FINANCIAL INFORMATION

[REDACTED]

Our [REDACTED] mainly include [REDACTED], professional fees paid to legal advisors and the Reporting Accountants for their services rendered in relation to the [REDACTED] and the [REDACTED]. The estimated total [REDACTED] expenses (based on the [REDACTED] of our indicative [REDACTED] for the [REDACTED] and assuming that the [REDACTED] is not exercised) for the [REDACTED] are approximately RMB[REDACTED] (equivalent to HK\$[REDACTED]), representing [REDACTED]% of the gross [REDACTED]. The estimated total [REDACTED] expenses consist of (i) [REDACTED]-related expenses (including but not limited to [REDACTED] and fees) of approximately RMB[REDACTED] (approximately HK\$[REDACTED]), and (ii) [REDACTED] related expenses of approximately RMB[REDACTED] (approximately HK\$[REDACTED]), which consist of fees and expenses of legal advisors and Reporting Accountants of approximately RMB[REDACTED] (approximately HK\$[REDACTED]), and other fees and expenses of approximately RMB[REDACTED] (approximately HK\$[REDACTED]). During the Track Record Period, we incurred [REDACTED] expenses of RMB[REDACTED], which is recognized as deferred issue costs included in trade and other receivables. Of our estimated [REDACTED] of approximately RMB[REDACTED] (equivalent to HK\$[REDACTED]), RMB[REDACTED] (equivalent to HK\$[REDACTED]) is expected to be charged to our consolidated statements of profit and loss and RMB[REDACTED] (equivalent to HK\$[REDACTED]) will be deducted from equity. The [REDACTED] expenses above are the best estimate as of the Latest Practicable Date and are for reference only and the actual amount may differ from such estimate.

UNAUDITED [REDACTED] ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

[REDACTED]

FINANCIAL INFORMATION

[REDACTED]

FINANCIAL INFORMATION

[REDACTED]

PROFIT ESTIMATE FOR [REDACTED]

The following profit estimate has been prepared based on (i) the audited consolidated results of our Group for the nine months ended September 30, 2024; and (ii) the unaudited consolidated results of our Group based on the management accounts of our Group for [REDACTED]. The profit estimate has been prepared on a basis consistent in all material respects with the accounting policies currently adopted by our Group as set out in the Accountants’ Report, the text of which is set forth in Appendix I to this document.

Estimated consolidated profit attributable to owners of our Company for [REDACTED]	Not less than RMB[REDACTED]
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See “Appendix IIB — Profit Estimate” in this document for further details.

NO MATERIAL ADVERSE CHANGE

After performing sufficient due diligence work which our Directors consider appropriate and after due and careful consideration, the Directors confirm that, up to the date of this document, there has been no material adverse change in our financial or [REDACTED] position or prospects since September 30, 2024, being the latest date of our consolidated financial statements as set out in Appendix I to this document, and there is no event since September 30, 2024 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, there was no circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

FUTURE PLANS AND USE OF [REDACTED]

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED], after deducting [REDACTED], fees and estimated expenses payable by us in connection with the [REDACTED], based on an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range stated in this document, assuming the [REDACTED] is not exercised.

We currently intend to apply these net [REDACTED] for the following purposes:

- Approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the research and development activities of our biologic drug candidates outside of mainland China.

To date, our overseas business includes an R&D center focused on innovative biopharmaceuticals in Seattle, U.S. which has extensive capabilities in antibody discovery, engineering and construction of antibodies, initial high-throughput screening and others. In the coming years, we plan to accelerate the clinical development of our biologic drug candidates for the global markets outside of mainland China, which will primarily include the initiation of a number of clinical trials in the U.S.

Within mainland China where most of our clinical trials for our biologic candidates are currently conducted, we plan to continue to rely on our existing cash resources (including our available cash balance and banking facilities) and the anticipated cash flow from operations to fund these ongoing and planned research and development activities. A breakdown of the funds we plan to utilize within this category include:

- Approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the research and development activities for BL-M07D1. Such activities will primarily include our ongoing Phase I clinical trial in the U.S. that commenced in February 2024, in which we are investigating for the treatment of HER2 expressing advanced tumors. If the results of our ongoing Phase I trial in the U.S. are favorable, we plan to initiate Phase III clinical trials in the U.S., such as but not limited to GC or BC depending on the results from our Phase I trial, which we then intend to use to support our first BLA filing for BL-M07D1 to the FDA.
- Approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the research and development activities for BL-B16D1, an innovative bispecific ADC which utilizes our proprietary new-generation payload developed from our platform. Such activities will primarily include our IND-enabling studies in the U.S. Based on the results, we plan to submit an IND application to the FDA in the first quarter of 2025 and within 12 months after IND is approved, we plan to complete our first Phase I clinical trial in the U.S. for BL-B16D1 targeting various solid tumors.

FUTURE PLANS AND USE OF [REDACTED]

- Approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the research and development activities for BL-M17D1, an innovative ADC which similar to BL-B16D1 utilizes our proprietary new-generation payload developed from our platform. With the IND approval for BL-M17D1 from FDA, we expect to commence the enrollment of patients in the Phase I trial for BL-M17D1 for the treatment of various solid tumors in the U.S. in the first quarter of 2025, with the trial projected to span approximately two years.
- Approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the research and development activities for our other ADC drug candidates, such as BL-M11D1, BL-M05D1, BL-M14D1 and other pre-clinical ADC drug candidates. Such activities will primarily include our ongoing IND-enabling studies for BL-M14D1 in the U.S., with the results of which we plan to submit an IND application to FDA in the first quarter of 2025, and aim to complete the Phase I trial in the U.S. within two years of its initiation following the IND approval. With the IND approval for BL-M11D1 from FDA, we have initiated and completed the dosing of the first patient in the Phase I trial for BL-M11D1 in the U.S. in the fourth quarter of 2024, and aim to complete the Phase I trial in 2027. With the IND approval for BL-M05D1 from FDA, we plan to complete the dosing of the first patient in the Phase I trial for BL-M05D1 in the U.S. in the first or second quarter of 2025, and aim to complete the Phase I trial within the subsequent two years. Additionally, we plan to carry out other planned IND-enabling studies and Phase I clinical trials for ADC drug candidates under our HIRE-ADC platform.
- Approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the research and development activities of the drug candidates under our GNC platform. Such activities will include continued clinical trials for GNC-077, an innovative multi-specific antibody molecule which in our *in vivo* studies have demonstrated robust anti-tumor efficacy across multiple solid tumors, for which we expect to submit an IND to FDA in the first quarter of 2025; as well as other pre-clinical and clinical studies for our first-generation GNC drug candidates such as GNC-038, GNC-035, GNC-039 and/or other next-generation pre-clinical GNC candidates. We expect to submit INDs to FDA for GNC-077 and GNC-038 in the first quarter of 2025, and an IND for GNC-035 to FDA in the second or third quarter of 2025.
- Approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the research and development activities of the drug candidates under our SEBA platform. Such activities will primarily include clinical trials for SI-B001 and SI-B003 for the treatment of various solid tumors.
- Approximately [REDACTED]%, or HK\$[REDACTED], will be used to establish our global supply chain, primarily to fund the construction or if an opportunity arises, the acquisition of, a new manufacturing facility for our biologic drug candidates outside of mainland China.

FUTURE PLANS AND USE OF [REDACTED]

As of the Latest Practicable Date, all of our manufacturing facilities were located in mainland China. However, as we (i) have commenced Phase I clinical trials for BL-M07D1 outside of mainland China; (ii) expect to commence a number of Phase I clinical trials for our other ADC, GNC and SEBA drug candidates outside of mainland China in the coming years; and (iii) expect these assets to rapidly progress towards late-stage clinical development and commercialization in the U.S. and other regions of the world, we plan to establish a new manufacturing facility outside of mainland China to meet the growing global production needs of these drug candidates for both clinical and commercial use.

As of the Latest Practicable Date, we are still in the process of identifying suitable locations to build our new overseas manufacturing facility. While we have not entered into any binding commitment, whether oral or written, or formulated any concrete construction plan as of the Latest Practicable Date, we plan to build a manufacturing facility that (i) has specifications similar to our Baili-Bio Base in Chengdu, including the ability to house various workshops that cover the full cycle of cell culture, antibody purification, ADC conjugation, filling, lyophilization and packaging; (ii) located in or in close proximity to key overseas markets such as, but not limited to, the U.S., Singapore and Ireland; and (iii) compliant with FDA, EMA and NMPA’s regulatory requirements and cGMP standards in U.S., Europe and China.

If an opportunity arises, we will also consider the potential acquisition of an existing manufacturing facility based on the same specifications listed above.

According to CIC, over US\$5.0 billion has committed to expanding ADC manufacturing capacities globally since 2023, as an increasing number of ADCs reach commercialization in the coming years and the global ADC market grows rapidly from US\$10.1 billion in 2023 to US\$42.8 billion in 2028 and further to US\$151.9 billion by 2033. Given the above CIC is of the view that biopharmaceutical manufacturing facilities specifically for ADCs will continue to become more readily available, both in the form of newly constructed facilities and the availability of suitable acquisition targets. As such, while we have not identified a specific location to build a new manufacturing facility or specific manufacturing facility to acquire to date, we believe that based on information provided from CIC, as well as our own industry intelligence, that there are a sufficient number of potentially suitable targets which we will continue to evaluate by leveraging our years of experience in commercial manufacturing of pharmaceutical products as well as our global network.

- Approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the working capital and other general corporate purposes for our operations outside of mainland China.

FUTURE PLANS AND USE OF [REDACTED]

If the [REDACTED] is set at HK\$[REDACTED] per Share, being the high end of the indicative [REDACTED] range, the net [REDACTED] from the [REDACTED] will increase by approximately HK\$[REDACTED]. If the [REDACTED] is set at HK\$[REDACTED] per Share, being the low end of the indicative [REDACTED] range, the net [REDACTED] from the [REDACTED] will decrease by approximately HK\$[REDACTED].

The allocation of the net [REDACTED] from the [REDACTED] above will be adjusted on a pro rata basis in the event that the [REDACTED] is fixed at a higher or lower level compared to the mid-point of the indicative [REDACTED] range stated in this document.

If the [REDACTED] is exercised in full, the net [REDACTED] that we will receive will be approximately HK\$[REDACTED] million, assuming an [REDACTED] of HK\$[REDACTED] per Share (being the mid-point of the indicative [REDACTED] range). In the event that the [REDACTED] is exercised in full, we intend to apply the additional net [REDACTED] to the purposes in the proportions stated above.

To the extent that the net [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 interest-bearing accounts at licensed commercial banks and/or other authorized financial institutions (as defined under the Securities and Futures Ordinance or applicable laws and regulations in other jurisdictions).

We will issue an appropriate announcement if there is any material change to the above proposed use of [REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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HOW TO APPLY FOR [REDACTED]

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HOW TO APPLY FOR [REDACTED]

[REDACTED]

APPENDIX I

ACCOUNTANTS’ REPORT

The following is the text of a report set out on pages I-1 to I-83 received from the Company’s reporting accountants, Deloitte Touche Tohmatsu, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this document..

Deloitte.

德勤

ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF SICHUAN BIOKIN PHARMACEUTICAL CO., LTD., GOLDMAN SACHS (ASIA) L.L.C., J.P. MORGAN SECURITIES (FAR EAST) LIMITED[#] AND CITIC SECURITIES (HONG KONG) LIMITED[#]

Introduction

We report on the historical financial information of 四川百利天恒藥業股份有限公司 (Sichuan Biokin Pharmaceutical Co., Ltd.) (the “Company”) and its subsidiaries (together, the “Group”) set out on pages I-4 to I-83 which comprises the consolidated statements of financial position of the Group as at December 31, 2021, 2022 and 2023 and September 30, 2024, the statements of financial position of the Company as at December 31, 2021, 2022 and 2023 and September 30, 2024 and the consolidated statements of profit or loss and other comprehensive income, the consolidated statements of changes in equity and the consolidated statements of cash flows of the Group for each of the three years ended December 31, 2023 and the nine months ended September 30, 2024 (the “Track Record Period”) and material accounting policy information and other explanatory information (together, the “Historical Financial Information”). The Historical Financial Information set out on pages I-4 to I-83 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 initial [REDACTED] of H shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

Directors’ responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in Note 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.

[#] In no particular order

APPENDIX I

ACCOUNTANTS’ REPORT

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.

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in Note 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 entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors of the Company, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountants’ report, a true and fair view of the Group’s financial position as at December 31, 2021, 2022 and 2023 and September 30, 2024, of the Company’s financial position as of December 31, 2021, 2022 and 2023 and September 30, 2024 and of the Group’s financial performance and cash flows for the Track Record Period in accordance with the basis of preparation set out in Note 1 to the Historical Financial Information.

Review of stub period comparative financial information

We have reviewed the stub period comparative financial information of the Group which comprises the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the nine months ended September 30, 2023 and other explanatory information (the “Stub Period Comparative Financial Information”). The directors of the Company are responsible for the preparation of the Stub Period Comparative Financial Information in accordance with the basis of preparation set out in Note 1 to the Historical Financial Information. Our responsibility is to express a conclusion on the Stub Period Comparative Financial Information based on our

APPENDIX I

ACCOUNTANTS’ REPORT

review. We conducted our review in accordance with International Standard on Review Engagements 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the International Auditing and Assurance Standards Board (“IAASB”). A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (“ISAs”) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has come to our attention that causes us to believe that the Stub Period Comparative Financial Information, for the purposes of the accountants’ report, is not prepared, in all material respects, in accordance with the basis of preparation set out in Note 1 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-4 have been made.

Dividends

We refer to Note 13 to the Historical Financial Information which contains information about dividends declared or paid by the Company in respect of the Track Record Period.

[Deloitte Touche Tohmatsu]

Certified Public Accountants

Hong Kong

[Date]

APPENDIX I

ACCOUNTANTS’ REPORT

HISTORICAL FINANCIAL INFORMATION OF THE GROUP

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of the accountants’ report.

The consolidated financial statements of the Group for the Track Record Period, on which the Historical Financial Information is based, have been prepared in accordance with the accounting policies which conform with International Financial Reporting Standards (“IFRSs”) issued by International Accounting Standards Board (the “IASB”) and were audited by us in accordance with ISAs issued by the IAASB (“Underlying Financial Statements”).

The Historical Financial Information is presented in Renminbi (“RMB”), which is also the functional currency of the Company, and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

		Year ended December 31,			Nine months ended	
	NOTES	2021	2022	2023	2023	2024
		RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
					(unaudited)	
Revenue	5	794,955	701,833	560,416	376,599	5,661,227
Cost of sales		(212,735)	(246,844)	(253,401)	(161,031)	(190,920)
Gross profit		582,220	454,989	307,015	215,568	5,470,307
Other income	6	70,311	70,489	59,249	42,906	163,819
Other gains and losses, net	7	2,434	(563)	(1,248)	(733)	(46,296)
Impairment losses under expected credit loss (“ECL”) model, net of reversal	8	2,998	(7,686)	6,442	6,224	1,477
Research and development expenses		(278,603)	(375,020)	(746,232)	(509,799)	(931,701)
Distribution and selling expenses		(391,296)	(324,297)	(251,193)	(179,718)	(156,046)
Administrative expenses		(79,869)	(82,194)	(115,397)	(87,211)	(122,322)
Other expenses		(3,939)	(2,311)	(2,970)	(2,441)	(1,748)
Finance costs	9	(16,343)	(22,481)	(24,679)	(18,492)	(27,798)
(Loss) profit before tax		(112,087)	(289,074)	(769,013)	(533,696)	4,349,692
Income tax credit (expense)	10	4,445	6,695	(11,486)	18,590	(284,324)
(Loss) profit for the year/period attributable to owners of the Company	11	<u>(107,642)</u>	<u>(282,379)</u>	<u>(780,499)</u>	<u>(515,106)</u>	<u>4,065,368</u>
Other comprehensive (expense) income:	12					
<i>Items that may be reclassified subsequently to profit or loss:</i>						
Fair value change on bills receivables at fair value through other comprehensive income (“FVTOCI”), net of income tax		285	(174)	(52)	127	118
Exchange differences on translation from a foreign operation		(622)	208	(1,615)	(2,535)	15,472
Total other comprehensive (expense) income for the year/period		<u>(337)</u>	<u>34</u>	<u>(1,667)</u>	<u>(2,408)</u>	<u>15,590</u>
Total comprehensive (expense) income for the year/period attributable to owners of the Company		<u><u>(107,979)</u></u>	<u><u>(282,345)</u></u>	<u><u>(782,166)</u></u>	<u><u>(517,514)</u></u>	<u><u>4,080,958</u></u>
(Loss) earnings per share (in RMB)	15					
Basic and diluted		<u>(0.31)</u>	<u>(0.78)</u>	<u>(1.95)</u>	<u>(1.28)</u>	<u>10.14</u>

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	NOTES	The Group				The Company			
		As at December 31,			As at	As at December 31,			As at
		2021	2022	2023	September 30,	2021	2022	2023	September 30,
		RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
NON-CURRENT ASSETS									
Property, plant and equipment	16	391,288	408,984	529,805	526,265	722	546	365	1,916
Right-of-use assets	17	43,221	40,329	33,191	49,527	3,834	2,720	1,210	2,647
Investment properties	18	2,091	1,842	1,593	1,405	–	–	–	–
Intangible assets	19	2,796	2,271	1,602	1,617	348	222	124	54
Deferred tax assets	20	65,798	83,226	76,177	222,082	8,428	11,779	–	–
Investment in subsidiaries	45	–	–	–	–	210,070	210,070	1,094,468	1,094,468
Deposits for acquisition of property, plant and equipment		22,450	28,436	6,911	17,734	1	3	–	27
		527,644	565,088	649,279	818,630	223,403	225,340	1,096,167	1,099,112
CURRENT ASSETS									
Inventories	21	82,327	101,327	140,908	164,878	6,941	7,616	2,600	2,129
Right to returned goods assets	22	6,924	6,619	5,951	6,079	1,248	1,090	1,464	1,345
Trade and other receivables	23	173,508	293,077	205,016	282,943	47,291	69,788	43,379	60,259
Tax recoverable		–	–	268	–	–	–	–	–
Amounts due from subsidiaries	24	–	–	–	–	179,333	404,107	640,708	1,346,974
Bills receivables at FVTOCI	25	6,831	20,581	19,714	12,344	1,921	5,723	12,809	3,381
Term deposits	26	–	–	–	698,790	–	–	–	–
Restricted bank balances	26	–	4,046	12,270	25,800	–	3,682	4,770	4,750
Cash and cash equivalents	26	154,222	1,000,695	391,693	4,950,699	128,172	942,456	42,538	88,194
		423,812	1,426,345	775,820	6,141,533	364,906	1,434,462	748,268	1,507,032
CURRENT LIABILITIES									
Borrowings	27	161,250	185,603	449,489	906,565	36,067	110,257	298,391	745,714
Trade and other payables	28	273,506	460,386	549,516	575,397	31,778	79,904	49,947	111,037
Amount due to a related party	14	14	14	14	12	14	14	14	12
Amounts due to subsidiaries	29	–	–	–	–	8,751	15,942	30,856	41,605
Contract liabilities	30	10,783	17,416	8,672	350,375	4,738	7,034	4,659	4,256
Refund liabilities	22	15,813	14,053	11,193	10,228	2,850	2,314	2,754	2,276
Sale and leaseback payable	31	19,019	61,858	41,430	7,599	–	–	–	–
Lease liabilities	32	5,215	6,965	4,702	8,219	1,347	1,513	923	936
Tax payable		1,538	4,963	10	220,165	–	–	–	–
Deferred income	35	558	801	1,594	1,468	–	–	–	–
		487,696	752,059	1,066,620	2,080,028	85,545	216,978	387,544	905,836
NET CURRENT (LIABILITIES) ASSETS									
		(63,884)	674,286	(290,800)	4,061,505	279,361	1,217,484	360,724	601,196
TOTAL ASSETS LESS CURRENT LIABILITIES									
		463,760	1,239,374	358,479	4,880,135	502,764	1,442,824	1,456,891	1,700,308

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ACCOUNTANTS’ REPORT

	NOTES	The Group				The Company			
		As at December 31,			As at	As at December 31,			As at
		2021	2022	2023	September 30,	2021	2022	2023	September 30,
		RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
CAPITAL AND RESERVES									
Share capital	34	360,900	401,000	401,000	401,000	360,900	401,000	401,000	401,000
Reserves	34	(29,140)	532,894	(249,127)	3,831,205	89,684	920,941	885,971	845,826
Equity attributable to owners of the Company		331,760	933,894	151,873	4,232,205	450,584	1,321,941	1,286,971	1,246,826
Non-controlling interests		–	–	–	9,694	–	–	–	–
TOTAL EQUITY		331,760	933,894	151,873	4,241,899	450,584	1,321,941	1,286,971	1,246,826
NON-CURRENT LIABILITIES									
Borrowings	27	50,000	239,960	183,920	613,830	50,000	119,960	169,920	452,430
Deferred tax liabilities	20	89	85	–	–	–	–	–	–
Sale and leaseback payable	31	42,455	47,223	7,636	–	–	–	–	–
Lease liabilities	32	8,970	5,723	1,017	14,286	2,180	923	–	1,052
Deferred income	35	30,486	12,489	14,033	10,120	–	–	–	–
		132,000	305,480	206,606	638,236	52,180	120,883	169,920	453,482
		463,760	1,239,374	358,479	4,880,135	502,764	1,442,824	1,456,891	1,700,308

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Attributable to owners of the Company									
	Share capital RMB'000	Capital reserve RMB'000 (Note i)	FVTOCI reserve RMB'000	Translation reserve RMB'000	Statutory reserve RMB'000 (Note ii)	Share-based payments reserve RMB'000	(Accumulated loss)/retained profits RMB'000	Sub-total RMB'000	Non-controlling interests RMB'000	Total RMB'000
As at January 1, 2021	360,900	(512,305)	(371)	3,467	13,537	297	(40,792)	(175,267)	–	(175,267)
Loss for the year	–	–	–	–	–	–	(107,642)	(107,642)	–	(107,642)
Other comprehensive income (expense) for the year	–	–	285	(622)	–	–	–	(337)	–	(337)
Total comprehensive income (expense) for the year	–	–	285	(622)	–	–	(107,642)	(107,979)	–	(107,979)
Conversion of redeemable shares	–	634,904	–	–	–	–	–	634,904	–	634,904
Share-based payments (Note 41)	–	–	–	–	–	102	–	102	–	102
Dividends recognized as distribution (Note 13)	–	–	–	–	–	–	(20,000)	(20,000)	–	(20,000)
As at December 31, 2021	360,900	122,599	(86)	2,845	13,537	399	(168,434)	331,760	–	331,760
Loss for the year	–	–	–	–	–	–	(282,379)	(282,379)	–	(282,379)
Other comprehensive (expense) income for the year	–	–	(174)	208	–	–	–	34	–	34
Total comprehensive (expense) income for the year	–	–	(174)	208	–	–	(282,379)	(282,345)	–	(282,345)
Issue of A shares (Note 34)	40,100	844,297	–	–	–	–	–	884,397	–	884,397
Share-based payments (Note 41)	–	–	–	–	–	82	–	82	–	82
As at December 31, 2022	401,000	966,896	(260)	3,053	13,537	481	(450,813)	933,894	–	933,894
Loss for the year	–	–	–	–	–	–	(780,499)	(780,499)	–	(780,499)
Other comprehensive expense for the year	–	–	(52)	(1,615)	–	–	–	(1,667)	–	(1,667)
Total comprehensive expense for the year	–	–	(52)	(1,615)	–	–	(780,499)	(782,166)	–	(782,166)
Share-based payments (Note 41)	–	–	–	–	–	145	–	145	–	145
As at December 31, 2023	401,000	966,896	(312)	1,438	13,537	626	(1,231,312)	151,873	–	151,873
Profit for the period	–	–	–	–	–	–	4,065,368	4,065,368	–	4,065,368
Other comprehensive income for the period	–	–	118	15,472	–	–	–	15,590	–	15,590
Total comprehensive income for the period	–	–	118	15,472	–	–	4,065,368	4,080,958	–	4,080,958
Share-based payments (Note 41)	–	–	–	–	–	(626)	–	(626)	9,694	9,068
As at September 30, 2024	401,000	966,896	(194)	16,910	13,537	–	2,834,056	4,232,205	9,694	4,241,899

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	Attributable to owners of the Company									
	Share capital	Capital reserve	FVTOCI reserve	Translation reserve	Statutory reserve	Share-based payments reserve	(Accumulated loss)/retained profits	Sub-total	Non-controlling interests	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
		(Note i)			(Note ii)					
As at January 1, 2023	401,000	966,896	(260)	3,053	13,537	481	(450,813)	933,894	-	933,894
Loss for the period	-	-	-	-	-	-	(515,106)	(515,106)	-	(515,106)
Other comprehensive income (expense) for the period	-	-	127	(2,535)	-	-	-	(2,408)	-	(2,408)
Total comprehensive income (expense) for the period	-	-	127	(2,535)	-	-	(515,106)	(517,514)	-	(517,514)
Share-based payments (Note 41)	-	-	-	-	-	49	-	49	-	49
As at September 30, 2023 (unaudited)	401,000	966,896	(133)	518	13,537	530	(965,919)	416,429	-	416,429

Notes:

- (i) The capital reserve as at January 1, 2021 included the effect of group reorganization in prior years and the amounts arising from the initial recognition of the convertible redeemable shares issued by the Company to certain institutional shareholders before the Track Record Period. The convertible redeemable shares were accounted for as financial liabilities initially and subsequently measured at the present value of the future redemption amounts. On March 31, 2021, these redemption rights were terminated as a result of the mutual agreement reached between the shareholders. Upon such termination, the redeemable shares were converted into ordinary shares and the financial liabilities were derecognized with the corresponding amount credited against the capital reserve.
- (ii) According to the relevant laws in the People’s Republic of China (the “PRC”), companies established in the PRC with limited liability are required to transfer at least 10% of their net profit after taxation, as determined under the PRC accounting regulations, to a non-distributable reserve fund until the reserve balance reaches 50% of their respective registered capital. The transfer to this reserve must be made before the distribution of a dividend to owners. Such reserve fund can be used to offset the previous years’ losses, if any, and is non-distributable other than upon liquidation.

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,			Nine months ended	
	2021	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
				(unaudited)	
OPERATING ACTIVITIES					
(Loss) profit before tax	(112,087)	(289,074)	(769,013)	(533,696)	4,349,692
Adjustments for:					
Interest income on bank deposits	(475)	(767)	(5,703)	(4,373)	(130,176)
Loss on bills receivables at FVTOCI reclassified from equity upon derecognition	371	86	260	260	312
Gain on early termination of leases	–	(7)	(114)	(114)	–
Loss on disposal/written-off of property, plant and equipment	447	465	254	216	134
Impairment losses under ECL model, net of reversal	(2,998)	7,686	(6,442)	(6,224)	(1,477)
Allowance for inventories	5,669	4,964	12,979	9,628	11,895
Gain on fair value change of financial assets at fair value through profit or loss (“FVTPL”)	(3,140)	–	(4)	(4)	(30,675)
Depreciation of property, plant and equipment	48,273	56,075	57,178	43,379	50,596
Depreciation of investment properties	249	249	249	187	188
Depreciation of right-of-use assets	3,894	6,289	7,292	4,753	7,268
Amortization of intangible assets	1,804	2,113	2,314	1,497	1,375
Finance costs	16,343	22,481	24,679	18,492	27,798
Net foreign exchange loss	140	55	1,107	632	76,807
Share-based payments expenses	102	82	145	49	9,068
Release of assets-related government subsidies	(558)	(801)	(1,060)	(719)	(1,196)
Release of expense-related government subsidies	(5,419)	(17,970)	(1,600)	(1,600)	(2,843)
Operating cash flows before movements in working capital	(47,385)	(208,074)	(677,479)	(467,637)	4,368,766
Increase in inventories	(22,222)	(23,964)	(52,560)	(44,589)	(35,865)
Decrease (increase) in bills receivables at FVTOCI	21,615	(14,044)	590	11,478	7,168
Decrease (increase) in trade and other receivables	102,851	(89,110)	126,093	106,106	(52,992)
(Increase) decrease in right to returned goods asset	(2,850)	305	668	628	(128)
(Decrease) increase in trade and other payables	(153,818)	80,483	6,083	(36,521)	17,285
(Decrease) increase in refund liabilities	(4,331)	(1,760)	(2,860)	1	(965)
(Decrease) increase in deferred income	(1,924)	169	–	–	–
(Decrease) increase in contract liabilities	(7,313)	6,633	(8,744)	(9,439)	337,087
Cash (used in) generated from operations	(115,377)	(249,362)	(608,209)	(439,973)	4,640,356
Income tax paid	(22,073)	(7,278)	(9,778)	(8,680)	(209,798)
NET CASH (USED IN) FROM OPERATING ACTIVITIES	(137,450)	(256,640)	(617,987)	(448,653)	4,430,558

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ACCOUNTANTS’ REPORT

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(unaudited)	
INVESTING ACTIVITIES					
Assets-related government subsidies received	1,705	848	4,997	3,134	–
Interest on bank balances received	475	767	5,703	4,373	114,292
Purchase of property, plant and equipment and intangible assets	(44,603)	(34,556)	(81,939)	(51,383)	(38,466)
Proceeds from disposal of property, plant and equipment	88	10	60	17	97
Purchase of financial assets at FVTPL	(279,200)	–	(20,050)	(20,050)	(1,619,270)
Proceeds from disposal of financial assets at FVTPL	479,880	–	20,054	20,054	1,649,945
Placement of term deposits	–	–	–	–	(697,257)
Placement of restricted bank balances	–	(14,046)	(45,403)	(45,280)	(40,605)
Withdrawal from restricted bank balances	–	10,000	37,179	20,576	27,075
NET CASH FROM (USED IN) INVESTING ACTIVITIES	158,345	(36,977)	(79,399)	(68,559)	(604,189)
FINANCING ACTIVITIES					
Interest paid	(7,177)	(21,258)	(25,615)	(18,524)	(28,049)
New bank borrowings raised	242,000	375,000	447,700	117,700	1,128,930
Repayment of bank borrowings	(181,000)	(161,000)	(239,740)	(114,030)	(242,960)
Repayment of lease liabilities	(2,786)	(4,887)	(7,009)	(5,031)	(6,818)
Proceeds from issue of shares	–	907,472	–	–	–
Proceeds from sale and leaseback of equipment	60,000	93,000	–	–	–
Repayment of sale and leaseback of equipment	–	(46,303)	(59,193)	(53,959)	(40,200)
Transaction costs attributable to issue of shares	(2,161)	(2,191)	(25,140)	(23,658)	(16,219)
Dividends paid	(20,000)	–	–	–	–
NET CASH FROM (USED IN) FINANCING ACTIVITIES	88,876	1,139,833	91,003	(97,502)	794,684
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	109,771	846,216	(606,383)	(614,714)	4,621,053
CASH AND CASH EQUIVALENTS AT THE BEGINNING OF THE YEAR/PERIOD	45,212	154,222	1,000,695	1,000,695	391,693
Effect of foreign exchange rate changes	(761)	257	(2,619)	(624)	(62,047)
CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR/PERIOD	154,222	1,000,695	391,693	385,357	4,950,699
Represented by:					
Bank balances and cash	152,976	999,333	386,720	380,347	4,752,635
Certificates of deposit	1,246	1,362	4,973	5,010	198,064
	154,222	1,000,695	391,693	385,357	4,950,699

APPENDIX I

ACCOUNTANTS’ REPORT

NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. GENERAL AND BASIS OF PREPARATION

The Company was incorporated in the PRC in 2006 as a limited liability company under the Company Law of the PRC. On January 6, 2023, the Company’s shares were listed on Shanghai Stock Exchange (the “A Share Listing”). The Company’s ultimate controlling party is Dr. Zhu Yi (朱義), who is also the chairman and the chief executive of the Company. The respective addresses of the registered office and the principal place of business of the Company are set out in the section headed “Corporate Information” to the Document.

The Company and together with other group entities engage in the businesses of innovative drug research and development, and manufacture and sale of pharmaceutical products. The principal operations and geographic markets of the Company and its subsidiaries are primarily the PRC and in the United States of America (the “U.S.”).

The Historical Financial Information has been prepared based on the accounting policies which conform with IFRSs issued by the IASB. Further details of the material accounting policy information are set out in Note 3.

The Historical Financial Information is presented in RMB, which is the currency of the primary economic environment in which the Company operates.

2. APPLICATION OF IFRSs

For the purpose of preparing and presenting the Historical Financial Information for the Track Record Period, the Group has consistently applied the accounting policies which conform with IFRSs, which are effective for the accounting period beginning on January 1, 2024, throughout the Track Record Period.

New and amendments to IFRSs in issue but not yet effective

At the date of this report, the Group has not early adopted the following new and amendments to IFRSs that have been issued but are not yet effective:

Amendments to IFRS 9 and IFRS 7	Amendments to the Classification and Measurement of Financial Instruments ³
Amendments to IFRS 9 and IFRS 7	Contracts Referencing Nature-dependent Electricity ³
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture ¹
Amendments to IFRS Accounting Standards	Annual Improvements to IFRS Accounting Standards- Volume 11 ³
Amendments to IAS 21	Lack of Exchangeability ²
IFRS 18	Presentation and Disclosure in Financial Statements ⁴

¹ Effective for annual periods beginning on or after a date to be determined

² Effective for annual periods beginning on or after January 1, 2025

³ Effective for annual periods beginning on or after January 1, 2026

⁴ Effective for annual periods beginning on or after January 1, 2027

IFRS 18 sets out requirements on presentation and disclosures in financial statements and it will replace IAS 1 “Presentation of Financial Statements”. The new IFRS 18 introduces new requirements to present specified categories and defined subtotals in the statement of profit or loss and other comprehensive income; provide disclosures on management-defined performance measures in the notes to the financial statements and improve aggregation and disaggregation of information to be disclosed in the financial statements. Minor amendments to IAS 7 “Statement of Cash Flows” and IAS 33 “Earnings per Share” are also made.

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IFRS 18 will be effective for annual periods beginning on or after January 1, 2027, with early application permitted. The application of the new standard is not expected to have material impact on the financial position of the Group but is expected to affect the presentation of the statement of profit or loss and other comprehensive income and statement of cash flows and disclosures in the future financial statements. The Group will continue to assess the impact of IFRS 18 on the Group’s consolidated financial statements.

Except as described above, the directors of the Company consider that the application of all the amendments to IFRSs is unlikely to have a material impact on the Group’s financial position and performance in foreseeable future.

3. MATERIAL ACCOUNTING POLICY INFORMATION

The Historical Financial Information have been prepared in accordance with IFRSs issued by the IASB. For the purpose of preparation of the Historical Financial Information, information is considered material if such information is reasonably expected to influence decisions made by primary users. In addition, the Historical Financial Information include applicable disclosures required by the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (“Listing Rules”) and by the Hong Kong Companies Ordinance.

The Historical Financial Information have been prepared on the historical cost basis except for certain financial instruments that are measured at fair values at the end of each reporting period, as explained in the accounting policies set out below.

Revenue from contracts with customers

Information about the Group’s accounting policies relating to contracts with customers is provided in Notes 5, 22 and 30.

Leases

The Group assesses whether a contract is or contains a lease based on the definition under IFRS 16 at inception of the contract. Such contract will not be reassessed unless the terms and conditions of the contract are subsequently changed.

The Group as a lessee

Short-term leases

The Group applies the short-term lease recognition exemption to leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option.

Right-of-use assets

The cost of right-of-use assets includes:

- the amount of the initial measurement of the lease liability;
- any lease payments made at or before the commencement date; and
- any initial direct costs incurred by the Group.

Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities.

Right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term.

The Group presents right-of-use assets as a separate line item on the consolidated statements of financial position.

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ACCOUNTANTS’ REPORT

Lease liabilities

At the commencement date of a lease, the Group recognizes and measures the lease liability at the present value of lease payments that are unpaid at that date. In calculating the present value of lease payments, the Group uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable.

The lease payments include fixed payments.

After the commencement date, lease liabilities are adjusted by interest accretion and lease payments.

The Group presents lease liabilities as a separate line item on the consolidated statements of financial position.

Lease modifications

The Group accounts for a lease modification as a separate lease if:

- the modification increases the scope of the lease by adding the right to use one or more underlying assets; and
- the consideration for the leases increases by an amount commensurate with the stand-alone price for the increase in scope and any appropriate adjustments to that stand-alone price to reflect the circumstances of the particular contract.

For a lease modification that is not accounted for as a separate lease, the Group remeasures the lease liability based on the lease term of the modified lease by discounting the revised lease payments using a revised discount rate at the effective date of the modification.

The Group accounts for the remeasurement of lease liabilities by making corresponding adjustments to the relevant right-of-use assets.

The Group as a lessor

Classification and measurement of leases

Leases for which the Group is a lessor are classified as finance or operating leases. Whenever the terms of the lease transfer substantially all the risks and rewards incidental to ownership of an underlying asset to the lessee, the contract is classified as a finance lease. All other leases are classified as operating leases.

Rental income from operating leases is recognized in profit or loss on a straight-line basis over the term of the relevant lease.

Sale and leaseback transactions

The Group applies the requirements of IFRS 15 “Revenue from Contracts with Customers” to assess whether sale and leaseback transaction constitutes a sale by the Group.

The Group as a seller-lessee

For a transfer that does not satisfy the requirements as a sale, the Group as a seller-lessee continues to recognize the assets and accounts for the transfer proceeds as sale and leaseback payable within the scope of IFRS 9 “Financial Instruments”.

Foreign currencies

In preparing the financial statements of each individual group entity, transactions in currencies other than the functional currency of that entity (foreign currencies) are recognized at the rates of exchanges prevailing on the dates of the transactions. At the end of each reporting period, monetary items denominated in foreign currencies are retranslated at the rates prevailing at that date. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated.

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Exchange differences arising on the settlement of monetary items, and on the retranslation of monetary items, are recognized in profit or loss in the period in which they arise.

For the purposes of presenting the Historical Financial Information, the assets and liabilities of the Group’s operations are translated into the presentation currency of the Group (RMB) using exchange rates prevailing at the end of each reporting period. Income and expenses items are translated at the average exchange rates for the period, unless exchange rates fluctuate significantly during that period, in which case the exchange rates at the date of transactions are used. Exchange differences arising, if any, are recognized in other comprehensive income and accumulated in equity.

Borrowing costs

Borrowing costs are recognized in profit or loss in the period in which they are incurred.

Government grants

Government grants are not recognized until there is reasonable assurance that the Group will comply with the conditions attaching to them and that the grants will be received.

Government grants are recognized in profit or loss on a systematic basis over the periods in which the Group recognizes as expenses the related costs for which the grants are intended to compensate. Specifically, government grants whose primary condition is that the Group should purchase, construct or otherwise acquire non-current assets are recognized as deferred income in the consolidated statements of financial position and transferred to profit or loss on a systematic basis over the useful lives of the related assets.

Government grants related to income that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future related costs are recognized in profit or loss in the period in which they become receivable. Such grants are presented under “other income”.

Employee benefits

Retirement benefit costs

The Group participates in government-managed retirement benefit schemes, which are defined contribution schemes, pursuant to which the Group pays a fixed percentage of its staff’s wages as contributions to the plans. Payments to defined contribution retirement benefit plans are recognized as an expense when employees have rendered service entitling them to the contributions.

Short-term employee benefits

Short-term employee benefits are recognized at the undiscounted amount of the benefits expected to be paid as and when employees rendered the services. All short-term employee benefits are recognized as an expense unless another IFRS requires or permits the inclusion of the benefit in the cost of an asset.

A liability is recognized for benefits accruing to employees (such as wages and salaries) after deducting any amount already paid.

Share-based payments

Equity-settled share-based payment transactions

Share options granted to employees

Equity-settled share-based payments to employees and others providing similar services are measured at the fair value of the equity instruments at the grant date.

The fair value of the equity-settled share-based payments determined at the grant date without taking into consideration all non-marketing vesting conditions is expensed on a straight-line basis over the vesting period, based on the Group’s estimate of equity instruments that will eventually vest, with a corresponding increase in equity included in share-based payments reserve. At the end of each reporting period, the Group revises its estimate of the number of equity instruments expected to vest based on assessment of all relevant non-market vesting conditions. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the share-based payments reserve.

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Taxation

Income tax expense represents the sum of the tax currently payable and deferred tax.

The tax currently payable is based on taxable profit for the year/period. Taxable profit differs from (loss) profit before taxation because of income or expense that are taxable or deductible in other years and items that are never taxable or deductible. The Group’s liability for current tax is calculated using tax rates that have been enacted or substantively enacted by the end of each reporting period.

Deferred tax is recognized on temporary differences between the carrying amounts of assets and liabilities in the Historical Financial Information and the corresponding tax bases used in the computation of taxable profit. Deferred tax liabilities are generally recognized for all taxable temporary differences. Deferred tax assets are generally recognized for all deductible temporary differences to the extent that it is probable that taxable profits will be available against which those deductible temporary differences can be utilized. Such deferred tax assets and liabilities are not recognized if the temporary difference arises from the initial recognition (other than in a business combination) of assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit and at the time of the transaction does not give rise to equal taxable and deductible temporary differences.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the period in which the liability is settled or the asset is realized, based on tax rate (and tax laws) that have been enacted or substantively enacted by the end of each reporting period.

The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the Group expects, at the end of each reporting period, to recover or settle the carrying amount of its assets and liabilities.

For leasing transactions in which the tax deductions are attributable to the lease liabilities, the Group applies IAS 12 “Income Taxes” requirements to recognize a deferred tax asset (to the extent that it is probable that taxable profit will be available against which the deductible temporary difference can be utilized) and a deferred tax liability for all taxable temporary differences.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to set off current tax assets against current tax liabilities and when they relate to income taxes to the same taxable entity levied by the same taxation authority.

Current and deferred tax are recognized in profit or loss, except when they relate to items that are recognized in other comprehensive income or directly in equity, in which case, the current and deferred tax are also recognized in other comprehensive income or directly in equity respectively.

Investment in subsidiaries

Investment in subsidiaries are stated at cost less accumulated impairment losses, if any.

Property, plant and equipment

Property, plant and equipment are tangible assets that are held for use in the production or supply of goods or services, or for administrative purposes other than construction in progress as described below. Property, plant and equipment are stated in the consolidated statements of financial position at cost less subsequent accumulated depreciation and subsequent accumulated impairment losses, if any.

Properties in the course of construction for production, supply or administrative purposes are carried at cost, less any recognized impairment loss. Costs include any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Depreciation of these assets, on the same basis as other property assets, commences when the assets are ready for their intended use.

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Depreciation is recognized so as to write off the cost of assets other than construction in progress less their residual values over their estimated useful lives, using the straight-line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each reporting period, with the effect of any changes in estimate accounted for on a prospective basis.

An item of property, plant and equipment is derecognized upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property, plant and equipment is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognized in profit or loss.

Intangible assets

Intangible assets acquired separately

Intangible assets with finite useful lives that are acquired separately are carried at costs less accumulated amortization and any accumulated impairment losses. Amortization for intangible assets with finite useful lives is recognized on a straight-line basis over their estimated useful lives. The estimated useful life and amortization method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis.

Internally-generated intangible assets – research and development expenditure

Expenditure on research activities is recognized as an expense in the period in which it is incurred.

An internally-generated intangible asset arising from development activities is recognized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. Where no internally-generated intangible asset can be recognized, development expenditure is recognized in profit or loss in the period in which it is incurred.

Subsequent to initial recognition, internally-generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses (if any), on the same basis as intangible assets that are acquired separately.

Impairment on property, plant and equipment, right-of-use assets, investment properties and intangible assets

At the end of each reporting period, the Group reviews the carrying amounts of its property, plant and equipment, right-of-use assets, investment properties and intangible assets with finite useful lives to determine whether there is any indication that these assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the relevant asset is estimated in order to determine the extent of the impairment loss (if any).

The recoverable amount of property, plant and equipment, right-of-use assets, investment properties and intangible assets are estimated individually. When it is not possible to estimate the recoverable amount individually, the Group estimates the recoverable amount of the cash-generating unit to which the asset belongs.

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In testing a cash-generating unit for impairment, corporate assets are allocated to the relevant cash-generating unit when a reasonable and consistent basis of allocation can be established, or otherwise they are allocated to the smallest group of cash-generating units for which a reasonable and consistent allocation basis can be established. The recoverable amount is determined for the cash-generating unit or group of cash-generating units to which the corporate asset belongs, and is compared with the carrying amount of the relevant cash-generating unit or group of cash-generating units.

Recoverable amount is the higher of fair value less costs of disposal and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset (or a cash-generating unit) for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or a cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or a cash-generating unit) is reduced to its recoverable amount. For corporate assets or portion of corporate assets which cannot be allocated on a reasonable and consistent basis to a cash-generating unit, the Group compares the carrying amount of a group of cash-generating units, including the carrying amounts of the corporate assets or portion of corporate assets allocated to that group of cash-generating units, with the recoverable amount of the group of cash-generating units. In allocating the impairment loss, the impairment loss is allocated first to reduce the carrying amount of any goodwill (if applicable) and then to the other assets on a pro-rata basis based on the carrying amount of each asset in the unit or the group of cash-generating units. The carrying amount of an asset is not reduced below the highest of its fair value less costs of disposal (if measurable), its value in use (if determinable) and zero. The amount of the impairment loss that would otherwise have been allocated to the asset is allocated pro rata to the other assets of the unit or the group of cash-generating units. An impairment loss is recognized immediately in profit or loss.

Where an impairment loss subsequently reverses, the carrying amount of the asset (or cash-generating unit or a group of cash-generating units) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset (or a cash-generating unit or a group of cash-generating units) in prior years. A reversal of an impairment loss is recognized immediately in profit or loss.

Cash and cash equivalents

Cash and cash equivalents presented on the consolidated statements of financial position include:

- (a) cash, which comprises of cash on hand and demand deposits; and
- (b) cash equivalents, which comprises of short-term (generally with original maturity of three months or less), highly liquid investments that are readily convertible to a known amount of cash and which are subject to an insignificant risk of changes in value. Cash equivalents are held for the purpose of meeting short-term cash commitments rather than for investment or other purposes.

For the purposes of the consolidated statement of cash flows, cash and cash equivalents consist of cash and cash equivalents as defined above.

Inventories

Inventories are stated at the lower of cost and net realizable value. Costs of inventories are determined on weighted average method. Net realizable value represents the estimated selling price for inventories less all estimated costs of completion and costs necessary to make the sale. Costs necessary to make the sale include incremental costs directly attributable to the sale and non-incremental costs which the Group must incur to make the sale.

Financial instruments

Financial assets and financial liabilities are recognized when a group entity becomes a party to the contractual provisions of the instrument. All regular way purchases or sales of financial assets are recognized and derecognized on a settlement date basis. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the time frame established by regulation or convention in the market place.

Financial assets and financial liabilities are initially measured at fair value except for trade receivables arising from contracts with customers which are initially measured in accordance with IFRS 15. Transaction costs that are directly attributable to the acquisition or issue of financial assets and financial liabilities are added to or deducted from the fair value of the financial assets or financial liabilities, as appropriate, on initial recognition.

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The effective interest method is a method of calculating the amortized cost of a financial asset or financial liability and of allocating interest income and interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash receipts and payments (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the financial asset or financial liability, or, where appropriate, a shorter period, to the net carrying amount on initial recognition.

Financial assets

Classification and subsequent measurement of financial assets

Financial assets that meet the following conditions are subsequently measured at amortized cost:

- the financial asset is held within a business model whose objective is to collect contractual cash flows; and
- the contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Debt instruments that meet the following conditions are subsequently measured at FVTOCI:

- the financial asset is held within a business model whose objective is achieved by both selling and collecting contractual cash flows; and
- the contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

All other financial assets are subsequently measured at FVTPL.

(i) Amortized cost and interest income

Interest income is recognized using the effective interest method for financial assets measured subsequently at amortized cost and bills receivables subsequently measured at FVTOCI. Interest income is calculated by applying the effective interest rate to the gross carrying amount of a financial asset, except for financial assets that have subsequently become credit-impaired (see below). For financial assets that have subsequently become credit-impaired, interest income is recognized by applying the effective interest rate to the amortized cost of the financial asset from the next reporting period. If the credit risk on the credit-impaired financial instrument improves so that the financial asset is no longer credit-impaired, interest income is recognized by applying the effective interest rate to the gross carrying amount of the financial asset from the beginning of the reporting period following the determination that the asset is no longer credit-impaired.

(ii) Bills receivables classified as at FVTOCI

Subsequent changes in the carrying amounts for bills receivables classified as at FVTOCI as a result of interest income calculated using the effective interest method, and foreign exchange gains and losses are recognized in profit or loss. All other changes in the carrying amount of these bills receivables are recognized in other comprehensive income and accumulated under the heading of FVTOCI reserve. Impairment allowances are recognized in profit or loss with corresponding adjustment to other comprehensive income without reducing the carrying amounts of these bills receivables. When these bills receivables are derecognized, the cumulative gains or losses previously recognized in other comprehensive income are reclassified to profit or loss.

(iii) Financial assets at FVTPL

Financial assets at FVTPL are measured at fair value at the end of each reporting period, with any fair value gains or losses recognized in profit or loss. The net gain or loss recognized in profit or loss includes any dividend or interest earned on the financial asset and is included in the “other gains and losses, net” line item.

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Impairment of financial assets subject to impairment assessment under IFRS 9

The Group performs impairment assessment under ECL model on financial assets (including trade and other receivables, amounts due from subsidiaries, term deposits, restricted bank balances, bank balances, certificates of deposit and bills receivables at FVTOCI) which are subject to impairment assessment under IFRS 9. The amount of ECL is updated at each reporting date to reflect changes in credit risk since initial recognition.

Lifetime ECL represents the ECL that will result from all possible default events over the expected life of the relevant instrument. In contrast, 12-month ECL (“12m ECL”) represents the portion of lifetime ECL that is expected to result from default events that are possible within 12 months after the reporting date. Assessments are done based on the Group’s historical credit loss experience, and factors that are specific to the debtors, general economic conditions and an assessment of both the current conditions at the reporting date as well as the forecast of future conditions.

The Group always recognizes lifetime ECL for trade receivables.

For all other instruments, the Group measures the loss allowance equal to 12m ECL, unless there has been a significant increase in credit risk since initial recognition, in which case the Group recognizes lifetime ECL. The assessment of whether lifetime ECL should be recognized is based on significant increases in the likelihood or risk of a default occurring since initial recognition.

(i) Significant increase in credit risk

In assessing whether the credit risk has increased significantly since initial recognition, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition. In making this assessment, the Group considers both quantitative and qualitative information that is reasonable and supportable, including historical experience and forward-looking information that is available without undue cost or effort.

In particular, the following information is taken into account when assessing whether credit risk has increased significantly:

- existing or forecast adverse changes in business, financial or economic conditions that are expected to cause a significant decrease in the debtor’s ability to meet its debt obligations;
- an actual or expected significant deterioration in the operating results of the debtor;
- an actual or expected significant adverse change in the regulatory, economic, or technological environment of the debtor that results in a significant decrease in the debtor’s ability to meet its debt obligations.

Irrespective of the outcome of the above assessment, the Group presumes that the credit risk has increased significantly since initial recognition when contractual payments are more than 30 days past due, unless the Group has reasonable and supportable information that demonstrates otherwise.

Despite the foregoing, the Group assumes that the credit risk on a bill receivable has not increased significantly since initial recognition if the bill receivable is determined to have low credit risk at the reporting date. A bill receivable is determined to have low credit risk if i) it has a low risk of default, ii) the borrower has a strong capacity to meet its contractual cash flow obligations in the near term and iii) adverse changes in economic and business conditions in the longer term may, but will not necessarily, reduce the ability of the borrower to fulfil its contractual cash flow obligations. The Group considers a bill receivable to have low credit risk when it has an internal or external credit rating of “investment grade” as per globally understood definitions.

The Group regularly monitors the effectiveness of the criteria used to identify whether there has been a significant increase in credit risk and revises them as appropriate to ensure that the criteria are capable of identifying significant increase in credit risk before the amount becomes past due.

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(ii) Definition of default

For internal credit risk management, the Group considers an event of default occurs when information developed internally or obtained from external sources indicates that the debtor is unlikely to pay its creditors, including the Group, in full (without taking into account any collaterals held by the Group).

(iii) Credit-impaired financial assets

A financial asset is credit-impaired when one or more events that have a detrimental impact on the estimated future cash flows of that financial asset have occurred. Evidence that a financial asset is credit-impaired includes observable data about the following events:

- (a) significant financial difficulty of the issuer or the borrower;
- (b) a breach of contract, such as a default or past due event;
- (c) the lender(s) of the borrower, for economic or contractual reasons relating to the borrower’s financial difficulty, having granted to the borrower a concession(s) that the lender(s) would not otherwise consider; or
- (d) it is becoming probable that the borrower will enter bankruptcy or other financial reorganization.

(iv) Write-off policy

The Group writes off a financial asset when there is information indicating that the counterparty is in severe financial difficulty and there is no realistic prospect of recovery, for example, when the counterparty has been placed under liquidation or has entered into bankruptcy proceedings. Financial assets written off may still be subject to enforcement activities under the Group’s recovery procedures, taking into account legal advice where appropriate. A write-off constitutes a derecognition event. Any subsequent recoveries are recognized in profit or loss.

(v) Measurement and recognition of ECL

The measurement of ECL is a function of the probability of default, loss given default (i.e. the magnitude of the loss if there is a default) and the exposure at default. The assessment of the probability of default and loss given default is based on historical data and forward-looking information. Estimation of ECL reflects an unbiased and probability-weighted amount that is determined with the respective risks of default occurring as the weights.

Generally, the ECL is the difference between all contractual cash flows that are due to the Group in accordance with the contract and the cash flows that the Group expects to receive, discounted at the effective interest rate determined at initial recognition.

Lifetime ECL for not credit-impaired trade receivables are assessed on a collective basis, taking into consideration past due information and relevant credit information such as forward looking macroeconomic information.

For collective assessment, the Group takes into consideration the following characteristics when formulating the grouping:

- Past-due status;
- Repayment history; and
- Nature, size and industry of debtor.

The grouping is regularly reviewed by management to ensure the constituents of each group continue to share similar credit risk characteristics.

Interest income is calculated based on the gross carrying amount of the financial asset unless the financial asset is credit-impaired, in which case interest income is calculated based on amortized cost of the financial asset.

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Except for investments in bills receivables that are measured at FVTOCI, the Group recognizes an impairment gain or loss in profit or loss for all financial instruments by adjusting their carrying amount, with the exception of trade receivables, bills receivables and other receivables where the corresponding adjustment is recognized through a loss allowance account. For bills receivables classified as at FVTOCI, the loss allowance is recognized in other comprehensive income and accumulated in the FVTOCI reserve without reducing the carrying amount of these bills receivables. Such amount represents the changes in the FVTOCI reserve in relation to accumulated loss allowance.

Derecognition of financial assets

The Group derecognizes a financial asset only when the contractual rights to the cash flows from the asset expire, or when it transfers the financial asset and substantially all the risks and rewards of ownership of the asset to another entity. If the Group neither transfers nor retains substantially all the risks and rewards of ownership and continues to control the transferred asset, the Group recognizes its retained interest in the asset and an associated liability for amounts it may have to pay. If the Group retains substantially all the risks and rewards of ownership of a transferred financial asset, the Group continues to recognize the financial asset and also recognizes a collateralized borrowing for the proceeds received.

On derecognition of a financial asset measured at amortized cost, the difference between the asset’s carrying amount and the sum of the consideration received and receivable is recognized in profit or loss.

On derecognition of an investment in a bill receivable at FVTOCI, the cumulative gain or loss previously accumulated in the FVTOCI reserve is reclassified to profit or loss.

Financial liabilities and equity

Classification as debt or equity

Debt and equity instruments issued by a group entity are classified as either financial liabilities or as equity instruments in accordance with the substance of the contractual arrangements and the definitions of a financial liability and an equity instrument.

Equity instruments

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the Company are recognized at the proceeds received, net of direct issue costs.

Financial liabilities at amortized cost

All financial liabilities including borrowings, sale and leaseback payable, trade and other payables, amounts due to subsidiaries and amount due to a related party are subsequently measured at amortized cost using the effective interest method.

Derecognition of financial liabilities

The Group derecognizes financial liabilities when, and only when, the Group’s obligations are discharged, cancelled or have expired. The difference between the carrying amount of the financial liability derecognized and the consideration paid and payable is recognized in profit or loss.

4. KEY SOURCES OF ESTIMATION UNCERTAINTY

In the application of the Group’s accounting policies, the directors of the Company are required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

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The following are the key sources of estimation uncertainty at the end of each reporting period that may have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next twelve months.

Key sources of estimation uncertainties

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 several 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.

The information about the Group’s deferred tax assets is disclosed in Note 20.

Estimated impairment of trade receivables

Trade receivables which considered credit-impaired are assessed on individual basis. In addition, the Group uses collective assessment to calculate ECL for trade receivables balances which are not assessed individually at the end of each reporting period. The ECL rates are based on internal credit ratings as groupings of various debtors that have similar loss patterns. The collective assessment is based on the Group’s historical default rates taking into consideration forward-looking information that is reasonable and supportable available without undue costs or effort.

At every reporting date, the historical observed default rates are reassessed and changes in the forward-looking information are considered.

The provision of ECL is sensitive to changes in estimates. The information about the Group’s trade receivables and the related ECL disclosures are disclosed in Notes 23 and 42, respectively.

5. REVENUE AND SEGMENT INFORMATION

Revenue

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
	(unaudited)				
Type of goods or service					
Sale of pharmaceutical products:					
– Distributors	788,031	697,712	554,687	371,489	325,030
– Direct sales to retail pharmacies	6,924	4,121	5,729	5,110	1,906
Others	–	–	–	–	2,567
	<u>794,955</u>	<u>701,833</u>	<u>560,416</u>	<u>376,599</u>	<u>329,503</u>
License fee income	–	–	–	–	5,331,724
Total	<u>794,955</u>	<u>701,833</u>	<u>560,416</u>	<u>376,599</u>	<u>5,661,227</u>
Timing of revenue recognition					
At point in time	<u>794,555</u>	<u>701,833</u>	<u>560,416</u>	<u>376,599</u>	<u>5,661,227</u>

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Performance obligations for contracts with customers and revenue recognition policies

Sale of pharmaceutical products

Revenue from the sale of pharmaceutical products is recognized at point in time when control of the goods has transferred, being when the goods have been shipped to the specific location and accepted, the customers have the primary responsibility for the risks of obsolescence and loss in relation to the goods while it can request return or refund only if the goods delivered do not meet the required quality standards.

At the point of sale, a corresponding adjustment to revenue is made for those products expected to be returned. The Group estimates the future sales return of the products sold based on the historical experience. A refund liability is recognized for sales in which revenue has yet to be recognized. Right to returned goods asset (and corresponding adjustment to cost of sales) is recognized for right to recover products from customers on settling the refund liability.

The credit period granted to customers by the Group is determined based on the characteristics of customers’ credit risk and there is no significant financing component. For customers with long-term relationships, the normal credit term granted ranges from 30 to 120 days upon delivery.

A contract liability represents the Group’s obligation to transfer goods or services to a customer for which the Group has received consideration (or an amount of consideration is due) from the customer. All the contracts that are unsatisfied are for periods of one year or less. As the Group applies the practical expedient in IFRS 15, the transaction price allocated to these unsatisfied contracts is not disclosed.

Under the standard contract terms, customers have a right to receive rebates. The Group uses its accumulated historical experience to estimate the amount of consideration to which it will be entitled using the most likely amount.

License fee income

In December 2023, the Group entered into an agreement with an independent third party pursuant to which the Group granted to the counterparty, amongst others, primarily an exclusive right of development and further commercialization of BL-B01D1 in the rest of the world except in the PRC and the U.S.. In addition, the Group entered into collaboration arrangement with the counterparty for the development and commercialization activities of BL-B01D1 in the U.S. on which the contributions/rewards in relation to the activities are determined based on a fixed percentage of costs/profits to be incurred/generated in the future. In the opinion of the management, the collaboration arrangement constitutes a joint arrangement on which the Group shares the risks and benefits associated with such activities in the U.S..

BL-B01D1, internally discovered and developed, is the bispecific antibody-drug conjugates intended for the treatment of various solid tumors. The consideration for the agreement comprises a fixed element (a non-refundable and non-creditable upfront payment of US Dollar (“USD”) 800,000,000 (equivalent to approximately RMB5,679,703,000) (the “Upfront Payment”), several variable elements (i.e. further payments according to timing in achievements of various clinical trial milestones, regulatory milestones, sales milestones and sales-based royalties).

The Group determined that the consideration for the Upfront Payment relates to two performance obligations: (1) the grant of license and (2) the transfer of manufacturing technology relating to the process for the manufacture of BL-B01D1 and its related products. The Group allocates the total transaction price of the Upfront Payment into two performance obligations based on estimation of the standalone selling price for the transfer of manufacturing technology, which a customer in the market would be willing to pay, and then applying residual approach in the estimation of standalone selling price for the grant of license.

The revenue for grant of license, which represents a right to use the Group’s intellectual property, is recognized at a point in time at which the license transfers. During the nine months ended September 30, 2024, the transfer of license to the customer was completed and the Group recognized revenue of USD751,000,000 (equivalent to approximately RMB5,331,724,000) in relation to the grant of license. The remaining transaction price of USD49,000,000 (equivalent to approximately RMB347,979,000) is allocated to the performance obligation of transferring manufacturing technology, which is recorded in contract liability and the timing of transfer is at the discretion of the customer.

The above arrangement is set out in “BL-B01D1 (EGFR × HER3 bispecific ADC)” under the section “BUSINESS” of the Document.

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Segment information

For the purposes of resources allocation and performance assessment, Dr. Zhu Yi, the chairman and the chief executive of the Company, being the chief operating decision maker, reviews the consolidated results and financial position when making decisions about allocating resources and assessing performance of the Group as a whole and hence, the Group has only one reportable segment and no further analysis of this single segment is presented.

Entity-wide disclosures

Geographical information

An analysis of the Group’s revenue from external customers, analyzed by their respective country/region of domicile, is detailed below:

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
				(unaudited)	
Revenue					
– PRC	794,955	701,833	560,416	376,599	326,936
– U.S.	–	–	–	–	5,334,291
Total	<u>794,955</u>	<u>701,833</u>	<u>560,416</u>	<u>376,599</u>	<u>5,661,227</u>

Information about the Group’s non-current assets by geographical location of the assets is presented below:

	As at December 31,			As at September 30,
	2021	2022	2023	2024
	RMB’000	RMB’000	RMB’000	RMB’000
Non-current assets (Note)				
– PRC	443,878	470,198	562,321	572,724
– U.S.	17,968	11,664	10,781	23,824
Total	<u>461,846</u>	<u>481,862</u>	<u>573,102</u>	<u>596,548</u>

Note: Non-current assets excluding deferred tax assets.

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Information about major customers

Revenue from customers contributing over 10% of total revenue of the Group for each reporting period is as below:

	Type of revenue	Year ended December 31,			Nine months ended September 30,	
		2021	2022	2023	2023	2024
		RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
					(unaudited)	
Customer A (Note)	Sale of pharmaceutical products	150,156	110,106	83,550	59,464	#
Customer B	License fee income	–	–	–	–	5,331,724
		<u>150,156</u>	<u>110,106</u>	<u>83,550</u>	<u>59,464</u>	<u>5,331,724</u>

Note: Customer A is a group of companies under the common control of the same holding company.

Less than 10% of total revenue of the Group for the nine months ended September 30, 2024.

6. OTHER INCOME

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
				(unaudited)	
Interest income on bank deposits	475	767	5,703	4,373	130,176
Rental and rental-related income	1,601	1,403	1,429	1,083	1,333
Government grants (Note)	61,935	49,441	49,329	35,027	27,713
Release of expense-related government subsidies (Note 35)	5,419	17,970	1,600	1,600	2,843
Release of assets-related government subsidies (Note 35)	558	801	1,060	719	1,196
Others	323	107	128	104	558
Total	<u>70,311</u>	<u>70,489</u>	<u>59,249</u>	<u>42,906</u>	<u>163,819</u>

Note: The government grants recognized mainly represent subsidies granted by the PRC local authorities to support the operation activities of the Group, in which no future related cost is expected to be incurred. The government grants with no unfulfilled conditions are recognized when payments were received or became receivable.

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7. OTHER GAINS AND LOSSES, NET

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(unaudited)	
Loss on disposal/written-off of property, plant and equipment	(447)	(465)	(254)	(216)	(134)
Gain on fair value change of financial assets at FVTPL	3,140	–	4	4	30,675
Net foreign exchange loss	(140)	(55)	(1,107)	(632)	(76,807)
Others	(119)	(43)	109	111	(30)
Total	2,434	(563)	(1,248)	(733)	(46,296)

8. IMPAIRMENT LOSSES UNDER ECL MODEL, NET OF REVERSAL

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(unaudited)	
Impairment losses (reversed)/recognized on:					
– bills receivables	(676)	(216)	47	(319)	(424)
– trade receivables	(2,371)	7,585	(6,646)	(6,035)	(1,377)
– other receivables	49	317	157	130	324
Total	(2,998)	7,686	(6,442)	(6,224)	(1,477)

Details of impairment assessment are set out in Note 42.

9. FINANCE COSTS

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(unaudited)	
Interest expense on:					
– bank borrowings	6,806	12,494	18,500	13,645	26,154
– sale and leaseback payable	1,474	9,390	5,733	4,429	1,222
– lease liabilities	412	597	446	418	422
– redeemable shares	7,651	–	–	–	–
Total	16,343	22,481	24,679	18,492	27,798

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10. INCOME TAX (CREDIT) EXPENSE

	Year ended December 31,			Nine months ended	
	2021	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
				(unaudited)	
PRC Enterprise Income Tax (“EIT”)					
– current tax	11,306	7,380	854	3,581	171,010
– under-provision in prior years/periods	1,992	3,323	3,703	681	51
U.S. EIT	–	–	–	–	259,160
Deferred tax (<i>Note 20</i>)	(17,743)	(17,398)	6,929	(22,852)	(145,897)
	<u>(4,445)</u>	<u>(6,695)</u>	<u>11,486</u>	<u>(18,590)</u>	<u>284,324</u>

Under the Law of the PRC on Enterprise Income Tax (the “EIT Law”) and Implementation Regulation of the EIT Law, the tax rate of the Company and the group entities established in the PRC (other than those as described below) is 25% for the Track Record Period.

The subsidiary of the Company, namely 拉薩新博藥業有限責任公司 (Lhasa Xinbo Pharmaceutical Co., Ltd.*) (“Lhasa Xinbo”) that is engaged in the “Encouraged Industries in the Western Region” is eligible for the preferential EIT rate at 15% for the Track Record Period.

On November 11, 2019, the “Certificate of New Hi-tech Enterprise” was granted to a subsidiary of the Company, namely 四川百利藥業有限責任公司 (Sichuan Baili Pharmaceutical Co., Ltd.*) (“Baili Pharmaceutical”), which was expired in 2021 and renewed on December 12, 2023 with a valid period of three years. Hence, Baili Pharmaceutical is eligible for the preferential EIT rate of 15% for the years ended December 31, 2021 and 2023 and the nine months ended September 30, 2024. For the year ended December 31, 2022, Baili Pharmaceutical was engaged in the “Encouraged Industries in the Western Region” and was eligible for the preferential EIT rate at 15%.

On December 3, 2020, the “Certificate of New Hi-tech Enterprise” was granted to a subsidiary of the Company, namely 四川國瑞藥業有限責任公司 (Sichuan Guorui Pharmaceutical Co., Ltd.*) (“Guorui Pharmaceutical”), and was renewed on December 12, 2023 with a valid period of three years. Guorui Pharmaceutical is eligible for the preferential EIT rate at 15% for the Track Record Period.

Since 2023, two subsidiaries of the Company, namely 成都海亞特科技有限責任公司 (Chengdu Hiatt Technology Co., Ltd.*) (“Hiatt Technology”) and 拉薩天澤藥業有限責任公司 (Lhasa Tianze Pharmaceutical Co., Ltd.*) (“Tianze Pharmaceutical”), are qualified as small and micro enterprises and are eligible for the preferential EIT rate at 20%.

Since 2024, a subsidiary of the Company, namely 成都百利多特生物藥業有限責任公司 (Baili-Bio (Chengdu) Pharmaceutical Co., Ltd.*) (“Baili-Bio”), that is engaged in the “Encouraged Industries in the Western Region”, is eligible for the preferential EIT rate at 15%.

SystImmune, INC. (“SystImmune”), a subsidiary of the Company, is subject to U.S. EIT representing 21% of the applicable U.S. Federal Income Tax rate and blended average rate of 3.52% of the State Income Tax arising from applicable States in the U.S..

Taxation arising in other jurisdictions is calculated at the rates prevailing in the relevant jurisdictions.

* *English name for identification only*

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The taxation for the years/periods can be reconciled to the (loss) profit before tax per the consolidated statements of profit or loss and other comprehensive income as follows:

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(unaudited)	
(Loss) profit before tax	(112,087)	(289,074)	(769,013)	(533,696)	4,349,692
Tax (credit) expense at the PRC EIT rate of 25%	(28,022)	(72,269)	(192,253)	(133,424)	1,087,423
Income tax at concessionary rate	4,530	4,307	3,369	5,604	(474,036)
Under-provision in prior years	1,992	3,323	3,703	681	51
Tax effect of expenses not deductible for tax purposes	3,089	4,492	16,629	5,451	6,560
Utilization of tax losses previously not recognized	(122)	(321)	(332)	(306)	(347,310)
Tax effect of tax losses or deductible temporary differences not recognized	63,329	117,381	293,017	199,509	438,644
Reversal of previously recognized deferred tax assets	–	–	11,764	–	–
Extra deduction of research and development expenses	(39,633)	(55,804)	(122,678)	(95,400)	(141,143)
Recognition of deductible temporary differences previously not recognized	–	–	–	–	(11,297)
Tax effect of income not taxable for tax purpose (Note)	–	–	–	–	(269,157)
Others	(9,608)	(7,804)	(1,733)	(705)	(5,411)
Income tax (credit) expense	(4,445)	(6,695)	11,486	(18,590)	284,324

Note: Pursuant to the relevant tax rules and regulation in the PRC, certain revenue generated from license income which was categorized as a technology transfer by the relevant tax authority and such portion of revenue was partially exempted from EIT.

11. (LOSS) PROFIT FOR THE YEAR/PERIOD

(Loss) profit for the year/period has been arrived at after charging:

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(unaudited)	
Depreciation of property, plant and equipment	48,273	56,075	57,178	43,379	50,596
Depreciation of investment properties	249	249	249	187	188
Depreciation of right-of-use assets	3,894	6,289	7,292	4,753	7,268
Total depreciation	52,416	62,613	64,719	48,319	58,052
Capitalized in inventories	(19,404)	(21,915)	(21,260)	(15,927)	(19,986)
Total depreciation	33,012	40,698	43,459	32,392	38,066

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	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Amortization of intangible assets	1,804	2,113	2,314	1,497	1,375
Staff costs					
Directors’, chief executive’s and supervisors’ remuneration (Note 14)	5,226	5,386	7,510	5,370	9,851
Other staff costs	171,926	215,429	266,163	188,660	250,144
Other staffs’ benefits	25,802	32,878	40,637	27,489	61,964
Other staffs’ share-based payments	102	82	22	19	8,791
Total staff costs	203,056	253,775	314,332	221,538	330,750
Capitalized in inventories	(41,654)	(51,102)	(52,008)	(38,304)	(42,102)
	161,402	202,673	262,324	183,234	288,648
Cost of inventories recognized as expenses (Note)	178,745	213,778	211,669	142,726	172,815

Note: The amount includes allowance for inventories amounted to RMB5,669,000, RMB4,964,000, RMB12,979,000, RMB9,628,000 (unaudited) and RMB11,895,000 for each of the three years ended December 31, 2023 and the nine months ended September 30, 2023 and 2024, respectively.

12. OTHER COMPREHENSIVE (EXPENSE) INCOME

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Other comprehensive (expense) income includes:					
<i>Items that may be reclassified subsequently to profit or loss:</i>					
Fair value change arising from bills receivables at FVTOCI	(86)	(260)	(312)	(133)	(194)
Reclassification to profit or loss during the year/period upon derecognition of bills receivables at FVTOCI	371	86	260	260	312
Exchange differences on translation of financial statements	(622)	208	(1,615)	(2,535)	15,472
	(337)	34	(1,667)	(2,408)	15,590

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Income tax effect relating to other comprehensive (expense) income:

	Year ended December 31, 2021			Year ended December 31, 2022			Year ended December 31, 2023		
			Net-of-			Net-of-			Net-of-
	Before-tax amount RMB'000	Tax charge RMB'000	income tax amount RMB'000	Before-tax amount RMB'000	Tax credit RMB'000	income tax amount RMB'000	Before-tax amount RMB'000	Tax charge RMB'000	income tax amount RMB'000
<i>Items that may be reclassified subsequently to profit or loss:</i>									
Fair value gain (loss) on bills receivables at FVTOCI	345	(60)	285	(208)	34	(174)	(17)	(35)	(52)
Exchange differences on translation from a foreign operation	(622)	–	(622)	208	–	208	(1,615)	–	(1,615)
	<u>(277)</u>	<u>(60)</u>	<u>(337)</u>	<u>–</u>	<u>34</u>	<u>34</u>	<u>(1,632)</u>	<u>(35)</u>	<u>(1,667)</u>

	Nine months ended September 30, 2023			Nine months ended September 30, 2024		
			Net-of-			Net-of-
	Before-tax amount RMB'000 (unaudited)	Tax charge RMB'000 (unaudited)	income tax amount RMB'000 (unaudited)	Before-tax amount RMB'000	Tax credit RMB'000	income tax amount RMB'000
<i>Items that may be reclassified subsequently to profit or loss:</i>						
Fair value gain (loss) on bills receivables at FVTOCI	147	(20)	127	110	8	118
Exchange differences on translation from a foreign operation	(2,535)	–	(2,535)	15,472	–	15,472
	<u>(2,388)</u>	<u>(20)</u>	<u>(2,408)</u>	<u>15,582</u>	<u>8</u>	<u>15,590</u>

13. DIVIDENDS

The Group and the Company

	Year ended December 31,			Nine months ended	
	2021	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Dividends for shareholders of the Company recognized: 2021 Final – RMB0.06 per share	<u>20,000</u>	<u>–</u>	<u>–</u>	<u>–</u>	<u>–</u>

No dividend was paid or proposed for ordinary shareholders of the Company since the end of the Track Record Period.

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14. DIRECTORS’, CHIEF EXECUTIVES’, SUPERVISORS’ AND EMPLOYEES’ EMOLUMENTS

Directors’, chief executives’ and supervisors’ emoluments

Directors’, chief executives’ and supervisors’ remuneration for the Track Record Period, disclosed pursuant to the applicable Listing Rules and Hong Kong Companies Ordinance, is as follows:

Year ended December 31, 2021

	Fees <i>RMB’000</i>	Basic salaries <i>RMB’000</i>	Retirement benefit <i>RMB’000</i>	Total <i>RMB’000</i>
Executive directors:				
Dr. Zhu Yi (<i>Note i</i>)	–	1,120	14	1,134
Ms. Zhang Suyu (<i>Note ii</i>)	–	1,000	–	1,000
Mr. Zhu Xi	–	1,003	13	1,016
Mr. Zhu Mingdong (<i>Note iii</i>)	–	112	3	115
Mr. Kang Jian	–	566	14	580
Mr. Zhuo Shi (<i>Note iv</i>)	–	528	11	539
Independent non-executive directors:				
Mr. Li Mingyuan	120	–	–	120
Mr. Yu Xiong	120	–	–	120
Mr. Yang Min	120	–	–	120
Supervisors:				
Ms. Lin Xia	–	206	13	219
Mr. Ding Yang	–	107	14	121
Mr. Liu Liang	–	129	13	142
	<u>360</u>	<u>4,771</u>	<u>95</u>	<u>5,226</u>

Year ended December 31, 2022

	Fees <i>RMB’000</i>	Basic salaries <i>RMB’000</i>	Retirement benefit <i>RMB’000</i>	Total <i>RMB’000</i>
Executive directors:				
Dr. Zhu Yi (<i>Note i</i>)	–	1,120	15	1,135
Ms. Zhang Suyu (<i>Note ii</i>)	–	1,000	–	1,000
Mr. Zhu Xi	–	1,003	15	1,018
Mr. Kang Jian	–	677	15	692
Mr. Zhuo Shi	–	768	15	783
Independent non-executive directors:				
Mr. Li Mingyuan	120	–	–	120
Mr. Yu Xiong	120	–	–	120
Mr. Yang Min	120	–	–	120
Supervisors:				
Ms. Lin Xia	–	220	15	235
Mr. Ding Yang	–	–	15	15
Mr. Liu Liang	–	134	14	148
	<u>360</u>	<u>4,922</u>	<u>104</u>	<u>5,386</u>

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Year ended December 31, 2023

	Fees <i>RMB'000</i>	Basic Salaries <i>RMB'000</i>	Retirement benefit <i>RMB'000</i>	Total <i>RMB'000</i>
Executive directors:				
Dr. Zhu Yi (<i>Note i</i>)	–	2,460	61	2,521
Ms. Zhang Suyu (<i>Note ii</i>)	–	1,000	–	1,000
Mr. Zhu Xi	–	1,002	21	1,023
Mr. Kang Jian	–	699	21	720
Mr. Zhuo Shi	–	1,273	23	1,296
Independent non-executive directors:				
Mr. Li Mingyuan	120	–	–	120
Mr. Yu Xiong	120	–	–	120
Mr. Yang Min	120	–	–	120
Supervisors:				
Ms. Lin Xia (<i>Note v</i>)	–	44	4	48
Mr. Ding Yang (<i>Note vi</i>)	–	–	16	16
Mr. Liu Liang	–	155	17	172
Ms. Wang Jie (<i>Note v</i>)	–	95	13	108
Ms. Fu Ting (<i>Note vi</i>)	–	109	14	123
	<u>360</u>	<u>6,837</u>	<u>190</u>	<u>7,387</u>

Nine months ended September 30, 2023 (unaudited)

	Fees <i>RMB'000</i>	Basic salaries <i>RMB'000</i>	Retirement benefit <i>RMB'000</i>	Total <i>RMB'000</i>
Executive directors:				
Dr. Zhu Yi (<i>Note i</i>)	–	1,762	40	1,802
Ms. Zhang Suyu (<i>Note ii</i>)	–	750	–	750
Mr. Zhu Xi	–	752	12	764
Mr. Kang Jian	–	525	12	537
Mr. Zhuo Shi	–	860	12	872
Independent non-executive directors:				
Mr. Li Mingyuan	90	–	–	90
Mr. Yu Xiong	90	–	–	90
Mr. Yang Min	90	–	–	90
Supervisors:				
Ms. Lin Xia (<i>Note v</i>)	–	44	4	48
Mr. Ding Yang (<i>Note vi</i>)	–	–	16	16
Mr. Liu Liang	–	112	11	123
Ms. Wang Jie (<i>Note v</i>)	–	65	9	74
Ms. Fu Ting (<i>Note vi</i>)	–	75	9	84
	<u>270</u>	<u>4,945</u>	<u>125</u>	<u>5,340</u>

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Nine months ended September 30, 2024

	Fees	Basic	Performance	Retirement	Total
	<i>RMB’000</i>	<i>salaries</i>	<i>related</i>	<i>benefit</i>	<i>RMB’000</i>
		<i>RMB’000</i>	<i>bonuses</i>	<i>RMB’000</i>	<i>RMB’000</i>
Executive directors:					
Dr. Zhu Yi (<i>Note i</i>)	–	2,108	–	50	2,158
Ms. Zhang Suyu (<i>Note ii</i>)	–	750	–	–	750
Mr. Zhu Xi (<i>Note vii</i>)	–	50	–	7	57
Mr. Kang Jian	–	532	–	65	597
Mr. Zhuo Shi	–	1,194	–	65	1,259
Dr. Zhu Hai (<i>Note viii</i>)	–	2,554	1,421 [^]	82	4,057
Independent non-executive directors:					
Mr. Li Mingyuan	90	–	–	–	90
Mr. Yu Xiong	90	–	–	–	90
Mr. Yang Min	90	–	–	–	90
Dr. Xiao Geng (<i>Note ix</i>)	28	–	–	–	28
Supervisors:					
Mr. Liu Liang	–	129	–	28	157
Ms. Wang Jie	–	86	–	25	111
Ms. Fu Ting	–	102	–	28	130
	<u>298</u>	<u>7,505</u>	<u>1,421</u>	<u>350</u>	<u>9,574</u>

[^] The executive director of the Company is entitled to bonus payments which are determined based on a percentage of the Group’s milestone payments from certain customer.

Notes:

- (i) Dr. Zhu Yi is the executive director and the chief executive of the Company.
- (ii) Ms. Zhang Suyu is the executive director and the chief financial officer of the Company.
- (iii) Mr. Zhu Mingdong resigned as the executive director of the Company on March 5, 2021.
- (iv) Mr. Zhuo Shi was appointed as the executive director of the Company on March 25, 2021.
- (v) Ms. Lin Xia tendered her resignation as a supervisor with effect from March 6, 2023 whereas Ms. Wang Jie was appointed as a supervisor on the same day.
- (vi) Mr. Ding Yang tendered his resignation as a supervisor with effect from March 6, 2023 whereas Ms. Fu Ting was appointed as a supervisor on the same day.
- (vii) Mr. Zhu Xi resigned as the executive director of the Company on January 30, 2024.
- (viii) Dr. Zhu Hai was appointed as the executive director of the Company on February 19, 2024.
- (ix) Dr. Xiao Geng was appointed as the independent non-executive director of the Company on July 8, 2024.

Dr. David Guowei Wang is an non-executive director of the Company and has agreed to waive his remuneration during the Track Record Period.

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In addition, 200,750 share options of SystImmune (as disclosed in Note 41) were granted to Dr. Zhu Yi on March 1, 2023 and 50,000 share options of SystImmune were granted to Dr. Zhu Hai on June 14, 2023. During the year ended December 31, 2023 and the nine months ended September 30, 2023 and 2024, Dr. Zhu Yi received share-based payments amounted to approximately RMB123,000, RMB30,000 (unaudited) and RMB217,000, respectively, and his total emoluments amounted to RMB2,644,000, RMB1,832,000 (unaudited) and RMB2,375,000, respectively. Dr. Zhu Hai received share-based payments amounted to approximately RMB60,000 during the nine months ended September 30, 2024 and his total emoluments amounted to RMB4,117,000 for the nine months ended September 30, 2024.

The emoluments of executive directors shown above were mainly for their services in connection with the management of the affairs of the Company and the Group. The independent non-executive directors’ and supervisors’ emoluments shown above were for their services as directors and supervisors of the Group, respectively. The performance related bonuses were determined by the management of the Group by reference to the performance.

Five individuals with the highest emoluments

The five highest paid individuals of the Group included 1, 1, 1, 1 (unaudited) and 2 directors for the years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, respectively, whose emoluments are included in the disclosures above. The emoluments of the remaining 4, 4, 4, 4 (unaudited) and 3 individuals for the years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, respectively, are as follows:

	Year ended December 31,			Nine months ended	
	2021	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
				(unaudited)	
Salaries, wages and allowance	3,957	5,932	9,734	7,212	5,737
Performance related bonuses	792	1,504	3,081	2,342	3,223
Retirement benefit	112	106	258	216	128
	<u>4,861</u>	<u>7,542</u>	<u>13,073</u>	<u>9,770</u>	<u>9,088</u>

The number of the highest paid employees who are not the directors nor the supervisors of the Company whose remuneration fell within the following bands is as follows:

	Number of employees			Nine months ended	
	Year ended December 31,	2022	2023	September 30,	2024
	2021			2023	
				(unaudited)	
Emolument bands					
Hong Kong Dollar (“HK\$”)					
1,000,001 to HK\$1,500,000	3	2	–	–	–
HK\$1,500,001 to HK\$2,000,000	1	1	–	–	–
HK\$2,000,001 to HK\$2,500,000	–	–	–	2	–
HK\$2,500,001 to HK\$3,000,000	–	–	2	–	1
HK\$3,000,001 to HK\$3,500,000	–	–	–	2	1
HK\$4,000,001 to HK\$4,500,000	–	1	2	–	1
	<u>4</u>	<u>4</u>	<u>4</u>	<u>4</u>	<u>3</u>

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No emoluments were paid by the Group to the directors, the supervisors of the Company or the five highest paid individuals (including directors and employees), as an inducement to join or upon joining the Group or as compensation for loss of office during the Track Record Period. Except for aforesaid Dr. David Guowei Wang, there was none of other directors or supervisors waived any emoluments during the Track Record Period.

15. (LOSS) EARNINGS PER SHARE

The calculation of the basic (loss) earnings per share attributable to owners of the Company is based on the following data:

	Year ended December 31,			Nine months ended September 30,	
	2021	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(unaudited)	
(Loss) earnings for the year/period:					
(Loss) earnings for the purpose of basic					
(loss) earnings per share	(107,642)	(282,379)	(780,499)	(515,106)	4,065,368
Number of shares ('000)					
Weighted average number of ordinary					
shares for the purpose of basic (loss)					
earnings per share	348,782	361,559	401,000	401,000	401,000

Diluted (loss) earnings per share for each reporting period is same as the basic (loss) earnings per share as (i) the assumed conversion of the Company’s outstanding redeemable shares would result in a decrease in loss per share for the year ended December 31, 2021; and (ii) the assumed exercise of the outstanding share options granted by the Company’s subsidiary, SystImmune, as disclosed in Note 41 would result in a decrease in loss per share for each of the three years ended December 31, 2023 and for the nine months ended September 30, 2023 (unaudited) and an increase in earnings per share for the nine months ended September 30, 2024.

16. PROPERTY, PLANT AND EQUIPMENT

The Group

	Buildings and structures	Equipment	Motor vehicles	Buildings improvements	Construction in progress	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Cost						
At January 1, 2021	252,697	351,098	12,631	19,365	76,713	712,504
Additions	–	21,684	–	284	37,117	59,085
Transfer	48,341	38,300	–	9,014	(95,655)	–
Disposals/written-off	(219)	(3,215)	(747)	–	–	(4,181)
At December 31, 2021	300,819	407,867	11,884	28,663	18,175	767,408
Additions	–	14,222	–	826	59,198	74,246
Transfer	1,519	8,642	–	–	(10,161)	–
Disposals/written-off	(113)	(2,784)	–	–	–	(2,897)
At December 31, 2022	302,225	427,947	11,884	29,489	67,212	838,757
Additions	–	15,333	–	691	162,289	178,313
Transfer	2,330	102,400	–	43,403	(148,133)	–
Disposals/written-off	–	(3,317)	–	(2)	–	(3,319)

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ACCOUNTANTS’ REPORT

	Buildings and structures	Equipment	Motor vehicles	Buildings 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>
At December 31, 2023	304,555	542,363	11,884	73,581	81,368	1,013,751
Additions	694	24,821	1,757	3,700	16,315	47,287
Transfer	29,753	29,974	–	17,869	(77,596)	–
Disposals/written-off	–	(2,228)	–	–	–	(2,228)
At September 30, 2024	335,002	594,930	13,641	95,150	20,087	1,058,810
Depreciation						
At January 1, 2021	117,032	195,239	9,625	9,597	–	331,493
Provided for the year	11,847	33,018	685	2,723	–	48,273
Eliminated on disposals/written-off	(108)	(2,820)	(718)	–	–	(3,646)
At December 31, 2021	128,771	225,437	9,592	12,320	–	376,120
Provided for the year	14,226	37,774	670	3,405	–	56,075
Eliminated on disposals/written-off	(63)	(2,359)	–	–	–	(2,422)
At December 31, 2022	142,934	260,852	10,262	15,725	–	429,773
Provided for the year	13,346	39,116	586	4,130	–	57,178
Eliminated on disposals/written-off	–	(3,005)	–	–	–	(3,005)
At December 31, 2023	156,280	296,963	10,848	19,855	–	483,946
Provided for the period	11,243	34,011	327	5,015	–	50,596
Eliminated on disposals/written-off	–	(1,997)	–	–	–	(1,997)
At September 30, 2024	167,523	328,977	11,175	24,870	–	532,545
Carrying values						
At December 31, 2021	172,048	182,430	2,292	16,343	18,175	391,288
At December 31, 2022	159,291	167,095	1,622	13,764	67,212	408,984
At December 31, 2023	148,275	245,400	1,036	53,726	81,368	529,805
At September 30, 2024	167,479	265,953	2,466	70,280	20,087	526,265

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The Company

	Equipment <i>RMB'000</i>	Motor vehicles <i>RMB'000</i>	Buildings Improvements <i>RMB'000</i>	Total <i>RMB'000</i>
Cost				
At January 1, 2021	2,237	1,888	1,497	5,622
Additions	137	–	–	137
Disposals	(153)	–	–	(153)
At December 31, 2021	2,221	1,888	1,497	5,606
Additions	137	–	–	137
Disposals	(258)	–	–	(258)
At December 31, 2022	2,100	1,888	1,497	5,485
Additions	79	–	–	79
Disposals	(48)	–	–	(48)
At December 31, 2023	2,131	1,888	1,497	5,516
Additions	136	1,645	–	1,781
Disposals	(183)	–	–	(183)
At September 30, 2024	2,084	3,533	1,497	7,114
Depreciation				
At January 1, 2021	1,963	1,244	1,497	4,704
Provided for the year	125	200	–	325
Eliminated on disposals	(145)	–	–	(145)
At December 31, 2021	1,943	1,444	1,497	4,884
Provided for the year	100	200	–	300
Eliminated on disposals	(245)	–	–	(245)
At December 31, 2022	1,798	1,644	1,497	4,939
Provided for the year	108	150	–	258
Eliminated on disposals	(46)	–	–	(46)
At December 31, 2023	1,860	1,794	1,497	5,151
Provided for the period	92	130	–	222
Eliminated on disposals	(175)	–	–	(175)
At September 30, 2024	1,777	1,924	1,497	5,198
Carrying values				
At December 31, 2021	278	444	–	722
At December 31, 2022	302	244	–	546
At December 31, 2023	271	94	–	365
At September 30, 2024	307	1,609	–	1,916

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The above items of property, plant and equipment, except for construction in progress, after taking into account the residual values, are depreciated on a straight-line basis over their estimated useful lives at the following rates per annum:

Buildings and structures	4.75%
Equipment	9.50%-31.67%
Motor vehicles	9.50%-23.75%
Buildings improvements	10.00%-33.33%

17. RIGHT-OF-USE ASSETS

The Group

	Leasehold lands RMB'000	Buildings RMB'000	Total RMB'000
At January 1, 2021	30,144	6,847	36,991
Addition	–	10,124	10,124
Charge for the year	(913)	(2,981)	(3,894)
At December 31, 2021	29,231	13,990	43,221
Additions	–	3,685	3,685
Derecognition upon termination of leases	–	(288)	(288)
Charge for the year	(913)	(5,376)	(6,289)
At December 31, 2022	28,318	12,011	40,329
Additions	–	1,489	1,489
Derecognition upon termination of leases	–	(1,335)	(1,335)
Charge for the year	(913)	(6,379)	(7,292)
At December 31, 2023	27,405	5,786	33,191
Additions	–	23,604	23,604
Charge for the period	(684)	(6,584)	(7,268)
At September 30, 2024	26,721	22,806	49,527

The above items of right-of-use-assets are depreciated on a straight-line basis over their estimated useful lives based on lease terms at the following rates per annum:

Leasehold lands	2.00%-2.32%
Buildings	14.29%-66.67%

	Year ended December 31,			Nine months ended	
	2021	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(unaudited)	
Expense relating to short-term leases	1,714	120	1,065	316	467
Total cash outflow for leases	4,912	5,604	8,520	5,765	7,707

During the Track Record Period, the Group leases buildings for its operations. Lease contracts are entered into for fixed term of 18 to 84 months. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. In determining the lease term and assessing the length of the non-cancellable period, the Group applies the definition of a contract and determines the period for which the contract is enforceable.

In addition, the Group owns several industrial buildings where its manufacturing facilities and office buildings are primarily located. The Group is the registered owner of these property interests, including the underlying leasehold lands. Lump sum payments were made upfront to acquire these property interests. The leasehold land components of these owned properties are presented separately only if the payments made can be allocated reliably.

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Restrictions or covenants on leases

The lease agreements do not impose any covenants other than the security interests in the leased assets that are held by the lessor. Leased assets may not be used as security for borrowing purposes.

The Company

	Buildings <i>RMB'000</i>
At January 1, 2021	576
Addition	3,546
Charge for the year	(288)
	<hr/>
At December 31, 2021	3,834
Addition	657
Derecognition upon termination	(288)
Charge for the year	(1,483)
	<hr/>
At December 31, 2022	2,720
Charge for the year	(1,510)
	<hr/>
At December 31, 2023	1,210
Addition	2,570
Charge for the period	(1,133)
	<hr/>
At September 30, 2024	2,647
	<hr/> <hr/>

18. INVESTMENT PROPERTIES

The Group

	Buildings <i>RMB'000</i>
Cost	
At January 1, 2021, December 31, 2021, 2022, 2023 and September 30, 2024	5,248
	<hr/>
Amortization	
At January 1, 2021	2,908
Charge for the year	249
	<hr/>
At December 31, 2021	3,157
Charge for the year	249
	<hr/>
At December 31, 2022	3,406
Charge for the year	249
	<hr/>
At 31 December 2023	3,655
Charge for the period	188
	<hr/>
At September 30, 2024	3,843
	<hr/>
Carrying values	
At December 31, 2021	2,091
	<hr/> <hr/>
At December 31, 2022	1,842
	<hr/> <hr/>
At December 31, 2023	1,593
	<hr/> <hr/>
At September 30, 2024	1,405
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19. INTANGIBLE ASSETS

The Group

	Proprietary technologies <i>RMB’000</i>	Computer software <i>RMB’000</i>	Trademark <i>RMB’000</i>	Database use right <i>RMB’000</i>	Total <i>RMB’000</i>
Cost					
At January 1, 2021	24,019	3,775	298	1,306	29,398
Addition	—	—	—	1,290	1,290
At December 31, 2021	24,019	3,775	298	2,596	30,688
Addition	—	—	—	1,588	1,588
At December 31, 2022	24,019	3,775	298	4,184	32,276
Addition	—	—	—	1,645	1,645
At December 31, 2023	24,019	3,775	298	5,829	33,921
Addition	—	—	—	1,390	1,390
At September 30, 2024	24,019	3,775	298	7,219	35,311
Amortization and impairment					
At January 1, 2021	22,293	2,766	298	731	26,088
Charge for the year	545	262	—	997	1,804
At December 31, 2021	22,838	3,028	298	1,728	27,892
Charge for the year	464	254	—	1,395	2,113
At December 31, 2022	23,302	3,282	298	3,123	30,005
Charge for the year	442	178	—	1,694	2,314
At December 31, 2023	23,744	3,460	298	4,817	32,319
Charge for the period	275	97	—	1,003	1,375
At September 30, 2024	24,019	3,557	298	5,820	33,694
Carrying values					
At December 31, 2021	1,181	747	—	868	2,796
At December 31, 2022	717	493	—	1,061	2,271
At December 31, 2023	275	315	—	1,012	1,602
At September 30, 2024	—	218	—	1,399	1,617

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The Company

Computer software RMB'000

Cost

At January 1, 2021, December 31, 2021, 2022, 2023 and September 30, 2024	1,523
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Amortization

At January 1, 2021	1,040
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Charge for the year	135
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At December 31, 2021	1,175
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Charge for the year	126
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At December 31, 2022	1,301
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Charge for the year	98
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At December 31, 2023	1,399
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Charge for the period	70
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At September 30, 2024	1,469
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Carrying values

At December 31, 2021	348
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At December 31, 2022	222
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At December 31, 2023	124
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At September 30, 2024	54
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The above intangible assets have finite useful lives, amortized on a straight-line basis over their estimated useful lives at the following rates per annum:

Proprietary technologies	10.00%
Computer software	10.00%-20.00%
Trademark	12.05%-62.50%
Database use right	33.33%-100.00%

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20. DEFERRED TAX ASSETS/LIABILITIES

The followings are the major deferred tax assets (liabilities) recognized and movements thereon during the Track Record Period:

The Group

	ECL provision RMB'000	Right-of-use assets RMB'000	Lease liabilities RMB'000	Tax losses RMB'000	Deferred income RMB'000	Selling rebates/refund liabilities RMB'000	Contract liabilities on transfer of manufacturing technology RMB'000	Timing difference on research and development expenses in U.S. RMB'000	Others RMB'000	Total RMB'000
At January 1, 2021	3,916	(1,595)	1,506	33,755	3,948	2,965	-	-	3,531	48,026
(Charge) credit to profit or loss	(723)	(1,560)	1,560	20,953	(351)	(1,283)	-	-	(853)	17,743
Charge to the other comprehensive income	-	-	-	-	-	-	-	-	(60)	(60)
At December 31, 2021	3,193	(3,155)	3,066	54,708	3,597	1,682	-	-	2,618	65,709
Credit (charge) to profit or loss	745	528	(524)	20,427	(2,735)	(118)	-	-	(925)	17,398
Credit to the other comprehensive income	-	-	-	-	-	-	-	-	34	34
At December 31, 2022	3,938	(2,627)	2,542	75,135	862	1,564	-	-	1,727	83,141
(Charge) credit to profit or loss	(3,084)	1,546	(1,461)	(4,659)	(77)	(745)	-	-	1,551	(6,929)
Charge to the other comprehensive income	-	-	-	-	-	-	-	-	(35)	(35)
At December 31, 2023	854	(1,081)	1,081	70,476	785	819	-	-	3,243	76,177
(Charge) credit to profit or loss	(193)	(4,404)	4,404	6	(475)	(103)	52,164	93,051	1,447	145,897
Credit to the other comprehensive income	-	-	-	-	-	-	-	-	8	8
At September 30, 2024	661	(5,485)	5,485	70,482	310	716	52,164	93,051	4,698	222,082
At January 1, 2023	3,938	(2,627)	2,542	75,135	862	1,564	-	-	1,727	83,141
(Charge) credit to profit or loss	(1,336)	1,160	(1,096)	24,205	(559)	(550)	-	-	1,028	22,852
Charge to the other comprehensive income	-	-	-	-	-	-	-	-	(20)	(20)
At September 30, 2023 (unaudited)	2,602	(1,467)	1,446	99,340	303	1,014	-	-	2,735	105,973

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For the purpose of presentation in the consolidated statements of financial position, certain deferred tax assets and liabilities have been offset. The following is the analysis of the deferred tax balances for financial reporting purposes:

	As at December 31,			As at September 30,
	2021	2022	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
Deferred tax assets	65,798	83,226	76,177	222,082
Deferred tax liabilities	(89)	(85)	—	—
	<u>65,709</u>	<u>83,141</u>	<u>76,177</u>	<u>222,082</u>

As at December 31, 2021, 2022 and 2023 and September 30, 2024, the Group had unused tax losses of RMB680,458,000, RMB1,201,045,000, RMB2,231,390,000 and RMB702,912,000, under PRC EIT, respectively, available to offset against future profits. A deferred tax asset has been recognized in respect of RMB349,204,000, RMB476,299,000, RMB469,838,000 and RMB469,881,000 of such losses as at December 31, 2021, 2022 and 2023 and September 30, 2024, respectively. No deferred tax asset has been recognized in respect of the remaining approximately RMB331,254,000, RMB724,746,000, RMB1,761,552,000, and RMB233,031,000 as at December 31, 2021, 2022 and 2023 and September 30, 2024, respectively, due to the unpredictability of future profit streams. The losses as at December 31, 2021, 2022 and 2023 and September 30, 2024 will expire in various years before 2031, 2032, 2033 and 2034 respectively.

As at December 31, 2021, 2022 and 2023 and September 30, 2024, the Group had tax losses of RMB304,595,000, RMB332,998,000 and RMB479,680,000 and RMB nil, under U.S. EIT, respectively, available to offset against future profits. No deferred tax asset has been recognized in respect of all such tax losses due to unpredictability of future profit streams. The losses as at December 31, 2021, 2022 and 2023 will expire in various years before 2041, 2042 and 2043 respectively.

As at December 31, 2021, 2022 and 2023 and September 30, 2024, the Group had deductible temporary differences apart from tax losses of RMB nil, RMB46,325,000, RMB70,479,000 and RMB1,714,069,000, under U.S. EIT, respectively. No deferred tax asset has been recognized in relation to such deductible temporary differences due to unpredictability that future profits will be available against which the deductible temporary differences can be utilized.

The Company

	Right-of- use assets	Lease liabilities	Tax losses	Selling rebates/ refund liabilities	Others	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At January 1, 2021	—	—	3,746	710	2,297	6,753
(Charge) credit to profit or loss	(959)	880	2,072	(275)	(21)	1,697
Charge to the other comprehensive income	—	—	—	—	(22)	(22)
At December 31, 2021	(959)	880	5,818	435	2,254	8,428
Credit (charge) to profit or loss	279	(271)	3,406	(60)	(9)	3,345
Credit to the other comprehensive income	—	—	—	—	6	6

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	Right-of- use assets <i>RMB'000</i>	Lease liabilities <i>RMB'000</i>	Tax losses <i>RMB'000</i>	Selling rebates/ refund liabilities <i>RMB'000</i>	Others <i>RMB'000</i>	Total <i>RMB'000</i>
At December 31, 2022	(680)	609	9,224	375	2,251	11,779
Credit (charge) to profit or loss	370	(299)	(9,224)	(375)	(2,236)	(11,764)
Charge to the other comprehensive income	—	—	—	—	(15)	(15)
At December 31, 2023	(310)	310	—	—	—	—
(Charge) credit to profit or loss	(187)	187	—	—	—	—
At September 30, 2024	(497)	497	—	—	—	—
At January 1, 2023	(680)	609	9,224	375	2,251	11,779
Credit (charge) to profit or loss	344	(273)	5,561	(34)	(639)	4,959
Credit to the other comprehensive income	—	—	—	—	4	4
At September 30, 2023 (<i>unaudited</i>)	(336)	336	14,785	341	1,616	16,742

As at December 31, 2021, 2022 and 2023 and September 30, 2024, the Company had unused tax losses of RMB23,274,000, RMB36,899,000, RMB55,366,000 and RMB94,652,000, respectively, available to offset against future profits. A deferred tax asset has been recognized in respect of RMB23,274,000, RMB36,899,000, nil and nil of such losses as at December 31, 2021, 2022 and 2023 and September 30, 2024 respectively. No deferred tax asset has been recognized in respect of the remaining approximately nil, nil, RMB55,366,000, and RMB94,652,000 as at December 31, 2021, 2022 and 2023 and September 30, 2024, respectively, due to the unpredictability of future profit streams. The losses as at December 31, 2021, 2022 and 2023 and September 30, 2024 will expire in various years before 2026, 2027, 2028 and 2029, respectively.

21. INVENTORIES

The Group

	As at December 31,			As at September 30,
	2021	2022	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Raw materials and consumables	34,323	46,453	64,109	80,208
Work in progress	22,378	25,989	22,000	27,746
Finished goods	29,489	21,196	56,611	58,942
Goods in transit	76	9,242	3,337	1,898
	86,266	102,880	146,057	168,794
Less: provision	(3,939)	(1,553)	(5,149)	(3,916)
	82,327	101,327	140,908	164,878

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The followings are the inventory provision recognized and movements thereon during the Track Record Period:

	As at December 31,			As at September 30,
	2021	2022	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
At the beginning of the year/period	1,737	3,939	1,553	5,149
Recognition as cost of sales	5,669	4,964	12,979	11,895
Written off	(3,467)	(7,350)	(9,383)	(13,128)
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
At the end of the year/period	<u>3,939</u>	<u>1,553</u>	<u>5,149</u>	<u>3,916</u>

As at the end of each reporting period, all the inventories of the Group are expected to be recovered within 12 months.

The Company

	As at December 31,			As at September 30,
	2021	2022	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
Raw materials and consumables	14	15	21	7
Finished goods	4,916	1	76	700
Goods in transit	2,011	7,600	2,503	1,560
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
	6,941	7,616	2,600	2,267
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Less: provision	<u>—</u>	<u>—</u>	<u>—</u>	<u>(138)</u>
	<u>6,941</u>	<u>7,616</u>	<u>2,600</u>	<u>2,129</u>

The followings are the inventory provision recognized and movements thereon during the Track Record Period:

	As at December 31,			As at September 30,
	2021	2022	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
At the beginning of the year/period	—	—	—	—
Recognition as cost of sales	—	—	—	169
Written off	—	—	—	(31)
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
At the end of the year/period	<u>—</u>	<u>—</u>	<u>—</u>	<u>138</u>

As at the end of each reporting period, all the inventories of the Company are expected to be recovered within 12 months.

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22. RIGHT TO RETURNED GOODS ASSETS/REFUND LIABILITIES

The right to returned goods assets represents the Group’s right to recover products from customers where customers exercise their right of return under the customary industry practice. The Group uses its accumulated historical experience to estimate the number of returns on a portfolio level using the expected value method.

The refund liabilities are related to customers’ right to return products under customary industry practice. At the point of sale, a refund liability and a corresponding adjustment to revenue is recognized for those products expected to be returned. The Group uses its accumulated historical experience to estimate the number of returns on a portfolio level using the expected value method.

23. TRADE AND OTHER RECEIVABLES

The Group

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Trade receivables – contract with customers	118,846	247,233	109,429	79,120
Less: allowance for credit losses	(13,664)	(18,730)	(11,034)	(9,657)
	<u>105,182</u>	<u>228,503</u>	<u>98,395</u>	<u>69,463</u>
Bills receivables	24,144	19,831	20,775	12,312
Less: allowance for credit losses	(1,207)	(992)	(1,039)	(615)
	<u>22,937</u>	<u>18,839</u>	<u>19,736</u>	<u>11,697</u>
Other receivables	3,877	6,379	5,305	25,444
Less: allowance for credit losses	(927)	(1,243)	(1,400)	(1,724)
	<u>2,950</u>	<u>5,136</u>	<u>3,905</u>	<u>23,720</u>
Prepayments to suppliers	22,916	29,845	57,199	92,306
Value-added tax recoverable	17,240	7,708	25,237	60,114
Prepaid expenses	122	3,046	544	664
Deferred issue costs	2,161	–	–	24,979
	<u>173,508</u>	<u>293,077</u>	<u>205,016</u>	<u>282,943</u>

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As at January 1, 2021, the carrying amount of trade receivables net of allowance for credit losses from contracts with customers amounted to RMB163,255,000.

The following is an aging analysis of trade receivables and bills receivables (net of allowance for credit losses) presented based on the dates of goods delivery at the end of each reporting period:

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Within 1 year	124,912	243,275	115,701	79,327
1-2 years	980	3,080	1,171	1,014
2-3 years	1,358	417	1,023	328
Over 3 years	869	570	236	491
	<u>128,119</u>	<u>247,342</u>	<u>118,131</u>	<u>81,160</u>

The normal credit term to the customers ranged between 30 to 120 days. The Group does not hold any collateral over these balances.

The Company

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Trade receivables – contract with customers	40,672	61,470	37,669	31,986
Less: allowance for credit losses	<u>(8,240)</u>	<u>(8,235)</u>	<u>(6,321)</u>	<u>(6,173)</u>
	<u>32,432</u>	<u>53,235</u>	<u>31,348</u>	<u>25,813</u>
Bills receivables	10,747	7,934	7,662	3,238
Less: allowance for credit losses	<u>(537)</u>	<u>(397)</u>	<u>(383)</u>	<u>(82)</u>
	<u>10,210</u>	<u>7,537</u>	<u>7,279</u>	<u>3,156</u>
Other receivables	481	450	484	715
Less: allowance for credit losses	<u>(202)</u>	<u>(311)</u>	<u>(394)</u>	<u>(411)</u>
	<u>279</u>	<u>139</u>	<u>90</u>	<u>304</u>
Prepayments to suppliers	1,776	11	–	–
Value-added tax recoverable	433	6,134	4,629	5,246
Prepaid expenses	–	2,732	33	761
Deferred issue costs	<u>2,161</u>	<u>–</u>	<u>–</u>	<u>24,979</u>
	<u>47,291</u>	<u>69,788</u>	<u>43,379</u>	<u>60,259</u>

As at January 1, 2021, the carrying amount of trade receivables net of allowance for ECL from contracts with customers amounted to RMB30,985,000.

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The following is an aging analysis of trade receivables and bills receivables (net of allowance for credit losses) presented based on the dates of goods delivery at the end of each reporting period:

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Within 1 year	40,110	57,679	36,839	27,744
1-2 years	624	2,287	641	483
2-3 years	1,321	284	950	327
Over 3 years	587	522	197	415
	<u>42,642</u>	<u>60,772</u>	<u>38,627</u>	<u>28,969</u>

The normal credit term to the customers is ranged between 30 to 120 days. The Company does not hold any collateral over these balances.

Details of impairment assessment of trade receivables, bills receivables and other receivables are set out in Note 42.

24. AMOUNTS DUE FROM SUBSIDIARIES

The Company

	Maximum amount outstanding during								
	As at	As at December 31,			As at	the year ended December 31,			the nine
	January 1,	2021	2022	2023	September 30,	2021	2022	2023	months ended
	2021	2021	2022	2023	2024	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	2024
									RMB'000
Trade in nature									
Baili Pharmaceutical	27,593	50,636	145,480	196,779	72,832	N/A	N/A	N/A	N/A
Guorui Pharmaceutical	866	19,108	11,344	18,764	573	N/A	N/A	N/A	N/A
Hiatt Technology	2,098	–	–	–	–	N/A	N/A	N/A	N/A
Lhasa Xinbo	–	1,411	1,178	–	–	N/A	N/A	N/A	N/A
Baili-Bio	–	–	343	343	–	N/A	N/A	N/A	N/A
	<u>30,557</u>	<u>71,155</u>	<u>158,345</u>	<u>215,886</u>	<u>73,405</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
Non-trade in nature									
Lhasa Xinbo^	301	33,094	124,560	97,498	118,281	40,936	129,191	141,198	118,281
Baili-Bio^	–	–	31	9,743	1,145,186	–	51	9,743	1,145,186
Baili Pharmaceutical^	65,381	75,084	89,399	241,222	–	111,084	125,401	277,222	371,394
成都精西藥業有限責任公司 (Chengdu Jingxi Pharmaceutical Co., Ltd.*) (“Jingxi Pharmaceutical”)^	–	–	26	6,773	1,451	–	26	6,773	12,278
Hayate Technology^	–	–	1	1	774	–	1	1	774
Tianze Pharmaceutical^	–	–	–	1	1	–	–	1	1
Guorui Pharmaceutical^	–	–	31,745	69,584	7,876	–	31,745	69,584	95,179
	<u>65,682</u>	<u>108,178</u>	<u>245,762</u>	<u>424,822</u>	<u>1,273,569</u>				
	<u>96,239</u>	<u>179,333</u>	<u>404,107</u>	<u>640,708</u>	<u>1,346,974</u>				

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* English name for identification only

^ The amounts are non-trade in nature, unsecured, interest-free and are repayable on demand.

The following is an aged analysis of amounts due from subsidiaries which are trade in nature presented based on the dates of goods delivery at the end of each reporting period.

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Within 1 year	71,155	158,345	215,886	73,405

The normal credit term to the subsidiaries is ranged within one year. None of the balance is past due as at December 31, 2021, 2022 and 2023 and September 30, 2024.

25. BILLS RECEIVABLES AT FVTOCI

The Group

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Bills receivables	6,831	20,581	19,714	12,344

The Company

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Bills receivables	1,921	5,723	12,809	3,381

Under IFRS 9, certain bills which were held by the Group for the practice of endorsing to suppliers before the bills due for payment were classified as “bills receivables at FVTOCI”. At the end of each reporting period, all the bills are with a maturity period of less than one year.

The Group considers the credit risk is limited because counterparties are banks with good credit standing and are highly likely to be paid, and the ECL are considered as insignificant.

Details of impairment assessment are set out in Note 42.

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26. TERM DEPOSITS/RESTRICTED BANK BALANCES/CASH AND CASH EQUIVALENTS

The Group

Cash and cash equivalents include bank balances and certificates of deposit.

The Group’s restricted bank balances were pledged to banks for issuing bills as detailed in Note 36 and are classified as current assets.

Term deposits are bank deposits with terms ranging from 3 months to 1 year.

The ranges of effective interest rate of the Group’s bank balances, certificates of deposit, restricted bank balances and term deposits are:

	As at December 31,			As at
	2021	2022	2023	September 30, 2024
Interest rate per annum:				
– Bank balances	0.00%-1.00%	0.00%-1.50%	0.00%-1.90%	0.00%-5.40%
– Certificates of deposit	1.65%	1.65%	1.65%-3.93%	1.65%-3.93%
– Restricted bank balances	N/A	0.25%	0.17%-1.55%	0.17%-1.55%
– Term deposits	N/A	N/A	N/A	3.65%-4.77%

The Company

Restricted bank balances and cash and cash equivalents comprising of bank balances and cash carry interest at prevailing market interest rates ranging from 0.01% to 1.50% per annum as at the end of each reporting period.

The Company’s restricted bank balances were pledged to banks for issuing bills as detailed in Note 36 and are classified as current assets. Restricted bank balances carry interest at prevailing market interest rates ranges from 0.20% to 0.27% per annum as at December 31, 2022 and 2023 and September 30, 2024.

Details of impairment assessment of bank balances, certificates of deposit, restricted bank balances and term deposits are set out in Note 42.

27. BORROWINGS

The Group

	As at December 31,			As at
	2021	2022	2023	September 30, 2024
	RMB'000	RMB'000	RMB'000	RMB'000
Bank borrowings				
– Secured	211,250	355,483	543,365	1,227,167
– Unsecured	–	70,080	90,044	293,228
	<u>211,250</u>	<u>425,563</u>	<u>633,409</u>	<u>1,520,395</u>
– Fixed-rate borrowings	161,232	155,133	275,117	651,465
– Floating-rate borrowings	<u>50,018</u>	<u>270,430</u>	<u>358,292</u>	<u>868,930</u>
	<u>211,250</u>	<u>425,563</u>	<u>633,409</u>	<u>1,520,395</u>

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	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Carrying amount repayable: (based on scheduled payment terms)				
Within one year	161,250	185,603	449,489	906,565
Within a period of more than one year but not more than two years	–	170,040	183,920	380,900
Within a period of more than two years but not more than five years	50,000	69,920	–	232,930
	211,250	425,563	633,409	1,520,395
Less: Amount due for settlement within 12 months shown under current liabilities	(161,250)	(185,603)	(449,489)	(906,565)
Amount due for settlement after 12 months shown under non-current liabilities	50,000	239,960	183,920	613,830

The ranges of effective interest rate of the Group’s bank borrowings are:

	As at December 31,			As at
	2021	2022	2023	September 30,
				2024
Effective interest rate per annum:				
– Fixed-rate borrowings	4.38%-4.90%	3.85%-4.80%	3.60%-3.90%	2.85%-3.85%
– Floating-rate borrowings	4.45%	4.10%-4.65%	3.70%-4.45%	2.65%-4.45%

The Company

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Bank borrowings				
– Secured	86,067	160,137	398,275	934,921
– Unsecured	–	70,080	70,036	263,223
	86,067	230,217	468,311	1,198,144
– Fixed-rate borrowings	36,049	110,069	248,100	543,621
– Floating-rate borrowings	50,018	120,148	220,211	654,523
	86,067	230,217	468,311	1,198,144

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	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Carrying amount repayable: (based on scheduled payment terms)				
Within one year	36,067	110,257	298,391	745,714
Within a period of more than one year but not more than two years	–	50,040	169,920	219,500
Within a period of more than two years but not more than five years	50,000	69,920	–	232,930
	86,067	230,217	468,311	1,198,144
Less: Amount due for settlement within 12 months shown under current liabilities	(36,067)	(110,257)	(298,391)	(745,714)
Amount due for settlement after 12 months shown under non-current liabilities	50,000	119,960	169,920	452,430

The ranges of effective interest rate of the Company’s bank borrowings are:

	As at December 31,			As at
	2021	2022	2023	September 30,
				2024
Effective interest rate per annum:				
– Fixed-rate borrowings	4.38%-4.45%	3.85%-4.38%	3.60%-3.85%	2.95%-3.85%
– Floating-rate borrowings	4.45%	4.10%-4.45%	3.70%-4.30%	2.65%-4.10%

28. TRADE AND OTHER PAYABLES

The Group

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Trade payables	45,962	116,854	128,999	104,406
Trade payables settled with endorsed bills	22,059	13,719	11,176	9,913
Bills payables	–	11,993	31,170	104,560
	68,021	142,566	171,345	218,879

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	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Salaries and wages payables	27,585	39,996	44,292	53,598
Other tax payables	10,080	30,723	18,350	3,200
Accruals	11,584	44,275	110,078	146,228
Accrual for promotional cost	90,368	104,478	87,878	47,329
Consideration payable for acquisition of property, plant and equipment	15,005	24,020	68,821	31,915
Deposits from suppliers	46,224	44,503	43,762	55,884
Accrual for issue costs	–	25,140	–	8,760
Other payables	4,639	4,685	4,990	9,604
	<u>205,485</u>	<u>317,820</u>	<u>378,171</u>	<u>356,518</u>
	<u>273,506</u>	<u>460,386</u>	<u>549,516</u>	<u>575,397</u>

The normal credit term to the Group ranged between 30 to 180 days.

The following is an aging analysis of trade payables/bills payables presented based on the invoice date/issuance date at the end of each reporting period:

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Within 1 year	66,492	141,447	170,513	218,469
1-2 years	1,245	945	695	257
2-3 years	87	43	6	16
Over 3 years	197	131	131	137
	<u>68,021</u>	<u>142,566</u>	<u>171,345</u>	<u>218,879</u>

As at December 31, 2022 and 2023 and September 30, 2024, the Group’s bills payables were issued by banks with maturities within six months and were secured by the Group’s restricted bank balances.

The Company

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Trade payables	6,843	14,384	13,689	8,388
Trade payables settled with endorsed bills	2,730	1,531	1,853	3,069
Bills payables	–	11,993	6,170	62,460
	<u>9,573</u>	<u>27,908</u>	<u>21,712</u>	<u>73,917</u>

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	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Salaries and wages payables	3,041	3,332	3,419	4,126
Other tax payables	695	3,406	4,094	5,544
Accruals	456	575	437	590
Accrual for promotional cost	1,741	1,932	1,965	388
Deposits from suppliers	15,642	16,841	17,719	16,992
Accrual for issue costs	–	25,140	–	8,760
Other payables	630	770	601	720
	<u>22,205</u>	<u>51,996</u>	<u>28,235</u>	<u>37,120</u>
	<u>31,778</u>	<u>79,904</u>	<u>49,947</u>	<u>111,037</u>

The normal credit term to the Company is ranged between 30 to 180 days.

The following is an aging analysis of trade payables/bills payables presented based on the invoice date/issuance date at the end of each reporting period:

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Within 1 year	8,587	27,906	21,106	73,705
1-2 years	986	2	606	212
	<u>9,573</u>	<u>27,908</u>	<u>21,712</u>	<u>73,917</u>

At December 31, 2022 and 2023 and September 30, 2024, the Company’s bills payables were issued by banks with maturities within six months and were secured by the Company’s restricted bank balances.

29. AMOUNTS DUE TO SUBSIDIARIES

The Company

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Trade in nature				
Guorui Pharmaceutical	2,205	1,467	44	–
Baili Pharmaceutical	6,399	14,475	30,812	41,605
Lhasa Xinbo	147	–	–	–
	<u>8,751</u>	<u>15,942</u>	<u>30,856</u>	<u>41,605</u>

The normal credit term to the Company is ranged between 30 to 180 days.

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The following is an aged analysis of an amounts due to subsidiaries which is trade in nature presented based on the invoice/issuance date at the end of each reporting period.

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Within 1 year	8,751	15,942	30,856	41,605

30. CONTRACT LIABILITIES

The Group

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Sale of goods	9,617	15,424	7,026	5,314
Selling rebates liabilities	1,166	1,992	1,646	1,682
Transfer of manufacturing technology	—	—	—	343,379
	10,783	17,416	8,672	350,375

As at January 1, 2021, the Group had contract liabilities of RMB18,096,000, including contract liabilities for sale of goods amounting to RMB16,293,000 and selling rebates liabilities amounting to RMB1,803,000.

The following table shows the revenue recognized to carried-forward contract liabilities and how much relates to performance obligations that were satisfied in prior periods.

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Sale of goods				
Balance at the beginning of the year/period	16,293	9,617	15,424	7,026
Decrease in contract liabilities as a result of recognition of revenue during the year/period	(16,293)	(9,617)	(15,424)	(7,026)
Increase in contract liabilities as a result of receiving prepayments for sale of goods during the year/period	9,617	15,424	7,026	5,314
Balance at the end of the year/period	9,617	15,424	7,026	5,314

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The Company

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Sale of goods	4,600	6,758	4,518	4,125
Selling rebates liabilities	138	276	141	131
	<u>4,738</u>	<u>7,034</u>	<u>4,659</u>	<u>4,256</u>

As at January 1, 2021, the Company had contract liabilities of RMB4,738,000 including contract liabilities for sale of goods amounting to RMB4,228,000 and selling rebates liabilities amounting to RMB510,000.

The following table shows the revenue recognized to carried-forward contract liabilities and how much relates to performance obligations that were satisfied in prior periods.

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Sale of goods				
Balance at the beginning of the year/period	4,228	4,600	6,758	4,518
Decrease in contract liabilities as a result of recognition of revenue during the year/period	(4,228)	(4,600)	(6,758)	(4,518)
Increase in contract liabilities as a result of receiving prepayments for sale of goods during the year/period	<u>4,600</u>	<u>6,758</u>	<u>4,518</u>	<u>4,125</u>
Balance at the end of the year/period	<u>4,600</u>	<u>6,758</u>	<u>4,518</u>	<u>4,125</u>

Contract liabilities are all expected to be settled within the Group’s and the Company’s normal operating cycle, and are classified as current based on the Group’s and the Company’s earliest obligation to transfer goods to the customers. Revenue recognized during each reporting period with performance obligation satisfied includes whole contract liability balance at the beginning of each reporting period.

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31. SALE AND LEASEBACK PAYABLE

The Group

	As at December 31,			As at September 30,
	2021	2022	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
Within one year	19,019	61,858	41,430	7,599
Within a period of more than one year but not more than two years	20,455	39,666	7,636	–
Within a period of more than two years but not more than five years	22,000	7,557	–	–
	61,474	109,081	49,066	7,599
Less: Amount due for settlement within 12 months shown under current liabilities	(19,019)	(61,858)	(41,430)	(7,599)
Amount due for settlement after 12 months shown under non-current liabilities	42,455	47,223	7,636	–

The Group sold and leased back some equipment with financing institutions. The Group continues to recognize the assets and accounts for the transfer proceeds as borrowings, because the transfer does not satisfy the requirements as a sale. The effective borrowing rate applied to sale and leaseback payable is 7.55%, 7.54%-10.04%, 7.54%-10.04%, 7.54% per annum respectively, as at December 31, 2021, 2022 and 2023 and September 30, 2024.

32. LEASE LIABILITIES

The Group

	As at December 31,			As at September 30,
	2021	2022	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
Within one year	5,215	6,965	4,702	8,219
Within a period of more than one year but not more than two years	5,410	4,754	1,017	7,301
Within a period of more than two years but not more than five years	3,560	969	–	6,985
	14,185	12,688	5,719	22,505
Less: Amount due for settlement within 12 months shown under current liabilities	(5,215)	(6,965)	(4,702)	(8,219)
Amount due for settlement after 12 months shown under non-current liabilities	8,970	5,723	1,017	14,286

The weighted average incremental borrowing rates applied to lease liabilities is 4.75% as at December 31, 2021, 2022 and 2023 and September 30, 2024.

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The Company

	As at December 31,			As at September 30,
	2021	2022	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
Within one year	1,347	1,513	923	936
Within a period of more than one year but not more than two years	1,257	923	–	722
Within a period of more than two years but not more than five years	923	–	–	330
	3,527	2,436	923	1,988
Less: Amount due for settlement within 12 months shown under current liabilities	(1,347)	(1,513)	(923)	(936)
Amount due for settlement after 12 months shown under non-current liabilities	2,180	923	–	1,052

The weighted average incremental borrowing rates applied to lease liabilities is 4.75% as at December 31, 2021, 2022 and 2023 and September 30, 2024.

33. RETIREMENT BENEFIT PLANS

In accordance with the rules and regulations in the PRC, the PRC based employees of the Group participate in various defined contribution retirement benefit plans organized by the relevant municipal and provincial governments in the PRC under which the Group and the PRC based employees are required to make monthly contributions to these plans calculated at a certain percentage of the employees’ salaries.

The municipal and provincial governments undertake to assume the retirement benefit obligations of all existing and future retired PRC based employees’ payable under the plans described above. Other than the monthly contributions, the Group has no further obligation for the payment of retirement and other post-retirement benefit of its employees. The assets of these plans are held separately from those of the Group in independently administrated funds managed by the PRC government. The contributions to these plans recognized as employee benefit charged to profit or loss and capitalized as production costs as incurred for the years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024 under such arrangement are RMB11,905,000, RMB15,719,000, RMB17,449,000, RMB13,554,000 (unaudited) and RMB24,588,000, respectively.

A subsidiary in the U.S. maintains multiple qualified contributory savings plans as allowed under Section 401(k) of the Internal Revenue Code in the U.S.. These plans are defined contribution plans covering substantially all its qualifying employees and provide for voluntary contributions by employees, subject to certain limits. The contributions are made by both the employees and the employer. The employees’ contributions are primarily based on specified dollar amounts or percentages of employee compensation. The employer’s contributions are primarily based on the smaller of three percent of the employees’ compensation and the half of the employees’ contributions.

The only obligation of the U.S. subsidiary with respect to the retirement benefits plans is to make the specified contributions under the plans. The contributions to these plans recognized as employee benefit charged to profit or loss as incurred for the years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024 under such arrangement are RMB1,878,000, RMB2,362,000, RMB4,725,000, RMB2,668,000 (unaudited) and RMB6,453,000 respectively.

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34. SHARE CAPITAL

Ordinary shares of RMB1 each	Number of shares '000	Share capital RMB'000
Authorized:		
At January 1 and December 31, 2021	360,900 [#]	360,900
Increase on A share issuing (<i>Note</i>)	40,100	40,100
At December 31, 2022 and 2023 and September 30, 2024	401,000	401,000
Issued and fully paid:		
At January 1 and December 31, 2021	360,900 [#]	360,900
Increase on A share issuing (<i>Note</i>)	40,100	40,100
At December 31, 2022 and 2023 and September 30, 2024	401,000	401,000

Included 49,145,000 issued convertible redeemable shares, which were presented as financial liabilities as at January 1, 2021 and converted into ordinary shares at par value of RMB1.00 each on a one-for-one basis on March 31, 2021.

Note: The Company issued 40,100,000 A shares at RMB1.00 per share upon A Share Listing. The share issue price is RMB24.70 per share, amounting to total proceeds of RMB990,470,000. The net proceeds from the A Share Listing amounted to RMB884,397,000 after deducting the listing expenses amounted to RMB106,073,000.

Reserves of the Company:

Below table sets out the details of the reserves of the Company:

	Capital reserve RMB'000	FVTOCI reserve RMB'000	Statutory reserve RMB'000	Accumulated loss RMB'000	Total RMB'000
As at January 1, 2021	(451,391)	(91)	13,537	(73,448)	(511,393)
Loss for the year	–	–	–	(13,891)	(13,891)
Other comprehensive income for the year	–	64	–	–	64
Total comprehensive income (expense) for the year	–	64	–	(13,891)	(13,827)
Conversion of preferred shares	634,904	–	–	–	634,904
Dividends recognized as distribution	–	–	–	(20,000)	(20,000)
As at December 31, 2021	183,513	(27)	13,537	(107,339)	89,684
Loss for the year	–	–	–	(13,023)	(13,023)
Other comprehensive expense for the year	–	(17)	–	–	(17)
Total comprehensive expense for the year	–	(17)	–	(13,023)	(13,040)
Issue of A shares	844,297	–	–	–	844,297

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	Capital reserve <i>RMB’000</i>	FVTOCI reserve <i>RMB’000</i>	Statutory reserve <i>RMB’000</i>	Accumulated loss <i>RMB’000</i>	Total <i>RMB’000</i>
As at December 31, 2022	1,027,810	(44)	13,537	(120,362)	920,941
Loss for the year	–	–	–	(34,797)	(34,797)
Other comprehensive expense for the year	–	(173)	–	–	(173)
Total comprehensive expense for the year	–	(173)	–	(34,797)	(34,970)
As at December 31, 2023	1,027,810	(217)	13,537	(155,159)	885,971
Loss for the period	–	–	–	(40,311)	(40,311)
Other comprehensive income for the period	–	166	–	–	166
Total comprehensive income (expense) for the period	–	166	–	(40,311)	(40,145)
As at September 30, 2024	<u>1,027,810</u>	<u>(51)</u>	<u>13,537</u>	<u>(195,470)</u>	<u>845,826</u>
As at January 1, 2023	1,027,810	(44)	13,537	(120,362)	920,941
Loss for the period	–	–	–	(14,670)	(14,670)
Other comprehensive expense for the period	–	(13)	–	–	(13)
Total comprehensive expense for the period	–	(13)	–	(14,670)	(14,683)
As at September 30, 2023 (unaudited)	<u>1,027,810</u>	<u>(57)</u>	<u>13,537</u>	<u>(135,032)</u>	<u>906,258</u>

35. DEFERRED INCOME

The Group

	As at December 31,			As at
	2021	2022	2023	September 30,
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	2024 <i>RMB’000</i>
Assets-related government subsidies	8,800	8,847	12,784	11,588
Expense-related government subsidies (<i>Note</i>)	<u>22,244</u>	<u>4,443</u>	<u>2,843</u>	<u>–</u>
Total	<u>31,044</u>	<u>13,290</u>	<u>15,627</u>	<u>11,588</u>

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	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Analyzed as:				
Current	558	801	1,594	1,468
Non-current	30,486	12,489	14,033	10,120
	<u>31,044</u>	<u>13,290</u>	<u>15,627</u>	<u>11,588</u>

Note: Expense-related government subsidies are specifically for the incentive and other subsidies for research and development activities, which are recognized upon completion of the activities.

For the years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, the Group received RMB1,705,000, RMB3,131,000, RMB4,997,000, RMB3,134,000 (unaudited) and nil, respectively, in relation to incentives for certain plants and equipment acquired by the Group. The amounts were recorded as deferred income and released to profit or loss on a systematic basis over the useful lives of the relevant assets when conditions are met. During the years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, assets-related government subsidies of approximately RMB558,000, RMB801,000, RMB1,060,000, RMB719,000 (unaudited) and RMB1,196,000, respectively, were released to profit or loss and expense-related government subsidies of approximately RMB5,419,000, RMB17,970,000, RMB1,600,000, RMB1,600,000 (unaudited) and RMB2,843,000, respectively, were released to profit or loss.

36. PLEDGE OF ASSETS

At the end of each reporting period, the Group and the Company had pledged the following assets to banks and other financing institutions as securities against general facilities, including banks borrowings, sale and leaseback payable and/or bills payables issued by the Group and the Company:

The Group

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Property, plant and equipment	161,918	200,641	214,654	192,278
Investment properties	2,091	1,842	1,593	1,405
Right-of-use assets	16,645	16,084	21,469	20,941
Restricted bank balances	–	4,046	12,270	25,800
	<u>180,654</u>	<u>222,613</u>	<u>249,986</u>	<u>240,424</u>

The Company

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Restricted bank balances	–	3,682	4,770	4,750

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37. TRANSFER OF FINANCIAL ASSETS

As at December 31, 2021, 2022, 2023 and September 30, 2024, the Group endorsed bills receivables amounted to RMB22,059,000, RMB13,719,000, RMB11,176,000 and RMB9,913,000, respectively, for the settlement of trade and other payables on a full recourse basis. If the bills are not paid on maturity, the suppliers have the right to request the Group to pay the unsettled balance. As the Group has not transferred the significant risks and rewards relating to the bills receivables to its suppliers upon endorsement, it continues to recognize the full carrying amounts of bills receivables and trade and other payables.

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Carrying amount of transferred assets	22,059	13,719	11,176	9,913
Carrying amount of associated liabilities	22,059	13,719	11,176	9,913

During the Track Record Period, the Group have derecognized certain bills endorsed to certain suppliers on a full recourse basis. In the opinion of the directors of the Company, the Group has transferred the significant risks and rewards relating to these bills receivables, and the Group’s obligations to the corresponding counterparties were discharged in accordance with the commercial practice in the PRC and the risk of the default in payment of the endorsed bills receivable is low because all endorsed bills receivables are issued and guaranteed by the reputable PRC banks. The maximum exposure to the Group that may result from the default of these endorsed bills receivables at the end of each reporting period are as follows:

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Outstanding endorsed bills receivables	54,561	39,166	46,158	27,883

The outstanding endorsed bills receivables are with maturities no more than 6 months.

38. RELATED PARTIES’ TRANSACTIONS

Details of transactions between the Group and other related parties are disclosed below.

(a) Transactions with related parties

As at December 31, 2021, 2022 and 2023, Dr. Zhu Yi provided financial guarantees in respect of certain banking facilities and sale and leaseback payables granted to the Group amounted to RMB271,000,000, RMB473,869,000, RMB621,709,000, respectively. As at September 30, 2024, Dr. Zhu Yi provided financial guarantees in respect of sale and leaseback payables of the Group amounted to RMB7,304,000.

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(b) Compensation of key management personnel

The remuneration of key management personnel of the Group during the Track Record Period was as follows:

	Year ended December 31,			Nine months ended	
	2021	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(unaudited)	
Salaries and allowance	2,686	2,797	4,159	3,037	4,294
Share-based payments	–	–	123	30	217
Retirement benefit	28	30	82	52	174
	<u>2,714</u>	<u>2,827</u>	<u>4,364</u>	<u>3,119</u>	<u>4,685</u>

Key management represents certain executive directors of the Company disclosed in Note 14 who are the senior management personnel of the Group. The remuneration of key management is determined with reference to the performance of the Group and of the individual.

39. CAPITAL COMMITMENTS

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Capital expenditure in respect of:				
the acquisition of property, plant				
and equipment and intangible				
assets contracted for but not				
provided in the Historical				
Financial Information	<u>76,296</u>	<u>76,721</u>	<u>11,800</u>	<u>24,819</u>

40. CAPITAL RISK MANAGEMENT

The Group manages its capital to ensure that entities in the Group will be able to continue as a going concern while maximizing the return to stakeholders through the optimization of the debt and equity balance. The Group’s overall strategy remains unchanged throughout the Track Record Period.

The capital structure of the Group consists of net debt (which includes borrowings, lease liabilities, sale and leaseback payable, net of cash and cash equivalents) and equity attributable to owners of the Company (comprising share capital and reserves).

The management of the Group reviews the capital structure from time to time. As a part of this review, the management considers the cost of capital and the risks associated with the capital. Based on recommendations of the management, the Group will balance its overall capital structure through the payment of dividends, issue of new shares, new debts or the redemption of existing debts.

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41. SHARE-BASED PAYMENTS

Equity-settled share option scheme of a subsidiary of the Company

Since 2014, SystImmune, a wholly-owned subsidiary of the Company in the U.S., entered into share option arrangements with certain eligible employees to recognize their contributions and to strive for the future development of the Group’s overseas operations. The maximum number of share options of SystImmune that may be granted under the share option arrangements shall be 19,001,000 in aggregate as at the end of each reporting period. The share options of SystImmune were awarded under three tranches: awards issued before September 2018 with a vesting period of five years (“Tranche 1”), awards issued after September 2018 with a vesting period of six years (“Tranche 2”) and awards issued after January 2024 with a vesting period of four years (“Tranche 3”). Under Tranche 1, 20% and 20% of the share options shall vest and become exercisable on the first and second anniversaries of grant date, respectively; and at the third anniversary of grant date, the remaining 60% of the share options shall vest over the next 24 months and become exercisable at the end of each month. Under Tranche 2, 20% and 20% of the share options shall vest and become exercisable on the second and third anniversaries of grant date, respectively; and at the fourth anniversary of grant date, the remaining 60% of the share options shall vest over the next 24 months and become exercisable at the end of each month. Under Tranche 3, 15%, 25%, 25% and 35% of the share options shall vest and become exercisable on the first, second, third and fourth anniversaries of grant date, respectively. Should all of the share options outstanding at the end of each reporting period were exercised by the eligible employees, the Company would hold 99.94%, 99.92%, 99.78% and 96.89% effective interest in SystImmune, respectively.

The following table discloses movements of the granted share options during each reporting period:

	Tranche 1	Tranche 2	Tranche 3	Total
At January 1, 2021	109,000	118,800	–	227,800
Granted during the year	–	55,500	–	55,500
Forfeited during the year	(18,000)	(55,300)	–	(73,300)
At December 31, 2021	91,000	119,000	–	210,000
Granted during the year	–	231,500	–	231,500
Forfeited during the year	–	(120,500)	–	(120,500)
At December 31, 2022	91,000	230,000	–	321,000
Granted during the year	–	591,500	–	591,500
Forfeited during the year	–	(40,250)	–	(40,250)
At December 31, 2023	91,000	781,250	–	872,250
Granted during the period	–	–	12,193,465	12,193,465
Forfeited during the period	(37,500)	(136,500)	(3,000)	(177,000)
At September 30, 2024	53,500	644,750	12,190,465	12,888,715

As at December 31, 2021, 2022 and 2023 and September 30, 2024, the weighted average exercise prices per share option for outstanding share options are USD0.17, USD0.28, USD0.36 and USD0.60, respectively.

As at December 31, 2021, 2022 and 2023 and September 30, 2024, the exercisable share options are 97,350, 57,350, 131,500 and 139,450, respectively and the weighted average exercise prices per share option are USD0.13, USD0.16, USD0.27 and USD0.27, respectively. No eligible employees exercised their exercisable share options during the Track Record Period.

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The estimated fair value of the share options granted during the years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2024, are RMB80,000, RMB370,000, RMB1,544,000, RMB60,979,000, respectively.

The fair value of share options granted determined by using the Binomial model and significant inputs into the model for the awarding batch granted on May 28, 2024 were as follows, while the directors of the Company consider remaining batches of grants are insignificant.

Exercise price	USD0.62
Expected volatility	48.68%
Dividend yield	0%
Expected life	10 years
Risk-free rate	4.54%

Expected volatility was determined by using the historical volatility of comparable companies’ share prices over the previous 10 years. The expected life used in the model has been adjusted, based on the directors’ best estimate, for the effects of non-transferability, exercise restrictions and behavioural considerations.

Share options outstanding at December 31, 2021, 2022 and 2023 and September 30, 2024 had a weighted average remaining contractual life of 6.32, 7.97, 8.48 and 9.49 years, respectively.

The Group recognized a total expense of RMB102,000, RMB82,000, RMB145,000, RMB49,000 (unaudited) and RMB9,068,000 for the years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024 in the profit or loss against the share-based payments reserve of SystImmune, which is presented under non-controlling interests of the Group as at September 30, 2024.

In October 2024, the shareholder and board of directors of SystImmune approved additional 25,001,000 shares that may be granted under the share option arrangements. Subsequently, share options of 9,928,000 and 2,834,000 were granted by SystImmune to Dr. Zhu Yi and Dr. Zhu Hai, respectively.

42. FINANCIAL INSTRUMENTS

Categories of financial instruments

The Group

	As at December 31,			As at
	2021	2022	2023	September 30,
	RMB'000	RMB'000	RMB'000	2024
				RMB'000
Financial assets				
Bills receivables at FVTOCI	6,831	20,581	19,714	12,344
At amortized cost				
– Cash and cash equivalents	154,222	1,000,695	391,693	4,950,699
– Restricted bank balances	–	4,046	12,270	25,800
– Term deposits	–	–	–	698,790
– Trade and other receivables*	131,069	252,478	122,036	104,880
	285,291	1,257,219	525,999	5,780,169
	292,122	1,277,800	545,713	5,792,513

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	As at December 31,			As at September 30,
	2021	2022	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
Financial liabilities				
<i>At amortized cost</i>				
– Borrowings	211,250	425,563	633,409	1,520,395
– Trade and other payables**	133,889	240,914	288,918	325,042
– Amount due to a related party	14	14	14	12
– Sale and leaseback payable	61,474	109,081	49,066	7,599
	<u>406,627</u>	<u>775,572</u>	<u>971,407</u>	<u>1,853,048</u>

The Company

	As at December 31,			As at September 30,
	2021	2022	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
Financial assets				
Bills receivables at FVTOCI	<u>1,921</u>	<u>5,723</u>	<u>12,809</u>	<u>3,381</u>
<i>At amortized cost</i>				
– Cash and cash equivalents	128,172	942,456	42,538	88,194
– Restricted bank balances	–	3,682	4,770	4,750
– Amounts due from subsidiaries	179,333	404,107	640,708	1,346,974
– Trade and other receivables*	<u>42,921</u>	<u>60,911</u>	<u>38,717</u>	<u>29,273</u>
	<u>350,426</u>	<u>1,411,156</u>	<u>726,733</u>	<u>1,469,191</u>
	<u>352,347</u>	<u>1,416,879</u>	<u>739,542</u>	<u>1,472,572</u>

Financial liabilities

<i>At amortized cost</i>				
– Borrowings	86,067	230,217	468,311	1,198,144
– Trade and other payables**	25,845	70,659	40,032	100,389
– Amount due to a related party	14	14	14	12
– Amounts due to subsidiaries	<u>8,751</u>	<u>15,942</u>	<u>30,856</u>	<u>41,605</u>
	<u>120,677</u>	<u>316,832</u>	<u>539,213</u>	<u>1,340,150</u>

* Value-added tax recoverable, prepayments to suppliers, deferred issue costs and prepaid expenses are excluded.

** Salaries and wages payables, accruals, accrual for promotional cost and other tax payables are excluded.

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Financial risk management objectives and policies

The Group’s and Company’s major financial instruments include cash and cash equivalents, restricted bank balances, term deposits, amounts due from subsidiaries, trade and other receivables, bills receivables at FVTOCI, borrowings, trade and other payables, amount(s) due to a related party/subsidiaries, sale and leaseback payable and lease liabilities. Details of these financial instruments are disclosed in respective notes. The risks associated with these financial instruments include market risk (currency risk, interest rate risk and other price risk), credit risk and liquidity risk. The policies on how to mitigate these risks are set out below. The management of the Group and the Company manages and monitors these exposures to ensure appropriate measures are implemented on a timely and effective manner.

Market risk

(i) Currency risk

Several subsidiaries of the Company have foreign currency trade payables and bank balances which expose the Group to foreign currency risk. In addition, Baili-Bio with functional currency as RMB has an intra-group balance due from SystImmune denominated in USD as at September 30, 2024 which also exposes the Group to foreign currency risk.

The carrying amounts of the Group’s and the Company’s foreign currency denominated monetary assets and monetary liabilities at the end of the reporting period are as follows:

The Group

	Liabilities				Assets			
	As at December 31,			As at	As at December 31,			As at
	2021	2022	2023	September 30, 2024	2021	2022	2023	September 30, 2024
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
USD	3,647	2,571	18,234	–	1,349	3,578	1,818	4,377,905
Euros (“EUR”)	–	–	–	–	22	23	24	–
Intra-group balance								
USD	–	–	–	–	–	–	–	955,056

The Company

	Liabilities				Assets			
	As at December 31,			As at	As at December 31,			As at
	2021	2022	2023	September 30, 2024	2021	2022	2023	September 30, 2024
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
USD	–	–	–	–	1	1	1	9
EUR	–	–	–	–	22	23	24	–

The Group and the Company currently do not have a foreign exchange hedging policy. However, the management of the Group and the Company monitors foreign exchange exposure and will consider hedging significant foreign exchange exposure should the need arise.

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Sensitivity analysis

The following table details the Group’s sensitivity to a 5% increase and decrease in RMB against the relevant foreign currencies. 5% is the sensitivity rate used when reporting foreign currency risk internally to key management personnel and represents management’s assessment of the reasonably possible change in foreign exchange rates. The sensitivity analysis includes only outstanding foreign currency denominated monetary items and adjusts their translation at the end of the reporting period for a 5% change in foreign currency rates. A positive number below indicates a decrease in post-tax profit or an increase in post-tax loss where RMB strengthen 5% against the relevant currency. For a 5% weakening of RMB against the relevant currency, there would be an equal and opposite impact on the profit and the amounts below would be negative.

The Group

	USD impact			As at
	As at December 31,		2023	September 30,
	2021	2022	2023	2024
	RMB’000	RMB’000	RMB’000	RMB’000
Profit or loss	(115)	50	(821)	226,651

This is mainly attributable to the exposure outstanding on trade payables, bank balances and intra-group balance denominated in USD at the end of each reporting period.

During the Track Record Period, the sensitivity of RMB against EUR is immaterial.

The director of the Company consider the Company’s exposure to foreign currency risk is not significant.

(ii) Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Group is exposed to fair value interest rate risk in relation to certain interest-bearing bank balances, certificates of deposit, restricted bank balances, term deposits, bills receivables at FVTOCI, sale and leaseback payables, fixed-rate borrowings and lease liabilities, all bear fixed interest rates. The Group is mainly exposed to cash flow interest rate risk in relation to borrowings at floating interest rates (depends on the PRC loan prime rate). The Group currently does not have an interest rate hedging policy. There are no concentration on the Group’s interest rate risks. However, the management will consider hedging significant interest rate risk should the need arise.

Sensitivity analysis

The sensitivity analysis below has been determined based on the exposure to cash flow interest rate for the floating-rate (depends on the PRC loan prime rate) borrowings, assuming that the floating-rate borrowings outstanding at the end of the reporting period was outstanding for the whole relevant period.

If the interest rate on the floating-rate borrowings had been 50 basis points higher/lower, and all other variables were held constant, the Group’s loss after tax would increase/decrease by approximately RMB188,000, RMB1,090,000, RMB1,413,000, respectively, for the years ended December 31, 2021, 2022 and 2023 and the Group’s profit after tax would decrease/increase by approximately RMB1,820,000 for the nine months ended September 30, 2024.

If the interest rate on the floating-rate borrowings had been 50 basis points higher/lower, and all other variables were held constant, the Company’s profit after tax would decrease/increase by approximately RMB188,000, RMB451,000, RMB826,000 and RMB746,000, respectively, for the years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2024.

This is mainly attributable to the Group’s and the Company’s exposure to interest rates on its floating-rate borrowings as at December 31, 2021, 2022 and 2023 and September 30, 2024.

No sensitivity analysis on cash equivalents is presented as the directors of the Company consider that the exposure of cash flow interest rate risk arising from cash equivalents is minimal.

In the directors’ opinion, the sensitivity analysis above is unrepresentative for the interest rate risk as the exposure at the end of reporting period does not reflect the exposure during each reporting period.

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(iii) Other price risk

The Group is exposed to other price risk arising from money market funds classified as financial assets at FVTPL.

No sensitivity analysis is performed as the directors of the Company consider that the exposure of other price risk arising from the money market funds is insignificant because investments in money market funds are mainly on debt securities with high credit rating and liquidity.

Credit risk and impairment assessment

Credit risk refers to the risk that the Group’s and the Company’s counterparties default on their contractual obligations resulting in financial losses to the Group and the Company. The Group’s and the Company’s credit risk exposures are primarily attributable to bank balances, certificates of deposit, restricted bank balances, term deposits, trade and other receivables, bills receivables at FVTOCI and amounts due from subsidiaries. The Group does not hold any collateral or other credit enhancements to cover its credit risks associated with its financial assets, except that the credit risks associated with bills receivables is mitigated because settlement of certain bills receivables are backed by bills issued by reputable financial institutions.

The Group manages the risk with respect to bank balances, certificates of deposit, restricted bank balances and term deposits by placing in or entered into the contract with the banks with high reputation.

The Group has policies in place to ensure that sales are made to reputable and creditworthy customers with an appropriate financial strength and credit history. It also has other monitoring procedures to ensure that follow-up action is taken to recover overdue debts.

In addition, the Group reviews regularly the authorization of credit limits to individual customers and recoverable amount of each individual trade receivables to ensure that adequate impairment losses are made for irrecoverable amounts. In respect of the business of sale of pharmaceutical products, the Group normally grants a credit period from 30 to 120 days upon delivery to customers.

During the Track Record Period, the Group has endorsed and derecognized certain bills receivables for the settlement of trade and other payables with full recourse. In the opinion of the directors of the Group, the risks of the default of these derecognized endorsed bills receivables are low because all endorsed bills receivables are issued and guaranteed by reputable PRC banks.

The Group has the receivables from different customers and debtors operate in different areas and have different commercial scales. Thus, the Group classified the above assets into below categories:

- Category 1: trade receivables;
- Category 2: bills receivables;
- Category 3: other receivables; and
- Category 4: amounts due from subsidiaries.

(i) Trade receivables

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables. To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics by reference to aging based on the dates of goods delivery.

The expected loss rates are based on the payment profiles of sales over a period of 36 months before each reporting period and the corresponding historical credit losses occurred within the respective period. The historical loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors affecting the ability of the customers to settle the receivables. The Group has identified the consumer price index to be the most relevant factors for pharmaceutical customers, and accordingly adjusts the historical loss rates based on expected changes in these factors.

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On that basis, the loss allowance as at December 31, 2021, 2022 and 2023 and September 30, 2024 was listed as follows:

The Group

	Within 1 year RMB'000	1-2 years RMB'000	2-3 years RMB'000	3-4 years RMB'000	4-5 years RMB'000	Over 5 years RMB'000	Total RMB'000
Trade receivables as at December 31, 2021							
Expected loss rate	5%	10%	30%	50%	80%	100%	
Gross carrying amount (excluding receivables assessed individually)	107,342	1,089	1,939	1,042	1,742	4,706	117,860
Loss allowance provision	5,367	109	581	521	1,394	4,706	12,678
Individually impaired receivables	–	–	–	–	–	986	986
Loss allowance provision	–	–	–	–	–	986	986
Total loss allowance provision	<u>5,367</u>	<u>109</u>	<u>581</u>	<u>521</u>	<u>1,394</u>	<u>5,692</u>	<u>13,664</u>

	Within 1 year RMB'000	1-2 years RMB'000	2-3 years RMB'000	3-4 years RMB'000	4-5 years RMB'000	Over 5 years RMB'000	Total RMB'000
Trade receivables as at December 31, 2022							
Expected loss rate	5%	10%	30%	50%	80%	100%	
Gross carrying amount (excluding receivables assessed individually)	236,249	3,422	595	842	747	4,392	246,247
Loss allowance provision	11,813	342	178	421	598	4,392	17,744
Individually impaired receivables	–	–	–	–	–	986	986
Loss allowance provision	–	–	–	–	–	986	986
Total loss allowance provision	<u>11,813</u>	<u>342</u>	<u>178</u>	<u>421</u>	<u>598</u>	<u>5,378</u>	<u>18,730</u>

	Within 1 year RMB'000	1-2 years RMB'000	2-3 years RMB'000	3-4 years RMB'000	4-5 years RMB'000	Over 5 years RMB'000	Total RMB'000
Trade receivables as at December 31, 2023							
Expected loss rate	5%	10%	30%	50%	80%	100%	
Gross carrying amount (excluding receivables assessed individually)	101,015	1,301	1,461	332	354	4,289	108,752
Loss allowance provision	5,050	130	438	166	284	4,289	10,357
Individually impaired receivables	–	–	–	–	–	677	677
Loss allowance provision	–	–	–	–	–	677	677
Total loss allowance provision	<u>5,050</u>	<u>130</u>	<u>438</u>	<u>166</u>	<u>284</u>	<u>4,966</u>	<u>11,034</u>

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	Within 1 year RMB'000	1-2 years RMB'000	2-3 years RMB'000	3-4 years RMB'000	4-5 years RMB'000	Over 5 years RMB'000	Total RMB'000
Trade receivables as at September 30, 2024							
Expected loss rate	5%	10%	30%	50%	80%	100%	
Gross carrying amount (excluding receivables assessed individually)	71,189	1,127	469	912	176	1,657	75,530
Loss allowance provision	3,559	113	141	456	141	1,657	6,067
Individually impaired receivables	–	–	–	–	–	3,590	3,590
Loss allowance provision	–	–	–	–	–	3,590	3,590
Total loss allowance provision	<u>3,559</u>	<u>113</u>	<u>141</u>	<u>456</u>	<u>141</u>	<u>5,247</u>	<u>9,657</u>

The Company

	Within 1 year RMB'000	1-2 years RMB'000	2-3 years RMB'000	3-4 years RMB'000	4-5 years RMB'000	Over 5 years RMB'000	Total RMB'000
Trade receivables as at December 31, 2021							
Expected loss rate	5%	10%	30%	50%	80%	100%	
Gross carrying amount (excluding receivables assessed individually)	31,474	693	1,887	711	1,157	3,764	39,686
Loss allowance provision	1,574	69	566	356	925	3,764	7,254
Individually impaired receivables	–	–	–	–	–	986	986
Loss allowance provision	–	–	–	–	–	986	986
Total loss allowance provision	<u>1,574</u>	<u>69</u>	<u>566</u>	<u>356</u>	<u>925</u>	<u>4,750</u>	<u>8,240</u>

	Within 1 year RMB'000	1-2 years RMB'000	2-3 years RMB'000	3-4 years RMB'000	4-5 years RMB'000	Over 5 years RMB'000	Total RMB'000
Trade receivables as at December 31, 2022							
Expected loss rate	5%	10%	30%	50%	80%	100%	
Gross carrying amount (excluding receivables assessed individually)	52,781	2,541	406	803	605	3,348	60,484
Loss allowance provision	2,639	254	122	402	484	3,348	7,249
Individually impaired receivables	–	–	–	–	–	986	986
Loss allowance provision	–	–	–	–	–	986	986
Total loss allowance provision	<u>2,639</u>	<u>254</u>	<u>122</u>	<u>402</u>	<u>484</u>	<u>4,334</u>	<u>8,235</u>

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	Within 1 year RMB'000	1-2 years RMB'000	2-3 years RMB'000	3-4 years RMB'000	4-5 years RMB'000	Over 5 years RMB'000	Total RMB'000
Trade receivables as at December 31, 2023							
Expected loss rate	5%	10%	30%	50%	80%	100%	
Gross carrying amount (excluding receivables assessed individually)	31,116	712	1,357	256	346	3,205	36,992
Loss allowance provision	1,556	71	407	128	277	3,205	5,644
Individually impaired receivables	–	–	–	–	–	677	677
Loss allowance provision	–	–	–	–	–	677	677
Total loss allowance provision	1,556	71	407	128	277	3,882	6,321

	Within 1 year RMB'000	1-2 years RMB'000	2-3 years RMB'000	3-4 years RMB'000	4-5 years RMB'000	Over 5 years RMB'000	Total RMB'000
Trade receivables as at September 30, 2024							
Expected loss rate	5%	10%	30%	50%	80%	100%	
Gross carrying amount (excluding receivables assessed individually)	25,882	537	467	770	154	1,637	29,447
Loss allowance provision	1,294	54	140	385	124	1,637	3,634
Individually impaired receivables	–	–	–	–	–	2,539	2,539
Loss allowance provision	–	–	–	–	–	2,539	2,539
Total loss allowance provision	1,294	54	140	385	124	4,176	6,173

Trade receivables are written off when there is no reasonable expectation of recovery. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to engage in a repayment plan with the Group.

Impairment losses on trade receivables are presented as net impairment losses in the profit or loss. Subsequent recoveries of amounts previously written off are credited against the same line item.

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The following table shows the movement in lifetime ECL that has been recognized for trade receivables under the simplified approach.

The Group

	Lifetime ECL (not credit-impaired) RMB’000	Lifetime ECL (credit-impaired) RMB’000	Total RMB’000
As at January 1, 2021	16,437	995	17,432
– Impairment losses reversed	(2,371)	–	(2,371)
– Write-offs	(1,388)	(9)	(1,397)
As at December 31, 2021	12,678	986	13,664
– Impairment losses recognized	7,585	–	7,585
– Write-offs	(2,519)	–	(2,519)
As at December 31, 2022	17,744	986	18,730
– Impairment losses reversed	(6,646)	–	(6,646)
– Write-offs	(741)	(309)	(1,050)
As at December 31, 2023	10,357	677	11,034
– Transfer to credit-impaired	(2,913)	2,913	–
– Impairment losses reversed	(1,377)	–	(1,377)
As at September 30, 2024	6,067	3,590	9,657

In the opinion of the management, there was no significant changes to the loss rates for each ageing category during the Track Record Period.

The Company

	Lifetime ECL (not credit-impaired) RMB’000	Lifetime ECL (credit-impaired) RMB’000	Total RMB’000
As at January 1, 2021	7,586	995	8,581
– Impairment losses recognized	549	–	549
– Write-offs	(881)	(9)	(890)
As at December 31, 2021	7,254	986	8,240
– Impairment losses recognized	2,175	–	2,175
– Write-offs	(2,180)	–	(2,180)
As at December 31, 2022	7,249	986	8,235
– Impairment losses reversed	(922)	–	(922)
– Write-offs	(683)	(309)	(992)
As at December 31, 2023	5,644	677	6,321
– Transfer to credit-impaired	(1,862)	1,862	–
– Impairment losses reversed	(148)	–	(148)
As at September 30, 2024	3,634	2,539	6,173

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In the opinion of the management, there was no significant changes to the loss rates for each ageing category during the Track Record Period.

(ii) *Bills receivables*

The Group assesses the credit losses of bills receivables individually using three-stage approach. The credit risk of bills receivables is considered not significantly increased since initial recognition, and thus the impairment provision is determined as 12m ECL. As at December 31, 2021, 2022, 2023 and September 30, 2024, amount of RMB1,207,000, RMB992,000, RMB1,039,000 and RMB615,000 were provided as loss allowance for bills receivables respectively.

The Company assesses the credit losses of bills receivables individually using three-stage approach. The credit risk of bills receivables is considered not significantly increased since initial recognition, and thus the impairment provision is determined as 12m ECL. As at December 31, 2021, 2022, 2023 and September 30, 2024, amount of RMB537,000, RMB397,000, RMB383,000 and RMB82,000 were provided as loss allowance for bills receivables respectively.

(iii) *Other receivables*

The Group applies the IFRS 9 three-stage approach to measure ECL. Other receivables comprise advances to staff, deposits and others. Since the credit risk of other receivables is considered not significantly increased since initial recognition, therefore the impairment provision is determined as 12m ECL. As at December 31, 2021, 2022 and 2023 and September 30, 2024, amount of RMB927,000, RMB1,243,000, RMB1,400,000 and RMB1,724,000, respectively, were provided as loss allowance for other receivables.

The Company applies the IFRS 9 three-stage approach to measure ECL. Other receivables comprise advances to staff, deposit and others. Since the credit risk of other receivables is considered not significantly increased since initial recognition, therefore the impairment provision is determined as 12m ECL. As at December 31, 2021, 2022, 2023 and September 30, 2024, amount of RMB202,000, RMB311,000, RMB394,000 and RMB411,000 were provided as loss allowance for other receivables.

(iv) *Amounts due from subsidiaries*

Since the credit risk of amounts due from subsidiaries is considered not significantly increased since initial recognition, therefore the impairment provision is determined as 12m ECL. No loss allowance for amounts due from subsidiaries were provided as at December 31, 2021, 2022, 2023 and September 30, 2024.

Liquidity risk

The management of the Group and the Company are satisfied that the Group and Company will have sufficient financial resources to meet its financial obligations as they fall due in the foreseeable future by taking into account the Group’s and the Company’s cash flow projection, and the Group’s and the Company’s future capital expenditure in respect of its non-cancellable capital commitments, the management considers that the Group and the Company has sufficient working capital to meet in full its financial obligations as they fall due for at least the next twelve months from the end of each reporting period.

The Group and the Company relies on bank borrowings as a significant source of liquidity. As at December 31, 2021, 2022, 2023 and September 30, 2024, the Group had unutilized bank facilities of approximately RMB65,000,000, RMB186,605,000, RMB76,100,000 and RMB486,220,000, respectively. And as at December 31, 2021, 2022, 2023 and September 30, 2024, the Company had unutilized bank facilities of approximately RMB55,000,000, RMB111,605,000, RMB600,000 and RMB179,270,000, respectively.

The following table details the Group’s and the Company’s remaining contractual maturity for its financial liabilities and lease liabilities. The table has been drawn up based on the undiscounted cash flows. The table includes both interest and principal cash flows, where applicable.

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The Group

	Range of interest rate	On demand or within 1 year RMB'000	1 to 2 years RMB'000	2 to 5 years RMB'000	Total undiscounted cash flows RMB'000	Total carrying amount RMB'000
As at December 31, 2021						
<i>Non-interest bearing</i>						
Trade and other payables	N/A	133,889	–	–	133,889	133,889
Amount due to a related party	N/A	14	–	–	14	14
		<u>133,903</u>	<u>–</u>	<u>–</u>	<u>133,903</u>	<u>133,903</u>
<i>Interest bearing</i>						
Borrowings	4.38%-4.90%	167,904	2,225	52,176	222,305	211,250
Sale and leaseback payable	7.55%	22,674	22,674	22,674	68,022	61,474
Lease liabilities	4.75%	5,998	5,714	3,630	15,342	14,185
		<u>196,576</u>	<u>30,613</u>	<u>78,480</u>	<u>305,669</u>	<u>286,909</u>
		<u>330,479</u>	<u>30,613</u>	<u>78,480</u>	<u>439,572</u>	<u>420,812</u>
As at December 31, 2022						
<i>Non-interest bearing</i>						
Trade and other payables	N/A	240,914	–	–	240,914	240,914
Amount due to a related party	N/A	14	–	–	14	14
		<u>240,928</u>	<u>–</u>	<u>–</u>	<u>240,928</u>	<u>240,928</u>
<i>Interest bearing</i>						
Borrowings	3.85%-4.80%	199,841	178,683	72,151	450,675	425,563
Sale and leaseback payable	7.54%-10.04%	65,979	43,698	7,566	117,243	109,081
Lease liabilities	4.75%	7,274	4,900	1,037	13,211	12,688
		<u>273,094</u>	<u>227,281</u>	<u>80,754</u>	<u>581,129</u>	<u>547,332</u>
		<u>514,022</u>	<u>227,281</u>	<u>80,754</u>	<u>822,057</u>	<u>788,260</u>
As at December 31, 2023						
Trade and other payables	N/A	288,918	–	–	288,918	288,918
Amount due to a related party	N/A	14	–	–	14	14
		<u>288,932</u>	<u>–</u>	<u>–</u>	<u>288,932</u>	<u>288,932</u>
<i>Interest bearing</i>						
Borrowings	3.60%-4.45%	470,497	186,431	–	656,928	633,409
Sale and leaseback payable	7.54%-10.04%	43,759	7,735	–	51,494	49,066
Lease liabilities	4.75%	4,966	1,037	–	6,003	5,719
		<u>519,222</u>	<u>195,203</u>	<u>–</u>	<u>714,425</u>	<u>688,194</u>
		<u>808,154</u>	<u>195,203</u>	<u>–</u>	<u>1,003,357</u>	<u>977,126</u>

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	Range of interest rate	On demand or within 1 year <i>RMB'000</i>	1 to 2 years <i>RMB'000</i>	2 to 5 years <i>RMB'000</i>	Total undiscounted cash flows <i>RMB'000</i>	Total carrying amount <i>RMB'000</i>
As at September 30, 2024						
<i>Non-interest bearing</i>						
Trade and other payables	N/A	325,042	–	–	325,042	325,042
Amount due to a related party	N/A	12	–	–	12	12
		<u>325,054</u>	<u>–</u>	<u>–</u>	<u>325,054</u>	<u>325,054</u>
<i>Interest bearing</i>						
Borrowings	2.65%-4.45%	935,724	409,139	240,515	1,585,378	1,520,395
Sale and leaseback payable	7.54%	7,740	–	–	7,740	7,599
Lease liabilities	4.75%	9,271	8,030	7,377	24,678	22,505
		<u>952,735</u>	<u>417,169</u>	<u>247,892</u>	<u>1,617,796</u>	<u>1,550,499</u>
		<u>1,277,789</u>	<u>417,169</u>	<u>247,892</u>	<u>1,942,850</u>	<u>1,875,553</u>

The Company

	Range of interest rate	On demand or within 1 year <i>RMB'000</i>	1 to 2 years <i>RMB'000</i>	2 to 5 years <i>RMB'000</i>	Total undiscounted cash flows <i>RMB'000</i>	Total carrying amount <i>RMB'000</i>
As at December 31, 2021						
<i>Non-interest bearing</i>						
Trade and other payables	N/A	25,845	–	–	25,845	25,845
Amount due to a related party	N/A	14	–	–	14	14
Amounts due to subsidiaries	N/A	8,751	–	–	8,751	8,751
		<u>34,610</u>	<u>–</u>	<u>–</u>	<u>34,610</u>	<u>34,610</u>
<i>Interest bearing</i>						
Borrowings	4.38%-4.45%	39,024	2,225	52,176	93,425	86,067
Lease liabilities	4.75%	1,548	1,260	945	3,753	3,527
		<u>40,572</u>	<u>3,485</u>	<u>53,121</u>	<u>97,178</u>	<u>89,594</u>
		<u>75,182</u>	<u>3,485</u>	<u>53,121</u>	<u>131,788</u>	<u>124,204</u>

As at December 31, 2022

<i>Non-interest bearing</i>						
Trade and other payables	N/A	70,659	–	–	70,659	70,659
Amount due to a related party	N/A	14	–	–	14	14
Amounts due to subsidiaries	N/A	15,942	–	–	15,942	15,942
		<u>86,615</u>	<u>–</u>	<u>–</u>	<u>86,615</u>	<u>86,615</u>

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	Range of interest rate	On demand or within 1 year RMB'000	1 to 2 years RMB'000	2 to 5 years RMB'000	Total undiscounted cash flows RMB'000	Total carrying amount RMB'000
<i>Interest bearing</i>						
Borrowings	3.85%-4.45%	117,939	55,083	72,151	245,173	230,217
Lease liabilities	4.75%	1,602	945	–	2,547	2,436
		119,541	56,028	72,151	247,720	232,653
		206,156	56,028	72,151	334,335	319,268
As at December 31, 2023						
<i>Non-interest bearing</i>						
Trade and other payables	N/A	40,032	–	–	40,032	40,032
Amount due to a related party	N/A	14	–	–	14	14
Amounts due to subsidiaries	N/A	30,856	–	–	30,856	30,856
		70,902	–	–	70,902	70,902
<i>Interest bearing</i>						
Borrowings	3.60%-4.30%	314,340	172,403	–	486,743	468,311
Lease liabilities	4.75%	945	–	–	945	923
		315,285	172,403	–	487,688	469,234
		386,187	172,403	–	558,590	540,136
As at September 30, 2024						
<i>Non-interest bearing</i>						
Trade and other payables	N/A	100,389	–	–	100,389	100,389
Amount due to a related party	N/A	12	–	–	12	12
Amounts due to subsidiaries	N/A	41,605	–	–	41,605	41,605
		142,006	–	–	142,006	142,006
<i>Interest bearing</i>						
Borrowings	2.65%-4.10%	771,084	235,429	240,515	1,247,028	1,198,144
Lease liabilities	4.75%	1,018	761	338	2,117	1,988
		772,102	236,190	240,853	1,249,145	1,200,132
		914,108	236,190	240,853	1,391,151	1,342,138

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ACCOUNTANTS’ REPORT

Fair value

The management of the Group have closely monitored and determined the appropriate valuation techniques and inputs for fair value measurements.

In estimating the fair value of financial instruments, the Group uses market-observable data to the extent it is available.

The following table gives information about how the fair values of these financial assets are determined (in particular, the valuation technique(s) and inputs used).

The Group

Financial assets	Fair value				Fair value hierarchy	Valuation technique(s) and key input(s)
	As at December 31,		2023	As at September 30,		
	2021	2022		2024		
Bills receivables at FVTOCI	Assets- RMB6,831,000	Assets- RMB20,581,000	Assets- RMB19,714,000	Assets- RMB12,344,000	Level 2	Discounted cash flow. Future cash flows are estimated based on discount rate observed in the available market.

The Company

Financial assets	Fair value				Fair value hierarchy	Valuation technique(s) and key input(s)
	as at December 31,		2023	As at September 30,		
	2021	2022		2024		
Bills receivables at FVTOCI	Assets- RMB1,921,000	Assets- RMB5,723,000	Assets- RMB12,809,000	Assets- RMB3,381,000	Level 2	Discounted cash flow. Future cash flows are estimated based on discount rate observed in the available market.

Fair value of financial assets and financial liabilities that are not measured at fair value on a recurring basis (but fair value disclosures are required)

The management considers that the carrying amounts of financial assets and financial liabilities at amortized cost recognized in the consolidated statements of financial position approximate their fair values.

APPENDIX I

ACCOUNTANTS’ REPORT

43. RECONCILIATION OF LIABILITIES/ASSETS ARISING FROM FINANCING ACTIVITIES

The table below details changes in the Group’s liabilities/assets arising from financing activities, including both cash and non-cash changes. Liabilities/assets arising from financing activities are those 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.

	Borrowings	Sale and leaseback payable	Dividend payable	Lease liabilities	Redeemable shares	(Deferred)/ accrued share issue costs	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>	<i>RMB'000</i>
At January 1, 2021	150,209	–	–	6,847	627,253	–	784,309
Financing cash flows (<i>Note</i>)	54,235	60,000	(20,000)	(3,198)	–	(2,161)	88,876
Dividend declared	–	–	20,000	–	–	–	20,000
New lease entered	–	–	–	10,124	–	–	10,124
Conversion of redeemable shares	–	–	–	–	(634,904)	–	(634,904)
Finance costs recognized	6,806	1,474	–	412	7,651	–	16,343
At December 31, 2021	211,250	61,474	–	14,185	–	(2,161)	284,748
Financing cash flows (<i>Note</i>)	201,819	38,217	–	(5,484)	–	(2,191)	232,361
New lease entered	–	–	–	3,685	–	–	3,685
Leases early terminated	–	–	–	(295)	–	–	(295)
Finance costs recognized	12,494	9,390	–	597	–	–	22,481
Share issued costs recognized in capital reserve	–	–	–	–	–	29,492	29,492
At December 31, 2022	425,563	109,081	–	12,688	–	25,140	572,472
Financing cash flows (<i>Note</i>)	189,346	(65,748)	–	(7,455)	–	(25,140)	91,003
New lease entered	–	–	–	1,489	–	–	1,489
Leases early terminated	–	–	–	(1,449)	–	–	(1,449)
Finance costs recognized	18,500	5,733	–	446	–	–	24,679
At December 31, 2023	633,409	49,066	–	5,719	–	–	688,194
Deferred issue costs recognized	–	–	–	–	–	24,979	24,979
Financing cash flows (<i>Note</i>)	860,832	(42,689)	–	(7,240)	–	(16,219)	794,684
New lease entered	–	–	–	23,604	–	–	23,604
Finance costs recognized	26,154	1,222	–	422	–	–	27,798
At September 30, 2024	1,520,395	7,599	–	22,505	–	8,760	1,559,259

APPENDIX I

ACCOUNTANTS’ REPORT

	Borrowings	Sale and leaseback payable	Dividend payable	Lease liabilities	Redeemable shares	(Deferred)/ accrued share issue costs	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At December 31, 2022	425,563	109,081	–	12,688	–	25,140	572,472
Financing cash flows (<i>Note</i>)	(10,007)	(58,388)	–	(5,449)	–	(23,658)	(97,502)
New lease entered	–	–	–	1,489	–	–	1,489
Leases early terminated	–	–	–	(1,449)	–	–	(1,449)
Finance costs recognized	13,645	4,429	–	418	–	–	18,492
At September 30, 2023 (unaudited)	<u>429,201</u>	<u>55,122</u>	<u>–</u>	<u>7,697</u>	<u>–</u>	<u>1,482</u>	<u>493,502</u>

Note: The cash flows represent interest paid, new bank borrowings raised, repayment of bank borrowings, repayment of lease liabilities, proceeds from sale and leaseback of equipment, repayment of sale and leaseback of equipment, transaction costs attributable to issue of shares and dividends paid.

44. MAJOR NON-CASH TRANSACTIONS

During the years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, the Group endorsed bills receivables amounted to RMB43,583,000, RMB38,249,000, RMB31,693,000, RMB28,366,000 (unaudited) and RMB15,872,000 respectively, for the settlement of purchase of long-term assets.

During the years ended December 31, 2021, 2022 2023 and the nine months ended September 30, 2023 and 2024, the Group entered into five, three, one, one (unaudited) and eight lease agreements for the use of leased properties for 3 years, 2-3 years, 1.5 years, 1.5 years (unaudited) and 1.5-7 years, respectively. On the lease commencement, the Group recognized right-of-use assets of RMB10,124,000, RMB3,685,000, RMB1,489,000, RMB1,489,000 (unaudited) and RMB23,604,000, respectively and lease liabilities of RMB10,124,000, RMB3,685,000, RMB1,489,000, RMB1,489,000 (unaudited) and RMB23,604,000, respectively.

45. PARTICULARS OF SUBSIDIARIES

The Company

	2021	2022	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
Unlisted investments, at cost				
– Baili Pharmaceutical	205,320	205,320	1,089,718	1,089,718
– Lhasa Xinbo (<i>Note</i>)	<u>4,750</u>	<u>4,750</u>	<u>4,750</u>	<u>4,750</u>
	<u>210,070</u>	<u>210,070</u>	<u>1,094,468</u>	<u>1,094,468</u>

Note: The Company directly holds 22.35% equity interest in Lhasa Xinbo

APPENDIX I

ACCOUNTANTS’ REPORT

As at the date of this report, the Company had direct or indirect interests in the following subsidiaries.

		Equity interest attributable to the Group						
Name of subsidiaries	Place and date of establishment/ incorporation				As at	At date of this report	Issued and fully paid share capital/registered capital	Principal activities
		As at December 31,		September 30,				
		2021	2022	2023	2024			
		%	%	%	%	%		
Directly held:								
Baili Pharmaceutical	PRC August 23, 1996	100	100	100	100	100	As at December 31, 2021 and 2022: RMB105,000,000 As at December 31, 2023 and as at September 30, 2024 and date of this report: RMB[125,000,000]	Production, research and development of pharmaceutical products
Indirectly held:								
Guorui Pharmaceutical	PRC December 7, 2005	100	100	100	100	100	RMB20,000,000	Production, research and development of pharmaceutical products
Lhasa Xinbo	PRC August 22, 2013	100	100	100	100	100	RMB21,250,000	Sales and distribution of pharmaceutical products
Panku Capital Limited (“Panku Capital”)	British Virgin Islands April 16, 2014	100	100	100	100	100	As at December 31, 2021: USD46,841,413 As at December 31, 2022: USD56,247,970 As at December 31, 2023: USD79,403,416 As at September 30, 2024 and date of this report: USD[98,007,125]	Investment holding
SystImmune	The U.S. April 21, 2014	100	100	100	100	100	USD2,895	Research and development of pharmaceutical products
Jingxi Pharmaceutical	PRC September 29, 2014	100	100	100	100	100	RMB5,000,000	Production, research and development of pharmaceutical products

APPENDIX I

ACCOUNTANTS’ REPORT

Equity interest attributable to the Group								
Name of subsidiaries	Place and date of establishment/ incorporation	Equity interest attributable to the Group				At date of this report	Issued and fully paid share capital/registered capital	Principal activities
		As at December 31,		September 30,	As at			
		2021	2022					
		%	%	%	%	%		
Hiatt Technology	PRC September 29, 2014	100	100	100	100	100	RMB1,000,000	Production, research and development of pharmaceutical products
Baili-Bio	PRC February 21, 2017	100	100	100	100	100	As at December 31, 2021, 2022 and 2023: RMB5,000,000 As at September 30, 2024 and date of this report: RMB[200,000,000]	Production, research and development of pharmaceutical products
Tianze Pharmaceutical	PRC November 26, 2020	100	100	100	100	100	RMB nil (issued and fully paid capital)/ RMB10,000,000	Production of pharmaceutical products

All the subsidiaries of the Company are limited liability companies. None of the subsidiaries had any debt securities outstanding as at December 31, 2021, 2022 and 2023 and September 30, 2024 or at any time during the Track Record Period.

The statutory financial statements of the Company and all of its subsidiaries established in the PRC for each of the years ended December 31, 2021, 2022 and 2023 were prepared in accordance with relevant accounting principles and financial regulations applicable to the PRC enterprise and were audited by BDO China Shu Lun Pan Certified Public Accountants LLP 立信會計師事務所(特殊普通合伙), certified public accountants registered in the PRC.

The statutory financial statements of SystImmune for each of the years ended December 31, 2021, 2022 and 2023 were prepared in accordance with relevant accounting principles generally accepted in the U.S. and were audited by UHY LLP, certified public accountants registered in the U.S..

No statutory financial statements have been prepared for Panku Capital since there are no statutory audit requirements in the jurisdiction where it was established/incorporated.

46. EVENTS AFTER REPORTING PERIOD

Other than those disclosed elsewhere in the Historical Financial Information, the Group has no other significant event took place subsequent to September 30, 2024.

47. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements of the Company, any of its subsidiaries or the Group have been prepared in respect of any period subsequent to September 30, 2024.

APPENDIX IIA

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX IIA

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX IIA

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX IIA

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX IIA

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX IIB

PROFIT ESTIMATE

Our estimate of the consolidated profit attributable to the owners of the Company for [REDACTED] is set out in the paragraph headed “Profit estimate for [REDACTED]” under the section headed “Financial Information” in this Document.

A. OVERVIEW

Our Directors estimate that, on the bases set out in Part B of this Appendix IIB and in the absence of unforeseen circumstances, the estimate of the consolidated profit attributable to the owners of our Company for [REDACTED] will be not less than RMB[REDACTED].

Note: The estimated consolidated profit attributable to the owners of our Company for [REDACTED] has been taken into account of the [REDACTED] expenses incurred during [REDACTED] of approximately RMB[REDACTED].

B. BASES

Our Directors have prepared the estimate of the consolidated profit attributable to the owners of our Company for [REDACTED] based on (i) the audited consolidated results of our Group for the nine months ended September 30, 2024; and (ii) the unaudited consolidated results of our Group based on the management accounts of our Group for [REDACTED].

The estimate has been prepared on a basis consistent in all material respects with the accounting policies currently adopted by our Group as set out in the Accountants’ Report, the text of which is set forth in Appendix I to this Document.

C. LETTERS

The letters set out in Parts D and E of this Appendix IIB are prepared for the purpose of incorporation in this Document received from Deloitte Touche Tohmatsu, Certified Public Accountants, Hong Kong, being the Reporting Accountant, and from the Joint Sponsors in connection with the estimated consolidated profit attributable to the owners of our Company for [REDACTED].

APPENDIX IIB

PROFIT ESTIMATE

D. LETTER FROM THE REPORTING ACCOUNTANTS

The following is the text of a letter, prepared for inclusion in this document, received from the Company’s reporting accountants, Deloitte Touche Tohmatsu, Certified Public Accountants, Hong Kong, in connection with the estimate of the consolidated profit attributable to owners of the Company for [REDACTED].

Deloitte.

德勤

[Date of document]

The Directors
四川百利天恒藥業股份有限公司
Sichuan Biokin Pharmaceutical Co., Ltd.
1#, Building 1, No. 161, Baili Road
Cross-Strait Science and Technology Industrial Park,
Wenjiang District, Chengdu City, Sichuan Province,
The People’s Republic of China

Goldman Sachs (Asia) L.L.C.
68/F, Cheung Kong Center
2 Queen’s Road Central
Hong Kong

J.P. Morgan Securities (Far East) Limited*
28/F, Chater House
8 Connaught Road Central
Hong Kong

CITIC Securities (Hong Kong) Limited*
18/F, One Pacific Place
88 Queensway
Hong Kong

(* in no particular order)

Dear Sirs,

四川百利天恒藥業股份有限公司 Sichuan Biokin Pharmaceutical Co., Ltd. (the “Company”)

PROFIT ESTIMATE FOR [REDACTED]

We refer to the estimate of the consolidated profit of the Group attributable to owners of the Company for [REDACTED] (the “Profit Estimate”) set forth in the section headed “Financial Information– Profit Estimate for [REDACTED]” in the document of the Company dated [date of document] (the “Document”).

APPENDIX IIB

PROFIT ESTIMATE

DIRECTORS’ RESPONSIBILITIES

The Profit Estimate has been prepared by the directors of the Company based on the audited consolidated results of the Company and its subsidiaries (collectively referred to as the “Group”) for the nine months ended September 30, 2024 and the unaudited consolidated results based on the management accounts of the Group for [REDACTED]. The Company’s directors are solely responsible for the Profit Estimate.

OUR INDEPENDENCE AND QUALITY CONTROL

We have complied with the independence and other ethical requirements of the “Code of Ethics for Professional Accountants” issued by the Hong Kong Institute of Certified Public Accountants (the “HKICPA”), which is founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior.

Our firm applies Hong Kong Standard on Quality Management (HKSQM) 1 “Quality Management for Firms that Perform Audits or Reviews of Financial Statements, or Other Assurance or Related Services Engagements” issued by the HKICPA, which requires the firm to design, implement and operate a system of quality management including policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

REPORTING ACCOUNTANTS’ RESPONSIBILITIES

Our responsibility is to express an opinion on the accounting policies and calculations of the Profit Estimate based on our procedures. We conducted our engagement in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 500 “Reporting on Profit Forecasts, Statements of Sufficiency of Working Capital and Statements of Indebtedness” and with reference to Hong Kong Standard on Assurance Engagements 3000 (Revised) “Assurance Engagements Other Than Audits or Reviews of Historical Financial Information” issued by the HKICPA. Those standards require that we plan and perform our work to obtain reasonable assurance as to whether, so far as the accounting policies and calculations are concerned, the Company’s directors have properly compiled the Profit Estimate in accordance with the bases adopted by the directors and as to whether the Profit Estimate is presented on a basis consistent in all material respects with the accounting policies normally adopted by the Group. Our work is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing issued by the HKICPA. Accordingly, we do not express an audit opinion.

APPENDIX IIB

PROFIT ESTIMATE

OPINION

In our opinion, so far as the accounting policies and calculations are concerned, the Profit Estimate has been properly compiled in accordance with the bases adopted by the directors as set out in Appendix IIB of the Document and is presented on a basis consistent in all material respects with the accounting policies normally adopted by the Group as set out in our accountants’ report dated [date], the text of which is set out in Appendix I of the Document.

Yours faithfully,

[Deloitte Touche Tohmatsu]

Certified Public Accountants

Hong Kong

APPENDIX IIB

PROFIT ESTIMATE

E. LETTER FROM THE JOINT SPONSORS

Goldman Sachs

J.P. Morgan

CITIC Securities

(in no particular order)

The Board of Directors

Sichuan Biokin Pharmaceutical Co., Ltd. 四川百利天恒藥業股份有限公司

[REDACTED]

Dear Sirs,

We refer to the profit estimate of the consolidated profit attributable to owners of Sichuan Biokin Pharmaceutical Co., Ltd. (the “**Company**”) for [REDACTED] (the “**Profit Estimate**”) set forth in the section headed “[Financial Information — Profit estimate for [REDACTED]]” in the document of the Company dated [REDACTED] (the “**Document**”).

The Profit Estimate, for which you as the Directors of the Company are solely responsible for, has been prepared by the Directors of the Company based on the audited consolidated results of the Company and its subsidiaries (collectively, the “**Group**”) for the nine months ended September 30, 2024 as set out in the Accountant’s Report in Appendix I in the Document and the unaudited consolidated results based on the management accounts of the Group for [REDACTED].

We have discussed with you the bases made by the Directors of the Company as set forth in Appendix IIB to the Document, upon which the Profit Estimate has been made. We have also considered, and relied upon, the letter dated [REDACTED] addressed to you and us from Deloitte Touche Tohmatsu, the reporting accountants of the Company (the “**Reporting Accountants**”), regarding the accounting policies and calculations upon which the Profit Estimate has been made.

On the basis of the information comprising the Profit Estimate and on the basis of the accounting policies and calculations adopted by you and reviewed by the Reporting Accountants, we are of the opinion that the Profit Estimate, for which you as the Directors of the Company are solely responsible for, has been made after due and careful enquiry.

Yours faithfully,

For and on behalf of
Goldman Sachs (Asia)
L.L.C.
[Name]
[Title]

For and on behalf of
J.P. Morgan Securities
(Far East) Limited*
[Name]
[Title]

For and on behalf of
CITIC Securities
(Hong Kong) Limited*
[Name]
[Title]

(in no particular order)*

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

TAXATION OF SECURITY HOLDERS

Income tax and capital gains tax of holders of the H shares is subject to the laws and practices of the PRC and of jurisdictions in which holders of the H shares are resident or otherwise subject to tax. The following summary of certain relevant taxation provisions is based on current laws and practices, and has not taken in to account the expected change or amendment to the relevant laws or policies and does not constitute any opinion or advice. The discussion does not deal with all possible tax consequences relating to an investment in the H shares, nor does it take into account the specific circumstances of any particular investor, 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 or adjustment and may have retrospective effect.

This discussion does not address any aspects of PRC taxation other than income tax, capital gains tax and profits tax, sales tax, value-added tax, stamp duty and estate duty. Prospective investors are urged to consult their financial advisers regarding the PRC and other tax consequences of owning and disposing of the H shares.

Taxation In mainland China

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 most recently 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 most recently 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 of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) (hereinafter referred to as the “Arrangement for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《對所得避免雙重徵稅和防止偷漏稅的安排》)”) signed by the Mainland of China and the Hong Kong Special Administrative Region on August 21, 2006, the PRC government may impose tax on dividends paid by a PRC company to a Hong Kong resident (including natural person and legal entity), but such tax shall not exceed 10% of the total amount of dividends payable. If a Hong Kong resident directly holds 25% or more of equity interest in a PRC company and the

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

Hong Kong resident is the beneficial owner of the dividends and meets other conditions, such tax shall not exceed 5% of the total amount of dividends payable by the PRC company. The Fifth Protocol to the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income (《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 “Fifth Protocol (《第五協議書》)”) issued by the SAT and became effective on December 6, 2019 provides that such provisions shall not apply to arrangements or transactions made for one of the primary purposes of obtaining such tax benefits.

Enterprise Investors

In accordance with the Enterprise 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 and latest amended on December 29, 2018 and the Implementation Provisions of the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》) issued by the State Council on December 6, 2007, came into effect on January 1, 2008 and amended on April 23, 2019 (hereinafter collectively referred to as the “EIT Law”), a non-resident enterprise is generally subject to a 10% enterprise 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. Such withholding tax may be reduced or exempted pursuant to an applicable treaty for the avoidance of double taxation.

The Circular of the State Administration of Tax on Issues Relating to the Withholding and Remitting of Enterprise 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》), which was issued and implemented by the SAT on November 6, 2008, further clarified that a PRC-resident enterprise must withhold corporate income tax at a rate of 10% on the dividends paid to non-PRC resident enterprise holders of H Shares which are derived out of profit generated since 2008. Non-PRC resident enterprise shareholders who need to enjoy tax treaty benefits, the relevant provisions of such tax treaty shall apply.

Pursuant to the Arrangement for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《對所得避免雙重徵稅和防止偷漏稅的安排》), the PRC government may impose tax on dividends paid by a PRC company to a Hong Kong resident (including natural person and legal entity), but such tax shall not exceed 10% of the total amount of dividends payable. If a Hong Kong resident directly holds 25% or more of equity interest in a PRC company and the Hong Kong resident is the beneficial owner of the dividends and meets other conditions, such tax shall not exceed 5% of the total amount of dividends payable by the PRC company. The Fifth Protocol (《第五協議書》) provides that such provisions shall not apply to arrangements or transactions made for one of the primary purposes of obtaining such tax benefits.

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

Although there may be other provisions under the Arrangement for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《對所得避免雙重徵稅和防止偷漏稅的安排》), the treaty benefits under the criteria shall not be granted in the circumstance where relevant gains, after taking into account all relevant facts and conditions, are reasonably deemed to be one of the main purposes for the arrangement or transactions which will bring any direct or indirect benefits under this Arrangement, except when the grant of benefits under such circumstance is consistent with relevant objective and goal under the Arrangement. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax law and regulation, such as the Notice of the 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》).

Tax Treaties

Non-resident investors residing in jurisdictions which have entered into treaties or adjustments for the avoidance of double taxation with the PRC might be entitled to a reduction of the Chinese corporate income tax imposed on the dividends received from PRC companies. The PRC currently has entered into Avoidance of Double Taxation Treaties or Arrangements with a number of countries and regions including Hong Kong Special Administrative Region, Macau Special Administrative Region, Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the United States. Non-PRC resident enterprises entitled to preferential tax rates in accordance with the relevant taxation treaties or arrangements are required to apply to the Chinese tax authorities for a refund of the corporate income tax in excess of the agreed tax rate, and the refund application is subject to approval by the Chinese tax authorities.

Taxation on Share Transfer

VAT and Local Additional Tax

Pursuant to the Notice of Ministry of Finance and State Administration of Taxation on Fully Implementing the Pilot Reform for the Transition from Business Tax to Value-added Tax (《財政部、國家稅務總局關於全面推開營業稅改徵增值稅試點的通知》) (the “Circular 36”), which was implemented on May 1, 2016 and partially repealed on July 1, 2017, January 1, 2018 and April 1, 2019, entities and individuals engaged in the services sale in the PRC are subject to VAT and “engaged in the services sale in the PRC” means that the seller or buyer of the taxable services is located in the PRC. Circular 36 also provides that transfer of financial products, including transfer of the ownership of marketable securities, shall be subject to VAT at 6% on the taxable revenue (which is the balance of sales price upon deduction of purchase price), for a general or a foreign VAT taxpayer. However, individuals who transfer financial products are exempt from VAT, which is also provided in the Notice of Ministry of Finance and State Administration of Taxation on Several Tax Exemption Policies for Business Tax on Sale and Purchase of Financial Commodities by Individuals (《財政部、國家稅務總局關於個人金融商品買賣等營業稅若干免稅政策的通知》) effective on January 1, 2009. According to these regulations, if the holder is a non-resident individual, the PRC VAT is exempted from the sale

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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 the PRC, 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, it is still uncertain whether the non-Chinese resident enterprises are required to pay the PRC VAT for the disposal of H shares in practice.

At the same time, VAT payers are also required to pay urban maintenance and construction tax, education surtax and local education surcharge, which shall be usually subject to 12% of the VAT payable (if any).

Income Tax

Individual Investors

According to the IIT Law, gains on the transfer of equity interests in the PRC resident enterprises are subject to individual income tax at a rate of 20%.

Pursuant to the Circular on Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) issued by the Ministry of Finance 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 Ministry of Finance and the SAT have not expressly stated whether they will continue to exempt tax on income of individuals from transfer of the shares of listed enterprises in the latest amended IIT Law.

However, on December 31, 2009, the Ministry of Finance, 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》), which came into effect on January 1, 2010, which states that individuals' income from the transfer of listed shares obtained from the public offering of listed companies and transfer market on the Shanghai Stock Exchange and the Shenzhen Stock Exchange shall continue to be exempted from individual income tax, except for the relevant shares which are subject to sales restriction (as defined in the Supplementary Notice on Issues Concerning the Levy of Individual Income Tax on Individuals' Income from the Transfer of Restricted Stocks of Listed Companies (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的補充通知》) 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.

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Enterprise Investors

In accordance with the EIT 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. Such tax may be reduced or exempted pursuant to relevant tax treaties or agreements on avoidance of double taxation.

Stamp Duty

According to the Stamp Duty Law of the PRC (《中華人民共和國印花稅法》), which was promulgated on June 10, 2021 and came into effect on July 1, 2022, PRC stamp duty only applies to specific taxable document executed or received within the PRC, having legally binding force in the PRC and protected under the PRC laws, thus the requirements of the stamp duty imposed on the transfer of shares of PRC listed companies shall not apply to the acquisition and disposal of H Shares by non-PRC investors outside of the PRC.

Estate Duty

As of the date of this document, no estate duty has been levied in the PRC under the PRC laws.

EIT

According to the EIT Law, enterprises and other income-generating organizations (hereinafter collectively referred to as “an enterprise” or “enterprises”) within the territory of the PRC are the taxpayers of enterprise income tax and shall pay enterprise income tax in accordance with the provisions of the EIT Law. The Enterprise Income Tax rate is 25%. 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》), which was promulgated by the Ministry of Science and Technology, the Ministry of Finance and the State Administration of Taxation on April 14, 2008, amended on January 29, 2016 and became effective on January 1, 2016, an enterprise recognized as a high and new technology enterprise may apply for a preferential enterprise income tax rate of 15% pursuant to the relevant requirements of the EIT Law.

VAT

Pursuant to the Interim Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例》) issued on December 13, 1993 by the State Council, came into effect on January 1, 1994, and revised on November 10, 2008, February 6, 2016 and November 19, 2017, as well as the Implementation Rules for the Interim Regulations on Value-Added Tax of the

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PRC (《中華人民共和國增值稅暫行條例實施細則》) issued on December 25, 1993 by the MOF, came into effect on the same day and revised on December 15, 2008 and October 28, 2011, any entities and individuals engaged in the sale of goods, supply of processing, repair and replacement services, and import of goods within the territory of the PRC are taxpayers of VAT and shall pay the VAT in accordance with the law and regulation. The rate of VAT for sale of goods is 17% unless otherwise specified, such as the rate of VAT for sale of transportation is 11%. With the VAT reforms in the PRC, the rate of VAT has been changed several times. The MOF and the SAT issued the Notice of on Adjusting VAT Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer’s VAT taxable sale or import of goods to 16% and 10%, respectively, this adjustment became effect on May 1, 2018. Subsequently, the MOF, the SAT and the General Administration of Customs jointly issued the Announcement on Relevant Policies for Deepening the VAT Reform (《財政部稅務總局海關總署關於深化增值稅改革有關政策的公告》) on March 20, 2019 to make a further adjustment, which came into effect on April 1, 2019. The tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

MAJOR TAXATION OF OUR COMPANY IN THE PRC

Enterprise Income Tax

The Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (“the EIT Law”), promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and amended on February 24, 2017 and December 29, 2018, as well as the Implementation Rules of the EIT Law (《中華人民共和國企業所得稅法實施條例》) (“the Implementation Rules”), promulgated by the State Council on December 6, 2007, came into force on January 1, 2008 and amended on April 23, 2019, are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and its Implementation Rules, enterprises are classified into resident enterprises and non-resident enterprises. Resident enterprises refer to enterprises that are legally established in the PRC, or are established under foreign laws but whose actual management bodies are located in the PRC. And non-resident enterprises refer to enterprises that are legally established under foreign laws and have set up institutions or sites in the PRC but with no actual management body in the PRC, or enterprises that have not set up institutions or sites in the PRC but have derived incomes from the PRC. A uniform income tax rate of 25% applies to all resident enterprises and non-resident enterprises that have set up institutions or sites in the PRC to the extent that such incomes are derived from their set-up institutions or sites in the PRC, or such income are obtained outside the PRC but have an actual connection with the set-up institutions or sites. And non-resident enterprises that have not set up institutions or sites in the PRC or have set up institutions or sites but the incomes obtained by the said enterprises have no actual connection with the set-up institutions or sites, shall pay enterprise income tax at the rate of 10% in relation to their income sources from the PRC.

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VAT

The major PRC law and regulation governing value-added tax are the Interim Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例》) issued on December 13, 1993 by the State Council, came into effect on January 1, 1994, and revised on November 10, 2008, February 6, 2016 and November 19, 2017, as well as the Implementation Rules for the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值稅暫行條例實施細則》) issued on December 25, 1993 by the Ministry of Finance (中華人民共和國財政部) (the “MOF”), came into effect on the same day and revised on December 15, 2008 and October 28, 2011, any entities and individuals engaged in the sale of goods, supply of processing, repair and replacement services, and import of goods within the territory of the PRC are taxpayers of VAT and shall pay the VAT in accordance with the law and regulation. The rate of VAT for sale of goods is 17% unless otherwise specified, such as the rate of VAT for sale of transportation is 11%. With the VAT reforms in the PRC, the rate of VAT has been changed several times. The MOF and the STA issued the Notice of on Adjusting VAT Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer’s VAT taxable sale or import of goods to 16% and 10%, respectively, this adjustment became effect on May 1, 2018. Subsequently, the MOF, the STA and the General Administration of Customs jointly issued the Announcement on Relevant Policies for Deepening the VAT Reform (《財政部稅務總局海關總署關於深化增值稅改革有關政策的公告》) on March 20, 2019 to make a further adjustment, which came into effect on April 1, 2019. The tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

FOREIGN EXCHANGE ADMINISTRATION IN THE PRC

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 (the “PBOC”), is empowered with the functions of administering all matters relating to foreign exchange, including the enforcement of foreign exchange control regulations.

The Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which was issued by the State Council on January 29, 1996, implemented on April 1, 1996 and latest amended on 5 August, 2008, classifies all international payments and transfers into current items and capital items. Current items are subject to the reasonable examination of the veracity of transaction documents and the consistency of the transaction documents and the foreign exchange receipts and payments by financial institutions engaging in conversion and sale of foreign currencies and supervision and inspection by the foreign exchange control authorities. For capital items, overseas organizations and overseas individuals making direct investments in the PRC shall, upon approval by the relevant authorities in charge, process registration formalities with the foreign exchange control authorities. Foreign exchange income received overseas can be repatriated or deposited overseas, and foreign exchange and foreign exchange settlement funds under the capital

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account are required to be used only for purposes as approved by the competent authorities and foreign exchange administrative authorities. In the event that international revenues and expenditure occur or may occur a material misbalance, or the national economy encounters or may encounter a severe crisis, the State may adopt necessary safeguard and control measures on international revenues and expenditure.

The Regulations for the Administration of Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》), which was promulgated by the PBOC on June 20, 1996 and implemented on July 1, 1996, removes other restrictions on convertibility of foreign exchange under current items, while imposing existing restrictions on foreign exchange transactions under capital account items.

According to the Announcement on Improving the Reform of the Renminbi Exchange Rate Formation Mechanism (《關於完善人民幣匯率形成機制改革的公告》), which was issued by the PBOC and implemented on July 21, 2005, the PRC has started to implement a managed floating exchange rate system in which the exchange rate would be determined based on market supply and demand and adjusted with reference to a basket of currencies since July 21, 2005. Therefore, the Renminbi exchange rate was no longer pegged to the U.S. dollar. PBOC would publish the closing price of the exchange rate of the Renminbi against trading currencies such as the U.S. dollar in the interbank foreign exchange market after the closing of the market on each working day, as the central parity of the currency against Renminbi transactions on the following working day.

According to the relevant laws and regulations in the PRC, PRC enterprises (including foreign investment enterprises) which need foreign exchange for current item transactions may, without the approval of the foreign exchange administrative authorities, effect payment through foreign exchange accounts opened at the designated foreign exchange bank, on the strength of valid transaction 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 (such as our Company) may, on the strength of resolutions of the board of directors or the shareholders’ meeting on the distribution of profits, effect payment from foreign exchange accounts at the designated foreign exchange bank, or effect exchange and payment at the designated foreign exchange bank.

According to the Decisions on Matters including Canceling and Adjusting a Batch of Administrative Approval Items (《國務院關於取消和調整一批行政審批項目等事項的決定》) which was promulgated by the State Council on October 23, 2014, it decided to cancel the approval requirement of the SAFE and its branches for the remittance and settlement of the proceeds raised from the overseas listing of the foreign shares into RMB domestic accounts.

According to the Notice of the State Administration of Foreign Exchange 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》) issued by the SAFE and implemented on December 26, 2014, a domestic company shall, within 15 business days from the date of the end of its

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overseas listing issuance, register the overseas listing with the local branch office of state administration of foreign exchange at the place of its establishment; the proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the document and other disclosure documents.

According to the Notice of the State Administration of Foreign Exchange of the PRC on Revolutionizing and Regulating Capital Account Settlement Management Policies (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) which was promulgated by the SAFE and implemented on June 9, 2016, foreign currency earnings in capital account that relevant policies of willingness exchange settlement have been clearly implemented on (including the recalling of raised capital by overseas listing) may undertake foreign exchange settlement in the banks according to actual business needs of the domestic institutions.

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SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

This Appendix summarizes certain aspects of PRC laws and regulations, which are relevant to the Company’s operations and business. Laws and regulations relating to taxation in the PRC are discussed separately in “Appendix III — Taxation and Foreign Exchange.” This Appendix also contains a summary of certain Hong Kong legal and regulatory provisions, including summaries of certain material differences between the PRC Company Law and the Companies (Winding Up and Miscellaneous Provisions) Ordinance, certain requirements of the Listing Rules and additional provisions required by the Stock Exchange for inclusion in the articles of association of PRC issuers. The principal objective of this summary is to provide potential [REDACTED] with an overview of the principal laws and regulatory provisions applicable to the Company. This summary is not intended to include all the information which are important to the potential [REDACTED]. For discussion of laws and regulations which are relevant to the Company’s business, see “Regulatory Overview.”

PRC LAWS AND REGULATIONS

PRC Legal System

The PRC legal system is based on the Constitution of the PRC (《中華人民共和國憲法》) (the “Constitution”) and is made up of written laws, administrative regulations, local regulations, separate regulations, autonomous regulations, rules and regulations of departments, rules and regulations of local governments, international treaties of which the PRC government is a signatory, and other regulatory documents. Court verdicts do not constitute binding precedents. However, they may be used as judicial reference and guidance.

According to the Constitution and the Legislation Law of the PRC (2023 revision) (《中華人民共和國立法法(2023修正)》) (the “Legislation Law”), the National People’s Congress (the “NPC”) and the Standing Committee of the National People’s Congress (the “SCNPC”) are empowered to exercise the legislative power of the State. The NPC has the power to formulate and amend basic laws governing civil and criminal matters, state organs and other matters. The SCNPC is empowered to formulate and amend laws other than those required to be enacted by the NPC and to supplement and amend any parts of laws enacted by the NPC during the adjournment of the NPC, provided that such supplements and amendments are not in conflict with the basic principles of such laws.

The State Council is the highest organ of the PRC administration and has the power to formulate administrative regulations based on the Constitution and laws.

The people’s congresses of provinces, autonomous regions and municipalities and their respective standing committees may formulate local regulations based on the specific circumstances and actual requirements of their own respective administrative areas, provided that such local regulations do not contravene any provision of the Constitution, laws or administrative regulations.

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The ministries and commissions of the State Council, PBOC, National Audit Office of the PRC as well as the other organs endowed with administrative functions directly under the State Council may, in accordance with the laws as well as the administrative regulations, decisions and orders of the State Council and within the limits of their power, formulate rules.

The people’s congresses of cities divided into districts and their respective standing committees may formulate local regulations in terms of urban and rural development and management, environmental protection, and historical and cultural protection based on the specific circumstances and actual requirements of such cities, which 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 but such local regulations shall conform with the Constitution, laws, administrative regulations, and the relevant local regulations of the relevant provinces or autonomous regions. 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 nationality (nationalities) in the areas concerned.

The people’s governments of the provinces, autonomous regions, and municipalities directly under the central government and the cities divided into districts or autonomous prefectures may enact rules, in accordance with laws, administrative regulations and the local regulations of their respective provinces, autonomous regions or municipalities. The Constitution has supreme legal authority and no laws, administrative regulations, local regulations, autonomous regulations or separate regulations may contravene the Constitution.

The authority of laws is greater than that of administrative regulations, local regulations and rules. The authority of administrative regulations is greater than that of local regulations and rules. The authority of local regulations is greater than that of the rules of the local governments at or below the corresponding level. The authority of the rules enacted by the people’s governments of the provinces or autonomous regions is greater than that of the rules enacted by the people’s governments of the city divided into districts or autonomous prefecture within the administrative areas of the provinces and the autonomous regions.

The NPC has the power to alter or annul any inappropriate laws enacted by the SCNPC, and to annul any autonomous regulations or separate regulations which have been approved by the SCNPC but which contravene the Constitution or the Legislation Law. The SCNPC has the power to annul any administrative regulations that contravene the Constitution and laws, to annul any local regulations that contravene the Constitution, laws or administrative regulations, and to annul any autonomous regulations or local regulations which have been approved by the standing committees of the people’s congresses of the relevant provinces, autonomous regions or municipalities directly under the central government, but which contravene the Constitution and the Legislation Law. The State Council has the power to alter or annul any inappropriate ministerial rules and rules of local governments. The people’s congresses of provinces, autonomous regions or municipalities directly under the central government have the power to alter or annul any inappropriate local regulations enacted or approved by their respective standing committees. The people’s governments of provinces and autonomous regions have the power to alter or annul any inappropriate rules enacted by the people’s governments at a lower level.

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According to the Constitution and the Legislation Law, the power to interpret laws is vested in the SCNPC. According to the Decision of the Standing Committee of the NPC Regarding the Strengthening of Interpretation of Laws (《全國人民代表大會常務委員會關於加強法律解釋工作的決議》) passed on June 10, 1981, the Supreme People’s Court of the PRC (the “Supreme People’s Court”) has the power to give general interpretation on questions involving the specific application of laws and decrees in court trials. The State Council and its ministries and commissions are also vested with the power to give interpretation of the administrative regulations and department rules which they have promulgated. At the regional level, the power to give interpretations of the local laws and regulations as well as administrative rules is vested in the regional legislative and administrative organs which promulgate such laws, regulations and rules.

PRC Judicial System

Under the Constitution and the PRC Law on the Organization of the People’s Courts (2018 revision) (《中華人民共和國人民法院組織法(2018年修訂)》), the PRC judicial system is made up of the Supreme People’s Court, the local people’s courts and special people’s courts.

The local people’s courts are comprised of the primary people’s courts, the intermediate people’s courts and the higher people’s courts. The higher level people’s courts supervise the primary and intermediate people’s courts. The people’s procuratorates also have the right to exercise legal supervision over the civil proceedings of people’s courts of the same level and lower levels. The Supreme People’s Court is the highest judicial body in the PRC. It supervises the judicial administration of the people’s courts at all levels.

The PRC Civil Procedure Law (2023 revision) (《中華人民共和國民事訴訟法(2023修正)》) (the “Civil Procedure Law”), which was adopted in 1991 and last amended by SCNPC on September 1, 2023, and came into effect on January 1, 2024, sets forth the criteria for instituting a civil action, the jurisdiction of the people’s courts, the procedures to be followed for conducting a civil action and the procedures for enforcement of a civil judgment or order. All parties to a civil action conducted within the PRC must comply with the Civil Procedure Law. Generally, a civil case is initially heard by a local court of the municipality or province in which the defendant resides. The parties to a contract may, by express agreement, select a judicial court where civil actions may be brought, provided that the judicial court is either the plaintiff’s or the defendant’s domicile, the place of execution or implementation of the contract or the place of the object of the action, provided that such choice shall not violate the requirements of the level of jurisdiction and exclusive jurisdiction.

A foreign national or enterprise generally has the same litigation rights and obligations as a citizen or legal person of the PRC. If a foreign country’s judicial system limits the litigation rights of PRC citizens and enterprises, the PRC courts may apply the same limitations to the citizens and enterprises of that foreign country within the PRC.

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If any party to a civil action refuses to comply with a judgment or ruling made by a people’s court or an award made by an arbitration panel in the PRC, the other party may apply to the people’s court for the enforcement of the same. There are time limits of two years imposed on the right to apply for such enforcement. If a person fails to satisfy a judgment made by the court within the stipulated time, the court will, upon application by either party, enforce the judgment in accordance with the law.

A party seeking to enforce a judgment or ruling of a people’s court against a party who is not personally or whose property is not within the PRC may apply to a foreign court with jurisdiction over the case for recognition and enforcement of the judgment or ruling. A foreign judgment or ruling may also be recognized and enforced by the people’s court according to PRC enforcement procedures if the PRC has entered into or acceded to an international treaty with the relevant foreign country, which provides for such recognition and enforcement, or if the judgment or ruling satisfies the court’s examination according to the principle of reciprocity, unless the people’s court finds that the recognition or enforcement of such judgment or ruling will result in a violation of the basic legal principles of the PRC, its sovereignty or security or against social and public interest.

The Company Law, the Trial Measures for Overseas Listing and the Guidelines

A joint stock limited company which was incorporated in the PRC and seeking a listing on the Hong Kong Stock Exchange is mainly subject to the following three laws and regulations in the PRC:

The Company Law of the PRC (《中華人民共和國公司法》) (the “Company Law”) which was promulgated by the Standing Committee of the NPC on December 29, 1993, came into effect on July 1, 1994, and was latest revised on December 29, 2023 and came into effect on July 1, 2024.

The Trial Measures for Overseas Listing which were promulgated by the CSRC on February 17, 2023 and came into effect on March 31, 2023, and were applicable to the overseas offering and listing of PRC domestic companies’ securities.

The Guidelines for Articles of Association of Listed Companies (2023 revision) (《上市公司章程指引(2023修正)》) (the “Guidelines”) which were issued by the CSRC on December 16, 1997, latest revised on December 15, 2023 and came into effect on the same date, providing the guidelines for the Articles of Association. As such, the contents provided in the Guidelines are set out in the Articles of Association of the Company, the summary of which is set out in the section entitled “Appendix V — Summary of Articles of Association” in this document.

Set out below is a summary of the major provisions of the Company Law, the Trial Measures for Overseas Listing and the Guidelines applicable to the Company.

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SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

General

A joint stock limited company refers to an enterprise legal person incorporated in accordance with the Company Law with its registered capital divided into shares of equal par value. The liability of its shareholders is limited to the amount of shares held by them and the company is liable to its creditors for an amount equal to the total value of its assets.

A joint stock limited company shall conduct its business in accordance with laws and administrative regulations. It may invest in other limited liability companies and joint stock limited companies and its liabilities with respect to such invested companies are limited to the amount invested. Unless otherwise provided by laws, the joint stock limited company may not be a contributor that undertakes joint and several liabilities for the debts of the invested companies.

Incorporation

A joint stock limited company may be incorporated by promotion or public subscription.

A joint stock limited company may be incorporated by a minimum of two but not more than 200 promoters, and at least half of the promoters must have residence within the PRC.

The promoters must convene an inaugural meeting within 30 days after the issued shares have been fully paid up and must give notice to all subscribers or make an announcement of the date of the inaugural meeting 15 days before the meeting. The inaugural meeting may be convened only with the presence of promoters or subscribers representing at least half of the shares in the company. At the inaugural meeting, matters including the adoption of articles of association and the election of members of the board of directors and members of the board of supervisors of the company will be dealt with. All resolutions of the meeting require the approval of subscribers with more than half of the voting rights present at the meeting.

Within 30 days after the conclusion of the inaugural meeting, the board of directors must apply to the registration authority for registration of the establishment of the joint stock limited company. A company is formally established, and has the status of a legal person, after the business license has been issued by the relevant registration authority. Joint stock limited companies established by the subscription method shall file the approval on the offering of shares issued by the securities administration department of the State Council with the company registration authority for record.

A joint stock limited company’s promoters shall be liable for: (i) the payment of all expenses and debts incurred in the incorporation process jointly and severally if the company cannot be incorporated; (ii) the refund of subscription monies to the subscribers, together with interest, at bank rates for a deposit of the same term jointly and severally if the company cannot be incorporated; and (iii) damages suffered by the company as a result of the default of the promoters in the course of incorporation of the company. According to the Interim Provisional

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Regulations on the Administration of Share Issuance and Trading (《股票發行與交易管理暫行條例》) promulgated by the State Council on April 22, 1993 (which is only applicable to the issuance and trading of shares in the PRC and their related activities), if a company is established by means of public subscription, the promoters of such company are required to sign on the document to ensure that the document does not contain any misrepresentation, serious misleading statements or material omissions, and assume joint and several responsibility for it.

Registered Capital

The promoters may make a capital contribution in currencies, or non-monetary assets such as in kind or intellectual property rights or land use rights which can be appraised with monetary value and transferred lawfully, except for assets which are prohibited from being contributed as capital by the laws or administrative regulations. If a capital contribution is made in non-monetary assets, a valuation of the assets contributed must be carried out pursuant to the provisions of the laws or administrative regulations on valuation without any over-valuation or under-valuation.

The transfer of shares by shareholders should be conducted via the legally established stock exchange or in accordance with other methods as stipulated by the State Council.

Transfer of registered shares by a shareholder must be made by means of an endorsement or by other means stipulated by laws or administrative regulations.

Increase of Registered Capital and Issue of Shares

According to the Company Law, in the event a company proposes to issue new shares, resolutions shall be passed at general meeting in accordance with the articles of association to determine the class, amount and issue price of the new shares. All issue of shares of a joint stock limited company shall be based on the principles of equality and fairness. The same class of shares must carry equal rights. Shares issued at the same time and within the same class must be issued on the same conditions and at the same price. It may issue shares at par value or at a premium, but it may not issue shares below the par value.

After the new share issuance has been paid up, the change shall be registered with the company registration authorities and an announcement shall be made.

According to the Company Law, when the company issues shares in registered form, it shall maintain a register of shareholders, stating the following matters:

- the name and domicile of each shareholder;
- the number of shares held by each shareholder;

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- the serial numbers of shares held by each shareholder; and
- the date on which each shareholder acquired the shares.

Reduction of Registered Capital

A company may reduce its registered capital in accordance with the following procedures prescribed by the Company Law:

- the company shall prepare a balance sheet and an inventory of the assets;
- the reduction of registered capital shall be approved by a general meeting;
- the company shall inform its creditors of the reduction in registered capital within 10 days and publish an announcement of the reduction in the newspaper within 30 days after the shareholders’ resolution approving the reduction has been passed;
- creditors shall within 30 days after receiving the notice, or within 45 days of the public announcement if no notice has been received, require the company to pay its debts or provide corresponding guarantees covering the debts;
- the company shall apply to the relevant administration of registration for the registration of the reduction in registered capital.

Repurchase of Shares

According to the Guidelines, a joint stock limited company may not purchase its shares other than for one of the following purposes: (i) to reduce its registered capital; (ii) to merge with another company that holds its shares; (iii) to grant its shares for carrying out an employee stock ownership plan or equity incentive plan; (iv) to purchase its shares from shareholders who vote against the resolution regarding the merger or division with other companies at a general meeting; (v) to apply shares for conversion of convertible corporate bonds issued by a listed company; and (vi) to maintain the company value and protect the shareholders’ interests of a listed company as necessary.

Repurchase of its own shares on the grounds set out in (i) and (ii) above shall be subject to resolution passed by the general meeting; repurchase of its own shares on the grounds set out in (iii), (v) or (vi) above shall be subject to a resolution of the company’s board of directors made by a two-third majority of directors attending the meeting in accordance with the provisions of the company’s articles of association or as authorized by the general meeting.

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Following the repurchase of its own shares in accordance with (i) above, such shares shall be canceled within 10 days from the date of repurchase; the shares shall be transferred or canceled within six months if the repurchase of its own shares is in accordance with either (ii) or (iv) above; and the shares repurchased in accordance with (iii), (v) or (vi) above shall not exceed 10% of the company’s total issued shares, and shall be transferred or canceled within three years.

A listed company shall perform its obligation of information disclosure according to the provisions of the Securities Law when repurchasing its own shares. In the event the repurchase of its own shares is in accordance with (iii), (v) or (vi) above, centralized public trading shall be adopted.

A company shall not accept its own shares as the subject matter of a mortgage.

Transfer of Shares

Shares held by shareholders may be transferred in accordance with the relevant laws and regulations. Pursuant to the Company Law, transfer of shares by shareholders shall be carried out at a legally established securities exchange or in other ways stipulated by the State Council.

No modifications of registration in the share register caused by transfer of registered shares shall be carried out within 20 days prior to the convening of a general meeting or 5 days prior to the base date for determination of dividend distributions. However, where there are separate provisions by law on alternation of registration in the share register of listed companies, those provisions shall prevail.

According to the Company Law, shares issued prior to the public issuance of shares shall not be transferred within 1 year from the date of the joint stock limited company’s listing on a stock exchange. Directors, supervisors and the senior management shall declare to the company their shareholdings in the company and any changes of such shareholdings; they shall not transfer more than 25% of all the shares they hold in the company annually during their tenure; and they shall not transfer the shares they hold within one year from the date on which the company’s shares are listed and commenced trading on a stock exchange, nor within 6 months after their resignation from their positions with the company.

Shareholders

According to the Company Law and the Guidelines, the rights of holders of ordinary shares of a joint stock limited company include:

- the right to attend or appoint a proxy to attend general meetings and to vote thereat;
- the right to transfer shares in accordance with laws, administrative regulations and provisions of the articles of association;

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- the right to inspect the company’s articles of association, share register, counterfoil of company debentures, minutes of general meetings, resolutions of meetings of the board of directors, resolutions of meetings of the board of supervisors and financial and accounting reports and to make proposals or enquiries on the company’s operations;
- the right to bring an action in the people’s court to rescind resolutions passed by general meetings and board of directors where the articles of association is violated by the above resolutions;
- the right to receive dividends and other types of interest distributed in proportion to the number of shares held;
- in the event of the termination or liquidation of the company, the right to participate in the distribution of residual properties of the company in proportion to the number of shares held; and
- other rights granted by laws, administrative regulations, other regulatory documents and the company’s articles of association.

The obligations of a shareholder include the obligation to abide by the Company’s articles of association, to pay the subscription moneys in respect of the shares subscribed for and in accordance with the form of making capital contributions, to be liable for the company’s debts and liabilities to the extent of the amount of his or her subscribed shares and any other shareholders’ obligation specified in the company’s articles of association.

General Meetings

The general meeting is the organ of authority of the company, which exercises its powers in accordance with the Company Law. According to the Company Law, the general meeting exercises the following principal powers:

- to elect or remove the directors and supervisors (other than the representative of the employees of the company) and to decide on matters relating to the remuneration of directors and supervisors;
- to examine and approve reports of the board of directors;
- to examine and approve reports of the board of supervisors;
- to examine and approve the company’s proposals for profit distribution plans and loss recovery plans;
- to decide on any increase or reduction of the company’s registered capital;

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- to decide on the issue of bonds by the company;
- to decide on issues such as merger, division, dissolution and liquidation of the company and other matters;
- to amend the company’s articles of association; and
- other powers as provided for in the articles of association.

According to the Guidelines, annual general meeting is required to be held once every year; extraordinary general meeting is required to be held within two months after the occurrence of any of the following:

- the number of directors is less than the number stipulated by the law or less than two thirds of the number specified in the articles of association;
- the aggregate losses of the company which are not recovered reach one-third of the company’s total paid-in registered capital;
- when shareholders individually or in aggregate holding 10% or more of the company’s shares request the convening of an extraordinary general meeting;
- whenever the board of directors deems necessary;
- when the board of supervisors so requests; or
- other circumstances as provided for in the articles of associations.

According to the Company Law, general meetings shall be convened by the board of directors, and presided over by the chairman of the board of directors. In the event that the chairman is incapable of performing or does not perform his duties, the meeting shall be presided over by the vice chairman. In the event that the vice chairman is incapable of performing or not performing his duties, a director nominated by more than half of directors shall preside over the meeting.

Where the board of directors is incapable of performing or not performing its duties of convening the general meeting, the board of supervisors shall convene and preside over such meeting in a timely manner. In case the board of supervisors fails to convene and preside over such meeting, shareholders alone or in aggregate holding more than 10% of the company’s shares for 90 days consecutively may unilaterally convene and preside over such meeting.

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According to the Company Law, notice of annual general meeting shall state the time and venue of and matters to be considered at the meeting and shall be given to all shareholders 20 days before the meeting. Notice of extraordinary general meetings shall be given to all shareholders 15 days prior to the meeting.

There is no specific provision in the Company Law regarding the number of shareholders constituting a quorum in a general meeting.

According to the Company Law, shareholders present at general meeting have one vote for each share they hold, save that shares held by the company are not entitled to any voting rights.

Pursuant to the provisions of the articles of association or a resolution of the general meeting, the accumulative voting system may be adopted for the election of directors and supervisors at the general meeting. Under the accumulative voting system, each share shall be entitled to vote equivalent to the number of directors or supervisors to be elected at the general meeting and shareholders may consolidate their voting rights when casting a vote.

Pursuant to the Company Law, resolutions of the general meeting shall be adopted by more than half of the voting rights held by the shareholders present at the meeting. However, resolutions of the general meeting regarding the following matters shall be adopted by more than two-thirds of the voting rights held by the shareholders present at the meeting: (i) amendments to the articles of association; (ii) the increase or decrease of registered capital; (iii) the merger, division, dissolution, liquidation or change in the form of the company; (iv) other circumstances as provided for in the articles of associations.

According to the Company Law, meeting minutes shall be prepared in respect of decisions on matters discussed at the general meeting. The chairman of the meeting and directors attending the meeting shall sign to endorse such minutes. The minutes shall be kept together with the shareholders' attendance register and the proxy forms.

Board

According to the Company Law, a joint stock limited company shall have a board of directors, which shall consist of at least 3 members. Members of the board of directors may include representatives of the employees of the company, who shall be democratically elected by the company's staff at the staff representative assembly, general staff meeting or otherwise.

The term of a director shall be stipulated in the articles of association, but no term of office shall last for more than three years. Directors may serve consecutive terms if re-elected. A director shall continue to perform his duties in accordance with the laws, administrative regulations and 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 term of office, or if the resignation of directors results in the number of directors being less than the quorum.

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According to the Company Law, the board of directors mainly exercises the following powers:

- to convene the general meetings and report on its work to the general meetings;
- to implement the resolutions passed in general meetings;
- to decide on the company’s business plans and investment proposals;
- to formulate the company’s profit distribution proposals and loss recovery proposals;
- to formulate proposals for the increase or reduction of the company’s registered capital and the issuance of corporate bonds;
- to prepare plans for the merger, division, dissolution and change in the form of the company;
- to decide on the hiring or dismissal the company’s manager and his salary and compensation, and by recommendation of the manager, to decide on the hiring or dismissal of deputy manager(s) and the persons in charge of finance as well as their salaries and compensations;
- to formulate the company’s basic management system; and
- to exercise any other power under the articles of association or authorized by the shareholders.

Board Meetings and Chairman of Board

According to the Company Law, meetings of the board of directors of a joint stock limited company shall be convened at least twice a year. Notice of meeting shall be given to all directors and supervisors 10 days before the meeting. Interim board meetings may be proposed to be convened by shareholders representing more than 10% of voting rights, more than one-third of the directors or the board of supervisors. The chairman shall convene and preside over such meeting within 10 days after receiving such proposal. Meetings of the board of directors shall be held only if half or more 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 resolutions to be approved by the board of directors. Directors shall attend board meetings in person. If a director is unable to attend a board meeting, he may appoint another director by a written power of attorney specifying the scope of the authorization to attend the meeting on his behalf.

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If a resolution of the board of directors violates the laws, administrative regulations or the articles of association, and as a result of which the company 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 may be released from that liability.

According to the Company Law, the board of directors shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman are elected with approval of more than half of all the directors. The chairman shall convene and preside over board meetings and examine the implementation of board resolutions. The vice chairman shall assist the work of the chairman. In the event that the chairman is incapable of performing or not performing his duties, the duties shall be performed by the vice chairman. In the event that the vice chairman is incapable of performing or not performing his duties, a director nominated by more than half of the directors shall perform his duties.

Qualification of Directors

The Company Law provides that the following persons may not serve as a director:

- a person who is unable or has limited ability to undertake any civil liabilities;
- a person who has been convicted of an offense of bribery, corruption, embezzlement or misappropriation of property, or the destruction of socialist market economy 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;
- 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;
- 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 and 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; or
- a person who is liable for a relatively large amount of debts that are overdue.

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Board of Supervisors

A joint stock limited company shall have a board of supervisors composed of not less than three members. The board of supervisors is made up of representatives of the shareholders and an appropriate proportion of representatives of the employees of the company. The actual proportion shall be stipulated in the articles of association, provided that the proportion of representatives of the employees shall not be less than one third of the supervisors.

Representatives of the employees of the company in the board of supervisors shall be democratically elected by the employees at the employees’ representative assembly, employees’ general meeting or otherwise.

The directors and senior management may not act concurrently as supervisors.

The board of supervisors shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman of the board of supervisors are elected with approval of more than half of all the supervisors. The chairman of the board of supervisors shall convene and preside over the meetings of the board of supervisors. In the event that the chairman of the board of supervisors is incapable of performing or not performing his duties, the vice chairman of the board of supervisors shall convene and preside over the meetings of the board of supervisors. In the event that the vice chairman of the board of supervisors is incapable of performing or not performing his duties, a supervisor nominated by more than half of the supervisors shall convene and preside over the meetings of the board of supervisors.

Each term of office of a supervisor is three years and he or she may serve consecutive terms if re-elected. A supervisor shall continue to perform his duties in accordance with the laws, administrative regulations and 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 term of office, or if the resignation of supervisors results in the number of supervisors being less than the quorum.

The board of supervisors of a company shall hold at least one meeting every six months.

According to the Company Law, a resolution of the board of supervisors shall be passed by more than half of all the supervisors, while according to the Opinions on Supplementary Amendment to Articles of Associations by Companies to be listed in Hong Kong (《關於到香港上市公司對公司章程作補充修改的意見的函》), a resolution of the board of supervisors shall be passed by more than two-thirds of all the supervisors.

The board of supervisors exercises the following powers:

- to review the company’s financial position;

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- 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 the resolutions of the general meeting;
- when the acts of directors and senior management are harmful to the company’s interests, to require correction of those acts;
- to propose the convening of extraordinary general meetings and to convene and preside over general meetings when the board of directors fails to perform the duty of convening and presiding over general meeting under this law;
- to initiate proposals for resolutions to general meeting;
- to initiate proceedings against directors and senior management; and
- other powers specified in the articles of association.

Supervisors may attend board meetings and make enquiries or proposals in respect of board resolutions. The board of supervisors may initiate investigations into any irregularities identified in the operation of the company and, where necessary, may engage an accounting firm to assist their work at the company’s expense.

Manager and Senior Management

According to the Company Law, a company shall have a manager who shall be appointed or removed by the board of directors. The manager shall report to the board of directors and may exercise the following powers:

- to supervise the business and administration of the company and arrange for the implementation of resolutions of the board of directors;
- to arrange for the implementation of the company’s annual business plans and investment proposals;
- to formulate the general administration system of the company;
- to formulate the company’s detailed rules;
- to recommend the appointment and dismissal of deputy managers and person in charge of finance;
- to appoint or dismiss other administration officers (other than those required to be appointed or dismissed by the board of directors); and
- to other powers conferred by the board of directors or the articles of association.

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The manager shall comply with other provisions of the articles of association concerning his/her powers. The manager shall attend board meetings.

According to the Company Law, senior management shall mean the manager, deputy manager(s), person-in-charge of finance, board secretary (in case of a listed company) of a company, and other personnel as stipulated in the articles of association.

Duties of Directors, Supervisors and Senior Management

Directors, supervisors, and senior management of the company are required in accordance with the Company Law to comply with the relevant laws, regulations and the articles of association, and have fiduciary and diligent duties to the company. Directors, supervisors and senior management are prohibited from abusing their powers to accept bribes or other unlawful income and from misappropriating of the company’s properties. Directors and senior management are prohibited from:

- misappropriation of the company’s funds;
- depositing the company’s funds into accounts under his own name or the name of other individuals;
- loaning company funds to others or providing guarantees in favor of others supported by the company’s assets in violation of the articles of association or without prior approval of the general meeting or board of directors;
- entering into contracts or deals with the company in violation of the articles of association or without prior approval of the general meeting;
- using their position and powers to procure business opportunities for themselves or others that should have otherwise been available to the company or operating for their own benefits or managing on behalf of others businesses similar to that of the company without prior approval of the general meeting;
- accept and possess commissions paid by a third party for transactions conducted with the company;
- unauthorized divulgence of confidential business information of the company; or
- other acts in violation of their duty of loyalty to the company.

A director, supervisor or senior management who contravenes any law, regulation or the company’s articles of association in the performance of his duties resulting in any loss to the company shall be personally liable to the company.

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Finance and Accounting

According to the Company Law, a company shall establish financial and accounting systems in accordance with laws, administrative regulations and the regulations of the financial department of the State Council and shall at the end of each financial year prepare a financial and accounting report which shall be audited by an accounting firm as required by law. The company’s financial and accounting report shall be prepared in accordance with provisions of the laws, administrative regulations and the regulations of the financial department of the State Council.

Pursuant to the Company Law, the company shall deliver its financial and accounting reports to all shareholders within the time limit stipulated in the articles of association and make its financial and accounting reports available at the company for inspection by the shareholders at least 20 days before the convening of an annual general meeting of shareholders. A company that makes public stock offerings shall publish its financial and accounting reports.

When distributing each year’s after-tax profits, it shall set aside 10% of its after-tax profits into a statutory common reserve fund (except where the fund has reached 50% of its registered capital).

If its statutory common reserve fund is not sufficient to make up losses of the previous year, profits of the current year shall be applied to make up losses before allocation is made to the statutory common reserve fund pursuant to the above provisions.

After allocation of the statutory common reserve fund from after-tax profits, it may, upon a resolution passed at the general meeting, allocate discretionary common reserve fund from after-tax profits.

The remaining after-tax profits after making up losses and allocation of common reserve fund shall be distributed in proportion to the number of shares held by the shareholders, unless otherwise stipulated in the articles of association.

Shares held by the Company shall not be entitled to any distribution of profit.

The premium received through issuance of shares at prices above par value and other incomes required by the financial department of the State Council to be allocated to the capital reserve fund shall be allocated to the company’s capital reserve fund.

The Company’s reserve fund shall be applied to make up losses of the company, expand its business operations or be converted to increase the registered capital of the company.

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However, the capital reserve fund may not be applied to make up the company’s losses. Upon the conversion of statutory common reserve fund into capital, the balance of the statutory common reserve fund shall not be less than 25% of the registered capital of the company before such conversion.

The Company shall have no other accounting books except the statutory accounting books. Its assets shall not be deposited in any accounts opened in the name of any individual.

Appointment and Retirement of Accounting Firms

Pursuant to the Company Law, the appointment or dismissal of accounting firms responsible for the auditing of the company shall be determined by general meeting or board of directors in accordance with provisions of articles of association. The accounting firm should be allowed to make representations when the general meeting or board of directors conducts a vote on the dismissal of the accounting firm. The company should provide true and complete accounting evidences, books, financial and accounting reports and other accounting data to the accounting firm it employs without any refusal, withholding and misrepresentation.

Distribution of Profits

According to the Company Law, a company shall not distribute profits before losses are covered and the statutory common reserve is drawn.

Amendments to Articles of Association

Any amendments to the company’s articles of association must be made in accordance with the procedures set out in the company’s articles of association. In relation to matters involving the company’s registration, the amendment to articles of association shall be registered with the relevant authority in accordance with the applicable laws.

Dissolution and Liquidation

According to the Company Law, a company shall be dissolved by reason of the following: (i) the term of its operations set down in the articles of association has expired or other events of dissolution specified in the articles of association have occurred; (ii) the general meeting resolve to dissolve the company; (iii) the company is dissolved by reason of merger or division; (iv) the business license is revoked; the company is ordered to close down or be dissolved; or (v) 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 its shareholders, on the grounds that the company suffers significant hardship in its operation and management that cannot be resolved through other means, and the ongoing existence of the company would bring significant losses for shareholders.

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In the event of (i) or (ii) above, if the company has not yet distributed its assets to shareholders, it may carry on its existence by amending its articles of association or upon approval by resolution of the shareholders’ meeting. The amendment of the articles of association in accordance with provisions set out above shall require approval of more than two thirds of voting rights of shareholders attending a general meeting.

Where the company is dissolved in the circumstances described in subparagraphs (i), (ii), (iv), or (v) above, a liquidation group shall be established and the liquidation process shall commence within 15 days after the occurrence of an event of dissolution.

The members of the company’s liquidation group shall be composed of its directors or the personnel appointed by the general meeting. If a liquidation group is not established within the stipulated period, creditors may apply to the people’s court and request the court to appoint relevant personnel to form the liquidation group. The people’s court should accept such application and form a liquidation group to conduct liquidation in a timely manner.

The liquidation group shall exercise the following powers during the liquidation period:

- to handle the company’s assets and to prepare a balance sheet and an inventory of the assets;
- to notify creditors through notice or public announcement;
- to deal with the company’s outstanding businesses related to liquidation;
- to pay any tax overdue as well as tax amounts arising from the process of liquidation;
- to claim credits and pay off debts;
- to handle the company’s remaining assets after its debts have been paid off; and
- to represent the company in civil lawsuits.

The liquidation group shall notify the company’s creditors within 10 days after its establishment and issue public notices in newspapers within 60 days. A creditor shall lodge his claim with the liquidation group within 30 days after receiving notification, or within 45 days of the public notice if he did not receive any notification. A creditor shall state all matters relevant to his creditor rights in making his claim and furnish evidence. The liquidation group shall register such creditor rights. The liquidation group shall not make any debt settlement to creditors during the period of claim.

Upon liquidation of properties and the preparation of the balance sheet and inventory of assets, the liquidation group shall draw up a liquidation plan to be submitted to the general meeting or people’s court for confirmation.

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The company’s remaining assets after payment of liquidation expenses, wages, social insurance expenses and statutory compensation, outstanding taxes and debts shall be distributed to shareholders according to their shareholding proportion. It shall continue to exist during the liquidation period, although it can only engage in any operating activities that are related to the liquidation. The company’s properties shall not be distributed to the shareholders before repayments are made in accordance to the foregoing provisions.

Upon liquidation of the company’s properties and the preparation of the balance sheet and inventory of assets, if the liquidation group becomes aware that the company does not have sufficient assets to meet its liabilities, it must apply to the people’s court for a declaration for bankruptcy.

Following such declaration, the liquidation group shall hand over all matters relating to the liquidation to the people’s court.

Upon completion of the liquidation, the liquidation group shall submit a liquidation report to the general meeting or the people’s court for verification. Thereafter, the report shall be submitted to the registration authority of the company in order to cancel the company’s registration, and a public notice of its termination shall be issued. Members of the liquidation group are required to discharge their duties honestly and in compliance with the relevant laws.

Members of the liquidation group shall be prohibited from abusing their powers to accept bribes or other unlawful income and from misappropriating the company’s properties.

A member of the liquidation group is liable to indemnify the company and its creditors in respect of any loss arising from his intentional or gross negligence.

Merger and Demerger

Companies may merge through absorption or through the establishment of a newly merged entity. If it merges by absorption, the company which is absorbed shall be dissolved. If it merges by forming a new corporation, both companies will be dissolved.

Overseas Listing

According to the Trial Measures for Overseas Listing, a Chinese domestic company that seeks overseas listing shall file the application with the CSRC according to the administrative filing procedures necessary for the Trial Measures for Overseas Listing.

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SECURITIES LAW AND REGULATIONS

The PRC has promulgated a number of regulations that relate to the issue and trading of shares and disclosure of information. In October 1992, the State Council established the Securities Committee and the CSRC. The Securities Committee is responsible for coordinating the drafting of securities regulations, formulating securities-related policies, planning the development of securities markets, directing, coordinating and supervising all securities related institutions in the PRC and administering the CSRC. The CSRC is the regulatory arm of the Securities Committee and is responsible for the drafting of regulatory provisions of securities markets, supervising securities companies, regulating public offers of securities by PRC companies in the PRC or overseas, regulating the trading of securities, compiling securities related statistics and undertaking relevant research and analysis. In April 1998, the State Council consolidated the two departments and reformed the CSRC.

The Interim Provisional Regulations on the Administration of Share Issuance and Trading (《股票發行與交易管理暫行條例》) deals with the application and approval procedures for public offerings of equity securities, trading in equity securities, the acquisition of listed companies, deposit, clearing and transfer of listed equity securities, the disclosure of information with respect to a listed company, investigation, penalties and dispute settlement.

On December 25, 1995, the State Council promulgated and implemented the 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規定》). These regulations deal mainly with the issue, subscription, trading and declaration of dividends and other distributions of domestic listed and foreign invested shares and disclosure of information of joint stock limited companies having domestic listed and foreign invested shares.

The Securities Law of the People’s Republic of China (《中華人民共和國證券法》) (the “Securities Law”) took effect on July 1, 1999 and was revised on August 28, 2004, October 27, 2005, June 29, 2013, August 31, 2014 and December 28, 2019, respectively. The latest revised Securities Law came into effect on March 1, 2020. This is the first national securities law in the PRC, which is divided into 14 chapters and 226 articles regulating, among other things, the issuance and trading of securities, takeovers by listed companies, securities exchanges, securities companies and the duties and responsibilities of the State Council’s securities regulatory authorities. The Securities Law comprehensively regulates activities in the PRC securities market. Article 224 of the Securities Law provides that domestic enterprises shall comply with the relevant provisions of the State Council to list its shares outside the PRC.

Currently, the issuance and trading of foreign issued shares (including H shares) are mainly governed by the rules and regulations promulgated by the State Council and the CSRC.

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SUMMARY OF MATERIAL DIFFERENCES BETWEEN HONG KONG AND PRC COMPANY LAW

The Hong Kong law applicable to a company incorporated in Hong Kong is based on the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Companies Ordinance and is supplemented by common law and the rules of equity that are applicable to Hong Kong. As a joint stock limited company established in the PRC that is seeking a [REDACTED] of shares on the Hong Kong Stock Exchange, we are 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 company law applicable to a company incorporated in Hong Kong and the PRC Company Law applicable to a joint stock limited company incorporated and existing under the PRC Company Law. This summary is, however, not intended to be an exhaustive comparison.

Corporate Existence

Under Hong Kong company law, a company with share capital is incorporated by the Registrar of Companies in Hong Kong, which issues a certificate of incorporation to the Company upon its incorporation, and the company will acquire an independent corporate existence henceforth. A company may be incorporated as a public company or a private company. Pursuant to the Companies Ordinance, the articles of association of a private company incorporated in Hong Kong shall contain certain pre-emptive provisions. A public company's articles of association do not contain such pre-emptive provisions.

Under the PRC Company Law, a joint stock limited company may be incorporated by promotion or public subscription.

Hong Kong law does not prescribe any minimum capital requirement for a Hong Kong company.

Share Capital

Under the Companies Ordinance, the concept of the nominal value (also known as par value) of shares of a Hong Kong company has been abolished, and the companies have increased flexibility to alter its share capital by (i) increasing its share capital; (ii) capitalizing its profits; (iii) allotting and issuing bonus shares with or without increasing its share capital; (iv) converting its shares into larger or smaller number of shares; and (v) cancelling its shares. The concept of authorized capital no longer applies to a Hong Kong company formed on or after March 3, 2014 as well. Hence, the directors of a Hong Kong company may, with the prior approval of the shareholders if required, issue new shares of the company. The PRC Company Law has no provisions on minimum registered capital of joint stock companies, except that laws, administrative regulations and State Council decisions have separate provisions on paid-in registered capital and the minimum registered capital of joint stock companies, in

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which case the company should follow such provisions. The Company’s registered capital is the amount of its issued share capital. Any increase in the Company’s registered capital must be approved at the general meeting and shall be approved by/filed with the relevant PRC governmental and regulatory authorities (if applicable).

The Companies Ordinance does not prescribe any minimum capital requirement 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 or administrative regulations). For non-monetary assets to be used as capital contributions, appraisals must be carried out to ensure there is no over-valuation or under-valuation of the assets. There is no such restriction on a company incorporated in Hong Kong.

Restrictions on Shareholding and Transfer of Shares

Generally, domestic shares, which are denominated and subscribed for in Renminbi, can be subscribed for and traded by PRC investors, qualified overseas institutional investors or qualified overseas strategic investors.

Overseas listed shares, which are denominated in Renminbi and subscribed for in a currency other than Renminbi, may only be subscribed for, and traded by, investors from Hong Kong, Macau and Taiwan or any country and territory outside the PRC, or qualified domestic institutional investors. If the H shares are eligible securities under the Southbound Trading Link, they are also subscribed for and traded by PRC investors in accordance with the rules and limits of Shanghai-Hong Kong Stock Connect or Shenzhen-Hong Kong Stock Connect. When the application for “full circulation” has been approved by the CSRC, the domestic unlisted shares of the H-share listed company might be listed and circulated on the Stock Exchange.

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 a public offering of the company cannot be transferred within one year from the listing date of the shares on a stock exchange. Shares in a joint stock limited liability company held by its directors, supervisors and senior management and transferred each year during their term of office shall not exceed 25% of the total shares they held in a company, and the shares they held in a company cannot be transferred within one year from the listing date of the shares, and also cannot be transferred within half a year after the said personnel has left office. The articles of association may set other restrictive requirements on the transfer of a 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 law apart from the six-month lockup on the company’s issue of shares and the 12-month lockup on controlling shareholders’ disposal of shares, as illustrated by the undertakings given by the Company and our controlling shareholder to the Hong Kong Stock Exchange.

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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.

Notice of Shareholders' General Meetings

Under the PRC Company Law, notices of an annual session of the shareholders' assembly and an interim meeting of the shareholders' assembly must be given to shareholders 20 days and 15 days before the meeting, respectively. For a limited liability company incorporated in Hong Kong, the minimum period of notice is 14 days in case of other shareholders' meetings other than an annual general meeting and 21 days in the case of an annual general meeting.

Quorum for Shareholders' General Meetings

Under Hong Kong company law, the quorum for a shareholders' general meeting must be two members unless the articles of association of the company otherwise provide. For companies with only one member, the quorum must be one member. The PRC Company Law does not specify any quorum requirement for a shareholders' assembly.

Voting at Shareholders' General Meeting

Under the PRC Company Law, the passing of any resolution of a shareholders' assembly requires affirmative votes of shareholders representing more than half of the voting rights represented by the shareholders who attend the assembly except in cases of resolutions on amendments to a company's articles of association, increase or decrease of registered capital, merger, division or dissolution, or change of corporation form, which require affirmative votes of shareholders representing more than two-thirds of the voting rights represented by the shareholders who attend the assembly.

Under Hong Kong law, (i) an ordinary resolution may be passed by a simple majority of affirmative votes of the shareholders who attend the shareholders' general meeting in person or by proxy, and (ii) a special resolution may be passed by no less than three fourths of affirmative votes of the shareholders who attend the shareholders' general meeting in person or by proxy.

Variation of Class Rights

The PRC Company Law makes no specific provision relating to variation of class rights. However, the PRC Company Law states that the State Council can promulgate requirements relating to other kinds of shares.

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Under the Companies Ordinance, no rights attached to any class of shares can be varied except (i) with the passing of a special resolution by the shareholders of the relevant class at a separate meeting sanctioning the variation, (ii) with the written consent of shareholders representing at least three-fourths of the total voting rights of shareholders of the relevant class, or (iii) if there are provisions in the articles of association relating to the variation of those rights, then in accordance with those provisions.

Derivative Action by Minority Shareholders

Under Hong Kong company law, a shareholder may, with the leave of the Court, start a derivative action on behalf of a company for any misconduct committed by its directors against the company. For example, leave may be granted where the directors control a majority of votes at a general meeting, and could thereby prevent the company from suing the directors in its own name.

Pursuant to the PRC Company Law, in the event where the directors and senior management of a joint stock limited company violate laws, administrative regulations or its articles of association, resulting in losses to the company, the shareholders individually or jointly holding 1% or more of the shares in the company for more than one hundred and eighty (180) consecutive days may request in writing the board of supervisors to initiate proceedings in the people’s court. In the event that the board of supervisors violates as such, the above said shareholders may send written request to the board of directors to initiate proceedings in the people’s court. Upon receipt of such 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 thirty (30) days upon receipt of the request, or if under urgent situations, failure of initiating immediate proceeding may cause irremediable damages to the company, the above said shareholders shall, for the benefit of the company’s interests, have the right to initiate proceedings directly to the court in their own name.

The Guidelines for the Articles of Association of Listed Companies also provide other remedies against the directors, supervisors and senior management who breach their duties to the company. In addition, as a condition to the listing of shares on the Stock Exchange, each director and supervisor of a joint stock limited company is required to give an undertaking in favor of the company acting as agent for the shareholders. This allows minority shareholders to take action against directors and supervisors of the company in default.

Minority Shareholder Protection

Under the Companies Ordinance, a shareholder who alleges that the affairs of a company 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

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given extensive statutory powers to investigate the affairs of a company incorporated or registered in Hong Kong. The PRC Company Law provides that any shareholders holding 10% or above of voting rights of all issued shares of a company may request a People’s Court to dissolve the company to the extent that the operation or management of the company experiences any serious difficulties and its continuous existence would cause serious losses to them, and no other alternatives can resolve such difficulties.

The Guidelines for the Articles of Association of Listed Companies also provide other remedies against the directors, supervisors and senior management who breach their duties to the company. In addition, as a condition to the listing of shares on the Stock Exchange, each director and supervisor of a joint stock limited company is required to give an undertaking in favor of the company acting as agent for the shareholders. This allows minority shareholders to take action against directors and supervisors of the company in default.

Directors

The PRC Company Law, unlike Hong Kong law, does not contain any requirements relating to the declaration of directors’ interests in material contracts, restrictions on directors’ rights to carry out major disposals or companies providing certain benefits, or prohibitions against compensation for loss of office without shareholders’ approval. The PRC Company Law restricts the directors of a listed company who have interests or associations in the enterprises involved in the resolution of the board meetings from voting on the said resolution. All the above provisions have been incorporated in the articles of association, which are summarized in Appendix V.

Supervisors

Under the PRC Company Law, a joint stock limited company’s directors and senior management are subject to the supervision of a board of supervisors. There is no mandatory requirement for the establishment of a board of supervisors for a company incorporated in Hong Kong.

Under the PRC Company Law, a joint stock limited company’s directors and members of the senior management are subject to the supervision of board of supervisors. There is no mandatory requirement for the establishment of board of supervisors for a company incorporated in Hong Kong. The Guidelines for the Articles of Association of Listed Companies stipulate that supervisors shall abide by the laws, administrative regulations and the articles of association of the company, owe the company a duty of loyalty and diligence, and shall not use their authority to accept bribes or other illegal income or misappropriate the property of the company.

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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 shall assume the duty of loyalty and diligence.

Financial Disclosure

Under the Company Law, a joint stock limited company is required to make available at the company for inspection by shareholders its financial report twenty (20) days before its annual general meeting. In addition, a joint stock limited company of which the shares are publicly offered 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 in its annual general meeting, not less than twenty one (21) days before such meeting. According to the PRC laws, a company shall prepare its financial accounting reports as at the end of each accounting year, and submit the same to accounting firms for auditing as required by law.

Information on Directors and Shareholders

The Company Law gives shareholders the right to inspect the company’s articles of association, minutes of the general meetings and financial and accounting reports. Under the articles of association, shareholders have the right to inspect and copy (at reasonable charges) certain information on shareholders and on directors which is similar to the rights of shareholders of Hong Kong companies under the Companies Ordinance.

Receiving Agent

Under the Hong Kong law, dividends once declared by the board of directors will become debts payable to shareholders. The limitation period for debt recovery action under Hong Kong law is six years, while under the PRC law this limitation period is three years.

Corporate Reorganization

Corporate reorganization involving a company incorporated in Hong Kong may be effected in a number of ways, such as a transfer of the whole or part of the business or property of the company in the course of voluntary winding up to another company pursuant to Section 237 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance or a compromise or arrangement between the company and its creditors or between the company and its members pursuant to Section 673 and Division 2 of Part 13 of the Companies Ordinance, which requires the sanction of the court. In addition, subject to the shareholders’ approval, an

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intra-group wholly-owned subsidiary company may also be amalgamated horizontally or vertically under the Companies Ordinance. Under PRC law, merger, division, dissolution or change to the status of a joint stock limited liability company has to be approved by shareholders in general meeting.

Mandatory Deductions

Under the Company Law, a joint stock limited liability company is required to make transfers equivalent to certain prescribed percentages of its after-tax profit to the statutory common reserve fund. There are no corresponding provisions under Hong Kong law.

Arbitration of Disputes

In Hong Kong, disputes between shareholders and a company or its directors, managers and other senior management may be resolved through the courts. The Guidelines for the Articles of Association of Listed Companies provide that shareholders may sue directors, supervisors, managers and other senior management of the company, and shareholders may sue the company, and the company may sue its shareholders, directors, supervisors, managers and other senior management personnel.

The Securities Arbitration Rules of the HKIAC contain provisions allowing, upon application by any party, an arbitral tribunal to conduct a hearing in Shenzhen for cases involving the affairs of companies incorporated in the PRC and listed on the Stock Exchange so that PRC parties and witnesses may attend. Where any party applies for a hearing to take place in Shenzhen, the tribunal shall, where satisfied that such application is based on bona fide grounds, order the hearing to take place in Shenzhen conditional upon all parties, including witnesses and arbitrators, being permitted to enter Shenzhen for the purpose of the hearing. Where a party, other than a PRC party or any of its witnesses or any arbitrator, is not permitted to enter Shenzhen, then the tribunal shall order that the hearing be conducted in any practicable manner, including the use of electronic media. For the purpose of the Securities Arbitration Rules of the HKIAC, a PRC party means a party domiciled in the PRC other than the territories of Hong Kong, Macau and Taiwan.

Remedies of a Company

Under the Company Law, if a director, supervisor or manager 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 manager should be responsible to the company for such damages. In addition, the Hong Kong Listing Rules require listed companies' articles to provide for remedies of the company similar to those available under Hong Kong law (including rescission of the relevant contract and recovery of profits from a director, supervisor or senior management).

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Dividends

The company has the power in certain circumstances to withhold, and pay to the relevant tax authorities, any tax payable under PRC law on any dividends or other distributions payable to a shareholder. Under Hong Kong law, the limitation period for an action to recover a debt (including the recovery of declared dividends) is six years, whereas under PRC laws, the relevant limitation period is three years. The company must not exercise its powers to forfeit any unclaimed dividend in respect of shares until after the expiry of the applicable limitation period.

Closure of Register of Shareholders

The Companies Ordinance requires that the register of shareholders of a company must not be closed for the registration of transfers of shares for more than thirty (30) days (extendable to sixty (60) days in certain circumstances) in a year. Unless otherwise stipulated by laws, share transfers shall not be registered within twenty (20) days prior to convening a shareholders' general meeting or five (5) days before the base date of distribution of dividends.

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SUMMARY OF ARTICLES OF ASSOCIATION

This Appendix contains a summary of the principal provisions of the Company’s Articles of Association. The major objective of this Appendix is to provide potential [REDACTED] with an overview of the Company’s Articles of Association, and therefore it may not contain all the information that may be important to potential [REDACTED].

SHARES AND REGISTERED CAPITAL

Shares of the Company shall take the form of share certificates. The par value of the shares shall be denominated in RMB.

The shares of the Company shall be issued in accordance with the principles of open, fairness and justice. Each share of the same class shall carry the same rights.

Shares of the same class and the same issuance 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 it/he/she subscribes for.

INCREASE, REDUCTION, REPURCHASE AND TRANSFER OF SHARES

Increase and Reduction of Shares

Based on its operation and development needs, in accordance with the relevant laws and regulations, and subject to the resolutions of the general meeting, the Company may increase its capital by any of the following ways:

- (i) public issuance of shares;
- (ii) non-public issuance of shares;
- (iii) distribution of bonus shares to existing Shareholders;
- (iv) conversion of capital reserve into share capital;
- (v) other means permitted by laws and administrative regulations and approved by the CSRC.

The Company may reduce its registered capital. The reduction of registered capital shall comply with the PRC Company Law and other relevant regulations as well as the procedures stipulated in the Articles of Association.

Repurchase of Shares

The Company shall not buy back its shares, except in one of the following circumstances:

- (i) reduction of the Company’s registered capital;

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- (ii) mergers with another company holding shares of the Company;
- (iii) use of shares for employee shareholding scheme or equity incentives;
- (iv) Shareholders who object to resolutions of the general meeting on merger or division of the Company requesting the Company to purchase their shares;
- (v) use of shares for conversion of corporate bonds issued by the Company which are convertible into shares;
- (vi) where it is necessary for the Company to preserve its value and Shareholders’ interest.

Where the Company purchases its shares under the circumstances set forth in items (i) and (ii) above, it shall be resolved at a general meeting. Where the Company purchases its shares under the circumstances set forth in items (iii), (v) and (vi) above, a resolution thereon may, pursuant to the securities regulatory rules of the place where the shares of the Company are listed, be resolved at a Board meeting that is attended by more than two-thirds of the Directors. Upon the purchase of its shares by the Company pursuant to the above provisions, under the circumstance set forth in item (i), such shares shall be cancelled within 10 days from the day of purchase; under the circumstances set forth in items (ii) and (iv), such shares shall be transferred or cancelled within six months; under the circumstances set forth in items (v) and (vi), the total number of shares held by the Company shall not exceed 10% of the total issued shares of the Company, and shall be transferred or cancelled within three years; under the circumstances set forth in items (iii), the total number of shares held by the Company shall not exceed 5% of the total issued shares of the Company, and the funds for the acquisition should be disbursed from the company’s after-tax profits; the shares acquired should be transferred to the employees within one year.

The Company may purchase its own shares by the centralized [REDACTED] on the stock exchange or other ways approved by the laws, administrative regulations, securities regulatory rules of the place where the shares of the Company are listed, and the CSRC and other stock exchanges of the place where the Company’s shares are listed.

Transfer of Shares

Shares of the Company held by the promoters shall not be transferred within one year from the date of the establishment of the Company. Shares issued prior to the public offering of A shares of the Company shall not be transferred within one year from the date on which the A shares of the Company are listed and traded on the stock exchange(s).

Directors, Supervisors and senior management of the Company shall report to the Company their holdings of shares of the Company and the changes thereof. During their term of office, the shares transferred by any of them each year shall not exceed 25% of the total shares of the Company held by them. The shares of the Company held by the aforesaid persons

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shall not be transferred within one year from the date on which the shares of the Company are listed and traded. The above personnel shall not transfer the shares of the Company held by them within 6 months after the expiry of their term of office.

Where Shareholders holding 5% or above shares of the Company, Directors, Supervisors and senior management sell the shares of the Company or other securities with an equity nature within 6 months after purchasing the same, or purchase the shares of the Company or other securities with an equity nature as held within 6 months after selling the same, the earnings arising therefrom shall belong to the Company, and the Board of the Company shall recover such earnings. However, the restriction shall not be applicable to a securities company holding 5% or above of the shares of the Company as a result of its purchase of the remaining unsold shares [REDACTED] by it and other circumstances stipulated by the CSRC. Other listing rules at the place where the shares of the Company are listed shall prevail.

SHAREHOLDERS AND GENERAL MEETINGS

Shareholders

The Company shall establish a register of members with the evidence provided by the securities registration authority of the place where the Company’s shares are listed. The register of members shall be sufficient evidence of the holding of the shares of the Company by the Shareholders. The original copy of the register of members of H shares [REDACTED] in Hong Kong shall be kept in Hong Kong for shareholders inspection. However, the Company may suspend the registration of Shareholders in accordance with the provisions of the applicable laws and regulations and the securities regulatory rules of the place where shares of the Company are listed. Shareholders shall enjoy the rights and assume the obligations according to the class of the shares they hold. Shareholders holding the same class of shares shall enjoy the same rights and assume the same obligations.

Shareholders of the Company shall enjoy the following rights:

- (i) to receive dividends and other distributions in proportion to the shares they hold;
- (ii) to request, convene, hold, attend or appoint a proxy to attend general meetings and exercise the corresponding voting rights in accordance with laws;
- (iii) to supervise, present suggestions on or make inquiries about the operations of the Company;
- (iv) to transfer, gift or pledge the shares it holds in accordance with laws, administrative regulations and regulations of the Articles of Association;
- (v) to inspect the Articles of Association, register of members, record of bondholders, minutes of general meetings, resolutions of Board meetings, resolutions of Supervisory Committee meeting and financial reports;

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- (vi) in the event of termination or liquidation of the Company, to participate in the distribution of the remaining property of the Company in proportion with the number of shares held by them;
- (vii) to require the Company to purchase their shares in the event of objection to the resolutions of the general meeting on merger or division of the Company;
- (viii) to enjoy other rights stipulated by laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the shares of the Company are listed and regulations of the Articles of Association.

If any resolution of a general meeting or the Board is in violation of the laws or administrative regulations, Shareholders shall have the right to request the People’s Court to invalidate the said resolution. If the convening procedures and voting method of the general meetings or Board meetings are in violation of the laws, administrative regulations or the Articles of Association or if the contents of any resolution are in breach of the Articles of Association, Shareholders shall have the right to request the People’s court to revoke such resolution within 60 days from the date on which the resolution is approved.

Shareholders of the Company shall assume the following obligations:

- (i) to abide by the laws, administrative regulations and the Articles of Association;
- (ii) to pay capital contribution as per the shares subscribed for and the method of subscription;
- (iii) not to return Shares unless prescribed otherwise in laws and regulations;
- (iv) not to abuse Shareholders⁵ rights to impair the interests of the Company or other Shareholders; not to abuse the independent status of legal person or Shareholders⁵ limited liabilities to impair the interests of the creditors of the Company.
- (v) to assume other obligations prescribed by the laws, administrative regulations and the Articles of Association.

Shareholders of the Company who abuse their Shareholders rights and thereby cause loss on the Company or other Shareholders shall be liable for loss compensation according to the laws. Where Shareholders of the Company abuse the Company’s position as an independent legal person and the limited liabilities of Shareholders for the purposes of evading repayment of debts, thereby materially impairing the interests of the creditors of the Company, such Shareholders shall be jointly and severally liable for the debts owed by the Company.

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General Provisions for General Meeting

The general meeting is the organ of authority of the Company and shall exercise the following duties and powers in accordance with laws:

- (i) to decide the operational policies and investment plans of the Company;
- (ii) to elect and replace Directors or Supervisors who are not employee representatives and to determine matters relating to the remuneration of the Directors or Supervisors;
- (iii) to consider and approve the reports of the Board;
- (iv) to consider and approve the reports of the Supervisory Committee;
- (v) to consider and approve the annual financial budgets and final accounts of the Company;
- (vi) to consider and approve the profit distribution plan and loss recovery plans of the Company;
- (vii) to resolve on the increase or reduction of the registered capital of the Company;
- (viii) to resolve on the issue of corporate bonds;
- (ix) to resolve on the merger, division, dissolution, liquidation or change in corporate form of the Company;
- (x) to amend the Articles of Association;
- (xi) to resolve on the appointment and dismissal of accounting firms by the Company;
- (xii) to consider and approve the guarantee issues specified in Article 41 of the Articles of Association;
- (xiii) to consider matters relating to the purchase and sale by the Company within 12 months of material assets valued at more than 30% of the audited total assets of the Company as at the most recent period;
- (xiv) to consider and approve matters relating to changes in the use of proceeds;
- (xv) to consider share incentive scheme and employee shareholding scheme;

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- (xvi) the annual general meeting of the company may authorize the board of directors to decide to issue a total amount of financing not exceeding RMB300 million and not exceeding 20% of the net assets at the end of the most recent year to specific objects; such authorization will expire on the date of the next annual general meeting;
- (xvii) to review all transactions with a percentage calculated in accordance with Rule 14.07 of the Listing Rules, where the percentage is not less than 25% (including one-off transactions and a series of transactions requiring the calculation of the percentage) and not less than 5% of related transactions (including one-off transactions and a series of transactions requiring the calculation of the percentage);
- (xviii) to consider other matters to be resolved by the general meeting as required by laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the shares of the Company are listed or the Articles of Association.

The following provision of external guarantees by the Company is subject to the consideration and approval of the general meeting:

- (i) the total amount of the external guarantees provided by the Company and its holding subsidiaries exceeding 50% of the latest audited net assets;
- (ii) the total amount of the external guarantees provided by the Company exceeding 30% of the latest audited total assets;
- (iii) the amount of the guarantees provided by the Company within one year exceeding 30% of the latest audited total assets;
- (iv) any guarantee to be provided to a recipient of such security whose asset to liability ratio is over 70%;
- (v) any single guarantee with an amount exceeding 10% of the latest audited net assets;
- (vi) any guarantee provided to Shareholders, de facto controllers, and their related parties;
- (vii) any guarantees to be considered and approved by the general meeting as required by relevant laws and regulations, listing rules at the place where the shares of the Company are listed and the Articles of Association.

When a guarantee mentioned in item (3) above is considered at the general meeting, it shall be passed by more than two-thirds of the voting rights held by the Shareholders present at the meeting.

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The general meetings are classified into annual general meetings and extraordinary general meetings. The annual general meetings shall be convened once a year within six months from the end of the previous fiscal year.

The Company shall convene an extraordinary general meeting within two months from the date of occurrence of any of the following circumstances:

- (i) when the number of Directors is less than the statutory minimum quorum provided for in the PRC Company Law or two-thirds of the number specified in the Articles of Association;
- (ii) when the uncovered loss of the Company reaches one-third of its total paid-up share capital;
- (iii) upon written request(s) by shareholder(s) individually or collectively holding 10% or above of the shares of the Company;
- (iv) when the Board deems it necessary;
- (v) when the Supervisory Committee proposes such a meeting be held;
- (vi) other circumstances required by the laws, administrative regulations, departmental rules, securities regulatory rules of the place where the shares of the Company are listed or the Articles of Association.

Summoning of General Meetings

Subject to the consent of more than half of all independent Directors, the independent Directors shall have the right to propose to the Board to convene an extraordinary general meeting. The Board shall, in accordance with relevant laws, administrative regulations and the Articles of Association, give a written response on whether or not it agrees to convene such an extraordinary general meeting within 10 days after the receipt of the proposal. If the Board agrees to convene an extraordinary general meeting, it shall give a notice convening such meeting within 5 days after it has so resolved. If the Board does not agree to convene the extraordinary general meeting, it shall give the reasons and make an announcement.

The Supervisory Committee shall have the right to propose to the Board in writing to convene an extraordinary general meeting. The Board shall, in accordance with relevant laws, administrative regulations and the Articles of Association, give a written response on whether or not it agrees to convene such an extraordinary general meeting within 10 days after the receipt of the proposal. If the Board agrees to convene an extraordinary general meeting, it shall give a notice convening such meeting within 5 days after it has so resolved. Any changes to be made to the original request in the notice shall be subject to approval of the Supervisory Committee. If the Board does not agree to convene an extraordinary general meeting or fails to give a response within 10 days after the receipt of the proposal, the Supervisory Committee may convene and preside over such meeting on its own.

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Shareholders that hold, individually or collectively, 10% or more of the shares in the Company shall have the right to request in writing the Board to convene an extraordinary general meeting. The Board shall, in accordance with relevant laws, administrative regulations and the Articles of Association, give a written response on whether or not it agrees to convene such an extraordinary general meeting within 10 days after the receipt of the proposal. If the Board agrees to convene an extraordinary general meeting, it shall give a notice convening such meeting within 5 days after it has so resolved. Any changes to be made to the original request in the notice shall be subject to approval of the relevant Shareholders. If the Board does not agree to convene an extraordinary general meeting or fails to give a response within 10 days after the receipt of the proposal, the Shareholders that hold, individually or collectively, 10% or more of the Shares of the Company may propose to the Supervisory Committee to convene an extraordinary general meeting. If the Supervisory Committee agrees to convene an extraordinary general meeting, it shall give a notice convening such meeting within 5 days after it has so resolved. Any changes to be made to the original request in the notice shall be subject to approval of the relevant Shareholders. If the Supervisory Committee fails to give the notice convening such meeting within the period specified hereinabove, it shall be deemed to have failed to convene and preside over such meeting. The Shareholders that hold, individually or collectively, 10% or more of the shares in the Company for 90 days or more consecutively may convene and preside over such meeting on their own.

Where the Supervisory Committee or the Shareholder(s) decide to convene a general meeting on its or their own, it or they shall notify the Board in writing and file with the stock exchange(s) pursuant to the securities regulatory rules of the place where the shares of the Company are listed. Before the announcement of the resolutions of the general meeting is made, the shareholding of the convening shareholder(s) shall not be less than 10%. Upon giving the notice of the general meeting and the announcement of the resolutions of the general meeting, the Supervisory Committee or the convening shareholder(s) shall file with the stock exchange(s) pursuant to the securities regulatory rules of the place where the shares of the Company are listed.

Where the Supervisory Committee or the Shareholder(s) convene a general meeting on its or their own, the Board and the board secretary shall provide assistance. The Board will provide the register of members as of the date of the share registration.

PROPOSALS AND NOTICES OF GENERAL MEETINGS

The content of proposals shall fall within the functions and powers of the general meeting, have clear subject for discussion and specific matters to be resolved and comply with relevant requirements of the laws, administrative regulations, the securities regulatory rules of the place where the shares of the Company are listed and the Articles of Association.

The Board, the Supervisory Committee or Shareholders that hold, individually or collectively, 3% or more of the Shares of the Company shall have the right to propose resolutions.

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Shareholders that hold, individually or collectively, 3% or more of the Shares of the Company may submit ad hoc proposals in writing to the convener 10 days before the convening of the general meeting. The convener shall give a supplemental notice of the general meeting within 2 days upon receipt of the proposals and announce the contents of the ad hoc proposals.

The convener of an annual general meeting shall notify all Shareholders by means of an announcement 21 days before the meeting; the convener of an extraordinary general meeting shall notify all Shareholders by means of an announcement 15 days before the meeting. When calculating the period for giving notice, the day of the meeting shall not be included.

A notice of a general meeting shall include the following:

- (i) the time, venue and duration of the meeting;
- (ii) matters and proposals submitted to the meeting for consideration;
- (iii) a prominent written statement that all Shareholders are entitled to attend general meeting and are entitled to appoint in writing a proxy to attend and vote at the meeting and that such proxy need not be a shareholder of the Company;
- (iv) the record date of registration of Shareholders entitled to attend the general meeting;
- (v) the name and contact method of the regular contact person for the meeting;
- (vi) the time and procedure for voting online or through other means.

Notices or supplementary notices of general meetings shall adequately and completely disclose the specific contents of all proposals. Where the opinions of an independent Director are required on the matters to be discussed, such opinions and reasons thereof shall also be disclosed when the notices or supplementary notices of general meetings are served.

CONVENING OF GENERAL MEETINGS

All Shareholders registered on the share right registration date or their proxies shall be entitled to attend the general meetings and exercise voting rights in accordance with relevant laws, regulations and the Articles of Association. Shareholder may attend the general meeting in person, or appoint a proxy (need not be a shareholder) to attend or vote on behalf of such Shareholder.

Individual shareholders attending the meeting in person shall present his or her identity card or other valid license or certificate or stock account card that can prove his or her identity. Proxies appointed to attend the meeting shall present valid proof of their identities and the power of attorney from the appointing shareholder.

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Shareholder that is a legal person shall attend the meeting by its legal representative or by proxies appointed by it. If a legal representative attends the meeting, he/she shall present his/her identity card or valid certificate proving his/her qualifications as a legal representative. Where the meeting is attended by proxy, he/she shall present his/her identity card and written power of attorney issued by the legal representative of the corporate shareholder unit in accordance with the law.

Where such Shareholder is a Recognized Clearing House (or its nominees) as defined by the relevant ordinances or regulations enacted in Hong Kong from time to time, it may authorize one or more persons or company representatives as it thinks fit to act as its representative(s) at any meeting (including but not limited to general meeting and creditor meeting); however, if more than one person are so authorized, the power of attorney shall specify the number and class of shares in respect of which each such person is so authorized, and be signed by the person authorized by the Recognized Clearing House. The person(s) so authorized will be entitled to attend meetings (without being required to present share certificate, notarized authorization and/or further evidence of formal authorization) to speak and exercise the same power on behalf of the Recognized Clearing House (or its nominees) at the meeting as if such person was an individual shareholder of the Company.

Shareholders shall appoint a proxy in writing, signed by the appointing shareholder or the agent entrusted by him in writing; if the appointing shareholder is a legal person, it shall be affixed with the seal of the legal person or signed by its director or formally appointed agent. The power of attorney issued by a shareholder to appoint a proxy to attend any general meeting shall contain the following:

- (i) name of the proxy;
- (ii) whether there are voting rights;
- (iii) instructions for voting for, against or abstaining from voting on each matter to be considered on the agenda of general meeting;
- (iv) the date of issuance and term of validity of the power of attorney;
- (v) the signature of the principal (or official seal); and a corporate seal should be affixed or signed by a legally authorized person if the principal is a corporate shareholder.

If the Shareholder does not give specific instructions on authorizing a proxy to attend the general meeting, the power of attorney shall state whether the proxy may vote as he/she thinks fit.

If the power of attorney is sign by other personnel authorized by consignor, the power of attorney for authorized signature or other authorization documents should be certified by a notary. The certificate of authorization or other authorization documents certified by a notary. The power of attorney or other authorization documents upon notarized shall, together with the

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power of attorney for voting, be placed at the domicile of the Company or such other location as specified in the notice of the meeting. If the consignor is a legal person, its legal representative or any person authorized by resolutions of the Board or other decision-making institutions shall attend the general meeting on behalf of the consignor.

All Directors, Supervisors and secretary to the Board shall attend general meetings of the Company, and the general manager and other senior management shall attend the meeting as non-voting participants. Subject to compliance with the securities regulatory rules of the place where the shares of the Company are listed, the aforementioned persons may attend the meeting through the internet, video, telephone or other means with equivalent effect.

A general meeting shall be presided over by chairman of the Board. Where the chairman of the Board is unable or fails to perform his/her duties, the meeting shall be presided over by a Director jointly elected by more than half of the Directors. A general meeting convened by the Supervisory Committee shall be presided over by the chairman of the Supervisory Committee. Where the chairman of the Supervisory Committee is unable or fails to perform his/her duties, the meeting shall be presided over by a Supervisor jointly elected by more than half of the Supervisors. A general meeting convened by Shareholders shall be presided over by a representative elected by convener(s). Where the host of the meeting violates the rules of procedure and makes it impossible to continue the meeting, with the consent of more than half of the Shareholders present at the meeting with voting rights, the general meeting may elect a person to serve as the host of the meeting and continue the meeting.

Voting of General Meetings

Resolutions of a general meeting are divided into ordinary resolutions and special resolutions. Ordinary resolutions of a general meeting shall be passed by votes representing more than half of the voting rights held by Shareholders (including proxies thereof) attending the general meeting. Special resolutions of a general meeting shall be passed by votes representing more than two-thirds of voting rights held by Shareholders (including proxies thereof) attending the general meeting.

The following matters shall be passed by ordinary resolutions at a general meeting:

- (i) work reports of the Board and the Supervisory Committee;
- (ii) profit distribution plans and plans for recovery of losses formulated by the Board;
- (iii) appointment and dismissal of members of the Board and the Supervisory Committee, their remunerations and methods of payment;
- (iv) the annual budgets and final accounts of the Company;
- (v) annual reports of the Company;

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- (vi) matters other than those required by the laws, administrative regulations, the securities regulatory rules of the place where the shares of the Company are listed or the Articles of Association to be passed by special resolution.

The following matters shall be passed by special resolutions at a general meeting:

- (i) increase or reduction of registered capital of the Company;
- (ii) division, spin-off, merger, dissolution and liquidation of the Company;
- (iii) the amendment of the Articles of Association;
- (iv) the purchase and sale of material assets or amount of guarantee provided by the Company within one year valued at more than 30% of the audited total assets of the Company as at the most recent period;
- (v) share incentive scheme;
- (vi) other matters as required by the laws, administrative regulations, the securities regulatory rules of the place where the shares of the Company are listed or the Articles of Association, and considered by the general meeting, by way of an ordinary resolution, to be of a nature which may have a material impact on the Company, shall be passed by a special resolution.

Shareholders (including proxies thereof) shall exercise their voting rights based on the number of voting shares they represent. Each share is entitled to one vote.

When considering the material matters affecting the interests of minority investors at the general meeting, the votes by minority investors shall be counted separately, and the results of such separate vote counting shall be publicly disclosed in a timely manner.

The shares of the Company held by the Company do not carry voting rights, and shall not be counted in the total number of voting shares represented by Shareholders attending a general meeting.

Shareholders who purchase the voting shares of the Company in violation of the provisions of Clause 1 and Clause 2 of Article 63 of the Securities Law shall not exercise the voting right of the shares that exceed the prescribed ratio within 36 months after the purchase, and such number shall not be counted in the total number of voting shares represented by Shareholders attending a general meeting.

The Board, independent Directors and Shareholders who hold more than one percent of voting shares of the Company or investors protection institutes established in accordance with laws, administrative regulations or the securities regulatory rules of the stock exchange(s) where the shares of the Company are listed may publicly solicit for the voting shares from

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Shareholders. Information including the specific voting intention shall be fully disclosed to the Shareholders from whom voting rights are being collected. Consideration or de facto consideration for soliciting Shareholders⁵ voting rights is prohibited. Except for statutory conditions, the Company shall not impose any minimum shareholding limitation for soliciting voting rights.

When a connected transaction is considered at a general meeting, the connected shareholders shall refrain from voting and the number of voting shares that they represent shall not be counted the total number of valid voting shares. Announcement of resolutions of the general meeting shall fully disclose the voting of non-connected shareholders.

BOARD OF DIRECTORS

Directors

Directors may include executive Directors, non-executive Directors, and independent Directors. Independent Directors refer to individuals who meet the requirements stipulated in Article 103 of the Articles of Association. Directors of the Company shall be natural persons and shall be subject to the qualification required by the laws, administrative regulations and the securities regulatory rules of the place where the shares of the Company are listed. A person may not serve as a Director of the Company in case of any of the following circumstances:

- (i) the person is without civil conduct capacity or with limited civil conduct capacity;
- (ii) the person who has committed an offence of corruption, bribery, conversion of property, misappropriation of property or sabotaging the market economic order of socialism and has been punished therefor; or who has been deprived of his/her political rights, in each case where less than five years have elapsed since the date of the completion of implementation of such punishment or deprivation;
- (iii) the person who is a former director, factory director or manager of a company or enterprise which is insolvent and under liquidation and he/she is personally liable for the insolvency of such company or enterprise, where less than three years have elapsed since the date of the completion of such insolvency and liquidation of the company or enterprise;
- (iv) the person who is a former legal representative of a company or enterprise which had its business license revoked and was ordered to shut down due to a violation of the law and who incurred personal liability, where less than three years have elapsed since the date of such revocation of the business license;
- (v) the person fails to repay a relatively large amount of due debts;
- (vi) the person has been banned by the CSRC from access to the securities market, and the term of prohibition has not expired;

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- (vii) the person is publicly deemed by a stock exchange as unsuitable to serve as a director, supervisor and senior management of a listed company, and the term of prohibition has not expired;
- (viii) other contents stipulated by laws, administrative regulations or departmental rules or the securities regulatory rules of the place where the shares of the Company are listed.

Directors shall be elected or replaced at the general meeting and may be dismissed by the general meeting prior to the expiry of the term of their office. The general meeting may depose any director whose term has not expired by ordinary resolution (but claims that may be made under any contract will not be affected). A Director shall serve a term of three years and may serve consecutive terms if re-elected upon the expiration of their terms in accordance with securities regulatory rules of the place where the shares of the Company are listed.

The term of office of a Director shall commence from the date of taking the position until the expiry of the term of office of the current session of the Board. Where a re-election fails to be carried out in a timely manner upon the expiry of the term of office of a Director, such Director shall continue to perform his/her duties as a Director in accordance with the laws, administrative regulations, departmental rules and the Articles of Association until the newly elected Director assumes the office.

Senior management officers may serve concurrently as Directors, provided that the total number of such Directors who concurrently serve as senior management officers and the employee representatives shall not exceed a half of the total number of the Directors of the Company.

Directors may resign prior to the expiration of their terms of office. The Directors who resign shall submit to the Board a written report in relation to their resignation. Relevant information shall be disclosed by the Board within 2 days. In the event that the resignation of any Director results in the number of members of the Board falling below the statutory minimum requirement, the resignation of an independent Director results in the proportion of independent directors in the Board of Directors or a special committee not complying with legal regulations or the provisions of the Articles of Association, or no accounting professionals are among the independent Directors, the resigned Directors shall continue to perform his/her duties in accordance with laws, administrative regulations, departmental rules and the Articles of Association until the newly elected Director assumes the office.

The terms of appointment, nomination and election procedures, functions and powers of independent Directors shall be implemented in accordance with the laws, the relevant the securities regulatory rules of the place where the shares of the Company are listed. The number of independent Directors shall not be less than three and shall not be less than one-third of all

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Directors, and at least one shall include financial or accounting expertise in compliance with the requirements of the Listing Rules. One independent Director should be permanently resident in Hong Kong. All independent Directors must possess the independence as provided under the Listing Rules.

Unless otherwise specified by relevant laws, administrative regulations, and the securities regulatory rules of the place where the shares of the Company are listed, the term “independent Director” as referred to in the Articles of Association includes “independent non-executive Directors” as defined in the Listing Rules.

Board of Directors

The Company has established a Board which shall be accountable to the general meetings. The Board shall comprise 9 to 19 Directors.

The Board shall exercise the following duties and powers:

- (i) to convene general meetings and report its work to the general meetings;
- (ii) to implement the resolutions of the general meetings;
- (iii) to formulate business operation plans and investment plans of the Company;
- (iv) to formulate annual budgets and final accounts of the Company;
- (v) to formulate the profit distribution plans and plans for recovery of losses of the Company;
- (vi) to formulate plans of the Company regarding increase or reduction of the registered capital, issuance of bonds or other securities and listing;
- (vii) to draft plans for major acquisitions of the Company, the purchase of Shares of the Company, merger, division, dissolution or change in the form of the Company;
- (viii) to determine, to the extent authorized by the general meeting, on such matters as the external investments, purchase or sale of assets, assets mortgage, external guarantee, entrusted wealth management, connected transactions and external donations of the Company;
- (ix) to determine the internal management structure of the Company;

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- (x) to determine the appointment or dismissal of the manager of the Company, the Board secretary or other senior management officers, and decide on their remuneration, rewards and penalties; and based on the nomination of the manager, to determine the appointment or dismissal of the senior management including vice manager(s) and chief financial officer of the Company and determine their remuneration, rewards and penalties;
- (xi) to formulate the basic management system of the Company;
- (xii) to formulate proposals for any amendment of the Articles of Association;
- (xiii) to manage the information disclosure of the Company;
- (xiv) to propose to the general meeting for appointment or replacement of the accounting firms which provide audit services to the Company;
- (xv) to listen to work reports of the manager of the Company and review his/her work;
- (xvi) other duties as stipulated in laws, administrative regulations, departmental rules, securities regulatory rules of the place where the shares of the Company are listed and the Articles of Association.

Special committees are set up under the Board of the Company, namely Audit Committee, Strategy Committee, Nomination Committee and Remuneration and Evaluation Committee.

Borrowing Powers

The Articles of Association do not contain any specific provisions regarding Directors exercise of borrowing powers, but there are relevant provisions regarding Directors power to determine, to the extent authorized by the general meeting, on such matters as the external investments, purchase or sale of assets, assets mortgage, external guarantee, entrusted wealth management, connected transactions and external donations of the Company.

The Board shall consider the following major transactions within the scope of permissions: (save for the Company's provision of guarantee):

- (i) the total amount of assets involved in the transaction exceeds 10% of the latest audited total assets of the Company; where the total amount of assets involved in the transaction exceeds 50% of the latest audited total assets of the Company, such transaction shall be submitted to the general meeting for consideration; and if such total amount of assets involved in the transaction has both book value and assessed value, the higher shall be used for calculation.

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- (ii) the transaction consideration exceeds 10% of the latest market value of the Company; where the transaction consideration exceeds 50% of the latest market value of the Company, such transaction shall be submitted to the general meeting for consideration.
- (iii) the net assets involved in the subject matter (such as equity interest) of the transaction in the most recent financial year exceeds 10% of the latest market value of the Company; where the net assets involved in the subject matter (such as equity interest) of the transaction in the most recent financial year exceeds 50% of the latest market value of the Company, such transaction shall be submitted to the general meeting for consideration.
- (iv) the operating revenue generated by the subject matter (such as equity interest) of the transaction in the most recent financial year exceeds 10% of the audited operating revenue of the Company in the most recent financial year, and the absolute amount of which exceeds RMB10 million; where the operating revenue generated by the subject matter (such as equity interest) of the transaction in the most recent financial year exceeds 50% of the audited operating revenue of the Company in the most recent financial year, and the absolute amount of which exceeds RMB50 million, such transaction shall be submitted to the general meeting for consideration.
- (v) the profit arising from the transaction exceeds 10% of the audited net profit of the Company in the most recent financial year, and the absolute amount of which exceeds RMB1 million; where the profit arising from the transaction exceeds 50% of the audited net profit of the Company in the most recent financial year, and the absolute amount of which exceeds RMB5 million, such transaction shall be submitted to the general meeting for consideration.
- (vi) the net profit generated by the subject matter (such as equity interest) of the transaction in the most recent financial year exceeds 10% of the audited net profit of the Company in the most recent financial year, and the absolute amount of which exceeds RMB1 million; where the net profit generated by the subject matter (such as equity interest) of the transaction in the most recent financial year exceeds 50% of the audited net profit of the Company in the most recent financial year, and the absolute amount of which exceeds RMB5 million, such transaction shall be submitted to the general meeting for consideration.

Transactions between the Company and its controlling subsidiaries or other entities under its control within the scope of consolidated statements, or transactions between the said controlling subsidiaries or other entities under its control, shall be exempted from the requirements of disclosure and fulfillment of the corresponding procedures in accordance with the Articles of Association, unless otherwise provided by the securities regulation authorities and stock exchanges where the shares of the Company are listed.

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The chairman of the Board shall be elected by more than half of all the Directors. The chairman of the Board shall exercise the following duties and powers:

- (i) to convene and preside over Board meetings, and to preside over general meetings;
- (ii) to supervise and examine the implementation of resolutions of Board;
- (iii) other duties and powers as authorized by the Board.

Where the chairman of the Board is unable or fails to perform his/her duties, the duties shall be performed by a Director jointly elected by more than half of the Directors.

The Board shall convene at least four meetings per year, and at least one meeting per quarter. Shareholders representing more than one-tenth of the voting rights, more than one-third of the Directors or the Supervisory Committee may propose to convene an extraordinary meeting of the Board. The chairman of the Board shall convene and preside over the extraordinary meeting of the Board within 10 days from the receipt of the proposal. The Board of Directors shall notify all Directors and Supervisors in writing 14 days before convening the regular meeting of the Board, while 5 days before convening the extraordinary meeting of the Board. If the notice is not delivered directly, it shall also be confirmed by telephone and recorded accordingly.

The quorum of a Board meeting shall consist of more than one half of all Directors. A resolution of the Board shall be passed by more than half of all Directors. When the Board considers a resolution on the guarantees of the Company within the Board's decision-making authority, the resolution shall be passed by more than two thirds of the Directors present at the meeting. When voting on the resolutions of the Board, each Director shall have one vote.

Where a Director has any connected relationship with the enterprise involved in the matter to be decided at the meeting, he/she shall not exercise his/her voting rights on the resolution, nor shall he/she exercise his/her voting rights on behalf of other Directors. Such a Board meeting may be held only if more than one half of the Directors without a connected relationship are present, and the resolutions made at such a Board meeting shall require adoption by more than one half of the Directors without a connected relationship. If the number of non-connected Directors in presence is less than 3 persons, the matter shall be submitted to the general meeting for consideration. If there are any additional restrictions imposed by laws and regulations and the securities regulatory rules of the place where the shares of the Company are listed on the participation of Directors in the Board meetings and voting, such provisions shall apply.

The voting in respect of a resolution made at a Board meeting shall be by open ballot. Each Director has the right to one vote. Resolutions of extraordinary meetings of the Board may be adopted by voting through telecommunication (including but not limited to telephone, facsimile etc.), provided that the Directors are allowed to freely express their views and the resolutions shall be signed by the attending Directors.

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Directors shall attend Board meetings in person. If any Director is unable to attend the meeting for any reason, he/she may by a written power of attorney appoint another Director to attend the meeting on his/her behalf. The power of attorney shall include the name of the proxy, the subject, scope of authorization and validity period, which shall be signed or officially sealed by the appointing Director. A Director appointed as the representative of another Director to attend the meeting shall exercise the rights of a Director within the scope of authorization. Where a Director does not attend a Board meeting and does not appoint a proxy to attend the meeting on his behalf, he/she shall be deemed to have waived his/her voting right at the meeting.

Managers and other senior management

The Company shall have one general manager, who shall be appointed or dismissed by the Board. The Company may have several deputy general managers as necessary. Deputy general managers shall be nominated by the general manager and appointed or dismissed by the Board, and the deputy general manager shall assist the general manager in his/her work.

The circumstances of disqualification for Directors prescribed in Article 94 of the Articles of Association, the fiduciary duty of the Directors prescribed in Article 96 of the Articles of Association, and the diligence duty prescribed in item (iv)-(vi) of Article 97 shall also be applicable to senior management.

The general manager shall serve for a term of 3 years and may serve consecutive terms if re-appointed.

The general manager shall report to the Board and exercise the following duties and powers:

- (i) to take charge of the production, operation and management of the Company, organize the implementation of the Board, and report to the Board;
- (ii) to organize the implementation annual business plans and investment plans of the Company;
- (iii) to draft the plans for establishment of the internal management organization of the Company;
- (iv) to draft the basic management system of the Company;
- (v) to formulate the rules and regulations of the Company;
- (vi) to propose to the Board the appointment or dismissal of the deputy general manager and chief financial officer of the Company;

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- (vii) to determine the appointment or dismissal of management personnel other than those whose appointment or dismissal shall be determined by the Board;
- (viii) other duties and powers as may be conferred by the Articles of Association or by the Board.

The Company shall have a Board secretary, who is responsible for preparing for general meeting and Board meetings, maintaining documents and managing Shareholders information, as well as handling information disclosure matters.

The senior management of the Company shall perform their duties faithfully and safeguard the best interests of the Company and all Shareholders. If the senior management of the Company fails to perform their duties faithfully or violates their fiduciary duties, causing damage to the interests of the Company and public Shareholders, they shall be liable for compensation in accordance with the laws.

SUPERVISORY COMMITTEE

Supervisors

The circumstances of disqualification for Directors prescribed in Article 94 of the Articles of Association shall be applicable to Supervisors. Directors, the general manager and other senior management shall not concurrently serve as Supervisors.

Supervisors shall comply with laws, administrative regulations and the Articles of Association and shall assume the duties of honesty and due diligence towards the Company. Supervisors shall not receive bribes or other illegal income in abuse of the position or authority, or embezzle the company assets.

A Supervisor shall serve for a term of 3 years and may serve consecutive terms if re-appointed upon expiry of a term.

Where a re-election fails to be carried out in a timely manner upon the expiry of the term of office of a Supervisor, or in the event that the resignation of the Supervisor during his/her term of office results in the number of members of the Supervisory Committee falling below the statutory minimum requirement, such Supervisor shall continue to perform his/her duties as a Supervisor in accordance with the laws, administrative regulations, departmental rules and the Articles of Association until the newly elected Supervisor assumes the office.

If the Supervisors of the Company violate the laws, administrative regulations, departmental rules and the Articles of Association when conducting their duties, causing damage to the interests of the Company, they shall be liable for compensation in accordance with the laws.

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Supervisory Committee

The Company shall have a Supervisory Committee. The Supervisory Committee comprises three Supervisors. It shall have one chairman, who shall be elected by more than half of all the Supervisors. The chairman of the Supervisory Committee shall convene and preside over Supervisory Committee meetings. Where the chairman of the Supervisory Committee is unable or fails to perform his/her duties, the Supervisory Committee meetings shall be convened or presided over by a Supervisor jointly elected by more than half of the Supervisors.

The Supervisory Committee shall include representatives of Shareholders and a proper proportion of employee representatives of the Company. The proportion of employee representatives shall be no less than one third of the Supervisors appointed. The employee representatives of the Supervisory Committee shall be elected at the employee representatives meeting, employee meeting or otherwise democratically.

The Supervisory Committee shall exercise the following duties and powers:

- (i) to review the periodic reports of the Company prepared by the Board and express its written opinion;
- (ii) to check the financial condition of the Company;
- (iii) to monitor the performance of duties in the Company by Directors and senior management and propose dismissal of Directors and senior management who have violated laws, administrative regulations, the Articles of Association or the resolutions of general meetings;
- (iv) to require Directors and the senior management to make corrections if their conduct has damaged the interests of the Company;
- (v) to propose the convening of extraordinary general meetings and, in the event that the Board fails to perform the obligations to convene and preside over the general meetings in accordance with PRC Company Law, to convene and preside over the general meetings;
- (vi) to propose proposals to the general meetings;
- (vii) to file lawsuit against Directors and senior management in accordance with Article 151 of the PRC Company Law;
- (viii) in case of any irregularity identified in the operations of the Company, investigations may be conducted, and if necessary, professional institutions such as accounting firms and law firms may be engaged to assist in their work at the expense of the Company.

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The Supervisory Committee shall convene at least one meeting every six months. Supervisors may propose to convene an extraordinary Supervisor Committee meeting. Resolutions of the Supervisory Committee shall be passed by more than half of the Supervisors.

FINANCIAL ACCOUNTING SYSTEM, DISTRIBUTION OF PROFITS AND AUDIT

Financial Accounting System

The Company shall formulate its financial and accounting systems in accordance with laws, administrative regulations and requirements of the securities regulatory rules of the place where the shares of the Company are listed.

A Share Reports: The Company shall report and disclose its annual reports to the CSRC and the stock exchange(s) within four months from the ending date of each fiscal year, and report and disclose its interim report to the delegated authority of the CSRC and the stock exchange(s) within two months from the end of the first half of each fiscal year. The aforementioned annual reports and interim reports shall be prepared in accordance with relevant laws, administrative regulations and regulations of the CSRC and the stock exchange(s).

H Share Reports: The company shall disclose a preliminary announcement of the annual performance within 3 months from the end of each accounting year and prepare and disclose the annual report within 4 months from the end of each accounting year, with at least 21 days before the annual general meeting of shareholders. The company shall disclose a preliminary announcement of the interim performance within 2 months from the end of the first 6 months of each accounting year and prepare and disclose the interim report within 3 months from the end of the first 6 months of each accounting year.

The Company shall not keep accounts other than those provided by law. Any assets of the Company shall not be kept under any account opened in the name of any individual.

Profit distribution

When distributing after-tax profits of the year, the Company shall set aside 10% of its after-tax profits for the Company’s statutory reserve fund. When the aggregate balance in the statutory reserve fund has reached 50% or more of the Company’s registered capital, the Company needs not make any further allocations to that fund. Where the Company’s statutory reserve fund is not enough to make up losses of the Company for the preceding year, the current year’s profits shall be applied firstly to make up the losses before being allocated to the statutory reserve in accordance with the preceding provision.

Subject to a resolution passed at a general meeting, after allocation has been made to the Company’s statutory reserve fund from its after-tax profits, the Company may set aside funds for the discretionary reserve fund. Except for those not distributed in proportion as prescribed

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in the Articles of Association, the remaining after-tax profit, after recovery of losses and appropriation of statutory reserve funds, shall be distributed to Shareholders in proportion to their shareholdings. Where the general meeting distributes its profits before recovery of losses and appropriation of statutory reserve funds to the shareholders in breach of the provisions of the preceding provision, Shareholders must refund to the Company the profits distributed in violation of the provisions. No profit shall be distributed in respect of the shares of the Company which are held by the Company.

The reserve fund of the Company shall be used for making up for the loss, expansion of the operation or increase of capital of the Company, provided that the capital reserve fund shall not be used for making up for the loss of the Company. When the statutory reserve fund is capitalized, the retained portion of the fund shall not be less than 25% of the registered capital of the Company before the capitalization.

The Company may distribute profits in the form of cash, shares or a combination of both, or in any other manner permitted by laws and regulations. The Company shall prioritize the use of cash dividends for profit distribution.

Internal audit

The Company shall implement an internal audit system which is equipped with dedicated audit personnel to conduct internal audits for supervision of financial income and expenditure and economic activities of the Company.

The internal audit system of the Company and the duties of audit personnel shall be implemented upon approval by the Board. The head of audit shall be accountable and report to the Board.

Appointment of an Accounting Firm

The Company shall appoint such accounting firm which has complied with the securities regulatory rules of the place where the shares of the Company are listed for carrying out the audit for the accounting statements, net asset verification, and other relevant consultancy services. The term of appointment shall be 1 year and can be re-appointed.

The appointment of accounting firm by the Company shall be subject to the approval of general meetings. The Board shall not appoint accounting firm before the approval of the general meeting.

The Company guarantees that it shall provide the appointed accounting firm with true and complete accounting proofs, accounting books, financial and accounting reports and other accounting information, and that it engages without any refusal, withholding, and misrepresentation.

The auditing fee of the accounting firm shall be determined by the general meeting.

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In the event of termination of the appointment or non-renewal of appointment of an accounting firm, the Company shall notify the accounting firm 30 days in advance; when the general meeting votes on termination of appointment of an accounting firm, the accounting firm shall be allowed to make its representation.

An accounting firm proposing to resign shall state at a general meeting whether the Company has committed any improper act.

MERGER, DIVISION, CAPITAL INCREASE, CAPITAL REDUCTION, DISSOLUTION AND LIQUIDATION

Merger, Division, Capital Increase and Capital Reduction

Merger of the Company may take the form of absorption or establishment of a new company.

In case of merger by absorption, a company absorbs any other company and the absorbed company is dissolved. In case of merger by new establishment, two or more companies merge into a new one and the parties to the merger are dissolved.

If the Company is involved in a merger, the parties to the merger shall enter into a merger agreement, and shall prepare a balance sheet and a property list. The Company shall notify its creditors within 10 days as of the date of the resolution for the merger and shall publish an announcement on the newspapers publicly issued at the provincial level or above and the website of the Hong Kong Stock Exchange (www.hkexnews.hk) within 30 days as of the date of such resolution. A creditor may within 30 days as of the receipt of the notice or, in case where he/she fails to receive such notice within 45 days of the date of the announcement, to demand the Company to repay its debts or provide guarantees for such debts. Other listing rules at the place where the shares of the Company are listed shall prevail.

When the Company is merged, the claims and debts of each party to the merger shall be succeeded to by the company surviving the merger or the new company established subsequent to the merger.

Where there is a division of the Company, its assets shall be divided accordingly.

Where there is a division of the Company, a balance sheet and property list shall be prepared. The Company shall notify its creditors within 10 days as of the date of the resolution for the division and shall publish an announcement on the newspapers publicly issued at the provincial level or above and the website of the Hong Kong Stock Exchange (www.hkexnews.hk) within 30 days as of the date of such resolution. Other listing rules at the place where the shares of the Company are listed shall prevail.

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Unless a written agreement has been entered into, before the division, by the Company and its creditors in relation to the repayment of debts, debts of the Company prior to the division shall be jointly assumed by the surviving companies after the division.

Where the Company needs to reduce its registered capital, it shall prepare a balance sheet and property list.

The Company shall notify its creditors within 10 days as of the date of the resolution for the reduction of its registered capital and shall publish an announcement on the newspapers publicly issued at the provincial level or above and the website of the Hong Kong Stock Exchange (www.hkexnews.hk) within 30 days as of the date of such resolution. A creditor may within 30 days as of the receipt of the notice or, in case where he/she fails to receive such notice within 45 days of the date of the announcement, to demand the Company to repay its debts or provide guarantees for such debts. Other listing rules at the place where the shares of the Company are listed shall prevail.

The registered capital of the Company after the reduction shall not be less than the statutory minimum amount.

Where there is a merger or division of the Company, the Company shall, in accordance with the laws, apply for change in its registration with the company registration authority for any changes of its registered information caused thereby. Where the Company is dissolved, the Company shall apply for cancellation of its registration in accordance with the laws. Where a new company is established, the Company shall apply for registration of incorporation in accordance with the laws.

Where there is an increase or reduction in the registered capital, the Company shall, in accordance with the laws, apply for change in registration with the company registration authority.

Dissolution and Liquidation

The Company shall be dissolved upon the occurrence of any of the following events:

- (1) expiry of the term of business provided in the Articles of Association or other cause of dissolution as specified therein;
- (2) a resolution on dissolution is passed by general meeting;
- (3) dissolution is required due to the merger or division of the Company;
- (4) the business license of the Company is revoked or the Company is ordered to close down or dissolved in accordance with the laws;

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- (5) the Company suffers significant hardships in operation and management that cannot be resolved through other means, and its continuation may cause substantial loss in Shareholders⁵ interests, Shareholders representing 10% or above of the total voting rights of the Company may plead the people’s court to dissolve the Company.

With regard to the occurrence of the situation described in sub-paragraph (1) above, the Company may continue to exist by amending the Articles of Association. Amendments to the Articles of Association pursuant to the preceding paragraph shall be subject to the approval of Shareholders representing two-thirds or above of the voting rights present at the general meetings.

Where the Company is dissolved pursuant to sub-paragraph (1), (2), (4) or (5) above, it shall establish a liquidation committee within 15 days as of the dissolution circumstance arises, and the liquidation shall be thereby started. The liquidation committee shall comprise Directors or those determined by the general meeting. If the liquidation committee is not duly set up, the creditors may plead the people’s court to designate related persons to form a liquidation committee to carry out the liquidation.

As of the date of its establishment, the liquidation committee shall notify the creditors within 10 days and make public announcement on the newspapers publicly issued at the provincial level or above and the website of the Hong Kong Stock Exchange (www.hkexnews.hk) within 60 days. Creditors shall, within 30 days as of the receipt of the notice or, in case where he/she fails to receive such notice, within 45 days as of the date of the announcement, declare their claims to the liquidation committee. Other listing rules at the place where the shares of the Company are listed shall prevail.

Creditors shall provide explanations and evidence for their claims upon their declarations of such claims. The liquidation committee shall record the creditors’ claims.

The liquidation committee shall not pay off any debts to any creditors during period of credit declaration.

After checking the assets of the Company and preparing a balance sheet and property list, the liquidation committee shall formulate a liquidation plan for the confirmation by general meeting or the people’s court. The remaining properties of the Company, after the payment for liquidation expenses, wages, social insurance premiums and statutory compensation of staffs, taxes and debts of the Company, shall be distributed to the shareholders in proportion to their shareholdings. During the liquidation period, the Company shall continue to exist but shall not carry out any business activities unrelated to liquidation. The assets of the Company shall not be distributed to the shareholders until the settlement of debts in accordance with the preceding article.

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If the liquidation committee, after checking the assets of the Company and preparing a balance sheet and property list, finds that the assets of the Company are insufficient to pay off its debts, it shall immediately file an application to the people’s court for bankruptcy. After the Company is declared bankrupt by the people’s court, the liquidation committee shall hand over the liquidation matters to the people’s court.

Upon completion of liquidation of the Company, the liquidation committee shall prepare a liquidation report and submit the report to the general meeting or the people’s court for confirmation, and submit the report to the company registration authority to apply for de-registration of the Company and announce the termination of the Company.

Where the Company is declared bankruptcy in accordance with law, it shall implement bankruptcy liquidation in accordance with the relevant laws relating to bankruptcy of enterprise.

Amendments to the Articles of Association

The Company shall amend the Articles of Association in any of the following circumstances:

- (1) after amendments are made to the PRC Company Law or other relevant laws, administrative regulations and regulatory rules at the place where the shares of the Company are listed, any term contained in the Articles of Association become inconsistent with the said amendments;
- (2) if certain changes of the Company occur resulting in the inconsistency with certain terms specified in the Articles of Association;
- (3) the general meeting has resolved to amend the Articles of Association.

Where the amendments to the Articles of Association passed by resolutions of the general meetings require approval of the competent authorities, the amendments shall be submitted to the relevant authorities for approval. Where the amendments involve registration matters of the Company, the involved change shall be registered in accordance with the laws.

The Board shall amend the Articles of Association in accordance with the resolution of the general meetings on amendment to the Articles of Association and the examination and approval opinions from relevant authorities.

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A. FURTHER INFORMATION ABOUT OUR GROUP

1. Incorporation of Our Company

Our Company was established as a limited liability company in the PRC on August 17, 2006 and was converted into a joint stock limited company on November 29, 2011 under the laws of the PRC. Our Company completed the listing of our A Shares on the SSE STAR Market (stock code: 688506) in January 2023. Accordingly, our corporate structure and Articles of Association are subject to the relevant laws and regulations of the PRC. The relevant PRC laws and regulatory provisions and a summary of our Articles of Association are set out in “Appendix IV — Summary of Principal Legal and Regulatory Provisions” and “Appendix V — Summary of Articles of Association,” respectively.

Our registered office is located at 1#, Building 1, No. 161, Baili Road, Cross-Strait Science and Technology Industrial Park, Wenjiang District, Chengdu City, Sichuan Province, PRC. We were registered as a non-Hong Kong company under Part 16 of the Companies Ordinance on July 22, 2024, and our principal place of business in Hong Kong is at 46/F, Hopewell Centre, 183 Queen’s Road East, Wanchai, Hong Kong. Mr. Lee Chung Shing (李忠成) has been appointed as our authorized representative for the acceptance of service of process and notices on behalf of our Company in Hong Kong. The address for service of process on our Company in Hong Kong is the same as our principal place of business in Hong Kong as set out above.

2. Changes in the Share Capital of Our Company

Save as disclosed in “History, Development and Corporate Structure,” there has been no alteration in the share capital of our Company within two years immediately preceding the date of this document.

Upon completion of the [REDACTED], but without taking into account any exercise of the [REDACTED], our registered share capital will increase from RMB401,000,000 to RMB[REDACTED], comprising 401,000,000 A Shares and [REDACTED] H Shares fully paid up, representing approximately [REDACTED]% and [REDACTED]% of our total issued share capital, respectively.

3. Changes in the Share Capital of Our Subsidiaries

Details of our subsidiaries are set out in “History, Development and Corporate Structure” and Note 45 to the Accountants’ Report in Appendix I to this document.

Save as disclosed below, there has been no alternation in the share capital of our subsidiaries within two years immediately preceding the date of this document.

On February 21, 2023, the registered capital of Baili Pharmaceutical was increased from RMB105,000,000 to RMB125,000,000.

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STATUTORY AND GENERAL INFORMATION

On February 22, 2023, the registered capital of Baili-Bio was increased from RMB5,000,000 to RMB200,000,000.

4. Resolutions of our Shareholders

Pursuant to the resolutions passed at a duly convened general meeting of our Shareholders on July 8, 2024, the following resolutions, among others, were passed by the Shareholders:

- (a) the [REDACTED] by our Company of H Shares of nominal value of RMB[REDACTED] each and such H Shares be [REDACTED] on the Stock Exchange;
- (b) the number of H Shares to be issued initially before the exercise of the [REDACTED] shall not be more than [REDACTED]% of the total issued share capital of our Company as enlarged by the [REDACTED], and the number of H Shares to be [REDACTED] pursuant to the exercise of the [REDACTED] shall not be more than [REDACTED]% of the number of H Shares to be [REDACTED] initially pursuant to the [REDACTED];
- (c) subject to the completion of the [REDACTED], the conditional adoption of the Articles of Association, which shall become effective on the [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
- (d) authorizing our Board and its authorized persons to handle all matters relating to, among other things, the [REDACTED], the [REDACTED] and [REDACTED] of the H Shares.

5. Restrictions on Repurchase

Please refer to “Appendix IV — Summary of Principal Legal and Regulatory Provisions” and “Appendix V — Summary of Articles of Association” for details of the restrictions on the shares repurchase by our Company.

APPENDIX VI STATUTORY AND GENERAL INFORMATION

B. FURTHER INFORMATION ABOUT OUR BUSINESS

1. Summary of Material Contract

We have entered into the following contract (not being contracts entered into in the ordinary course of business) within two years preceding the date of this document, which are or may be material:

(a) the [REDACTED].

2. Our Material Intellectual Property Rights

(a) Trademarks

As of the Latest Practicable Date, we have registered the following trademarks which we consider to be or may be material to our business:

No.	Trademark	Registered owner	Place of registration	Registration number	Class	Validity period
1		Our Company	PRC	12023054	35	June 28, 2024 to June 27, 2034
2		Guorui Pharmaceutical	PRC	7149088	5	August 14, 2020 to August 13, 2030
3		Guorui Pharmaceutical	PRC	7141450	5	August 14, 2020 to August 13, 2030
4		Guorui Pharmaceutical	PRC	3390406	5	July 28, 2024 to July 27, 2034
5		Jingxi Pharmaceutical	PRC	22398751	5	February 7, 2018 to February 6, 2028
6		Baili Pharmaceutical	PRC	73592189	42	April 28, 2024 to April 27, 2034






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No.	Trademark	Registered owner	Place of registration	Registration number	Class	Validity period
7		Baili Pharmaceutical	PRC	73591486	35	April 28, 2024 to April 27, 2034
8		Baili Pharmaceutical	PRC	71057791	42	October 14, 2023 to October 13, 2033
9		Baili Pharmaceutical	PRC	71040230	40	October 7, 2023 to October 6, 2033
10		Baili Pharmaceutical	PRC	71040223	35	October 7, 2023 to October 6, 2033
11		Baili Pharmaceutical	PRC	65434240	35	March 7, 2023 to March 6, 2033
12		Baili Pharmaceutical	PRC	59190269	5	May 14, 2022 to May 13, 2032
13		Baili Pharmaceutical	PRC	50675605	10	May 28, 2022 to May 27, 2032
14		Baili Pharmaceutical	PRC	48761260A	5	August 28, 2021 to August 27, 2031
15		Baili Pharmaceutical	PRC	50340444	5	July 7, 2021 to July 6, 2031
16		Baili Pharmaceutical	PRC	56488172	3	December 14, 2021 to December 13, 2031
17		Baili Pharmaceutical	PRC	22279704	35	January 28, 2018 to January 27, 2028

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No.	Trademark	Registered owner	Place of registration	Registration number	Class	Validity period
18	SYSTIMMUNE	Baili Pharmaceutical	PRC	22279638	42	January 28, 2018 to January 27, 2028
19	百利天恒药业	Baili Pharmaceutical	PRC	11374435	30	January 21, 2024 to January 20, 2034
20	百利天恒药业	Baili Pharmaceutical	PRC	11374417	35	January 21, 2024 to January 20, 2034
21	百利天恒	Baili Pharmaceutical	PRC	11374401	35	January 21, 2024 to January 20, 2034
22	百利天恒药业	Baili Pharmaceutical	PRC	11374286	5	January 21, 2024 to January 20, 2034
23	百利天恒	Baili Pharmaceutical	PRC	11374232	5	January 21, 2024 to January 20, 2034
24		Baili Pharmaceutical	PRC	8546146	5	August 14, 2021 to August 13, 2031
25		Baili Pharmaceutical	PRC	8546145	5	August 21, 2021 to August 20, 2031
26	百利	Baili Pharmaceutical	PRC	4193979	5	February 14, 2018 to February 13, 2028
27	金百利	Baili Pharmaceutical	PRC	4193978	5	February 28, 2018 to February 27, 2028


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No.	Trademark	Registered owner	Place of registration	Registration number	Class	Validity period
28		Baili Pharmaceutical	PRC	4193977	5	February 14, 2018 to February 13, 2028
29		Baili Pharmaceutical	PRC	1636408	5	September 21, 2021 to September 20, 2031
30		Baili Pharmaceutical	PRC	1636406	5	September 21, 2021 to September 20, 2031
31		Our Company	Hong Kong	306590719	5, 42	June 24, 2024 to June 23, 2034
32		Our Company	Hong Kong	306590728	5, 42	June 24, 2024 to June 23, 2034
33	Biokin Pharma	Our Company	Hong Kong	306590737	5, 42	June 24, 2024 to June 23, 2034

(b) Patents

For a discussion of the details of our material invention patents and material invention patent applications in connection with our innovative drugs, see “Business — Intellectual Property.”

As of the Latest Practicable Date, our Group was the registered proprietor of the following design patents which we consider to be or may be material to our business:

No.	Patent	Patent owner	Date of application
1		Baili Pharmaceutical	July 13, 2017

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No.	Patent	Patent owner	Date of application
2		Baili Pharmaceutical	July 13, 2017
3		Baili Pharmaceutical	July 25, 2017
4		Baili Pharmaceutical	January 3, 2020
5		Baili Pharmaceutical	September 10, 2020
6		Baili Pharmaceutical	September 10, 2020
7		Baili Pharmaceutical	September 30, 2022
8		Baili Pharmaceutical	September 30, 2022
9		Guorui Pharmaceutical	September 11, 2014
10		Guorui Pharmaceutical	September 11, 2014

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(c) Domain Names

As of the Latest Practicable Date, we owned the following domain names which we consider to be or may be material to our business:

No.	Domain name	Owner	Registration date	Expiry date
1	biokin-pharm.com	Our Company	March 20, 2023	March 20, 2028
2	biokin-pharm.cn	Our Company	March 20, 2023	March 20, 2028
3	biokin-pharm.com.cn	Our Company	May 23, 2024	May 23, 2029
4	biokin-pharm.net	Our Company	May 23, 2024	May 23, 2029
5	baili-pharm.com.cn	Our Company	May 23, 2024	May 23, 2029
6	baili-pharm.net	Our Company	May 23, 2024	May 23, 2029
7	baili-bio.com.cn	Our Company	June 17, 2024	June 17, 2029
8	baili-bio.cn	Our Company	June 17, 2024	June 17, 2029
9	biokin.co	Our Company	June 17, 2024	June 17, 2029
10	biokin.ltd	Our Company	June 17, 2024	June 17, 2029
11	biokin-pharm.co	Our Company	June 17, 2024	June 17, 2029
12	biokin-pharm.ltd	Our Company	June 17, 2024	June 17, 2029
13	baili-pharm.co	Our Company	June 17, 2024	June 17, 2029
14	baili-pharm.ltd	Our Company	June 17, 2024	June 17, 2029
15	baili-bio.com	Our Company	June 17, 2024	June 17, 2029
16	baili-bio.co	Our Company	June 17, 2024	June 17, 2029
17	baili-bio.ltd	Our Company	June 17, 2024	June 17, 2029
18	baili-bio.net	Our Company	June 17, 2024	June 17, 2029

(d) Copyrights

As of the Latest Practicable Date, we have registered the following copyrights which we consider to be or may be material to our business:

No.	Registered Owner	Copyright	Date of registration
1	Baili Pharmaceutical		August 11, 2010

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No.	Registered Owner	Copyright	Date of registration
2	Baili Pharmaceutical		October 20, 2014
3	Baili Pharmaceutical		July 3, 2019
4	Baili Pharmaceutical		July 4, 2019
5	Baili Pharmaceutical		December 3, 2019
6	Baili Pharmaceutical		August 28, 2020
7	Baili Pharmaceutical		December 22, 2020
8	Baili Pharmaceutical		December 11, 2020
9	Baili Pharmaceutical		December 11, 2020
10	Baili Pharmaceutical		June 15, 2021
11	Baili Pharmaceutical		June 15, 2021
12	Baili Pharmaceutical		June 15, 2021
13	Baili Pharmaceutical		August 19, 2022

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No.	Registered Owner	Copyright	Date of registration
14	Baili Pharmaceutical	 百利天恒 BIOKIN PHARMACEUTICAL 真诚伙伴, 健康快乐!!	May 31, 2023
15	Guorui Pharmaceutical		December 2, 2016

Save as disclosed above, as of the Latest Practicable Date, there were no other intellectual property rights which were or may be material in relation to our business.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

C. FURTHER INFORMATION ABOUT DIRECTORS, SUPERVISORS, SENIOR MANAGEMENT AND SUBSTANTIAL SHAREHOLDERS

1. Disclosure of Interests

(a) *Interests and short positions of our Directors, Supervisors and the chief executive of our Company in the Shares, underlying Shares and debentures of our Company and our associated corporations*

Immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised), the interests and short positions of our Directors, Supervisors and chief executive of our Company in our Shares, underlying Shares or debentures of our Company or any of our associated corporations (within the meaning of Part XV of the SFO) (i) 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 in which they are taken or deemed to have under such provisions of the SFO), or (ii) which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or (iii) 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 Issuers contained in the Listing Rules, in each case once our Shares are [REDACTED] on the Stock Exchange:

(i) *Interests in Shares and underlying Shares*

Name of Director/Supervisor/ chief executive	Position	Capacity/Nature of interest	Description of Shares	Number of Shares directly or indirectly held	Approximate percentage of shareholding in our A Shares ⁽¹⁾	Approximate percentage of shareholding in our total Share capital ⁽²⁾
Dr. Zhu	Executive Director, chairman of the Board, general manager and Chief Scientific Officer	Beneficial owner	A Shares	298,159,400	[REDACTED]%	[REDACTED]%
Ms. Zhang Suya (張蘇姪)	Executive Director, executive deputy general manager and chief financial officer	Beneficial owner	A Shares	9,575,543	[REDACTED]%	[REDACTED]%
Mr. Kang Jian (康健)	Executive Director and deputy general manager	Beneficial owner	A Shares	249,030	[REDACTED]%	[REDACTED]%
Mr. Liu Liang (劉亮)	Supervisor	Beneficial owner	A Shares	31,129	[REDACTED]%	[REDACTED]%

APPENDIX VI STATUTORY AND GENERAL INFORMATION

Notes:

- (1) The calculation is based on the total number of A Shares in issue immediately following the completion of the [REDACTED], assuming that no other changes are made to the number of issued Shares of our Company between the Latest Practicable Date and the [REDACTED].
- (2) The calculation is based on the total number of Shares in issue immediately following the completion of the [REDACTED], assuming that the [REDACTED] is not exercised, and no other changes are made to the issued Share capital of our Company between the Latest Practicable Date and the [REDACTED].

(ii) Interests in our associated corporation

Name of Director/ chief executive	Position	Capacity/Nature of interest	Associated corporation	Number of shares of the associated corporation underlying the share options ⁽¹⁾	Approximate percentage of shareholding interest in the associated corporation underlying the share options ⁽²⁾
Dr. Zhu	Executive Director, chairman of the Board, general manager and Chief Scientific Officer	Beneficial owner	SystImmune	10,128,407 ⁽³⁾	3.50%
Dr. Zhu Hai (朱海)	Executive Director	Beneficial owner	SystImmune	2,893,616 ⁽³⁾	1.00%

Notes:

- (1) The number of shares held by Dr. Zhu or Dr. Zhuhai represents the total number of shares of SystImmune underlying the share options granted to them under the SystImmune Incentive Plans, respectively. For further details of the SystImmune Incentive Plans, see “— D. SystImmune Incentive Plans.”
- (2) Assuming no new shares are issued pursuant to the outstanding options under the SystImmune Incentive Plans.
- (3) Consists of options corresponding to different classes of shares.

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(b) Interests of the substantial Shareholders in the Shares

Save as disclosed in “Substantial Shareholders,” immediately following the completion of the [REDACTED] and without taking into account any Shares which may be [REDACTED] pursuant to the exercise of the [REDACTED], our Directors are not aware of any other person (not being a Director or chief executive of our Company) who will have an interest or short position in our Shares or the underlying Shares which would fall to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or who is, directly or indirectly, interested in 10% or more of the issued voting shares of our Company.

(c) Interests of the substantial Shareholders in other members of our Group

So far as our Directors are aware, as of the Latest Practicable Date, no persons were, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any other members of our Group.

2. Particulars of Directors’ and Supervisors’ Service Contracts or Appointment Letters

We [have entered] into a service contract or an appointment letter with each of our Directors and Supervisors which contains provisions in relation to, among other things, compliance with relevant laws and regulations and observance of the Articles of Association. The principal particulars of these service contracts are: (a) each of the contracts is for a term of three years following his/her respective effective date of his/her appointment; and (b) each of the contracts is subject to termination in accordance with their respective terms. The contracts may be renewed in accordance with our Articles of Association and the applicable rules.

Save as disclosed in “Directors, Supervisors and Senior Management” and above, we have not entered into, and do not propose to enter into any service contracts with any of our Directors and Supervisors in their respective capacities as Directors or Supervisors (excluding agreements expiring or determinable by any member of our Group within one year without payment of compensation other than statutory compensation).

3. Remuneration of Directors and Supervisors

Save as disclosed in “Directors, Supervisors and Senior Management” and note 14 to the Accountants’ Report set out in Appendix I to this document for the three financial years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2024, none of our Directors or Supervisors received other remunerations of benefits in kind from us.

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4. Disclaimers

- (a) Save as disclosed in “— C. Further information about Directors, Supervisors, Senior Management and Substantial Shareholders — 1. Disclosure of Interests,” none of our Directors, Supervisors or our chief executive has any interest or short position in our Shares, underlying Shares or debentures of our Company or any of 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, or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required to be notified to our Company and the Stock Exchange pursuant to Model Code for Securities Transactions by Directors of Listed Issuers once the H Shares are [REDACTED] on the Stock Exchange.
- (b) So far as is known to our Directors, none of our Directors, Supervisors or their respective close associates (as defined under the Listing Rules) or Shareholders who are interested in more than 5% of the number of issued shares of our Company has any interest in the five largest customers or the five largest suppliers of our Group.
- (c) None of our Directors or Supervisors is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of our Group taken as a whole.
- (d) None of our Directors, Supervisors or any of the parties listed in “Qualifications of Experts” of this Appendix has any direct or indirect interest in the promotion of our Company, or in any assets which have been, within 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. SYSTIMMUNE INCENTIVE PLANS

The following is a summary of the principal terms of the SystImmune Incentive Plan I, SystImmune Incentive Plan II, SystImmune Incentive Plan III and SystImmune Incentive Plan IV as adopted by our subsidiary SystImmune in 2015, 2022, 2023 and 2024. The terms of the SystImmune Incentive Plans are not subject to the provisions of Chapter 17 of the Listing Rules, as SystImmune is not a principal subsidiary of the Company under Rule 17.14 of the Listing Rules. Terms of each of the SystImmune Incentive Plans are substantially similar.

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STATUTORY AND GENERAL INFORMATION

1. Summary of terms

(a) *Purpose*

The purpose of the SystImmune Incentive Plans is to motivate and retain employees within the Group or consultants to contribute to the growth of SystImmune.

(b) *Eligible participants*

Eligible participants of the SystImmune Incentive Plans may include: (i) employees (including officers, directors and other employees) of SystImmune and/or certain members within the Group, or (ii) consultants who provide services to SystImmune and/or certain members within the Group.

(c) *Administration*

Each of the SystImmune Incentive Plans is administered by the board of directors of SystImmune (“**SystImmune Board**”), or a committee or committees appointed by the SystImmune Board consisting of two or more members of, the SystImmune Board (collectively, the “**Plan Administrator**”).

(d) *Awards*

An award may take the form of option and/or restricted share.

(e) *Grant of awards*

Awards granted will be evidenced by a written agreement, which will contain the terms, conditions, limitations, and restrictions determined by the Plan Administrator. Such written agreements must include or incorporate by reference at least the following terms and conditions: number of shares, exercise price, vesting schedule, term and termination.

(f) *Validity period of the SystImmune Incentive Plans*

Unless being terminated earlier, the term of the SystImmune Incentive Plans is ten years from the date of adoption by the board or shareholders (as the case may be).

(g) *Term of options*

Unless determined by the Plan Administrator, the option has a term of 10 years commencing from the grant date.

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STATUTORY AND GENERAL INFORMATION

(h) *Vesting period of options*

The Plan Administrator will establish and include in each written agreement the time at which and the installments in which, the option granted will vest and become exercisable. The Plan Administrator may waive or accelerate any vesting requirement for any outstanding and unexercised options. The major vesting period arrangements are as follows:

	Vesting period	Maximum percentage that can be vested
<i>Four-year vesting period:</i>		
First vesting period	on the first anniversary of the grant date	15%
Second vesting period	on the second anniversary of the grant date	25%
Third vesting period	on the third anniversary of the grant date	25%
Fourth vesting period	on the fourth anniversary of the grant date	35%
<i>Five-year vesting period:</i>		
First vesting period	on the first anniversary of the grant date	20%
Second vesting period	on the second anniversary of the grant date	20%
Third vesting period	in 24 equal monthly increments beginning with the first calendar month following the third anniversary of the grant date	60%
<i>Six-year vesting period:</i>		
First vesting period	on the second anniversary of the grant date	20%
Second vesting period	on the third anniversary of the grant date	20%
Third vesting period	in 24 equal monthly increments beginning with the first calendar month following the fourth anniversary of the grant date	60%

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STATUTORY AND GENERAL INFORMATION

(i) Restricted shares

The Plan Administrator may award restricted shares, subject to conditions established by the Plan Administrator.

When a right to purchase or receive restricted share is granted under the SystImmune Incentive Plans, the participant will be advised in writing of the terms, conditions, and restrictions related to the offer, including the number of shares which may be purchased, the exercise price which will be determined by the Plan Administrator, and the time within which the participant may accept the offer.

(j) Exercise price

The exercise price for each award will be determined by the Plan Administrator, but may not be less than 100% of the fair market value of the share of SystImmune on the grant date.

(k) Maximum number of shares subject to the SystImmune Incentive Plans

The maximum number of shares of SystImmune underlying the awards that may be granted under the SystImmune Incentive Plans shall be 19,001,000 in aggregate.

2. Awards granted

As of the Latest Practicable Date, share options representing the right to subscribe for 25,771,988 SystImmune shares granted to 77 employees of the Group remain outstanding.

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 under the laws of the PRC.

2. Litigation

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 any member of our Group, that would have a material adverse effect on our Group’s results of operations or financial condition, taken as a whole.

3. Preliminary expenses

As of the Latest Practicable Date, our Company has not incurred material preliminary expenses in relation to the incorporation of our Company.

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STATUTORY AND GENERAL INFORMATION

4. Promoters

Information of our promoters as of the time of our Company’s conversion into a joint stock company in November 2011 is as follows:

No.	Name
1.	Dr. Zhu
2.	Ms. Zhang Suyu (張蘇婭)
3.	Ms. Zhu Ying (朱英)
4.	Xinjiang Xinxi Equity Investment Limited Partnership (新疆新璽股權投資有限合夥企業)
5.	Hangzhou Ronggao Equity Investment Co., Ltd. (杭州融高股權投資有限公司)

Save as disclosed in “Appendix I — Accountants’ Report — 38. Related Parties’ Transactions”, within the two years immediately preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given or is 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.

5. Taxation of Holders of H Shares

(a) Hong Kong

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 [REDACTED] of members of our Company, including in circumstances where such transaction is effected on the Stock Exchange. The current rate of Hong Kong stamp duty for such sale, purchase and transfer is 0.1% of the consideration or, if higher, the fair value of the H Shares being sold or transferred. For further details in relation to taxation, see “Appendix III — Taxation and Foreign Exchange.”

(b) Consultation with professional advisers

Potential [REDACTED] in the [REDACTED] are urged to consult their professional tax advisers if they are in any doubt as to the taxation implications of [REDACTED] for, purchasing, holding or disposing of or [REDACTED] in our H Shares (or exercising rights attached to them). None of us, the Joint Sponsors, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], or any other person or party involved in the [REDACTED] accept responsibility for any tax effects on, or liabilities of, any person, resulting from the [REDACTED], purchase, holding or disposal of, [REDACTED] in or the exercise of any rights in relation to our H Shares.

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STATUTORY AND GENERAL INFORMATION

6. 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 “Appendix I — Accountants’ Report — 38. Related Parties’ Transactions.”

7. No Material Adverse Change

After performing sufficient due diligence work which our Directors consider appropriate and after due and careful consideration, the Directors confirm that, up to the date of this document, there has been no material adverse change in our financial or [REDACTED] position or prospects since September 30, 2024, being the latest date of our consolidated financial statements as set out in Appendix I to this document, and there is no event since September 30, 2024 that would materially affect the information as set out in the Accountants’ Report included in Appendix I to this document.

8. Qualifications of Experts

The qualifications of the experts (as defined under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance) who have given opinion and/or advice in this document are as follows:

Name	Qualifications
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
J.P. Morgan Securities (Far East) Limited*	Licensed corporation to conduct type 1 (dealing in securities), type 4 (advising on securities) and type 6 (advising on corporate finance) 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
Deloitte Touche Tohmatsu	Certified public accountants and Registered Public Interest Entity Auditor
JunHe LLP	Legal adviser to our Company as to PRC laws
China Insights Consultancy	Independent industry consultant

* in no particular order

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

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.

9. Consents of Experts

Each of the experts as referred to “Qualifications of Experts” of this Appendix has given and has not withdrawn its respective written consent to the issue of this document with the inclusion of its report and/or letter and/or legal opinion (as the case may be) and the references to its name included herein in the form and context in which it is respectively included.

10. Compliance Adviser

We have appointed Messis Capital Limited as our Compliance Adviser upon the Listing in compliance with Rule 3A.19 of the Hong Kong Listing Rules.

11. Joint Sponsors

The Joint Sponsors have made an application on behalf of our Company to the Listing Committee of the Stock Exchange for the [REDACTED] of, and permission to [REDACTED], the H Shares of our Company. All necessary arrangements have been made to enable the securities to be admitted into [REDACTED].

As of the Latest Practicable Date, J.P. Morgan Securities plc (“JPMS”) held less than 5% of the total issued share capital of the Company. J.P. Morgan Securities (Far East) Limited (“JPM Far East”), a Joint Sponsor of the Company, and JPMS are both subsidiaries of JP Morgan Chase & Co. JPMS is a member of the sponsor group of JPM Far East as defined under the Listing Rules.

As of the Latest Practicable Date, CITIC Securities Company Limited (“CITICS Securities”) held less than 5% of the total issued share capital of the Company. CITIC Securities (Hong Kong) Limited (“CITICS Hong Kong”) is an indirectly wholly-owned subsidiary of CITICS Securities. CITICS Securities is a member of the sponsor group of CITICS Hong Kong as defined under the Listing Rules.

As none of the sponsor group of JPM Far East or CITICS Hong Kong, its directors or its directors’ close associates collectively holds and will, immediately following the completion of the [REDACTED], hold, directly or indirectly, more than 5% of the number of issued Shares (excluding treasury shares) of the Company, the independence of JPM Far East or CITICS Hong Kong as a sponsor would not be affected under Rule 3A.07 of the Listing Rules.

Therefore, all the Joint Sponsors satisfy the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules.

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STATUTORY AND GENERAL INFORMATION

Pursuant to the engagement letter entered into between the Company and the Joint Sponsors, the Joint Sponsors’ fees payable by us to each of the Joint Sponsors in respect of their services as sponsors in connection with the proposed [REDACTED] on the Stock Exchange is US\$500,000.

12. Binding Effect

This document shall have the effect, if an application is made in pursuance of it, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

13. Bilingual Document

The English and Chinese language versions of this document are being published separately, in reliance upon the exemption provided under section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

This document is written in the English language and contains a Chinese translation for information purpose only. Should there be any discrepancy between the English language of this document and the Chinese translation, the English language version of this document shall prevail.

14. Miscellaneous

Save as disclosed below:

- (i) within the two years immediately preceding the date of this document:
 - (a) save as disclosed in “— A. Further Information about Our Group — 2. Changes in the Share Capital of Our Company” and “— A. Further Information about Our Group — 3. Changes in the Share Capital of Our Subsidiaries,” no share or loan capital of our Company or any of our subsidiaries had been issued or agreed to be issued or proposed to be fully or partly paid either for cash or a consideration other than cash;
 - (b) save as disclosed in “— D. SystImmune Incentive Plans,” no share or loan capital of our Company or any of our subsidiaries had been under option or is agreed conditionally or unconditionally to be put under option;

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- (c) save for the A Shares of our Company that are listed on the SSE STAR Market, and save for the H Shares to be [REDACTED] in connection with the [REDACTED], no commissions, discounts, brokerages or other special terms had been granted or agreed to be granted in connection with the issue or sale of any share or loan capital of our Company or any of our subsidiaries; and
- (d) save for the A Shares of our Company that are listed on the SSE STAR Market, and save for the H Shares to be [REDACTED] in connection with the [REDACTED], no commission had been paid or payable for subscription, agreeing to subscribe, procuring subscription or agreeing to procure subscription of any share in our Company or any of our subsidiaries;
- (ii) there are no founder, management or deferred shares, convertible debt securities nor any debentures in our Company or any of our subsidiaries;
- (iii) 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;
- (iv) our Company has no outstanding convertible debt securities or debentures;
- (v) there is no arrangement under which future dividends are waived or agreed to be waived;
- (vi) save for the A Shares of our Company that are listed on the SSE STAR Market, and save for the H Shares to be [REDACTED] in connection with the [REDACTED], none of the equity and debt securities of our Company, if any, is listed or dealt with in any other stock exchange nor is any listing or permission to deal being or proposed to be sought; and
- (vii) all necessary arrangements have been made to enable the H shares to be [REDACTED] into [REDACTED] for clearing and settlement.

APPENDIX VII

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG AND AVAILABLE ON DISPLAY

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG

The documents attached to the copy of this document delivered to the Registrar of Companies in Hong Kong for registration were:

1. the written consents referred to in “Appendix VI — Statutory and General Information — E. Other Information — 9. Consents of Experts;” and
2. a copy of each of the material contracts referred to in “Appendix VI — Statutory and General Information — B. Further Information about our Business — 1. Summary of Material Contract.”

DOCUMENTS AVAILABLE ON DISPLAY

Electronic copies of the following documents will be available on display on the website of the Stock Exchange at www.hkexnews.hk and on the websites of our Company at www.baili-pharm.com during a period of 14 days from the date of this document:

1. the Articles of Association;
2. the accountants’ report prepared by Deloitte Touche Tohmatsu on the historical financial information of our Group, the text of which is set forth in Appendix I to this document;
3. the audited consolidated financial statements of our Company for the three years ended December 31, 2021, 2022 and 2023 and the nine months ended September 30, 2024;
4. the report prepared by Deloitte Touche Tohmatsu on the unaudited [REDACTED] financial information of our Group, the text of which is set forth in Appendix IIA to this document;
5. the industry report issued by CIC referred to in “Industry Overview;”
6. the legal opinion issued by JunHe LLP, our PRC Legal Advisor, in respect of, among other things, the general corporate matters and property interests of our Group under the PRC laws;
7. the material contract referred to in “Appendix VI — Statutory and General Information — B. Further Information about our Business — 1. Summary of Material Contract;”

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**DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES IN HONG KONG AND AVAILABLE ON DISPLAY**

8. the service contracts or appointment letters referred to in “Appendix VI — Statutory and General Information — C. Further Information about Directors, Supervisors, Senior Management and Substantial Shareholders — 2. Particulars of Directors’ and Supervisors’ Service Contracts or Appointment Letters;”
9. the written consents referred to in “Appendix VI — Statutory and General Information — E. Other Information — 9. Consents of Experts;” and
10. the PRC Company Law, Securities Law, and the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Enterprises, together with unofficial English translations thereof.