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Application Proof of

Xuanzhu Biopharmaceutical Co., Ltd.

軒竹生物科技股份有限公司

(the “Company”)

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

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Xuanzhu Biopharmaceutical Co., Ltd.

軒竹生物科技股份有限公司

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

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CONTENTS

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SUMMARY

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

OVERVIEW

We are an innovation-driven biopharmaceutical company in China with a global vision, leveraging our deep understanding of China’s pharmaceutical industry and profound insights of its unique clinical needs to better patient health and life. Since our inception in 2008, we have built a comprehensive in-house R&D platform that has supported our development of a highly competitive and balanced pipeline. As of the Latest Practicable Date, we had over ten drug assets under active development covering digestive diseases, oncology and non-alcoholic steatohepatitis (NASH), including one NDA approved asset, two drug programs with four indications in pivotal trial or NDA registration-stage, four drug programs in phase 1 clinical trial and four at IND-enabling stage or IND-approved. Within our pipeline, we have three Core Products, namely, KBP-3571, an NDA-approved innovative proton pump inhibitor (PPI) for digestive diseases, XZP-3287, an NDA-filed cyclin-dependent kinase 4/6 (CDK4/6) inhibitor targeting breast cancer (BC), and XZP-3621, an NDA-filed anaplastic lymphoma kinase (ALK) inhibitor targeting non-small cell lung cancer (NSCLC). This pipeline design strategically offers a balance in development risk and innovation, enabling our commercialized or late-stage assets to support the development of our early-stage innovative drugs.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR PIPELINE PRODUCTS, INCLUDING CORE PRODUCTS KBP-3571, XZP-3287 AND XZP-3621.

SUMMARY

The pipeline chart below summarizes our commercialized drug and drug candidates as of the Latest Practicable Date.

Therapeutic Area	Drug Candidate	Target	Category	Internal/ External	Clinical Indications	Partner	Current Stage					Current Status/ Next Milestone	Commercialization Rights
							Preclinical R&D	IND-enabling	Clinical Phase 1	Clinical Phase 2	Clinical Phase 3		
Digestion	KBP-3571 Ampirozole Sodium	PPI	Innovative small molecule drug	In-house R&D	Duodenal ulcer Adult reflux esophagitis		Approved for marketing					Approved for marketing	Global
	XZP-3287 Birececlib	CDK4/6	Innovative small molecule drug	In-house R&D	HR+/HER2- advanced breast cancer (Combo: fulvestrant) HR+/HER2- advanced breast cancer (Combo: AI) HR+/HER2- locally advanced or metastatic breast cancer		Obtain market approval in H1 2025 Submit NDA in H1 2025 Obtain market approval in H1 2025 Submit IND in H1 2025					Obtain market approval in H1 2025 Submit NDA in H1 2025 Obtain market approval in H1 2025 Submit IND in H1 2025	Global
	XZP-3621	ALK	Innovative small molecule drug	In-house R&D	First-line treatment for patients with ALK-positive advanced non-small cell lung cancer Post-operative adjuvant therapy for patients with ALK-positive non-small cell lung cancer ²		Obtain market approval in H2 2025 Enter clinical phase 3 in H2 2025					Obtain market approval in H2 2025 Enter clinical phase 3 in H2 2025	Global
Oncology	KM602	CD80 Fusion Protein	Innovative biological drug	Acquisition ¹	Solid tumors (melanoma, non-small cell lung cancer, etc.)	Beijing Xuanyi	Enter clinical phase 1 in 2026 ⁶					Finish China clinical phase 1 in 2026 ⁶	Global
	KM501	HER2/HER 2-ADC	Innovative biological drug	In-house R&D	HER2+ and HER2-low solid tumors (breast cancer, gastric cancer, etc.)		Finish clinical phase 1 in 2026					Finish clinical phase 1 in 2026	Global
	XZP-7797	PARP1 Inhibitor	Innovative small molecule drug	In-house R&D	Solid tumors (breast cancer, ovarian cancer, prostate cancer, pancreatic cancer, etc.)		Submit IND in Q4 2024					Submit IND in Q4 2024	Global
	XZP-6924	USP1 Inhibitor	Innovative small molecule drug	In-house R&D	Solid tumors (breast cancer, ovarian cancer, prostate cancer, pancreatic cancer, etc.)		Enter clinical phase 1 in H1 2026					Enter clinical phase 1 in H1 2026	Global
	XZB-0004	AXL	Innovative small molecule drug	License-in ¹	Solid tumors Myelodysplastic syndromes/ acute myeloid leukemia	SIGNALCHEM	Finish clinical phase 1 in 2025					Finish clinical phase 1 in 2025	Greater China
	XZP-6877	DNA-PK	Innovative small molecule drug	In-house R&D	Solid tumors		Enter clinical phase 1 in 2026					Enter clinical phase 1 in 2026	Global
	KM118	HER2	Biosimilar	In-house R&D Transfer ¹	Combine with trastuzumab and chemotherapy for HER2+ metastatic breast cancer (MBC)	康希诺	Enter clinical phase 1 in 2026					Enter clinical phase 1 in 2026	Commercialization rights transferred in full
	XZP-5610	FXR	Innovative small molecule drug	In-house R&D	Non-alcoholic steatohepatitis		Enter clinical phase 2 in 2026					Enter clinical phase 2 in 2026	Global
	XZP-6019	KHK	Innovative small molecule drug	In-house R&D	Non-alcoholic steatohepatitis		Enter clinical phase 1 in 2026					Enter clinical phase 1 in 2026	Global
	Others	XZP-5695	SGLT-2 Inhibitor	Innovative small molecule drug	In-house R&D Transfer ¹	Type II diabetes	康科生物	Approved for marketing					Approved for marketing
KBP-5081		Camptoparm Antibiotic	Innovative small molecule drug	In-house R&D License-out ¹	Complicated urinary tract infection	康科生物							Regions other than Greater China
XZP-5849		PDE-5	Innovative small molecule drug	In-house R&D License-out ¹	Erectile dysfunction Pulmonary arterial hypertension	康科生物							Europe, the U.S., Canada, Japan, South Korea, Australia, Brazil

★ Core Products ➔ Key Products // Waived/Potentially Waived from this phase of clinical trial □ R&D in the U.S.

Notes:

1. We plan to submit an IND application with the NMPA for XZP-3287 as an adjuvant therapy for HR+/HER2- early breast cancer (combo: endocrine therapy), which, if approved, would enable us to proceed directly to phase 3 clinical trial; 2. We have filed an IND application with the NMPA for XZP-3621 as a post-operative adjuvant therapy for patients with ALK-positive NSCLC, which, if approved, would enable us to proceed directly to phase 3 clinical trial; 3. We expect to complete phase 1 clinical trial for KM602 in 2026 in China and our development plan for KM602 in the U.S. is pending our progress made in China; 4. For details of our acquisition of KM602, license-in of XZB-0004, transfer of KM118 and XZP-5695, and license-out of KBP-5081 and XZP-5849, see “Business — Our License and Asset Acquisition Arrangements” in this document.

SUMMARY

We differentiate ourselves through driving drug development with speed and execution excellence, advancing at least one drug candidate on average to clinical trial every year since our inception, with a total of 18 IND approvals obtained as of the Latest Practicable Date. Within our pipeline are numerous industry firsts — KBP-3571, China’s first and only in-house developed PPI, KBP-5081, China’s first and only in-house developed carbapenem antibiotic (we out-licensed after the completion of phase 2 clinical trial), and XZP-5849, China’s first in-house developed phosphodiesterase type 5 (PDE5) inhibitor (we out-licensed to a third party after the completion of phase 1 clinical trial), according to CIC. With a dual-track approach of in-house development and asset out-licensing, we have rapidly progressed these candidates towards the market, with five NDAs obtained or filed (including XZP-5695 that was transferred at phase 3 clinical trial stage).

We deeply understand that successful drug commercialization is fundamental to the long-term sustainability of innovative drug development. As a participant in China’s pharmaceutical industry for the past 15 years, we have shaped our commercialization strategy with profound insights into the industry’s evolving market dynamics and regulatory environment. We believe that these insights have enabled us to effectively navigate the complexities of this industry, developing the ability to formulate comprehensive and bespoke commercial strategies for each product that take into account differentiated product features, competitive landscape, sales channels, market education, pricing and regulatory policies. In addition, we have inherited valuable commercialization experience from our Controlling Shareholder, Sihuan Pharm, which has been crucial to our capability build-up. Our commercialization capabilities are evidenced by the initial success of our first approved product KBP-3571, which achieved RMB16.1 million in sales since its commercialization up until June 30, 2024.

OUR PIPELINE

We are dedicated to the development and commercialization of innovative drugs for diseases with large patient populations and unmet medical needs, with a primary focus on digestive diseases, oncology and NASH. As of the Latest Practicable Date, we had established a pipeline of over ten drug assets under active development, including three Core Products and four key products. We pursue a staggered development strategy in each indication of focus. For digestive diseases, we obtained NDA approval from the NMPA for a Core Product, KBP-3571, for the treatment of duodenum ulcers (DU), and are expanding indication coverage to reflux esophagitis (RE), which has completed phase 2 clinical trial. For oncology, we have a robust drug franchise consisting of two NDA-filed innovative drugs, our Core Products XZP-3287 and XZP-3621, for BC and lung cancer, respectively. We are conducting further indication expansions for these Core Products, and also have a number of other oncology drug assets, including our four key products — KM602, KM501, XZP-7797 and XZP-6924, in phase 1 clinical trial or at IND-enabling stage. In addition, we are actively developing our NASH franchise with XZP-5610 in a phase 1 clinical trial and XZP-6019 at the IND stage.

SUMMARY

Our Core Products

KBP-3571

KBP-3571 is an internally developed innovative drug for which we hold global IP rights, and the first and only PPI independently developed by a PRC domestic company. Although PPIs are a relatively mature drug class with good effectiveness, there remain unmet needs for patients in China. Existing PPIs are faced with unpredictable metabolic profiles, high strain on hepatic and renal function, slow and short-lasting onset of action, which can significantly lower patient compliance especially when used as a long-term treatment. KBP-3571 has a differentiated metabolic profile that enables a reduced renal burden, a lowered risk of drug-drug interactions (DDIs), and a rapid and long-lasting onset of antisecretory effects. This demonstrates strong potential to compete favorably within the PPI class and address current unmet medical needs.

Importantly, according to CIC, among the seven PPIs approved in China as of the Latest Practicable Date, our KBP-3571 stands out as one of only two innovative drugs, with the other innovative PPI drug facing generic competition. This dynamic presents a crucial market opportunity for KBP-3571. Due to the government’s effort to increase drug accessibility, currently all generic PPI drugs are included in the VBP Scheme and the Key Supervision List, impacting their sales revenue. The only other innovative PPI, which has not yet been included in either program, has experienced a 79% increase in sales revenue between 2022 and 2023, according to CIC. However, generic competition is likely to alter its favorable market position. Given these market dynamics, we believe KBP-3571 is well-positioned to capture a significant market share. We obtained NDA approval for KBP-3571 for treatment of DU in June 2023, which was included in the NRDL since the beginning of 2024. We have also completed the phase 2 clinical trial for KBP-3571 for RE and expect to proceed to phase 3 trial in the second half of 2025. Our second indication in RE is expected to bring significant market upside given its large target patient population and bring synergies in commercialization.

XZP-3287

Our XZP-3287 is a CDK4/6 inhibitor with NDA filed both as a monotherapy and in combination with fulvestrant for HR+/HER2- advanced BC, with a phase 3 clinical trial ongoing for XZP-3287 in combination with aromatase inhibitor (AI). BC is the most prevalent cancer in the world with approximately 2.4 million new cases in 2023, of which HR+/HER2- patients account for approximately 75%. CDK4/6 inhibitors have a market size of RMB2.2 billion in 2023 in China for the treatment of BC, which is expected to increase to RMB13.0 billion by 2032. CDK4/6 inhibitors are the standard treatment in combination with endocrine therapy for HR+/HER2- advanced BC, indicating significant market demand.

SUMMARY

XZP-3287 can potentially cover a larger patient population with best-in-class potential, with demonstrated efficacy as a monotherapy in addition to combination therapy with AI for first-line and with fulvestrant for second-line endocrine treatment. We are exploring the use of XZP-3287 across a broad spectrum of patients with advanced HR+/HER2- BC, through both first- and second-line combination therapies and late-line monotherapies. To further expand patient coverage, we are also pursuing XZP-3287 as an adjuvant therapy for HR+/HER2- early BC in combination with endocrine therapy. As of the Latest Practicable Date, we had submitted the NDA application for XZP-3287 in combination with fulvestrant for second-line endocrine treatment of advanced HR+/HER2- BC, as well as for XZP-3287 monotherapy for late-line treatment of locally advanced or metastatic HR+/HER2- BC. Concurrently, we are conducting a phase 3 trial of XZP-3287 in combination with AI for advanced HR+/HER2- BC.

XZP-3621

XZP-3621 is a differentiated ALK-targeted treatment with NDA filed in China for the treatment of NSCLC. 22% of all cancer incidences in China in 2022 were lung cancer cases, of which NSCLC is the most common subtype representing approximately 85% of all lung cancer cases. Approximately 64% of patients with NSCLC have stage IV disease at diagnosis. In China, NSCLC cases increased from 764.4 thousand cases in 2018 to 937.6 thousand cases in 2023, and is projected to reach 1,236.4 thousand cases by 2032.

ALK genetic mutations are detected in approximately 5-6% of NSCLC cases, for which treatments are specifically developed to treat this subtype of NSCLC more effectively. Our XZP-3621 is highlighted by its ability to offer strong anti-tumor effects and serve as an alternative to patients resistant to other ALK-targeted treatments. Moreover, XZP-3621 has demonstrated a good safety profile, which is crucial for patients on long-term treatment. With the interim data from the phase 3 clinical trial of XZP-3621, we have filed the NDA application of XZP-3621 in the first-line treatment of patients with ALK-positive advanced NSCLC in April 2024. We are also pursuing XZP-3621 as a post-operative adjuvant therapy for patients with ALK-positive NSCLC to further broaden the clinical and commercial value of our product. We submitted the IND application for such indication expansion of XZP-3621 and received the acceptance notice to the IND application from the NMPA in November 2024.

Our Key Products

KM501

KM501, is a potential first-in-class HER2/HER2 bispecific antibody drug conjugate (ADC). KM501 is designed with patented technology of knocking out fucose and with the ability to target both trastuzumab (anti-HER2 domain IV) and pertuzumab (anti-HER2 domain II) epitopes at the same time, potentially translating to better endocytosis of the ADC. This may contribute to KM501’s strong anti-tumor activity in HER2 low expression tumors. To date, DS-8201 is the only ADC approved for HER2 low expressing BC globally and there are no approved ADCs for other HER2 low expressing tumors. In preclinical mice tumor models, KM501 was superior to or non-inferior to DS-8201 in inhibiting tumors. We obtained IND approval for KM501 with the NMPA in February 2023 and are conducting a phase 1 clinical trial.

SUMMARY

KM602

KM602, is the only clinical-stage anti-tumor cluster of differentiation 80 (CD80) Fc fusion protein drug in China, with first-in-class potential. CD80 plays an important role in T-cell activation and has become a promising approach for cancer immunotherapy. CD80 interacts with CD28 and PD-L1 to promote T-cell proliferation, differentiation and function. CD80 also interacts with cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) on the surface of T cells to suppress the response of specific effector T cells. Despite the availability of immune checkpoint inhibitors such as PD-1/PD-L1 drugs, many patients face low efficacy and drug resistance, which may be due to the lack of sufficient T cell co-stimulation in the tumor microenvironment. KM602 is designed to enhance the activation of T cells and has the potential to address the gap in this market. We obtained IND approval for KM602 with the NMPA and the FDA in February and September 2023, respectively, and are conducting a phase 1 clinical trial in China.

XZP-7797

XZP-7797, is a potent, highly selective and brain-penetrating poly ADP-ribose polymerase 1 (PARP1) inhibitor. First-generation PARP1/2 inhibitors have been approved for the treatment of a number of cancers, such as ovarian, prostate, pancreas, and breast cancers, with maximal activity against tumors harboring BRCA1/2 mutation or homologous recombination deficiency. However, PARP1/2 inhibitors have severe hematological toxicities due to the inhibition of PARP2, whereas data suggests that synthetic lethality with breast cancer susceptibility gene (BRCA) mutations is primarily caused by PARP1 inhibition. As such, we are developing XZP-7797 as a highly selective PARP1 inhibitor which is expected to reduce the hematological adverse effects associated with PARP2 inhibition while maintaining the required efficacy. Meanwhile, as approximately 20% of advanced cancer patients develop brain metastases, XZP-7797 also demonstrates an advantage over most first-generation PARP inhibitors with its ability to reach the brain lesions. We plan to submit an IND application for XZP-7797 to the NMPA by the end of 2024.

XZP-6924

XZP-6924, is a potential first-in-class ubiquitin-specific protease 1 (USP1) inhibitor. Research shows that inhibition of the DNA damage response (DDR) pathway can affect cancer cell replication and survival. Drugs targeting the DDR pathway are effective in the treatment of many types of cancers, such as PARP inhibitors, which, while demonstrating good clinical performance, is not effective in all patients and can be limited by treatment-related drug resistance. USP1 is involved in DNA damage repair processes, and in combination with PARP inhibitors, can synergistically target BRCA1/2 mutant cancers. XZP-6924 is a potent and highly selective USP1 inhibitor that has potential to be combined with PARP inhibitors to increase efficacy and overcome primary and acquired resistance to PARP inhibitors. We have observed a positive preclinical efficacy and safety profile for XZP-6924 and obtained IND approval from the NMPA in November 2024.

SUMMARY

Our Other Products

XZB-0004

XZB-0004 is a potent and selective oral small molecule anelexleto (AXL) inhibitor. AXL, a transmembrane cell surface receptor overexpressed in numerous hematological and solid cancers, is a putative driver of diverse cellular processes that are critical for the development, growth, survival and spread of tumors. AXL overexpression is known to be associated with poor clinical prognosis in many tumor types and inhibiting AXL activity has been shown to interfere with cancer cell survival, migration, invasion, proliferation and ultimately inhibiting tumor cell growth and metastasis. In September 2021, we entered into a license and cooperation agreement (as amended in November 2021) with SignalChem Lifesciences Corporation (“SignalChem”), to in-license certain patents and know-how owned by SignalChem relating to XZB-0004.

XZP-6877

XZP-6877 is a selective DNA-dependent protein kinase (DNA-PK) inhibitor which can block the main channels for repairing DNA double-strand breaks caused by radiotherapy or chemotherapy drugs, and improve the sensitivity of tumor cells to radiotherapy and chemotherapy. At the same time, it destroys the stability of telomere DNA structure to inhibit the proliferation and growth of tumor cells. The combination of the two mechanisms can enhance the anti-tumor efficacy and more effectively control tumors.

XZP-5610

XZP-5610, is a novel, potential first-in-class, non-steroid farnesoid X receptor (FXR) agonist poised to address the significant unmet medical needs in the treatment of NASH in China, a market currently lacking approved therapies. Preclinical studies have demonstrated XZP-5610’s potent FXR agonistic activity, effectively modulating downstream gene expression, reducing serum biomarkers, and improving key NASH histopathological features. Furthermore, XZP-5610 exhibits a favorable pharmacokinetic profile and a robust safety profile in preclinical models. We believe XZP-5610 has the potential to become a first-in-class therapy, offering a new and effective treatment option for patients with NASH. We are preparing the clinical study protocol for the phase 2 trial of XZP-5610.

XZP-6019

XZP-6019, a novel, potential first-in-class ketohexokinase (KHK) inhibitor, represents a promising therapeutic approach for the treatment of NASH. Preclinical studies have demonstrated XZP-6019’s potent KHK inhibitory activity, resulting in significant improvements in NASH-related parameters in animal models. Furthermore, XZP-6019 exhibits favorable pharmacokinetic and safety profiles, supporting its potential as a once-daily, well-tolerated treatment option. We are finalizing the clinical study protocol for the phase 1 trial of XZP-6019.

SUMMARY

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

OUR TECHNOLOGY PLATFORMS

Our commitment to addressing critical medical needs is powered by three core technology platforms, namely the small molecule drug R&D platform, the biological drug R&D platform and the clinical development platform. These proprietary platforms, built on our deep expertise in small molecule drug and biologics development, serve as the foundation for our discovery and development of innovative medicines. Designed to cover the entire R&D process across various drug modalities, these platforms work in concert, enabling valuable cross-functional synergies at key stages of drug development.

Small Molecule Drug R&D Platform

We are able to discover and design innovative small molecule drugs with superior features, such as high potency, selectivity, good safety, as well as the ability to cross the blood-brain barrier and to overcome resistance. This is achieved through our expertise and know-how in the analysis of molecular and protein structures, supported by our use of computer aided drug design (CADD), and structure-based drug design (SBDD) methods. We have built a comprehensive drug evaluation system to assess and verify quality and developability, with fully fledged capabilities in pharmacology, ADME and safety evaluation. Moreover, we have mastered formulation development to optimize drug delivery and enhance bioavailability, including oral dosage forms, injectables and novel drug delivery systems. In addition to the late clinical stage candidates developed under this platform, we are also developing a number of innovative drug candidates such as XZP-7797, a next-generation PARP1 inhibitor with less hematologic toxicity and the capability to cross the blood-brain barrier, and XZP-6924, a potential first-in-class USP1 inhibitor with potential for combination therapies with PARP1 inhibitor.

Biological Drug R&D Platform

Our biological drug R&D platform is distinguished by its sophisticated drug design capabilities and robust antibody expression systems. We adhere to a Quality by Design (QbD) paradigm in antibody development, leveraging an extensive knowledge base in protein engineering and manipulation of antibody fragments and functional domains. This enables us to engineer antibody therapeutics with high binding affinity, improved endocytosis capability and increased cytotoxicity against tumor cells. Furthermore, we have developed proprietary Chinese Hamster Ovary (CHO) cell lines with a complete knockout of the FUT8 gene, facilitating the production of antibodies with nearly 100% absence of fucose in the Fc region. This modification significantly amplifies the binding of antibodies to natural killer cells and macrophages via FcγRIII, thereby enhancing ADCC and ADCP functions against tumor cells. Our clinical pipeline includes KM501, a bispecific HER2/HER2 ADC, which exemplifies the innovative design principles of our platform.

SUMMARY

Clinical Development Platform

We have built a robust and experienced clinical R&D team, with expertise covering medical science, translational medicine, pharmacology, biostatistics and statistical programming, clinical operation, and pharmacovigilance. As of June 30, 2024, our clinical research team consisting of over 50 members has managed and advanced over 30 clinical trials over the past five years. These team members bring a wealth of expertise in professional trial design, execution, and management, along with a deep understanding of communication and regulatory affairs crucial for drug registration processes. Our clinical development capabilities enable us to control the R&D process more efficiently and reliably, giving us more flexibility in designing and adjusting development strategies and advancing clinical development with speed and excellence. For example, by leveraging quantitative pharmacology to support our dose selection for phase 3 study of XZP-5695, we were able to implement a streamlined development pathway that enabled us to advance directly from phase 1 to phase 3 clinical trials.

OUR COMPETITIVE STRENGTHS

We believe the following competitive strengths have differentiated us from our competitors: (i) rich pipeline of differentiated drug candidates in commercial or late clinical stage development, supported by a comprehensive and systematic in-house R&D platform; (ii) solid drug development strategy balancing commercial potential and long- and short-term returns with deep understanding of the pharmaceutical industry in China; (iii) highly competitive and differentiated drug pipeline led by commercialized or near-commercial assets with high development visibility; (iv) effective commercialization strategy tailored to our drug pipeline, leveraging our deep understanding of China’s pharmaceutical industry and strengths of our commercialization partners; and (v) visionary and experienced leadership with deep industry insights to guide and execute business strategies. For details, see “Business — Our Competitive Strengths.”

OUR DEVELOPMENT STRATEGIES

We intend to capitalize on our competitive strengths by pursuing the following development strategies: (i) continue to implement sustainable and highly effective commercialization strategies; (ii) continue to rapidly advance our pipeline; (iii) refine and enhance our R&D capabilities; (iv) improve operational efficiency for sustainable growth; and (v) pursue strategic investment, licensing and acquisitions in China and overseas. For details, see “Business — Our Development Strategies.”

RESEARCH AND DEVELOPMENT

We conduct R&D activities primarily through our in-house R&D team. Our R&D team comprises experienced scientists and researchers with a background in drug development. Many team members have previously held positions at established biopharmaceutical companies, bringing valuable knowledge across various stages of the drug development process. As of June 30, 2024, our R&D team, led by Dr. Li Jia Kui and Dr. Wang Li, comprised over 110 highly qualified professionals, with approximately 50% holding a master’s degree or higher, including 12 doctorates, reflecting the team’s strong academic foundation in medical science, pharmacology, biology, and chemistry. We also engage contract research organizations (“CROs”) from time to time to support our preclinical research and clinical trials.

SUMMARY

During the Track Record Period, we incurred research and development expenditure (including research and development expenses and capitalized research and development costs recorded as intangible assets) of RMB567.5 million, RMB383.9 million, RMB220.6 million, and RMB125.4 million in 2022, 2023 and the six months ended June 30, 2023 and 2024, respectively. In 2022, 2023 and the six months ended June 30, 2024, our research and development expenditure incurred for Core Products were RMB304.8 million, RMB253.4 million, and RMB89.6 million, representing 53.7%, 66.0%, and 71.4% of our total research and development expenditure, respectively. We expect that our expenditure in relation to R&D activities will continue to be significant in line with the future growth of our business.

OUR LICENSE AND ASSET ACQUISITION ARRANGEMENTS

We actively seek collaboration and licensing partnerships with leading biotech companies. Historically, we established multiple collaborations, including technology transfer, in-licensing and out-licensing deals, with various industry players. For details, see “Business — Our License and Asset Acquisition Arrangements.” We believe these partnerships enable us to maximize the clinical and commercial value of our pipeline and technology platforms. Moreover, they are strong endorsements of our ability to develop next-generation therapies and cutting-edge technologies.

MANUFACTURING

We currently outsource the production of our approved drug to industry recognized contract development and manufacturing organizations (“CDMOs”) in China, and we intend to continue doing so in the near future. We believe it is cost-effective and efficient to engage CDMOs for manufacturing activities as it reduces the capital expenditure required for setting up and maintaining the necessary production lines, and allows us to focus on the clinical development of our pipeline drugs. We select CDMOs by taking into account a number of factors, such as their manufacturing capacity and qualifications, geographic proximity and track record, as well as applicable regulations and guidelines. We maintain rigorous quality control throughout our manufacturing process to ensure the production of safe and effective therapies. This is achieved through comprehensive quality agreements with all CDMOs, regular on-site audits and inspections, batch-by-batch monitoring of drug product manufacturing and testing, thorough review of all manufacturing and testing documentation, and independent sample testing of finished products. For more details, see “Business — Manufacturing.”

COMMERCIALIZATION AND SALES NETWORK

Our commercial strategy is built on a flexible, tailored approach designed to maximize the strengths of each product and target market. This involves strategically leveraging external partnerships while simultaneously building a high-performing internal sales force. We believe in adapting our approach to the unique dynamics of each therapeutic area. As of the Latest Practicable Date, we had a commercialized product, KBP-3571. In addition, our XZP-3287, as a monotherapy and in combination therapy with fulvestrant, is anticipated to obtain NDA approval from the NMPA in the first half of 2025. With the successful commercialization of KBP-3571, and in anticipation of the approval of other late-stage assets, we have established a solid foundation for a commercialization system tailored to our key therapeutic areas that will have synergistic benefits for future products.

SUMMARY

To ensure our products reach patients efficiently, we are dedicated to building a robust sales network, which includes selectively partnering with distributors and building an in-house sales team. We primarily operate a seller-buyer model with our distributors, who then distribute our drugs to hospitals and pharmacies. As of June 30, 2024, we had over 70 distributors, covering a network of over 600 hospitals nationwide in China. We manage our distributors through distribution agreements, policies, and measures to ensure their sales reflect genuine market demand and compliance with distribution agreement terms and conditions. For details, see “Business — Sales Network.”

INTELLECTUAL PROPERTY

Intellectual property rights are important to the success of our business. As of the Latest Practicable Date, we (i) owned 84 issued patents in China, and 79 issued patents in the U.S. and other jurisdictions, and (ii) filed 46 published patent applications in China, and 53 published patent applications in the U.S. and other jurisdictions relating to certain of our drug assets and platform technologies, which we consider material to our business operations. As of the same date, with respect to our three Core Products, we owned 15 issued patents in China and 27 issued patents in the U.S. and other jurisdictions, as well as 21 patent applications, including 12 in China and nine in the U.S. and other jurisdictions.

CUSTOMERS, SUPPLIERS AND PROCUREMENT

During the Track Record Period, our customers were mainly distributors. Revenue generated from our five largest customers for the year ended December 31, 2023 and the six months ended June 30, 2024 amounted to RMB28.6 thousand and RMB6.7 million, representing approximately 100.0% and 42.1% of our total revenue for the respective year/period, respectively. We did not generate revenue for the year ended December 31, 2022. Revenue generated from our largest customer for the year ended December 31, 2023 and the six months ended June 30, 2024 amounted to RMB12.7 thousand and RMB2.6 million, representing approximately 44.5% and 16.2% of our total revenue for the respective year/period, respectively.

During the Track Record Period, our suppliers were mainly CROs, CDMOs, and raw materials and equipment providers. For the years ended December 31, 2022 and 2023 and the six months ended June 30, 2024, our purchases from our five largest suppliers in aggregate amounted to RMB154.9 million, RMB90.6 million and RMB21.8 million, accounting for 34.7%, 34.5% and 32.5% of our total purchases for the respective year/period, respectively, and our purchases from our largest supplier alone amounted to RMB64.8 million, RMB36.7 million and RMB5.7 million, accounting for 14.5%, 14.0% and 8.5% of our total purchases for the respective year/period, respectively.

SUMMARY

COMPETITIVE LANDSCAPE

The pharmaceutical industry is a dynamic and highly competitive landscape, characterized by rapid advancements and evolving market demands. While we are confident that our fully integrated platform, robust pipeline of approved drug and drug candidates, and experienced leadership team provide us with a competitive edge, we also recognize the challenges inherent in this dynamic environment. We face competition from a variety of sources, including established pharmaceutical giants, innovative biotech startups, renowned academic institutions, and government agencies, all endeavoring to develop breakthrough therapies in the same areas we are targeting. Moreover, any drug candidates we successfully bring to market will face competition not only from existing treatments but also from new therapies that may emerge in the future.

SUMMARY OF KEY FINANCIAL INFORMATION

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

Summary of Consolidated Statements of Profit or Loss

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

	For the year ended December 31,		For the six months ended June 30,	
	2022	2023	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
			<i>(unaudited)</i>	
Revenue	–	29	–	16,030
Cost of sales	–	(9)	–	(8,811)
Other income and gains . . .	40,531	40,800	17,405	7,492
Research and development expenses	(400,983)	(239,061)	(149,540)	(74,426)
Administrative expenses . . .	(96,401)	(87,845)	(52,208)	(36,486)
Other expenses	(53,670)	(3,267)	(9)	(8,198)
Loss before tax	(512,260)	(300,556)	(187,184)	(110,971)
Loss and total comprehensive loss for the year/period	(512,265)	(300,562)	(187,190)	(110,977)

SUMMARY

In June 2023, KBP-3571 received NDA approval from the NMPA, and began to generate revenue with RMB29 thousand in 2023 and RMB16.0 million in the six months ended June 30, 2024. We recorded net losses during the Track Record Period as we incurred significant operating expenses to finance our R&D activities and day-to-day operations. In 2022, 2023 and the six months ended June 30, 2023 and 2024, we incurred net losses of RMB512.3 million, RMB300.6 million, RMB187.2 million and RMB111.0 million, respectively.

Summary of Consolidated Statements of Financial Position

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

	As of December 31,		As of June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Total non-current assets	653,415	778,574	790,651
Total current assets	801,582	542,436	448,145
Total current liabilities	93,741	143,127	154,293
Net current assets	707,841	399,309	293,852
Total assets less current liabilities	1,361,256	1,177,883	1,084,503
Total non-current liabilities	22,713	67,636	55,138
Net assets	1,338,543	1,110,247	1,029,365

Summary of Consolidated Statements of Cash Flows

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

	For the year ended December 31,		For the six months ended June 30,	
	2022	2023	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Net cash used in operating activities	(386,237)	(115,952)	(134,610)	(52,898)
Net cash (used in)/from investing activities	(498,024)	44,732	156,684	(61,674)
Net cash used in financing activities	(12,156)	(9,903)	(4,342)	(2,871)
Net increase/(decrease) in cash and cash equivalents	(896,417)	(81,123)	17,732	(117,443)
Cash and cash equivalents at beginning of year/period	1,120,510	224,112	224,112	142,891

SUMMARY

	For the year ended December 31,		For the six months ended June 30,	
	2022	2023	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i> <i>(unaudited)</i>	<i>(RMB'000)</i>
Effect of foreign exchange				
rate changes, net.	19	(98)	(6)	(109)
Cash and cash equivalents				
at the end of year/period	<u>224,112</u>	<u>142,891</u>	<u>241,838</u>	<u>25,339</u>

Our Directors are of the opinion that, taking into account of the financial resources available to us, including cash and cash equivalents, revenue generated from the sales of our commercialized product, the estimated [REDACTED] from the [REDACTED], and our cash burn rate, we have sufficient working capital to cover at least 125% of our costs, including research and development costs, business development and marketing expenses, and administrative and operating costs for at least the next 12 months from the date of this document.

Our cash burn rate refers to the average monthly amount of net cash used in operating activities, capital expenditures, capitalized research and development expenditure, and other scheduled cash payment. We estimate that we will receive [REDACTED] of approximately HK\$[REDACTED] million, after deducting [REDACTED], fees and estimated expenses payable by us in connection with the [REDACTED], and assuming an [REDACTED] of HK\$[REDACTED] per H Share and the [REDACTED] is not exercised, being the [REDACTED] of the indicative [REDACTED] range stated in this document. Assuming an average cash burn rate going forward of 1.0 times the level in 2023, we estimate that our cash and cash equivalents and financial assets at FVTPL as of September 30, 2024 will be able to maintain our financial viability for [REDACTED] months from September 30, 2024, without taking into account the estimated [REDACTED] from the [REDACTED]; or, we estimate we will be able to maintain our financial viability for [REDACTED] months from September 30, 2024, if we take into account the estimated [REDACTED] from the [REDACTED]. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.

Key Financial Ratio

The following table set forth our key financial ratio as of the dates indicated:

	As of December 31,		As of June 30,
	2022	2023	2024
Current ratio ⁽¹⁾	8.6	3.8	2.9

Note:

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

SUMMARY

Cash Operating Costs

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

	For the year ended December 31,		For the six months ended June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Costs relating to research and development of our Core Products			
Staff cost	62,129	64,637	20,539
Trial and testing expenses	181,568	124,741	31,822
Raw materials and others	<u>42,759</u>	<u>22,879</u>	<u>4,541</u>
<i>Subtotal</i>	286,455	212,257	56,902
Costs relating to research and development of our other drug candidates			
Staff cost	57,712	47,994	14,128
Trial and testing expenses	129,691	15,841	14,395
Raw materials and others	<u>32,693</u>	<u>26,491</u>	<u>6,668</u>
<i>Subtotal</i>	220,097	90,326	35,191
Total	<u>506,552</u>	<u>302,583</u>	<u>92,093</u>
Workforce employment costs ⁽¹⁾	27,239	36,416	20,053
Direct production costs ⁽²⁾	–	2,062	8,596
Others	<u>23,423</u>	<u>14,955</u>	<u>10,660</u>
Total cash operating cost	<u>557,214</u>	<u>356,016</u>	<u>131,402</u>

Notes:

- (1) Workforce employment costs represent total non-research and development personnel costs mainly including salaries and benefits.
- (2) Direct production costs represent the payments we make to the CDMOs that we collaborate with and the movement in the balances of our inventory.

SUMMARY

SUMMARY OF MATERIAL RISK FACTORS

Our business faces risks including those set out in the section headed “Risk Factors.” As different [REDACTED] may have different interpretations and criteria when determining the significance of a risk, you should read the “Risk Factors” section in its entirety before you decide to [REDACTED] in our Company. Some of the major risks that we face include: (i) our business and prospects depend substantially on the success of our drugs and drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our drugs and drug candidates, or if we experience significant delays or cost overruns in doing any of the foregoing, our business and prospects could be materially and adversely affected; (ii) we may face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drugs and drug candidates; (iii) clinical development involves a lengthy and expensive process with uncertain outcomes, and results of preclinical studies and early phases of clinical trials may not be predictive of future trial results; (iv) we may not be able to identify, discover, in-license or develop new drug candidates, or to expand the therapeutic opportunities for our drug candidates; (v) 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; (vi) if we encounter delays or difficulties enrolling subjects in our clinical trials, our clinical development progress could be delayed or otherwise adversely affected; (vii) adverse events or undesirable side effects caused by our drug candidates could interrupt or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval; and (viii) we may be unable to successfully develop or market our drug candidates or may fail to obtain regulatory approvals in a timely manner, if safety, efficacy or other issues arise from any pharmaceutical product or medical treatment used, or intended to be used, in combination with our drug candidates.

THE [REDACTED]

The [REDACTED] constitutes a [REDACTED] of our Company by Sihuan Pharm under Practice Note 15. The proposal in relation to the [REDACTED] was submitted by Sihuan Pharm to the Stock Exchange for approval pursuant to Practice Note 15, and the Stock Exchange has confirmed that Sihuan Pharm may proceed with the [REDACTED].

Sihuan Pharm considers that the [REDACTED] and separate [REDACTED] of the H Share our Company will be commercially beneficial to Sihuan Pharm, our Company and our Shareholders as a whole. For details, please see “History and Corporate Structure — [REDACTED] of Our Group from the Sihuan Group.”

SUMMARY

OUR CONTROLLING SHAREHOLDER

As of the Latest Practicable Date, Sihuan Pharm, through its indirectly wholly-owned subsidiaries, Xuanzhu Biopharma and Hainan Sihuan, was interested in approximately 56.47% of the total issued share capital of our Company. Xuanzhu Biopharma was wholly owned by Xuanzhu Cayman, which in turn was indirectly wholly owned by Sihuan Pharm through Sun Moral. Hainan Sihuan was wholly owned by Sun Moral, which in turn was directly wholly owned by Sihuan Pharm.

As of the Latest Practicable Date, Dr. Che Fengsheng, Dr. Guo Weicheng, Mr. Meng Xianhui, and Dr. Zhang Jionglong, acting in concert through their respective wholly-owned entities were deemed to be indirectly interested in approximately 55.02% of the total issued share capital of Sihuan Pharm.

Immediately following the completion of the [REDACTED], (i) Sihuan Pharm will have an indirect interest in approximately [REDACTED]% of the Shares in issue (assuming the [REDACTED] is not exercised), (ii) our Company will remain as an indirect non-wholly owned subsidiary of Sihuan Pharm, and (iii) Dr. Che Fengsheng, Dr. Guo Weicheng, Mr. Meng Xianhui, Dr. Zhang Jionglong, their respective wholly-owned entities (Network Victory Limited, Proper Process International Limited, Successmax Global Holdings Limited, Victory Faith International Limited and Mingyao Capital Limited), Sihuan Pharm, Sun Moral, Xuanzhu Cayman, Xuanzhu Biopharma and Hainan Sihuan will be our Controlling Shareholders.

There is a clear delineation of business between our Group and the Remaining Sihuan Group. The Remaining Sihuan Group structured its business into various distinct business segments and each of them has a particular business focus, including the medical aesthetics business, the diabetes pharmaceutical business and the generic drug business. Our Group is primarily engaged in the business of R&D, manufacturing and commercialization of innovative drugs, focusing on a number of therapeutic areas such as digestion, oncology and NASH.

For further details, see the section headed “Relationship with Our Controlling Shareholders” in this document.

CONNECTED TRANSACTIONS

Prior to the [REDACTED], we have entered into a transaction in our ordinary and usual course of business with Beijing Huizhiheng Biotechnology Co., Ltd. (北京惠之衡生物科技有限公司) (“**Beijing Huizhiheng**”) who will, upon the [REDACTED], become a connected person of our Company. We will continue to engage in the connected transaction after the [REDACTED]. For details of such continuing connected transaction of our Group following the [REDACTED], see the section headed “Connected Transaction.”

SUMMARY

PRE-[REDACTED] INVESTORS

Since the establishment of our Company, we have received several rounds of equity financing from our Pre-[REDACTED] Investors. Our diverse base of Pre-[REDACTED] Investors consists of Sophisticated Investors such as MIIF and FIIF II, which held approximately 15.54% and 5.18%, respectively, of the total issued share capital of our Company as of the Latest Practicable Date. Pursuant to applicable PRC laws, the Pre-[REDACTED] Investors shall not dispose of any of the Shares held by them within 12 months following the [REDACTED] Date. For details of our Pre-[REDACTED] Investments, see “History and Corporate Structure — Pre-[REDACTED] Investments” in this document.

DIVIDENDS

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

[REDACTED] STATISTICS⁽¹⁾

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

SUMMARY

Notes:

- (1) All [REDACTED] statistics in the table are on the assumptions that the [REDACTED] is not exercised;
- (2) The calculation of [REDACTED] is based on [REDACTED] Shares expected to be in issue immediately after the completion of the [REDACTED];
- (3) The calculation of [REDACTED] is based on [REDACTED] H shares expected to be in issue immediately after the [REDACTED], comprising [REDACTED] H Shares to be issued pursuant to the [REDACTED] and [REDACTED] H Shares to be converted from the Unlisted Shares;
- (4) The unaudited [REDACTED] adjusted consolidated net tangible assets attributable to owners of our Company as of June 30, 2024 per Share is calculated after making the adjustments referred to in “Financial Information — Unaudited [REDACTED] Adjusted Net Tangible Assets.”

[REDACTED]

We estimate that we will receive [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED] million, after deducting [REDACTED] commissions, fees and estimated expenses payable by us in connection with the [REDACTED], and assuming an [REDACTED] of HK\$[REDACTED] per Share and that the [REDACTED] is not exercised, being the [REDACTED] of the indicative [REDACTED] range stated in this document. We currently intend to apply these [REDACTED] for the following purposes: (i) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for the research, development and commercialization of our Core Products, namely, KBP-3571, XZP-3287 and XZP-3621; (ii) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for the research and development of our key products, namely, KM602, KM501, XZP-7797 and XZP-6924; (iii) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund the research and development of other drug candidates, including XZB-0004, XZP-5610, XZP-6019 and XZP-6877; (iv) approximately [REDACTED]%, or HK\$[REDACTED] million, will be allocated to strengthening our commercialization and marketing capabilities, particularly through the expansion of our sales and marketing teams; and (v) approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for working capital and other general corporate purposes. For further details, please see the section headed “Future Plans and [REDACTED].”

[REDACTED]

[REDACTED] to be borne by us are estimated to be approximately HK\$[REDACTED] million (assuming an [REDACTED] of HK\$[REDACTED] per H Share, being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per H Share), representing approximately [REDACTED]% of the estimate [REDACTED] from the [REDACTED] assuming no Shares are issued pursuant to the [REDACTED]. The [REDACTED] consist of (i) [REDACTED]-related expenses, including [REDACTED] commission, of approximately HK\$[REDACTED] million, and (ii) non-[REDACTED]-related expenses of approximately HK\$[REDACTED] million, comprising (a) fees and expenses of our legal advisors and reporting accountants of approximately HK\$[REDACTED] million, and (b) other fees and expenses of approximately HK\$[REDACTED] million. During

SUMMARY

the Track Record Period, we did not incur [REDACTED] in connection with this proposed [REDACTED]. After the Track Record Period, approximately HK\$[REDACTED] million is expected to be charged to our consolidated statements of profit or loss, and approximately HK\$[REDACTED] million is expected to be accounted for as a deduction from equity upon the [REDACTED]. We do not believe any of the above fees or expenses are material or are unusually high to our Group. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

RECENT DEVELOPMENT AND NO MATERIAL ADVERSE CHANGE

Business Development

Since the end of the Track Record Period, we have continuously developed our business and continued to advance our pipeline. We submitted the IND application for indication expansion of XZP-3621 in post-operative adjuvant therapy for ALK-positive early NSCLC and received the acceptance notice to the IND application from the NMPA in November 2024. In addition, we obtained IND approval from the NMPA in November 2024 for XZP-6924.

As we strive to advance our pipeline and enhance our drug development capabilities, we expect that we will continue to recognize net losses in 2024, primarily because we will continue to incur significant research and development expenses and administrative expenses as we carry out and expand our preclinical and clinical development programs and maintain our day-to-day operations.

No Material Adverse Change

After performing due diligence work which our Directors consider appropriate and sufficient and after due and careful consideration, our Directors confirm that there has been no material adverse change in our business, financial condition and results of operations since June 30, 2024, being the latest balance sheet date of our consolidated financial statements in the Accountants’ Report set out in Appendix I to this document, and up to the date of this document.

DEFINITIONS

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

“affiliate” with respect to any specified person, any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person

“AFRC” the Accounting and Financial Reporting Council of Hong Kong

“Articles of Association” or “Articles” the articles of association of our Company adopted on November 17, 2024 which will become effective on the [REDACTED] and as amended from time to time, a summary of which is set out in Appendix V to this document

“associate(s)” has the meaning ascribed thereto under the Listing Rules

[REDACTED]

“Audit Committee” audit committee of the Board

[REDACTED]

“Beihai Baimei’en” Beihai Baimei’en Investment Partnership (Limited Partnership) (北海百美恩投資合夥企業(有限合夥)), a limited partnership established in the PRC on April 22, 2021, and one of our Incentive Platforms

“Beihai Jixin” Beihai Jixin Xuanzhu Investment Partnership (Limited Partnership) (北海吉鑫軒竹投資合夥企業(有限合夥)), a limited partnership established in the PRC on July 6, 2021, and one of our Incentive Platforms

DEFINITIONS

“Beihai Keya” Beihai Keya Xuanzhu Investment Partnership (Limited Partnership) (北海科雅軒竹投資合夥企業(有限合夥)), a limited partnership established in the PRC on July 6, 2021, and one of our Incentive Platforms

“Beijing Xuanzhu” Xuanzhu (Beijing) Biopharmaceutical Co., Ltd. (軒竹(北京)醫藥科技有限公司), a limited liability company established in the PRC on December 10, 2018, and a wholly-owned subsidiary of our Company

[REDACTED]

“Board” or “Board of Directors” the board of Directors of our Company

“Business Day” or “business day” any day (other than a Saturday, Sunday or public holiday in Hong Kong) on which banks in Hong Kong are generally open for normal banking business

[REDACTED]

“CDE” the Center of Drug Evaluation of the NMPA (國家藥品監督管理局藥品審評中心), a division of the NMPA mainly responsible for the review and approval of INDs and NDAs

“China” or “PRC” the People’s Republic of China, but for the purpose of this document and for geographical reference only and except where the context requires otherwise, references in this document to “China” and the “PRC” do not include Hong Kong, the Macau Special Administrative Region of the PRC and Taiwan

DEFINITIONS

“CIC”	China Insights Industry Consultancy Limited, a market research and consulting company and an Independent Third Party, which prepared the CIC Report
“CIC Report”	an independent market research report commissioned by us and prepared by CIC for the purpose of this document
“close associate(s)”	has the meaning ascribed thereto 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” or “our Company”	Xuanzhu Biopharmaceutical Co., Ltd. (軒竹生物科技股份有限公司), a limited liability company established in the PRC on September 5, 2018, and converted into a joint stock company with limited liability on November 22, 2021, formerly known as Xuanzhu Biopharmaceutical Limited Liability Company (軒竹生物科技有限公司)
“Company Law” or “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
“Compliance Advisor”	First Shanghai Capital Limited
“connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“connected transaction(s)”	has the meaning ascribed thereto under the Listing Rules
“Controlling Shareholder(s)”	has the meaning ascribed to it under the Listing Rules; for the purpose of this document, our Controlling Shareholders refer to Dr. Che Fengsheng, Dr. Guo Weicheng, Mr. Meng Xianhui, Dr. Zhang Jionglong, their respective wholly-owned entities (Network Victory Limited, Proper Process International Limited, Successmax Global Holdings Limited, Victory Faith International Limited and Mingyao Capital Limited), Sihuan Pharm, Sun Moral, Xuanzhu Cayman, Xuanzhu Biopharma and Hainan Sihuan. For further details, see section headed “Relationship with Our Controlling Shareholders” in this document

DEFINITIONS

“Conversion of Unlisted Shares into H Shares”	the conversion of [REDACTED] Unlisted Shares into H Shares on a one-for-one basis upon the completion of [REDACTED]. Filing of such conversion of Unlisted Shares into H shares [has been completed] with the CSRC on [REDACTED] and an application for H Shares to be [REDACTED] on the Stock Exchange has been made to the Listing Committee
“core connected person(s)”	has the meaning ascribed thereto under the Listing Rule
“Core Products”	has the meaning ascribed thereto in Chapter 18A of the Listing Rules; for the purpose of this document, our Core Products refer to KBP-3571, XZP-3287, and XZP-3621
“CSDC”	China Securities Depository and Clearing Co., Ltd. (中國證券登記結算有限責任公司)
“CSRC”	China Securities Regulatory Commission (中國證券監督管理委員會), a regulatory body responsible for the supervision and regulation of the PRC national securities markets
“Director(s)” or “our Director(s)”	the director(s) of our Company, including all executive, non-executive and independent non-executive directors
“EIT”	enterprise income tax
“EIT Law”	the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》), as amended, supplemented or otherwise modified from time to time
“Extreme Conditions”	the occurrence of “extreme conditions” as announced by any government authority of Hong Kong due to serious disruption of public transport services, extensive flooding, major landslides, large-scale power outage or any other adverse conditions before Typhoon Signal No. 8 or above is replaced with Typhoon Signal No. 3 or below
“FDA”	the United States Food and Drug Administration

DEFINITIONS

[REDACTED]

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

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

“Guide for New Listing Applicants” the Guide for New Listing Applicants as published by the Stock Exchange, as amended from time to time

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

[REDACTED]

“Hainan Huixuan” Hainan Huixuan Biopharmaceutical Co., Ltd. (海南慧軒醫藥科技有限公司), a limited liability company established in the PRC on August 10, 2020, and a wholly-owned subsidiary of our Company

“Hainan Sihuan” Hainan Sihuan Pharmaceutical Co., Ltd. (海南四環醫藥有限公司), a limited liability company established in the PRC on March 16, 2001, and a wholly-owned subsidiary of Sihuan Pharm

DEFINITIONS

[REDACTED]

“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong dollars,” “HK dollars” or “HK\$”	Hong Kong dollars, the lawful currency of Hong Kong

[REDACTED]

DEFINITIONS

[REDACTED]

“IASB”	International Accounting Standards Board
“IFRS”	the International Financial Reporting Standards as issued by the IASB, which comprise the IFRS Accounting Standards, International Accounting Standards, Interpretations developed by the IFRS Interpretations Committee or its predecessor body, the Standing Interpretations Committee
“Incentive Platform(s)”	Beihai Baimei’en, Beihai Jixin, Beihai Keya, Tianjin Guoding, Tianjin Hongteng, Tianjin Hongzekang, Tianjin Huize, Tianjin Pusheng, Tianjin Xuansheng and Tianjin Zhenxuan
“Independent Third Party(ies)”	an individual or a company which, to the best of our Directors’ knowledge, information and belief, having made all reasonable enquiries, is not a connected person of our Company within the meaning of the Listing Rules

DEFINITIONS

[REDACTED]

“Latest Practicable Date”

November 19, 2024, being the latest practicable date for the purpose of ascertaining certain information in this document prior to its publication

[REDACTED]

DEFINITIONS

“Listing Committee” the Listing Committee of the Stock Exchange

[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 GEM of the Stock Exchange

“MOFCOM” or “Ministry of Commerce” the Ministry of Commerce of the PRC (中華人民共和國商務部) (formerly known as the Ministry of Foreign Trade and Economic Cooperation of the PRC (中華人民共和國對外經濟貿易部))

“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 (中華人民共和國國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局)

“Nomination Committee” nomination committee of the Board

[REDACTED]

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

DEFINITIONS

“NRDL” National Reimbursement Drug List for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》)

[REDACTED]

“Overseas Listing Trial Measures” Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) released by the CSRC on February 17, 2023 and took effect on March 31, 2023

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

“Practice Note 15” Practice Note 15 of the Listing Rules

DEFINITIONS

[REDACTED]

“PRC Legal Advisor” Fangda Partners, the legal advisor to our Company as to the laws of the PRC

“PRC Securities Law” the Securities Law of the PRC (《中華人民共和國證券法》), as enacted by the 6th meeting of the 9th Standing Committee of the NPC on December 29, 1998, and became effective on July 1, 1999, as amended, supplemented or otherwise modified from time to time

[REDACTED]

“Pre-[REDACTED] Investment(s)” the pre-[REDACTED] investment(s) in our Company undertaken by the Pre-[REDACTED] Investor(s), details of which are set out in the section headed “History and Corporate Structure — Pre-[REDACTED] Investments” in this document

“Pre-[REDACTED] Investor(s)” the investor(s) of Pre-[REDACTED] Investment(s)

“document” this document being issued in connection with the [REDACTED]

“QIBs” qualified institutional buyers within the meaning of Rule 144A under the U.S. Securities Act

[REDACTED]

“R&D” research and development

DEFINITIONS

[REDACTED]

“Regulation S”	Regulation S under the U.S. Securities Act
“Remaining Sihuan Group”	Sihuan Pharm and its subsidiaries, excluding our Group
“Remuneration and Appraisal Committee”	remuneration and appraisal committee of the Board

[REDACTED]

“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“Rule 144A”	Rule 144A under the U.S. Securities Act
“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)
“SAMR”	State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局)
“Securities and Futures Ordinance” or “SFO”	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Series A-1 Investor(s)”	the investor(s) of our series A-1 financing, the details of which are set forth in “History and Corporate Structure — Our Corporate History — Establishment and Major Shareholding Changes of Our Company — Series A-1 Financing”
“Series A-2 Investor”	the investor of our series A-2 financing, the details of which are set forth in “History and Corporate Structure — Our Corporate History — Establishment and Major Shareholding Changes of Our Company — Series A-2 Financing”

DEFINITIONS

“Series B Investor(s)”	the investor(s) of our series B financing, the details of which are set forth in “History and Corporate Structure — Our Corporate History — Establishment and Major Shareholding Changes of Our Company — Series B Financing”
“SFC”	the Securities and Futures Commission of Hong Kong
“Shandong Xuanzhu”	Shandong Xuanzhu Pharma Co., Ltd. (山東軒竹醫藥科技有限公司), a limited liability company established in the PRC on April 23, 2002, and a wholly-owned subsidiary of our Company
“Share(s)”	ordinary share(s) in the capital of our Company with a nominal value of RMB1.00 each, comprising Unlisted Shares and H Shares
“Shareholder(s)”	holder(s) of our Share(s)
“Share Incentive Scheme”	the share incentive scheme adopted by our Company in April 2021 which was subsequently amended in January 2022 and November 2024, governing and rectifying all share incentives granted by our Company, the details of which are set out in “Appendix VI — Statutory and General Information — Further Information about Our Directors, Supervisors, Chief Executive and Substantial Shareholders — Share Incentive Scheme” to this document

[REDACTED]

“Sihuan Group”	Sihuan Pharm and its subsidiaries
“Sihuan Pharm”	Sihuan Pharmaceutical Holdings Group Ltd., an exempted company incorporated with limited liability in Bermuda on October 6, 2010, the shares of which are listed on the Stock Exchange (stock code: 460), and one of our Controlling Shareholders
“Sihuan Share(s)”	ordinary share(s) in the share capital of Sihuan Pharm
“Sihuan Shareholder(s)”	holder(s) of Sihuan Share(s)

DEFINITIONS

[REDACTED]

“Sophisticated Investor(s)” has the meaning ascribed to it under the Chapter 2.3 of the Guide for New Listing Applicants

“Specified Territory” jurisdiction outside Hong Kong where, taking into account the legal restrictions under the applicable laws or requirements of the relevant regulatory body or stock exchange of such jurisdiction, Sihuan Pharm and our Company consider the exclusion of the shareholders of Sihuan Pharm with registered addresses in or who are otherwise known by Sihuan Pharm to be residents of, such jurisdiction from the [REDACTED] to be necessary or expedient

[REDACTED]

“State Taxation Administration” State Taxation Administration of the PRC (中華人民共和國國家稅務總局)

[REDACTED]

“State Council” the State Council of the PRC (中華人民共和國國務院)

DEFINITIONS

“Stock Exchange” or “Hong Kong Stock Exchange”	The Stock Exchange of Hong Kong Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited
“subsidiarie(s)”	has the meaning ascribed thereto under the Listing Rules
“substantial shareholder(s)”	has the meaning ascribed thereto under the Listing Rules
“Sun Moral”	Sun Moral International (HK) Limited (耀忠國際(香港)有限公司), a company incorporated under the laws of Hong Kong, wholly-owned by Sihuan Pharm, and one of our Controlling Shareholders
“Supervisor(s)”	supervisor(s) of our Company
“Supervisory Committee”	supervisory committee of our Company
“Takeovers Code”	the Codes on Takeovers and Mergers and Share Buy-backs issued by the SFC, as amended, supplemented or otherwise modified from time to time
“Tianjin Guoding”	Tianjin Guoding Pharmaceutical Technology Partnership (Limited Partnership) (天津國鼎醫藥科技合夥企業(有限合夥)), a limited partnership established in the PRC on August 5, 2020, and one of our Incentive Platforms
“Tianjin Hongteng”	Tianjin Hongteng Pharmaceutical Technology Partnership (Limited Partnership) (天津泓騰醫藥科技合夥企業(有限合夥)), a limited partnership established in the PRC on August 5, 2020, and one of our Incentive Platforms
“Tianjin Hongzekang”	Tianjin Hongzekang Pharmaceutical Technology Partnership (Limited Partnership) (天津泓澤康醫藥科技合夥企業(有限合夥)), a limited partnership established in the PRC on August 4, 2020, and one of our Incentive Platforms
“Tianjin Huize”	Tianjin Huize Pharmaceutical Technology Partnership (Limited Partnership) (天津匯澤醫藥科技合夥企業(有限合夥)), a limited partnership established in the PRC on August 14, 2020, and one of our Incentive Platforms

DEFINITIONS

“Tianjin Pusheng”	Tianjin Pusheng Pharmaceutical Technology Partnership (Limited Partnership) (天津普晟醫藥科技合夥企業(有限合夥)), a limited partnership established in the PRC on August 4, 2020, and one of our Incentive Platforms
“Tianjin Xuansheng”	Tianjin Xuansheng Pharmaceutical Technology Partnership (Limited Partnership) (天津軒升醫藥科技合夥企業(有限合夥)), a limited partnership established in the PRC on August 3, 2020, and one of our Incentive Platforms
“Tianjin Zhenxuan”	Tianjin Zhenxuan Pharmaceutical Technology Partnership (Limited Partnership) (天津振軒醫藥科技合夥企業(有限合夥)), a limited partnership established in the PRC on August 4, 2020, and one of our Incentive Platforms
“Track Record Period”	the two years ended December 31, 2022 and 2023 and the six months ended June 30, 2024
“U.S. dollars,” “US\$” or “USD”	United States dollars, the lawful currency of the United States
“U.S. Securities Act”	the United States Securities Act of 1933, as amended and supplemented or otherwise modified from time to time, and the rules and regulations promulgated thereunder

[REDACTED]

“United States,” “US”, “USA” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“Unlisted Share(s)”	ordinary share(s) issued by our Company, with a nominal value of RMB1.00 each, which is/are not listed on any stock exchange
“VAT”	value added tax

DEFINITIONS

[REDACTED]

“Xuanzhu Biopharma”	Xuanzhu (HK) Biopharmaceutical Limited (軒竹(香港)醫藥科技有限公司), a company incorporated under the laws of Hong Kong on July 31, 2018, and one of our Controlling Shareholders
“Xuanzhu Cayman”	Xuanzhu Biopharmaceutical Ltd., a company incorporated under the laws of the Cayman Island, wholly-owned by Sihuan Pharm, and one of our Controlling Shareholders
“Xuanzhu Combio”	Beijing Xuanzhu Combio Co., Ltd. (北京軒竹康明生物科技有限公司), a limited liability company established in the PRC on March 24, 2021, and a wholly-owned subsidiary of our Company
“Xuanzhu HK”	Xuanzhu (HK) Biotechnology Limited (軒竹(香港)生物科技有限公司), a company incorporated under the laws of Hong Kong on June 3, 2021, and a wholly-owned subsidiary of our Company
“Xuanzhu US”	XZenith Biotechnology Inc, a company incorporated under the laws of the United States on June 18, 2021, and a wholly-owned subsidiary of our Company
“%”	per cent

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

GLOSSARY OF TECHNICAL TERMS

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

“95% CI”	95% confidence interval, a statistical range that estimates, with 95% probability, where the true population parameter lies based on the sample data
“ADC”	antibody drug conjugate, a class of biopharmaceutical drugs that comprise an antibody conjugated to a payload molecule, typically a cytotoxic agent, via a chemical linker
“ADCC”	antibody dependent cell-mediated cytotoxicity or antibody-dependent cellular cytotoxicity, a mechanism of cell-mediated immune defense whereby an effector cell of the immune system actively lyses a target cell, whose membrane-surface antigens have been bound by specific antibodies
“AE”	adverse event, which may be mild, moderate, or severe, any untoward medical occurrence in a patient or subject receiving a drug or other pharmaceutical product in a clinical trial and which does not necessarily have a causal relationship with the treatment
“AI”	aromatase inhibitor, a type of medications that block the enzyme aromatase, which converts androgens to estrogens, primarily used in treating HR+ BC
“ALK”	anaplastic lymphoma kinase, a receptor tyrosine kinase that, when abnormally activated through gene rearrangements or mutations, can drive cancer growth
“AXL”	anexelektro, a receptor tyrosine kinase that participates in a series of transmembrane signal process and regulates many physiological processes, including cell survival, proliferation, differentiation and immune responses
“BC”	breast cancer

GLOSSARY OF TECHNICAL TERMS

“BICR”	blinded independent central review, a methodology in clinical trials where an independent reviewer assesses outcomes without knowledge of treatment assignments to minimize bias
“bioavailability”	the fraction of an administered dose of drug that reaches systemic circulation, which is one of the principal pharmacokinetic properties of drugs
“bispecific ADC”	a novel type of ADC in which the payload molecule is conjugated to a bispecific antibody which confers targeting ability against two different antigens
“bispecific antibody”	antibody that combines two antigen-recognizing elements into a single construct, able to bind to two different antigens at the same time
“brain metastases”	cancerous tumors that have spread (metastasized) to the brain from primary cancer elsewhere in the body
“BRCA”	breast cancer susceptibility gene, of which there are two types, i.e., BRCA1 and BRCA2. BRCA genes are tumor suppressor genes that encode proteins responsible for repairing DNA. Deleterious BRCA mutations contribute to an increased risk of various types of cancers such as breast cancer and ovarian cancer
“CADD”	computer-aided drug design, the use of computers (workstations) to aid in the creation, modification, analysis, or optimization of novel compounds or biologics
“CAGR”	compound annual growth rate
“CBR”	clinical benefit rate, the percentage of patients who achieved a complete response, partial response, or stable disease while on a therapeutic intervention in clinical trials of antitumor agents
“CD80”	cluster of differentiation 80, a transmembrane protein expressed on antigen-presenting cells that acts as a costimulatory molecule by binding to CD28 or CTLA-4 on T cells, playing a crucial role in T cell activation and immune response regulation

GLOSSARY OF TECHNICAL TERMS

“CDK4/6”	cyclin-dependent kinase 4/6, protein kinases that partner with cyclin D to phosphorylate the retinoblastoma protein, promoting cell cycle progression from G1 to S phase
“CDMO”	contract development and manufacturing organization, which is a pharmaceutical company that develops and manufactures drugs for other pharmaceutical companies on a contractual basis
“chemotherapy”	a drug treatment that uses cytotoxic chemicals to kill fast-growing cells in a patient’s body. It is most often used as a cancer treatment as cancer cells grow and multiply much faster than most cells in the body
“cohort”	a group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time
“combination therapy”	a treatment that uses more than one medication or modality
“CRO”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“CTLA-4”	cytotoxic T-lymphocyte-associated protein 4, a protein expressed on all T cells and functions as an immune checkpoint that downregulates immune responses. It is one of the immune checkpoints commonly exploited by tumor cells to evade antitumor immune response
“CYP”	cytochrome P450, a family of enzymes primarily found in liver cells that play a crucial role in metabolizing drugs, toxins, and other substances in the body
“CYP2C19”	cytochrome P450 2C19, a specific enzyme in the cytochrome P450 family that metabolizes several important drugs, including proton pump inhibitors, antidepressants, and clopidogrel

GLOSSARY OF TECHNICAL TERMS

“DCR”	disease control rate, the total proportion of patients who demonstrate a response to treatment, equal to the sum of complete responses, partial responses and stable disease
“DDI”	drug-drug interaction, which occurs when two or more drugs interact, potentially altering their efficacy or increasing the risk of adverse effects
“DDR”	DNA damage response, a cellular mechanism that detects and repairs DNA damage to maintain genomic stability and prevent mutations
“digestive diseases”	health conditions associated with the digestive system
“DLT”	dose-limiting toxicity, side effects of a drug or other treatment that are serious enough to prevent an increase in dose of that treatment in a clinical trial
“DNA-PK”	DNA-dependent protein kinase, a nuclear serine/threonine kinase that plays a critical role in DNA double-strand break repair through the non-homologous end joining pathway
“DoR”	duration of response, the length of time that a tumor continues to respond to treatment without the cancer growing or spreading
“dose escalation”	a phase in a clinical trial in where the dose of a drug is gradually increased in different groups of people in order to determine the maximum tolerated dose
“dose expansion”	a trial enrolling additional participants to further evaluate the safety and preliminary efficacy of the selected doses
“double-blind”	with respect to a clinical trial or study, one in which neither the participants nor the persons or entities conducting the study know who is receiving a particular treatment. This procedure is utilized to prevent bias in research results
“DU”	duodenum ulcer(s), a sore that forms in the lining of the duodenum, the first part of the small intestine

GLOSSARY OF TECHNICAL TERMS

“FAS”	full analysis set, the set of subjects in a clinical trial that most closely represents the ideal of including all randomized subjects, following the intention-to-treat principle
“first-line”	with respect to any disease, the first-line treatment, which is the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment. It is also called primary treatment or therapy
“FXR”	farnesoid X receptor, a nuclear receptor primarily expressed in the liver and intestine that functions as a bile acid sensor, regulating bile acid synthesis, lipid and glucose metabolism, and maintaining metabolic homeostasis
“head-to-head trial”	a clinical trial that compares two therapies directly against each other. It is used to establish how well these treatments compare to each other when multiple treatment options are available
“HER2”	human epidermal growth factor receptor 2, the overexpression of which promotes the development of various types of cancer such as breast cancer, gastric cancer and colorectal cancer
“HR”	hormone receptor
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China or the U.S.
“IND-enabling”	the process of preparing the necessary preclinical data and documentation to support an investigational new drug application to the FDA, EMA or NMPA
“ <i>in vitro</i> ”	Latin for “within the glass”, studies using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells or biological molecules
“ <i>in vivo</i> ”	Latin for “within the living”, studies <i>in vivo</i> are those in which the effects of various biological or chemical substances are tested on whole, living organisms including animals, humans and plants, as opposed to a partial or dead organism, or those done <i>in vitro</i>

GLOSSARY OF TECHNICAL TERMS

“ITT”	intention-to-treat, a clinical trial analysis method where all participants are analyzed according to their initial treatment assignment, regardless of whether they completed the study protocol or received the treatment
“Key Supervision List”	a list of medications in China that require special monitoring and rational use management, established by the National Health Commission of the PRC to promote appropriate drug use and control healthcare costs
“KHK”	ketoheokinase, an enzyme involved in the metabolism of fructose, playing a role in carbohydrate metabolism
“kinase”	a type of enzyme that catalyzes the transfer of phosphate groups from high-energy, phosphate-donating molecules to specific substrates. The protein kinases make up the majority of all kinases. Protein kinases act on proteins, phosphorylating them on their serine, threonine, tyrosine, or histidine residues. These kinases play a major role in protein and enzyme regulation as well as signaling in the cell
“KOL”	key opinion leaders, influencers and trusted persons who have expert product knowledge and influence in a respective field and are an important part of burgeoning industries and businesses in China, including biotech/pharmaceutical industries
“MDA-MB-436”	a human TNBC cell line derived from pleural effusion, which is characterized by BRCA1 mutation and is commonly used in breast cancer research and drug development studies
“MMAE”	monomethyl auristatin E, a synthetic antimitotic agent that is highly potent and commonly used as the cytotoxic payload in ADCs. It works by disrupting microtubule assembly, leading to cell death
“monotherapy”	therapy that uses a single drug to treat a disease or condition
“MTD”	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects

GLOSSARY OF TECHNICAL TERMS

“NASH” or “MASH”	non-alcoholic steatohepatitis or metabolic dysfunction-associated steatohepatitis, liver inflammation and damage caused by accumulation of fat in the liver
“NDA”	new drug application
“neutropenia”	a hematological disorder characterized by an abnormally low number of neutrophils, the most important type of white blood cell, in the blood
“NSCLC”	non-small-cell lung cancer
“oncology”	a branch of medicine that deals with tumors, including study of their development, diagnosis, treatment and prevention
“open-label”	a type of clinical trial in which both the researchers and participants know which treatment is being administered, i.e. not blind
“ORR”	objective response rate, proportion of patients with a complete response or partial response to treatment
“OS”	overall survival, the length of time a patient diagnosed with the disease remains alive from the date of diagnosis or the start of treatment, used in clinical trials to measure the effectiveness of a drug
“OSR”	overall survival rate
“PARP”	poly ADP-ribose polymerase, a family of enzymes with PARP1 being the most abundant and well-characterized member, primarily involved in DNA replication and transcriptional regulation, which plays an important role in cell survival in response to DNA damage
“PARP1/2 inhibitor”	small molecule drug that selectively blocks the enzymatic activity of both PARP1 and PARP2, thereby preventing DNA repair and leading to synthetic lethality in cells with defective homologous recombination repair pathways
“PD”	pharmacodynamics, the study of a drug’s molecular, biochemical, and physiologic effects or actions

GLOSSARY OF TECHNICAL TERMS

“PD-1”	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages
“PDE5”	phosphodiesterase type 5, an enzyme that breaks down cyclic guanosine monophosphate in smooth muscle cells and is targeted by medications used to treat erectile dysfunction and pulmonary hypertension
“PD-L1”	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that binds to its receptor, PD-1, on the surface of the T cell that causes immune suppression of the T cells
“PFS”	progression-free survival, the length of time during and after the treatment that a patient lives without the disease getting worse
“phase 1 clinical trial”	a study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
“phase 2 clinical trial”	a study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance and optimal dosage
“phase 3 clinical trial”	a study in which a drug is administered to an expanded patient population generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the labeling of the product
“PI”	principal investigator, the lead researcher responsible for the design, conduct, and oversight of a clinical trial
“pivotal trial”	a clinical trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval

GLOSSARY OF TECHNICAL TERMS

“PK”	pharmacokinetics, a measurement of how fast and how completely the drug is absorbed into animal or human body, and the distribution, metabolism, and excretion of drugs in animal or human body
“pKa”	the negative logarithm of the acid dissociation constant, which measures the strength of an acid in solution
“placebo-controlled”	a term used to describe a method of research in which an inactive substance (a placebo) is given to one group of participants, while the treatment (usually a drug or vaccine) being tested is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective than the placebo
“PPI”	proton pump inhibitor, medications that reduce stomach acid production by blocking the H ⁺ /K ⁺ -ATPase enzyme system in gastric parietal cells, primarily used to treat acid-related digestive disorders
“PPS”	per protocol set, the set of subjects in a clinical trial who completed the study without major protocol deviations and received treatment exactly as planned
“PR”	partial response, referring to an at least 30% but below 100% decrease in the size of a tumor or in the extent of cancer in the body in response to treatment, according to Response Evaluation Criterial in Solid Tumors (RECIST)
“PU”	peptic ulcer(s), an open sore that develops in the lining of the stomach (gastric ulcer) or duodenum (duodenal ulcer)
“radiotherapy”	a cancer treatment that uses high doses of radiation to kill or damage cancer cells, aiming to shrink tumors and reduce symptoms
“RE”	reflux esophagitis, inflammation and damage to the esophageal lining caused by repeated backflow of stomach acid and digestive enzymes into the esophagus
“ROS1”	a receptor tyrosine kinase (encoded by the gene ROS1) highly-expressed in a variety of tumor cells

GLOSSARY OF TECHNICAL TERMS

“RP2D”	recommended phase 2 dose, the optimal dose level selected for phase 2 clinical trials, traditionally determined based on dose-limiting toxicities (DLTs). For molecularly targeted agents (MTAs), RP2D can be established using multiple parameters including toxicity profile, biological endpoints (such as pharmacokinetics and pharmacodynamics), and preliminary efficacy data. While RP2D is often associated with a 20-33% rate of DLTs in the first treatment cycle, it may not necessarily be the maximum tolerated dose (MTD), particularly for targeted therapies
“SAE”	serious adverse event, any medical occurrence in human drug trials that at any dose: results in death; is life-threatening; requires inpatient hospitalization or causes prolongation of existing hospitalization; results in persistent or significant disability/incapacity; may have caused a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage
“SBDD”	structure-based drug design, a drug discovery method that utilizes the three-dimensional structure information of a biological target to design and optimize potential drug molecules that can specifically bind to and modulate its function
“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
“solid tumors”	an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them. Examples of solid tumors are sarcomas (tumors arising from connective tissue), carcinomas (tumors arising from epithelial tissue), and lymphomas (tumors arising from the lymphatic system). Leukemias (cancers of the blood) generally do not form solid tumors
“SS”	safety analysis set, the set of subjects in a clinical trial who received at least one dose of study drug

GLOSSARY OF TECHNICAL TERMS

“synergistic effect”	an interaction between two or more drugs that causes the total effect of the drugs to be greater than the sum of the individual effects of each drug, which can be beneficial or harmful
“T cell”	a lymphocyte of a type produced or processed by the thymus gland and actively participating in the immune response, which plays a central role in cell-mediated immunity. T cells can be distinguished from other lymphocytes, such as B cells and NK cells, by the presence of a T cell receptor on the cell surface
“TEAE”	treatment-emergent adverse event, either an adverse event with onset after the initiation of the study medication or an adverse event with onset before study medication that worsened in severity after the initiation of study medication
“TNBC”	triple-negative breast cancer
“TRAE”	treatment-related adverse event, which is an adverse event that in the investigator’s opinion may have been caused by the study medication with reasonable possibility
“USP1”	ubiquitin-specific protease 1, a deubiquitinating enzyme that removes ubiquitin marks from target proteins, which plays key roles in DNA damage response and repair pathways
“VBP Scheme”	volume-based procurement scheme, 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
“xenograft model”	an experimental model where human tumor tissue or cancer cells are implanted in an immunodeficient mouse, which is used to study cancer biology, evaluate drug responses, and test potential therapies in a living system that approximates human cancer growth

FORWARD-LOOKING STATEMENTS

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

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

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

- the timing of initiation and completion, and the progress of our preclinical studies and clinical trials;
- the timing and likelihood of regulatory filings and approvals, such as INDs and NDAs;
- our license and collaboration agreements;
- the commercialization strategies and pricing policy of our drug candidates;
- the market opportunities of our drug candidates;
- our ability to attract and retain senior management and key employees;
- our operations and business prospects;
- our business strategies and plans to achieve these strategies;
- industry trends and competition;
- our ability to control costs and expenses;
- our ability to defend our intellectual rights and protect confidentiality;

FORWARD-LOOKING STATEMENTS

- our dividend policy;
- changes or volatility in interest rates, foreign exchange rates, equity prices, trading volumes, commodity prices and overall market trends;
- capital market developments;
- the actions and developments of our competitors;
- changes to regulatory and operating conditions in the industry and markets in which we operate; and
- all other risks and uncertainties described in the section headed “Risk Factors” in this document.

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

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

RISK FACTORS

An [REDACTED] in our H Shares involves various risks. You should carefully read and consider all of the information in this document, including the risks and uncertainties described below before deciding to make any [REDACTED] in our H Shares.

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

RISKS RELATING TO THE DEVELOPMENT OF OUR DRUGS AND DRUG CANDIDATES

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

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

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

- favorable safety and efficacy data from our preclinical studies and clinical trials;
- sufficient resources to discover or acquire additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- successful enrollment of patients in, and completion of, clinical trials;
- protocol adherence by enrolled patients;
- sufficient supplies of drug products that are either used in combination or in comparison with our drug candidates;

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- modifications to the protocols, which may delay the clinical program, regulatory approvals or commercialization, and require us to supplement, modify, or withdraw and refile our applications for regulatory approvals;
- the performance by CROs, CDMOs, or other third parties we engage to conduct clinical trials and preclinical studies and their compliance with our protocols and applicable laws without damaging or compromising the integrity of the resulting data;
- the capabilities and competence of our collaborators;
- the success of clinical trials conducted by, or jointly with, our collaborators;
- receipt of regulatory approvals for planned clinical trials or drug registrations, manufacturing and commercialization;
- commercial manufacturing capabilities, including through the CDMOs we engage;
- successful launch of commercial sales of our drug candidates, if and when approved;
- the obtaining and maintenance of favorable reimbursement from third-party payers for drugs, if and when approved;
- competition with other drug products;
- the obtaining, maintenance and enforcement of patents, trademarks, trade secrets and other intellectual property protections and regulatory exclusivity for our drugs and drug candidates;
- successful defense against any claims brought by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party; and
- the continued acceptable safety profile of our drug candidates following regulatory approval.

As of the Latest Practicable Date, except for KBP-3571, one of our Core Products, which had been approved for commercialization, all of our other drug candidates were in various phases of preclinical studies, clinical development and NDA filing. If we fail to achieve drug development milestones as disclosed in this document, our business prospects could be adversely affected. Our costs will also increase if we experience delays in the development of drug candidates or in obtaining regulatory approvals, which could result in us having to delay or suspend the trial until sufficient funding is procured, or we would have to abandon developing of the drug candidate completely. Significant preclinical study or clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates. Any of the above negative developments could have a material and adverse effect on our business, financial condition and results of operation.

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

The pharmaceutical industry in which we operate is intensely competitive and subject to rapid and significant technological changes. While our principal focus is to develop drug candidates with the potential to become novel or highly differentiated drugs, we face competition with respect to our current drugs and drug candidates, and any drug candidates that we may seek to develop or commercialize in the future. For example, our KBP-3571, one of our Core Products, is a PPI for the treatment of duodenal ulcer (DU). Apart from our KBP-3571, there were six other PPIs approved for marketing in China to date. Although most of existing marketed PPIs are generics, our product still faces inevitable competition from these established PPIs.

Our competitors mainly include large multinational pharmaceutical companies, well-established biopharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, governmental authorities and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Our competitors may have commercialized, are in the process of commercialization, or are pursuing the development of drugs for the treatment of indications which our drug candidates also target. Some of these competitive drugs and therapies are based on scientific approaches that are similar to our approach. For details, see “Business — Competition.” We cannot guarantee that we will be able to effectively compete with our competitors. Many of our competitors have substantially greater financial, technical and other resources, such as more advanced commercial infrastructure, more drug candidates in late-stage clinical development, more seasoned research and development staff and well-established marketing and manufacturing teams than us. Collaborations, mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or achieve better acceptance in the markets in which we operate or have established a competitive position. Even if successfully developed and subsequently approved by the NMPA or other comparable regulatory authorities, our drugs may still face competition in various aspects, including safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price and patent status.

Competition may further intensify as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in the industry. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective or less costly than any drug candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization, and market penetration than we do. To compete with an approved product, we must demonstrate compelling advantages in efficacy, safety or other aspects in order to overcome price

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competition and to be commercially successful. Furthermore, disruptive technologies and medical breakthroughs may further intensify the competition and render our drugs and drug candidates uneconomical or obsolete, and we may not be successful in marketing our drugs and drug candidates against competitors.

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

Clinical development is capital-intensive and may demand years of effort to complete, while its outcomes are inherently uncertain and may not be favorable. As of the Latest Practicable Date, we had obtained a total of 18 IND approvals. For details of our pipeline and clinical development of our drug candidates, see “Business — Our Pipeline.” We may encounter unexpected difficulties while executing our drug development plans for such drug candidates and our current and future drug candidates are susceptible to the risks of failure inherent at any stage of drug development, which would result in a material and adverse effect on our business, financial condition and results of operations. For instance:

- regulators, ethics committees, or other designated review bodies may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including negative results or a finding that participants are being exposed to unacceptable health and safety risks;
- we may not be able to reach agreements on acceptable terms with prospective CROs and hospitals as trial centers, the terms of which can be subject to extensive negotiation;
- we may encounter various manufacturing issues, including inability to reach agreements on acceptable terms with CDMOs, problems with quality control, or ensuring sufficient quantities of our drug candidates for use in a clinical trial;
- subject enrollment may be insufficient or slower than we anticipate, or subjects may drop out at a higher rate than anticipated;
- patent disputes or the failure to secure patents or other intellectual property protection for our drug candidates may affect the drug development process; and
- our drug candidates may cause adverse events and undesirable side effects, among other unexpected characteristics, which could result in a suspension or termination of an ongoing trial.

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Furthermore, the results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials, and favorable initial or interim results of a clinical trial do not necessarily indicate the success of final results. Drug candidates during later stages of clinical trials may fail to show the desired results in safety and efficacy despite having progressed through preclinical studies and initial clinical trials, and despite the level of scientific rigor in the design of such studies and trials and the adequacy of their execution. Many companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results at an earlier stage. 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 differences in the size and demographics of the enrolled patients, conditions of the individual subjects and their adherence to the treatment regimen and other compounding factors, such as other medications or pre-existing medical conditions. Differences in the number of clinical trial sites and regions involved may also lead to variability among clinical trials.

Therefore, we cannot guarantee that the results from our future research and development efforts will be favorable based on currently available clinical and preclinical data, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates. See also in this section “— Risks Relating to Government Regulations — The regulatory approval processes of the NMPA and other comparable regulatory authorities are time-consuming and may evolve over time. If we are unable to obtain without undue delay any regulatory approvals for our drug candidates in our target markets, our business may be subject to actual or perceived harm.”

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

Besides the continued clinical testing, potential approvals and commercialization of our existing drugs and drug candidates, the success of our business depends in part upon our ability to identify, discover, in-license or develop additional drug candidates. There can be no assurance that we will be successful in identifying and developing new drug candidates in the future. For example, although we have developed three proprietary technology platforms covering small molecule drugs and biologics, which we believe enables us to design, evaluate and select candidates and continue to enrich our pipeline, we cannot guarantee that we will successfully identify potential drug candidates as expected. Some drug candidates may be technically challenging to develop and manufacture. Drug candidates that we identify may later show side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approvals. We have also pursued, and may continue to pursue, collaboration with third parties in the discovery and development of potential drug candidates, including through license arrangements. For details, see “Business — Our License and Asset Acquisition Arrangements.” However, there can be no assurance that such license and collaboration will deliver the expected results.

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Research programs to identify and develop new drug candidates and to develop our drug candidates for additional indications require substantial technical, financial, and human resources. We may invest efforts and resources in potential drug candidates or indication expansions that ultimately prove to be unsuccessful. Any of the foregoing events will have a material and adverse effect on 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 selected indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that later may prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Furthermore, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through licensing, collaboration or royalty arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement, which could materially adversely affect our future growth and prospects.

If we encounter delays or difficulties enrolling subjects in our clinical trials, our clinical development progress could 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, or if there are delays in the enrollment of eligible subjects as a result of the competitive clinical enrollment environment. The inability to enroll a sufficient number of subjects who meet the applicable criteria set out in the protocol could result in significant delays in our clinical trials. In addition, some of our competitors may have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and subjects who would otherwise be eligible for our clinical trials may instead enroll in the clinical trials of our competitors' drug candidates, which may further delay our clinical trial enrollments.

Subject enrollment for our clinical trials may be affected by a variety of factors, including but not limited to the following:

- total size and nature of the relevant patient population;
- design and eligibility criteria for the clinical trial in question;

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- perceived risks and benefits of the drug candidate under study;
- severity of the disease under investigation;
- our resources to facilitate timely subject enrollment in clinical trials;
- patient referral practices of physicians;
- availability of competing therapies also undergoing clinical trials;
- our ability to obtain and maintain subject consents;
- our investigators’ or clinical trial sites’ efforts to screen and recruit eligible patients;
- proximity and availability of clinical trial sites for prospective patients; and
- occurrence of natural disasters, health epidemics, acts of war or other public events.

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

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

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

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

- regulatory authorities may withdraw their approvals of or revoke the licenses for the drug;
- we, or our collaborating partners, may have to suspend marketing of the drug;
- regulatory authorities may require additional warnings on the label;
- the NMPA or a comparable regulatory authority may require the establishment of a Risk Evaluation and Mitigation Strategy ("REMS"), or similar strategy that may, for instance, restrict distribution of our drug and impose stricter implementation requirements on us;
- we, or our collaborating partners, may be required to conduct specific post-marketing studies;
- we could become subject to litigation proceedings and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

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

We may be unable to successfully develop or market our drug candidates or may fail to obtain regulatory approvals in a timely manner, if safety, efficacy or other issues arise from any pharmaceutical product or medical treatment used, or intended to be used, in combination with our drug candidates.

We plan to develop certain of our drug candidates for use as a combination therapy. For example, we are developing a CDK4/6 inhibitor, our XZP-3287, in combination with fulvestrant for the treatment of advanced HR+/HER2- BC, for which we had filed an NDA, and in combination with AIs for the treatment of advanced HR+/HER2- BC, for which we had entered into phase 3 clinical trial as of the Latest Practicable Date. We may also seek to develop our drug candidates in combination with other drugs in the future. If the NMPA or another comparable regulatory authority revokes its approval of such treatments or drugs we intend to use in combination with our drug candidates, we may not be able to develop or market our drug

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candidates as a combination therapy as planned. If safety or efficacy issues arise with such treatments or drugs that we seek to combine with our drug candidates in the future, we may fail to obtain regulatory approvals in a timely manner, and we may be required to redesign or terminate the applicable clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any drugs we use in combination with, we may not be able to complete clinical development of our drug candidates as a combination therapy on our current timeline or within our current budget, or at all.

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

The global pharmaceutical market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For example, we have made significant efforts to develop our core technology platforms, including our proprietary small molecule drug R&D platform, biological drug R&D platform, and clinical development platform, which allow us to continuously develop a strong pipeline of drug candidates. For the years ended December 31, 2022 and 2023 and the six months ended June 30, 2023 and 2024, our research and development expenditure (including research and development expenses and capitalized research and development costs recorded as intangible assets) were RMB567.5 million, RMB383.9 million, RMB220.6 million, and RMB125.4 million, respectively. We intend to continue to strengthen our technical capabilities in the development of our drug candidates, which requires substantial capital and time. We cannot assure you that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, or obtain sufficient or any patent or other intellectual property protection for such new or enhanced products in a timely and cost-effective manner. Any failure to do so may render our previous efforts obsolete, which could significantly reduce the competitiveness of our technology platforms and drug candidates, and harm our business and prospects.

RISKS RELATING TO THE COMMERCIALIZATION OF OUR DRUGS AND DRUG CANDIDATES

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

As of the Latest Practicable Date, KBP-3571, one of our Core Products, had been approved for commercialization, and we had a number of other drug candidates in late-stage clinical trial or NDA filing stage. We cannot guarantee that our current and future approved drugs will obtain sufficient market acceptance in the medical community. Physicians and patients may prefer other drugs or drug candidates to ours. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from sales of our drugs or drug candidates and may not become profitable.

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The degree of market acceptance of our current and future approved drugs will depend on a number of factors, including, but not limited to:

- the clinical indications for which our drug candidates are approved;
- physicians, hospitals and patients considering our drugs or drug candidates as a safe and effective treatment;
- whether our drugs or drug candidates have achieved their potential advantages over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or package insert requirements of the NMPA or other comparable regulatory authorities;
- limitations or warnings contained in the labeling approved by the NMPA or other comparable regulatory authorities;
- timing of market introduction of our drugs and drug candidates, as well as competitive drugs also on the market;
- cost of treatment in relation to alternative treatments;
- availability of adequate coverage and reimbursement under the national and provincial reimbursement drug lists in the PRC;
- willingness of patients to pay any out-of-pocket expenses in the absence of coverage and reimbursement by third-party payors and governmental authorities;
- relative convenience and ease of administration, including as compared with alternative treatments and competitive drugs on the market; and
- the effectiveness of our sales and marketing efforts.

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

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

Our operations to date have been largely focused on developing our drug candidates, primarily undertaking preclinical studies and conducting clinical trials. Although members of our management have years of experience relating to marketing and commercialization, we have not yet demonstrated an ability to launch and commercialize any of our drugs or drug candidates. We recently started the process of building a commercial team and a sales force, and establishing a distribution network, for our drugs and drug candidates, which will require significant capital expenditures, management resources and time.

We will have to compete with other pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. We also plan to partnership with established distributors externally for quick entries into the market. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or, if we are able to do so, that effective sales forces and network will be established. Any revenue we receive will partially depend on the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. See also in this section “— Risks Relating to Dependence on Third Parties — We may fail to effectively manage our network of distributors for our current and future approved products. Actions taken by our distributors could materially and adversely affect our business, prospects and reputation.” We will also face competition in our search for reputable third parties to assist us with the sales and marketing efforts of our drugs and drug candidates. There can be no assurance that we will be able to develop established in-house sales and marketing capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

Our drugs and drug candidates may become subject to unfavorable insurance policies or reimbursement practices, either of which could harm our business, and we may also be subject to unfavorable pricing regulations.

We are actively seeking approval to market our drugs and drug candidates in China. In China, the pricing of certain drugs and biologics is subject to governmental regulations, which can take considerable time even after obtaining regulatory approval. Our ability to commercialize any approved drug candidates successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations.

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

KBP-3571, one of our Core Products, has been included in the NRDL. There can be no assurance that any of our future approved drug candidates will be included in the NRDL. If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL, our revenue from commercial sales would be highly dependent on patient self-payment, which can make our products less competitive. Patients may choose other drugs with similar efficiency but lower price which have been included in the NRDL. Additionally, even if the Ministry of Human Resources and Social Security of China or any of its local counterparts were to accept our application for the inclusion of products in the NRDL, our potential revenue from the sales of these products could still decrease as a result of the significantly lowered prices we may be required to charge for our products to be included in the NRDL.

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

There may also be significant delays in obtaining reimbursement for approved drug candidates, and reimbursement coverage may be more limited than the approved indications of the drug candidates by the NMPA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Payment rates may vary according to the uses of the drugs and the clinical setting in which the drugs are used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Our inability to promptly obtain reimbursement coverage at intended payment rates for our drug candidates and any new drug candidates that we develop could have a material adverse effect on our business, operating results, and overall financial conditions.

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

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

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

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

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

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Furthermore, certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or be fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system in countries or regions where we operate may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits could quickly erode the demand for our current and future approved drugs. In addition, thefts of our inventory at warehouses, plants or while in-transit could lead to our products being wrongfully stored and handled, and eventually sold through unauthorized channels. A patient who receives a counterfeit or unauthorized pharmaceutical product may be at risk for a number of dangerous health consequences, which potentially exposes us to product liability claims, government investigations, and other disputes and negative consequences. Our reputation and business could suffer harm as a result of counterfeit or unauthorized pharmaceutical products sold under our or our collaborators' brand name(s).

Negative results from off-label use of our current and future marketed drug products could harm our business reputation, product brand and financial condition and expose us to liability.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use. Off-label drug use is the prescription of a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. Even though the NMPA 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. This occurrence may render our products less effective or entirely ineffective and may cause adverse drug reactions or adverse events. Any of these occurrences can create negative publicity and materially and adversely affect our business reputation, product brand, business operations and financial conditions. These occurrences may also expose us to liability and cause a delay in the progress of our clinical trials and may ultimately result in failure to obtain regulatory approval for our drug candidates.

Guidelines, recommendations, and studies published by third-party organizations could adversely affect our drugs and drug candidates.

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

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RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred net losses since our inception. We anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability.

Investment in the development of pharmaceutical products is highly uncertain as it entails substantial upfront expenditures and significant risks that a drug candidate may fail to demonstrate efficacy and safety to gain regulatory or marketing approvals or become commercially viable. Although we have generated revenue from commercial product sales, we have incurred, and may continue to incur significant research and development expenses and other expenses related to our ongoing operations. As a result, we have incurred net losses in 2022 and 2023 and for the six months ended June 30, 2023 and 2024 of RMB512.3 million, RMB300.6 million, RMB187.2 million and RMB111.0 million, respectively.

Substantially all of our net losses have resulted from costs incurred in connection with our research and development activities, which exceeded the revenue we recognized from sales of commercialized products. For the years ended December 31, 2022 and 2023 and the six months ended June 30, 2023 and 2024, our research and development expenses were RMB401.0 million, RMB239.1 million, RMB149.5 million and RMB74.4 million, respectively. We also capitalized R&D expenditure during the Track Record Period, which amounted to RMB166.5 million, RMB144.8 million, and RMB51.0 million in 2022, 2023 and the six months ended June 30, 2024, respectively. See “Financial Information — Description of Selected Components of the Consolidated Statements of Profit or Loss and Other Comprehensive Income” for details. Our ability to generate revenue and achieve profitability depends significantly on our success in advancing drug candidates into later stages of clinical development, and obtaining regulatory approvals for each drug candidate, which we may not be able to do in a timely manner or at all.

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

- continue our ongoing and planned research and development activities;
- seek to discover, develop or in-license additional drug candidates and further expand our product pipeline;
- hire additional drug discovery, clinical, quality control and administrative personnel;
- develop, maintain, expand and protect our intellectual property portfolio;
- seek regulatory approvals for any drug candidates that successfully complete clinical trials;

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- establish sales, marketing and distribution infrastructure to commercialize our current and future approved drug products; and
- incur additional legal, accounting, investor relations, insurance and other expenses associated with operating as a public company following the completion of this [REDACTED].

The size of our future net losses will depend, among other factors, on our ability to generate revenues, the rate of the future growth of our expenses, and the timing and amount of milestone payments and other payments that we receive from or pay to third parties. If any of our drug candidates fails during clinical trials or does not gain regulatory approval, or, any of our current and future approved drugs fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our business, financial condition and results of operation.

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

We had cash used in operating activities of RMB386.2 million, RMB116.0 million, RMB134.6 million and RMB52.9 million for the years ended December 31, 2022 and 2023, and the six months ended June 30, 2023 and 2024, respectively, primarily for our research and development activities. We may experience net cash outflows from our operating activities from time to time. See also “Financial Information — Liquidity and Capital Resources — Cash Flows.” Our forecast of the period of time through which our capital resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect.

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

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

During the Track Record Period, we funded our operations primarily through equity financing. We expect our expenses to increase in connection with our ongoing development activities, particularly as we advance the clinical development of our clinical-stage drug candidates, continue the research and development of our preclinical stage drug candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. In addition, as we have started to commercialize our approved drugs, and we

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may obtain regulatory approvals for any of our drug candidates in the future, we expect to incur significant commercialization expenses relating to product manufacturing, marketing, sales and distribution and post-approval commitments to continue monitoring the efficacy and safety data of our future products on the market. We may also incur expenses as we create additional infrastructure to support our operations as a public company. Accordingly, we may need to secure substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources.

We expect to fund our future operations primarily with existing cash and cash equivalents, sales from commercialized drug products, and [REDACTED] from the [REDACTED]. Upon the successful commercialization of one or more of our current and future approved drugs, we expect to fund our operations in part with income generated from sales of our commercialized drug products. Changes in our ability to fund our operations may affect our cash flow and results of operations. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts.

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

As of December 31, 2022 and 2023, and June 30, 2024, we had financial assets at FVTPL of RMB482.2 million, RMB306.8 million and RMB332.4 million, respectively, which represented wealth management products that we purchased from creditworthy commercial banks in mainland China. For the years ended December 31, 2022 and 2023, and the six months ended June 30, 2023 and 2024, we recorded fair value gains on financial assets measured at FVTPL of RMB5.1 million, RMB1.7 million, RMB2.8 million and RMB3.7 million, respectively, and investment income on financial assets at FVTPL of RMB22.0 million, RMB14.0 million, RMB6.4 million and RMB1.8 million, respectively. After [REDACTED], we may continue to purchase low-risk wealth management products with a short maturity period based on our operational needs. We therefore face exposure to fair value change of financial assets measured at 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 our result of operations for future periods. In addition, the valuation of financial assets at FVTPL is subject to uncertainties due to the use of unobservable inputs. Such estimated fair values involve the exercise of professional judgment and the use of certain bases, assumptions and unobservable inputs, which, by their nature, are subjective and uncertain. As such, the valuation of financial assets at FVTPL has been, and will continue to be, subject to uncertainties in estimations, which may not reflect the actual fair value of these financial assets and result in fluctuations in profit or loss from year to year.

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

We currently benefit from certain preferential tax treatments. According to the EIT Law and its relevant regulations, entities that qualified as High and New Technology Enterprise are entitled to a preferential income tax rate of 15%. Our subsidiary Shandong Xuanzhu obtained its certificate of High and New Technology Enterprise in November 2019 and December 2022, respectively, and was entitled to preferential income tax of 15% during the Track Record Period. We cannot assure you that these preferential tax treatments will continue to be available to us in the future, or that these preferential tax treatments will not be changed, as a result of changes in government policy, administrative decisions or otherwise, in which case our financial condition and results of operations may be adversely affected. See note 10 to the Accountants’ Report in Appendix I to this document for details.

Moreover, we recorded government grants of RMB11.2 million, RMB23.5 million, RMB8.0 million and RMB1.8 million for the years ended December 31, 2022 and 2023, and the six months ended June 30, 2023 and 2024, respectively. These government grants primarily represent government subsidies from PRC local government authorities for the purpose of supporting our operating and R&D activities. These government grants are provided to us at the discretion of the relevant government authorities, who could determine from time to time to eliminate or reduce these financial incentives, and may therefore vary from period to period going forward. For more details, see “Financial Information — Description of Selected Components of the Consolidated Statements of Profit or Loss and Other Comprehensive Income — Other Income and Gains.”

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

If we determine our intangible assets to be impaired, our results of operations and financial condition may be adversely affected.

During the Track Record Period, we recorded other intangible assets of RMB391.8 million, RMB533.8 million and RMB567.0 million as of December 31, 2022 and 2023 and June 30, 2024, respectively, representing research and development costs, patents and licenses, and software. Research and development costs comprised a significant portion of our other intangible assets, primarily due to the capitalization of certain R&D expenditures. The value of other intangible assets is based on a number of assumptions made by the management. For

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a detailed discussion on intangible assets, see note 15 to the Accountants’ Report in Appendix I to this document. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, we may be required to have a significant write-off of our intangible assets and record a significant impairment loss. Furthermore, our determination on whether intangible assets are impaired requires an estimation of the carrying amount and recoverable amount of an intangible asset. If the carrying amount exceeds its recoverable amount, our intangible assets may be impaired. The impairment of intangible assets could have an adverse effect on our business, financial condition and results of operations.

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

We have adopted share incentive plans for the purpose of granting share-based compensation awards to employees, officers, or directors to incentivize their performance and align their interests with ours. In 2022 and 2023 and the six months ended June 30, 2023 and 2024, we incurred RMB70.1 million, RMB72.3 million, RMB49.1 million and RMB30.1 million of share-based payments relating to awards granted under our share incentive plans, respectively. We believe the granting of share-based compensation is of significant importance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based compensation awards to employees in the future. As a result, our expenses associated with share-based payments may increase, which may affect our financial condition and results of operations. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the grants under our currently effective employee incentive plans from time to time, and we may experience substantial change in our share-based payments in the reporting periods following this [REDACTED].

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

The Renminbi has fluctuated against the Hong Kong dollar and U.S. dollar, at times significantly and unpredictably. In 2022, we recorded net foreign exchange gains of RMB19 thousand. In 2023 and the six months ended June 30, 2023 and 2024, we recorded net foreign exchange losses of RMB98 thousand, RMB6 thousand and RMB0.1 million, respectively. There is no assurance that we will incur foreign exchange gains in the future or our foreign exchange losses will not incur in the future. The value of Renminbi against the U.S. dollar and other currencies is affected by changes in political and economic conditions and by foreign exchange policies, among other things. We cannot assure you that Renminbi will not appreciate or depreciate significantly in value against the Hong Kong dollar or U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between Renminbi and the Hong Kong dollar or U.S. dollar in the future.

The [REDACTED] from the [REDACTED] will be received in Hong Kong dollars. As a result, any appreciation of the Renminbi against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in the decrease in the value of our [REDACTED] from the [REDACTED]. Conversely, any depreciation of the Renminbi may adversely affect the value

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of, and any dividends payable on, our H Shares in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Furthermore, we are also currently required to complete filings with and obtain approvals from the State Administration of Foreign Exchange of the PRC (SAFE) before converting significant sums of foreign currencies into Renminbi. All of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our H Shares in foreign currency terms.

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

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

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

RISKS RELATING TO DEPENDENCE ON THIRD PARTIES

We have entered into license and collaboration agreements with third parties in the development, manufacturing and commercialization of our drugs and drug candidates, and may seek and establish additional license or other strategic partnerships in the future. We may not realize the benefits of such partnerships as expected.

We have in the past formed, and may continue to seek, strategic partnerships or other collaborations, including entering into license arrangements with third parties that we believe will complement or augment our drug development, manufacturing and commercialization efforts with respect to our drugs and drug candidates and any future drug candidates that we may develop. To date, we have entered into multiple collaboration deals with various industry players. See “Business — Our License and Asset Acquisition Arrangements” for details.

Our results of operations have been, and may continue to be, affected by such arrangements. For the year ended December 31, 2022 and the six months ended June 30, 2024, we recorded loss on disposal of items of other intangible assets of RMB52.3 million and

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RMB7.4 million, respectively, primarily in relation to the transfer of certain rights and interests derived from our out-licensing and technology transfer deals with certain third parties. Collaboration and license agreements involving our drug candidates are subject to various risks, which may include the followings:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- the license and collaboration agreements may be terminated upon a short notice, or if we or our business partners fail to comply with the obligations as set out in the respective agreements. Our business partners may elect to cease collaboration due to change in their strategic focus, potential acquisition of competitive drugs, availability of funding, or other external factors. Termination of license and collaboration arrangements may result in a need for additional capital to pursue further development or commercialization of the relevant drug candidates;
- 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;
- the milestone payments and royalties under the license agreements are conditioned upon the achievements of certain regulatory, development and commercialization targets. We cannot guarantee that we will be able to receive the aggregate amount as set out in the relevant license and collaboration agreements;
- 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;
- 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;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs or drug candidates;
- 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; and
- the license and collaboration relationships may be affected by geopolitical tensions, including cross-border data transmission restrictions, trade policies and export controls.

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

We face significant competition in seeking appropriate strategic partners and the negotiation process can be time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we may be required to relinquish some or all of the control over the future success of that drug candidate to the third party. The collaborators may also consider alternative drug candidates or technologies that may be available.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expenses. If we elect to fund and undertake development, manufacturing or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into license and collaboration arrangements or do not have sufficient funds or expertise to undertake the necessary development, manufacturing and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations and prospects.

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

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

We rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development, manufacture or commercialization of certain of our drug candidates and certain of these third parties from which we have been

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granted licenses themselves rely on licenses from other third parties. For example, we have entered into in-license agreement with SignalChem Lifesciences Corporation (“SignalChem”), under which we in-license certain patents and know-how relating to XZB-0004. For details, see “Business — Our License and Asset Acquisition Arrangements — Our In-licensing and Asset Acquisition Agreements — Agreement with SignalChem to In-license XZB-0004.”

The licenses we hold may not provide exclusive rights to use such intellectual property in all relevant fields of use or in all territories in which we may wish to develop or commercialize our future approved drugs. As a result, we may not be able to develop, export or sell our drug products outside of the fields or territories as stipulated by the license and collaboration agreements or prevent competitors from developing and commercializing competitive drug products in territories included in all of our licenses. Our existing or future collaborating partners may rely on third-party consultants or collaborators or on funds from third parties, or on upstream licenses from third parties, such that our collaborating partners are not the sole and exclusive owners of the intellectual property rights we in-license.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defense of patents and patent applications covering the drug candidates or components of the drug candidates that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our existing or future collaborating partners fail to prosecute, maintain, enforce or defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are subject to such licensed rights could be adversely affected.

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

Moreover, if any of our collaborating partners encounter financial problems or changes in business focus, some or all of our rights under the license agreements may be terminated. For details, see “Business — Our License and Asset Acquisition Arrangements.” As such,

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competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. Any of these events could have a material and adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We rely on third parties to monitor, support and/or conduct clinical trials and preclinical studies of our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially affected.

We have relied on and plan to continue to rely on third-party contract research organizations (“CROs”) and other third parties to monitor and manage data for some of our ongoing preclinical and clinical programs. For example, we rely on CROs to evaluate the safety profile of some of our drug candidates. We rely on these parties for the execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities.

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

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

Similarly, if other third parties fail to meet expected deadlines, timely transfer to us any requisite information, adhere to protocols or act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a sub-standard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, the clinical trials of our drug candidates may be compromised, delayed, prolonged, suspended or terminated, or our data may be rejected by the NMPA or other comparable regulatory authorities.

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In addition, the use of third-party service providers requires us to disclose our proprietary information or confidential information concerning the subjects enrolled in our clinical trials to these third parties, which could increase the risk that such information will be misappropriated. Though we carefully manage our relationships with our CROs and other third-party service providers, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material and adverse impact on our business, financial condition, results of operations and prospects.

Furthermore, we may not be able to enter into arrangements with alternative CROs and other third parties in a timely manner or do so on commercially reasonable terms, if our existing relationships with these third parties terminate. Switching or adding CROs and other third parties involves additional cost and delays, which can materially affect our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.

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

To date, we have outsourced manufacturing activities to reputable CDMOs in China. See “Business — Manufacturing” for details. Going forward, we intend to continue to engage third-party CDMOs to manufacture our drug candidates for our research and development activities and commercial sales, while gradually establishing our in-house manufacturing capabilities. Our reliance on third-party CDMOs exposes us to certain risks, including, but not limited to, the following:

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

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- our CDMOs may not be able to execute our manufacturing procedures and other logistical support requirements appropriately, or may otherwise fail to perform as agreed;
- our CDMOs may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- our CDMOs may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;
- our CDMOs could terminate their agreements with us;
- raw materials and products supplied by certain CDMOs may not be readily obtainable elsewhere; and
- natural or man-made disasters, labor disputes, unstable political environments and other events beyond our control may lead to interruption of the manufacturing process.

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

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

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

Any disruption in production or the inability of our suppliers or suppliers of our CROs and CDMOs to provide adequate quantities to meet our, our CROs' or CDMOs' needs could impair our operations, the research and development of our drug candidates and the commercialization of our approved drugs. Moreover, we expect our demand for such raw materials and products to increase as we expand our business scale and commercialize our drug candidates once approved, but there is no assurance that current suppliers have the capacity to meet our demand. We are also exposed to the possibility of increased costs, which we may not be able to pass on to customers and as a result, lower our profitability.

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In addition, the quality of the raw materials procured and products manufactured by CDMOs will depend significantly on the effectiveness of our quality control and quality assurance and that of our CDMOs. We cannot assure you that we and CDMOs will be able to identify and rectify all quality issues. See also in this section “— Risks Relating to the Manufacturing of Our Drugs and Drug Candidates — We may not be able to maintain effective quality control over our drug products.”

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

We may fail to effectively manage our network of distributors for our current and future approved products. Actions taken by our distributors could materially and adversely affect our business, prospects and reputation.

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

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

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

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Our relationships with certain principal investigators, KOLs, physicians and other industry experts may affect the clinical development and future marketing of our products.

Our relationships with principal investigators (“PIs”), key opinion leaders (“KOLs”), physicians and other industry experts play an important role in our research and development and marketing activities. We have established extensive interaction channels with PIs, KOLs, physicians and experts to gain first-hand knowledge of unmet clinical needs and clinical practice trends, which is critical to our ability to develop market-responsive drugs. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with PIs, KOLs, physicians and other industry experts, or that our efforts to maintain or strengthen such relationships will lead to 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 research and development process, may be inaccurate and lead us to develop products that do not have significant market potential. Even if their insights and perceptions are correct, we may fail to develop commercially viable products. Industry participants may no longer want to collaborate with us or attend our conferences, and our marketing strategy may no longer be able to yield results that are commensurate to our efforts spent. If we are unable to develop and maintain our relationships with industry participants as anticipated, our business, financial condition and results of operations may be materially and adversely affected.

RISKS RELATING TO INTELLECTUAL PROPERTY RIGHTS

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

Our commercial success depends, to a certain extent, on our ability to protect our proprietary technology and drugs and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the drugs and drug candidates and technology that we consider commercially important primarily by filing patent applications in China, the U.S. and other countries or regions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. As of the Latest Practicable Date, we owned 163 issued patents and had filed 99 published patent applications in China, the U.S., and other jurisdictions, which we consider material to our business operations. See “Business — Intellectual Property” for details. This process is expensive and time-consuming, and we or our business partners may not be able to file and prosecute all necessary or desirable patent applications and secure other intellectual property protection in all jurisdictions in a timely

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manner. It is also possible that we or our business partners will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we or our business partners may fail to timely identify third-party infringement of our intellectual property rights and take necessary actions to defend and enforce our rights, or at all.

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

Even if patents are issued on these applications, there can be no assurance that a third party will not challenge their validity, enforceability, or scope, which may result in the patent claims being narrowed or invalidated, or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our drugs and drug candidates. We or our business partners may become involved in interference, *inter partes* review, post-grant review, *ex parte* reexamination, derivation, opposition or similar other proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, drugs or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drugs and drug candidates without infringing third-party patent rights. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage.

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

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Patent protection depends on compliance with various procedural, regulatory and other requirements, 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 China National Intellectual Property Administration (the “CNIPA”) and other applicable patent authorities over the lifetime of a patent. The CNIPA and other applicable patent authorities require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions 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 such non-compliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but not limited to failure to respond to official actions within prescribed time limits, and non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our collaborating partners fail to maintain the patents and patent applications covering our drugs and drug candidates or if we or our collaborating partners otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our drug candidates in any indication for which they are approved. In addition, according to the PRC patent law and related regulations, we and our collaborating partners shall file the patent license agreements with the CNIPA within three months after the effective date thereof, otherwise we may lose our exclusive right to use our in-licensed patents if the licensor grants a *bona fide* third party a right to use the patent. Before such filings become effective, we may not be able to protect ourselves against challenges brought by *bona fide* third parties to whom the licensors may, for any reason, grant a right to use the same patents we have in-licensed.

If our patent terms expire before or soon after our drug candidates are approved, or if competitors successfully challenge our patents, our business may be materially harmed. Lack of protection under the applicable patent linkage and patent term extension laws and regulations could increase the risk of early generic competition.

Patents have a limited duration. Depending on the jurisdiction, various extensions may be available, but the life of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years from the date of application for inventions in China and generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority in the U.S. Even if patents covering our drugs and drug candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications, including biosimilar medications.

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Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates could 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. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities, including the NMPA and the CNIPA in China, and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we request. For example, the amendment to the PRC Patent Law which was promulgated in October 2020 introduces patent extensions to patents of new drugs that launched in the PRC, which may enable the patent owner to submit applications for a patent term extension of up to a maximum length of five years, and after the new drug is approved for marketing, the total effective term of the patent shall not exceed 14 years. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements.

Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. Also, the scope of our right to exclude during any patent term extension period may be limited or may not cover a competitor's product or product use. As a result, our revenue from applicable drug candidates, if approved, could be reduced, possibly materially.

Manufacturers of generic or biosimilar drugs may challenge the scope, validity, or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected. On the other hand, if we launch our drug candidates prior to the expiration of patents for any competing products, we may face potential claims for patent infringement.

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

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

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

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

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

We own a number of trademarks in China. 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 or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names.

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If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. In the future, we may license our trademarks and trade names to third parties, such as business partners and collaborators. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to our issued patents and pending patent applications, we rely on trade secret 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. Since we rely on third parties to manufacture or commercialize our current drugs and drug candidates or any future drug candidates, or if we collaborate with third parties for the development of our current or any future drug candidates, we must, at times, share trade secrets with them, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure, confidentiality and similar agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, CDMOs, consultants, advisors and other third parties. Any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Moreover, 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.

Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any third-party collaborators. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations. 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 we are unable to prevent unauthorized material disclosure of our trade secrets and confidential information to third parties, or misappropriation of our trade secrets and confidential information by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially and adversely affect our business, financial condition, and results of operations. 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.

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Furthermore, many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not wrongfully use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual’s former employer. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Further, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property.

Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs, be a distraction to our management and scientific personnel and have a material adverse effect on our business, financial condition, results of operations and prospects. See also in this section “— Risks Relating to Intellectual Property Rights — 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.”

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.

We cannot guarantee that our drug candidates or the sale or use of our future products do not and will not in the future infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights. There may be third-party issued patents with claims related to our drugs or drug candidates. Third parties could 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, or with respect to the use or manufacture of the compounds we have developed or are developing. Litigation relating to patents and other intellectual property rights in the pharmaceutical industries is common, including patent infringement lawsuits. The various markets in which we plan to operate are subject to frequent and extensive litigation

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regarding patents and other intellectual property rights. Third parties could 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. Some claimants may have substantially greater resources than we have and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could.

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. Publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications on, our drugs and drug candidates or for their uses, or that our drugs and drug candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our drugs and drug candidates or a similar invention, our patent application may be regarded as a competing application and may not be approved in the end. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

If a third party were to assert claims of patent infringement against us, even if we believe such third-party claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention, or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In addition, defending such claims would cause us to incur substantial expenses and could cause us to pay substantial damages, if we are found to be infringing a third party's patent rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully.

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 nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a drug candidate, or be forced, by court order or otherwise, to modify or 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.

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Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our drugs and drug candidates, our intellectual property rights could be challenged or invalidated. For example, although we believe that we have conducted our patent prosecution in accordance with a duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. On the other hand, competitors or other third parties may infringe or misappropriate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In any infringement proceeding, a court may decide that a patent of ours is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

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

An adverse result in any litigation proceedings could put one or more of our intellectual property rights at risk of being invalidated or interpreted narrowly. Even if successful, litigation may result in substantial costs and distraction of our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If the public, securities analysts or [REDACTED] perceive these results to be negative, or perceive that the presence or continuation of these cases creates a level of uncertainty regarding our ability to increase or sustain products sales, it could have a substantial adverse effect on the price of our H Shares. There is no assurance that our drug candidates will not be subject to the same risks.

Intellectual property and other laws and regulations are subject to change, which could diminish the value of our intellectual property in general, thereby impairing our ability to protect our drugs and drug candidates.

Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in China and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our future patents or in third-party patents. In addition, there are periodic proposals for changes to the patent laws in China and other countries that, if adopted, could impact our ability to enforce our proprietary technology.

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In China, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in the PRC. For example, on October 17, 2020, the Standing Committee of the National People’s Congress of the PRC (the “SCNPC”) promulgated the Amendment to the PRC Patent Law effective from June 1, 2021, which provides that, among others, the patentee of an invention patent relating to the new drug that has been granted the marketing authorization in the PRC is entitled to request the patent administration department under the State Council to grant a patent term extension of up to five years, in order to compensate the time required for the regulatory evaluation and approval for the commercialization of such a new drug; provided that, the total remaining patent term of such a new drug approved for commercialization shall not exceed fourteen (14) years after such approval. As a result, the terms of our PRC patents may be eligible for extension and allow us to extend patent protection of our products, and the terms of the patents owned by third parties may also be extended, which may in turn affect our ability to commercialize our products candidates, if and when approved, without facing infringement risks. The length of any such patent term extension is uncertain. If we are required to delay commercialization for an extended period of time, technological advances may develop and new competitor products may be launched, which may render our product non-competitive. We also cannot guarantee that other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce our current and future owned and licensed patents.

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

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

- others may be able to make drug candidates that are the same as or similar to our drug candidates but that are not covered by the claims of the patents that we own or may have exclusively licensed;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and
- we may not develop additional technologies that are patentable.

RISK FACTORS

RISKS RELATING TO GOVERNMENT REGULATIONS

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

The development and commercialization of pharmaceutical products are heavily regulated in various jurisdictions. While we focus on expanding our business in the PRC, we also consider development opportunities in the U.S. and other jurisdictions. These jurisdictions strictly regulate the pharmaceutical industry, and in doing so they employ a broad range of strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. Evolutions and differences in these regulatory regimes could lead to an increased and costly regulatory compliance burden.

We are required to obtain and maintain certain licenses and permits for conducting our business. The process of obtaining regulatory approvals and compliance with appropriate laws, regulations and guidance requires the expenditure of substantial time and financial resources. If any regulatory authorities consider that we were operating without the requisite approvals, licenses or permits or promulgates new laws and regulations that require additional approvals or licenses or imposes additional restrictions on the operation of any part of our business, it has the power, among other things, to levy fines, confiscate our income, revoke our business licenses, and require us to discontinue our relevant business or impose restrictions on the affected portion of our business. In particular, failure to comply with the applicable requirements at any time during the product development process and approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include refusal to approve pending applications, withdrawal of an approval, license revocation; clinical hold, voluntary or mandatory product recalls, product seizures; total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution and disgorgement, or other civil or criminal penalties. Failure to comply with these laws, regulations and guidance could have a material and adverse effect on our business and prospects.

In many countries or regions where a drug is intended to be ultimately sold, including China, the relevant government agencies and industry regulatory bodies impose high standards on the efficacy of such drug, as well as strict rules, regulations and industry standards on how we develop such drug. For example, we may need to obtain clearance from the NMPA or other regulatory authorities as part of an IND application to seek authorization to begin clinical trials, and file an NDA or other similar applications to seek marketing approval. Any failure to comply with existing laws, regulations and industry standards could result in fines or other punitive actions against us, the termination of ongoing research and the disqualification of data for submission to regulatory authorities, or a ban on the future sales of our drugs, each of which could have a material adverse impact on our reputation, business, financial condition, results of operations and prospects. In addition, any action against us for violation of the relevant laws, regulations or industry standards, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and adversely affect our reputation and financial results.

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

Generally, approval from the NMPA and other comparable regulatory authorities take many years to obtain, following the commencement of preclinical studies and clinical trials. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. Additional time, effort and expense may be required to bring our drug candidates, upon regulatory approval, to the markets in compliance with different regulatory processes.

Our drug candidates could fail to receive the regulatory approval of the NMPA or a comparable regulatory authority for many reasons, including, without limitation:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective and potent for its proposed indication;
- failure of our clinical trial results to meet the level of statistical significance required for approval;
- failure of our clinical trial process to pass relevant GCP inspections;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficient data collected from the clinical trials of our drug candidates to support the submission and filing of an NDA or other submissions or to obtain regulatory approval;
- failure of our drug candidates to pass cGMP, inspections during the regulatory review process or across the production cycle of our drug;
- failure of our clinical sites to pass audits carried out by the NMPA or comparable regulatory authorities, resulting in a potential invalidation of our research data;
- findings by the NMPA or comparable regulatory authorities of deficiencies related to the manufacturing of our products;

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- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval; and
- failure of our clinical trial process to keep up with any scientific or technological advancements required by approval policies or regulations.

The NMPA or a comparable regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans. Even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials, or approve a drug candidate with an indication that is not desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could affect the commercial prospects of our drug candidates.

Any of our current and future approved products will be subject to ongoing regulatory obligations and continued regulatory review. We may incur additional costs and devote substantial resources to comply with such requirements.

If the NMPA or other comparable regulatory authorities approve any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and record-keeping for the drug will be subject to extensive and ongoing regulatory requirements on pharmacovigilance. These requirements include submissions of safety and other post-marketing information and reports, registration, random quality control testing, adherence to any chemistry, manufacturing, and controls ("CMC"), variations, continued compliance with current cGMPs, and GCPs and potential post-approval studies for the purposes of license renewal.

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

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

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory recalls;
- fines, warning letters or holds on our clinical trials;

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- refusal by the NMPA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- refusal by the NMPA or comparable regulatory authorities to accept any of our other IND approvals and/or NDAs;
- 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.

Moreover, regulations or policies may change or additional government regulations may be finalized that could prevent, limit or delay regulatory approval of our drug candidates.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could significantly harm our business, financial condition and pipeline of pharmaceutical products.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties and other negative consequences that could have a material and adverse effect on the success of our business.

We and certain third parties we work with, such as our CROs, CDMOs and business partners, 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 hazardous materials and wastes. We generally contract with third parties for the disposal of wastewater and solid waste generated in our in-house research and development process, and we cannot guarantee our contractors could continuously maintain their qualifications with regard to such disposal. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources.

We also could incur significant costs associated with civil or criminal fines and penalties. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials. We may also incur liabilities due to injuries to our employees resulting from the use of or exposure to hazardous materials, and we do not maintain insurance covering such potential liabilities.

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In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

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

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, including the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》), the Provisions on Protection of Personal Information of Telecommunication and Internet Users (《電信和互聯網用戶個人信息保護規定》), the Cybersecurity Review Measures (《網絡安全審查辦法》) which became effective from February 15, 2022, the Data Security Law of the PRC (《中華人民共和國數據安全法》) which became effective from September 1, 2021, the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) which became effective from November 1, 2021, and the Measures for the Security Assessment of Data Export (《數據出境安全評估辦法》) which became effective from September 1, 2022. Under the Personal Information Protection Law of the PRC, in case of any personal information processing, such individual’s prior consent shall be obtained, unless other legal bases are satisfied. Further, any data processing activities, that are in relation to the sensitive personal information including but not limited to biometrics, medical health and personal information of teenagers under fourteen years old, are not allowed, unless such activities have a specific purpose, are highly necessary and strictly protective measures have been taken and separate consent has been obtained from the individuals involved.

These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance including, for example, substantial operational costs associated with changes to our data processing practices. Failure to comply with any of these laws could result in enforcement action against us, including and without limitation to fines, imprisonment of company officials and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material and adverse effect on our business, financial condition, and results of operations or prospects.

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The personal information of patients or subjects which might be involved in our clinical trials could be highly sensitive and we are subject to strict requirements under the applicable privacy protection regulations in the relevant jurisdictions. While we have adopted security policies and measures to protect our proprietary data and patients' privacy, such policies and measures might not satisfy all the requirements in every respect under the applicable laws and regulations. Data leakage and abuse and other misconduct related to data and personal information protection might not be completely avoided, due to hacking activities, human error, employee misconduct or negligence or system breakdown, among other reasons. We also cooperate with hospitals, CROs and other business partners, licensees, contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as a result of our failure. Any failure or perceived failure by us to prevent information security breaches or to comply with data/privacy policies or data/privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personal information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims.

We may be directly or indirectly subject to applicable anti-kickback laws, anti-bribery laws, fraud and abuse laws or similar healthcare and security laws and regulations, which could expose us to administrative sanctions, criminal sanctions, civil liabilities, contractual damages, reputational damage and diminished profits and future earnings.

Healthcare providers, doctors and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. When we begin commercializing our approved drugs in China, our operations become subject to various PRC fraud and abuse laws, including the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》) and PRC Criminal Law (《中華人民共和國刑法》). These laws may impact, among others, our proposed sales, marketing and education programs.

Law enforcement authorities are increasingly focusing on enforcing these laws. Efforts to ensure that our business arrangements with third parties are in compliance with applicable healthcare laws and regulations will involve substantial costs. Regulatory authorities could conclude that our business practices may not comply with current or future fraud, abuse or other healthcare laws or regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational damage, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a material adverse effect on our business and results of operations.

Furthermore, we are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing other improper advantages. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses,

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suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. See also “— Risks Relating to Our Operations — We may be unable to detect, deter and prevent all instances of bribery, fraud or other misconduct committed by our employees or third parties.”

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

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

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the “Scientific Data Measures”), which provides that enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the PRC government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. If and to the extent any data collected or generated in connection with our R&D activities of any drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, there is no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China.

On July 7, 2022, the Cyberspace Administration of China published the Measures for Security Assessment of Data Export (《數據出境安全評估辦法》) which took effect on September 1, 2022. It specifies the circumstances in which data processors providing data export shall apply for outbound data transfer security assessment with the Cyberspace Administration of China, including, among others, the outbound data transfer contains important data. On March 22, 2024, the Cyberspace Administration of China issued the Provisions on Facilitating and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》). It specifies 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 personal information (excluding sensitive personal information) of less than 100,000 individuals since the January 1 of the current year.

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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.

If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under applicable PRC laws and regulations, we may be subject to fines and other administrative penalties imposed by those government authorities.

Changes in political and economic policies, as well as the interpretation and enforcement of laws, rules and regulations, may affect our business, financial condition, results of operations and prospects.

A substantial portion of our operations are based in the PRC, our business, financial condition, results of operations and prospects may be affected by economic, political, social and legal developments in China. The Chinese government has implemented various measures to encourage economic growth and guide the allocation of resources; however, we cannot guarantee the extent to which our business operations will be able to benefit from such measures, if at all. In addition, laws, rules and regulations may also be amended from time to time, and the application, interpretation and enforcement of such evolving laws, rules and regulations may affect our business operations. Any of the foregoing may affect our business, financial condition, results of operations and prospects.

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

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

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

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Non-PRC resident enterprises that do not have establishments or premises in the PRC, or that have establishments or premises in the PRC but their income is not related to such establishments or premises are subject to PRC enterprise income tax (EIT) at the rate of 10% on dividends received from PRC companies and gains realized upon disposition of equity interests in the PRC companies pursuant to the EIT Law and other applicable PRC tax regulations and statutory documents, which may be reduced or eliminated under special arrangements or applicable treaties between the PRC and the jurisdiction where the non-resident enterprise resides. Pursuant to applicable regulations, we intend to withhold tax at a rate of 10% from dividends paid to non-PRC resident enterprise holders of our H Shares (including [REDACTED] and payments through [REDACTED]). Non-PRC resident enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty will be required to apply to the PRC tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, payment of any such refund will be subject to the PRC tax authorities’ verification. As of the Latest Practicable Date, there were no specific rules on how to levy tax on gains realized by non-resident enterprise holders of H Shares through the sale or transfer by other means of H Shares.

The interpretation and application of the relevant PRC tax laws by the PRC tax authorities, including whether and how individual income tax or EIT on gains derived by holders of our H Shares from their disposition of our H Shares may be collected, are subject to evolution and shall be determined in accordance with relevant laws and regulations in force at the time. If any such tax is collected, the value of our H Shares may be affected accordingly.

We may be subject to the approval, filing or other requirements of the CSRC or other PRC government authorities in connection with the [REDACTED] or any future capital raising activities, and, if required, we cannot predict whether we will be able to obtain such approval or complete such filing.

On February 17, 2023, the China Securities Regulatory Commission (CSRC) promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “Overseas Listing Trial Measures”) and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures have comprehensively improved and reformed the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities and will regulate both direct and indirect overseas offering and listing of PRC domestic companies’ securities. Any such domestic company that is deemed to conduct overseas offering and listing activities, including both the global offering and any further capital raising, shall file with the CSRC in accordance with the Overseas Listing Trial Measures.

We will file with the CSRC within the specific time limit as required by the Overseas Listing Trial Measures and seek guidance from the relevant regulator and/or our legal advisor to ensure our compliance in all respects. In addition, it is uncertain whether we can or how long it will take us to complete such filings. Any failure to complete such filings may impede the [REDACTED] and may subject us to sanctions by the CSRC or other PRC government authorities. Furthermore, such failure may adversely affect our ability to finance the development of our business and may have a material adverse effect on our business and financial condition.

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RISKS RELATING TO THE MANUFACTURING OF OUR DRUGS AND DRUG CANDIDATES

The manufacturing of pharmaceutical products is a complex process, and we have limited experience in manufacturing pharmaceutical products on a large commercial scale.

Currently, we rely on third-party CDMOs to manufacture our drug products for both clinical development and commercial sales. This reliance stems from our limited in-house manufacturing capabilities, as we have primarily focused on research and development to date. However, anticipating the potential approval and commercialization of additional drug candidates, we intend to establish our own manufacturing facilities in the future. Large-scale pharmaceutical manufacturing is complex, requiring strict adherence to regulatory requirements, an area where we are still developing expertise. Therefore, we cannot assure you that issues relating to our manufacturing process will not occur in the future. We also face certain risks in relation to the CDMOs we engage for manufacturing activities. See in this section “— Risks Relating to Dependence on Third Parties — We currently rely on third parties to manufacture our drug products for clinical development and commercial sales. Our business could be harmed if these third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality or price levels.”

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

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

If we are unable to meet the increasing demand for our products and future approved products by ensuring that we have adequate manufacturing resources, or if we are unable to successfully manage our anticipated growth or to precisely anticipate market demand, our business growth could be adversely affected.

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

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In anticipation of the commercialization of our drug candidates and market demand of our drug candidates, if approved, we may need to expand our manufacturing capacity. However, the timing and success of our capacity expansion are subject to significant uncertainty. Moreover, such plan is capital intensive and requires significant upfront investment, and there can be no assurance that we will be able to timely obtain such financing, if at all. Furthermore, we may not be able to fully utilize them immediately or within a reasonable period of time after we commence the operation. During the construction and ramp-up period, there may be significant changes in the pharmaceutical industry, including, among others, market demand, product and supply pricing, and customer preferences. Any adverse trends in these respects could result in operational inefficiency and excess capacity in our manufacturing facilities. We may also experience various unfavorable events in the course of developing our new manufacturing facilities, such as:

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

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

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

The quality of our products, including our commercialized drugs, and drug candidates we used for research and development purposes, will depend significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes, the quality and reliability of equipment used, the capabilities of the CDMOs we engage and our ability to ensure that they adhere to our quality control and quality assurance protocol. We operate a comprehensive quality control system, which is established and refined in accordance with the rigorous regulations and guidelines. See “Business — Quality Control.” However, we cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards or that our standard operating procedures will be complete or updated at all times. Any significant failure or deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, result in gaps in the audit of our processes, and/or harm our market reputation and relationship with business partners. Any such developments may have a material and adverse effect on our business, financial condition and results of operations.

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We may fail to adequately manage our inventories.

Our inventories consist of raw materials, work in progress and finished goods. As of December 31, 2022 and 2023, and June 30, 2024, our inventories amounted to RMB49.4 million, RMB62.3 million and RMB51.2 million, respectively. During the Track Record Period, we have not identified material inventory items requiring impairment provision. However, we cannot assure you that our inventory management system will be effective in the future and forecasts for our inventory levels are inherently uncertain. If our forecast demand is higher than actual demand, we may face risk of inventory obsolescence or write-offs, which may increase our inventory holding costs. Furthermore, as our business expands, our inventory level may increase and our inventory obsolescence risk may also increase accordingly, which could materially and adversely affect our financial condition and results of operations.

RISKS RELATING TO OUR OPERATIONS

Our future success depends in part on our ability to attract, retain and motivate senior management, qualified medical professionals and scientific employees.

We are highly dependent on the expertise of the members of our research and development team, as well as the principal members of our management. We have entered into employment agreements with our executive officers, but each of them may terminate their employment with us at any time with prior written notice.

Recruiting, retaining and motivating qualified management, scientific, clinical and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Further, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

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

Our future financial performance and our ability to commercialize our drugs and future approved drug candidates will also depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to implement our long-term development strategies. For details, see “Business — Our Development Strategies.” Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on capital and other resources.

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In addition, managing our growth and executing on our growth strategies will require, among other things, our ability to continue to identify and develop promising drug candidates in the highly competitive global and PRC pharmaceutical market, effective coordination and integration of new facilities and new teams that we may develop, successful hiring and training of personnel, as well as effective and efficient financial and management control and quality control.

All of these endeavors will require substantial management attention and efforts and significant additional expenditures. If we fail to expand at our expected pace, we may face capacity constraints in the future which may adversely affect our business and financial condition. We cannot assure you that we will be able to execute our business strategies and manage any future growth effectively and efficiently, and any failure to do so may materially and adversely affect our ability to capitalize on new business opportunities, which in turn may have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Our potential engagement in acquisitions or strategic partnerships may increase our capital requirements, cause dilution for our Shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

To enhance our growth, we may acquire businesses, products, technologies or know-how or enter into strategic partnerships that we believe would benefit us in terms of product development, technology advancement or distribution network. Any potential acquisition or strategic partnership may entail numerous risks, including, but not limited to:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities resulting in dilution to our Shareholders;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel, or failure to otherwise achieve intended synergies in the combined operations;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the counterparty, including the prospects of that party and its existing drugs or drug candidates;

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- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and
- changes in accounting principles relating to recognition and measurement of our investments that may have a significant impact on our financial results.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. 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.

We may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business.

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

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

We believe that market awareness and recognition of our brand image, and the maintenance of a positive brand image, is crucial to the success of our business. However, our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. While we will continue to promote our brands to remain competitive, we may not be successful in doing so. In addition, we may engage various third parties, such as CROs and CDMOs to expand our commercialization network and increase market access for our drugs, which can make it increasingly difficult to effectively manage our brand reputation, as we have relatively limited control over these third parties. See also in this section “— Risks Relating to Dependence on Third Parties.”

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

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

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

Failure to fully comply with the relevant regulations of social insurance and housing provident fund may adversely affect our financial position and operating results.

Pursuant to the Chinese laws and regulations, we are required to participate in the employee social welfare plan administered by local governments. Such plan consists of pension insurance, medical insurance, work-related injury insurance, maternity insurance, unemployment insurance and housing provident fund. The amount we are required to contribute for each of our employees under such plan should be calculated based on the actual income of our employees, together with the minimum and maximum level as from time to time prescribed by national laws and regulations and local authorities. Any failure to make timely and adequate social welfare contribution for its employees may trigger an order of correction from competent authority requiring the employer to make up the full amount of such overdue social welfare contribution within a specified period of time, and the competent authority may further impose fines or penalties. During the Track Record Period, we did not pay social insurance and housing provident fund in full for a small number of our employees. As a result, we may be required by competent authorities to pay the outstanding amount, and may be subject to late payment penalties or enforcement application made to the court. In addition, we use third-party agents to make contributions to social insurance and housing provident fund for some of our employees. If the relevant competent government authority is of the view that such arrangement of engaging third-party human resources agencies to pay social insurance and housing provident fund contributions does not satisfy the requirements under relevant PRC laws and regulations, we may be subject to rectification, administrative penalties, paying additional social insurance and housing provident fund contributions or other legal consequences.

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As of the Latest Practicable Date, no competent government authorities imposed administrative action, fine or penalty to us with respect to the above incidents or required us to make additional social insurance payments and housing provident fund contributions. We cannot guarantee you that the competent government authorities will not require us to rectify our arrangements, make additional payments on social insurance and housing provident fund or impose any penalties on us. Such actions may have a material and adverse impact on our financial position and results of operation.

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

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

As of the Latest Practicable Date, our construction on a parcel of land in Shijiazhuang had been delayed from the construction commencement date as stipulated in the relevant land grant contracts. We may be subject to liquidated damages as set out in the land grant contracts and idle land fees imposed by the relevant PRC government authorities, and in the worst case, forfeiture of land use rights without compensation. As advised by our PRC Legal Advisor, as of the Latest Practicable Date, the land parcel was not identified as “idle land” by the competent regulatory authorities, and we had not been subject to any related idle land fees or other penalties. However, there is no assurance that such land would not be identified as “idle land” in the future and therefore we would be subject to losses and penalties, which could affect our business, financial condition, results of operations and prospects.

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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 industry-standard benefit plans in accordance with relevant laws and regulations, based on our assessment of our operational needs and industry practice. 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. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

In line with general market practice, we have elected not to maintain certain types of insurances, such as business interruption insurance or key person insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

Changes in international trade policies and political tensions may adversely impact our business and results of operations.

We are susceptible to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. Tensions and political concerns among countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. Political relationships with foreign countries and regions may affect the prospects of our relationship with third parties, such as business partners, suppliers and future customers. There can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships among the relevant foreign countries or regions. Any tensions and political concerns among the relevant foreign countries or regions may cause a decline in the demand for our future products and adversely affect our business, financial condition, results of operations, cash flows and prospects. Rising trade and political tensions could reduce levels of trades, investments, technological exchanges and other economic activities among the other countries and regions, which would have an adverse effect on global economic conditions, the stability of global financial markets, and international trade policies.

Any rising trade and political tensions or unfavorable government policies on international trade, such as capital controls or tariffs, may affect the competitive position of our drug products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or prevent us from selling our drug products in certain countries. In particular, if any new tariffs, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated, such changes

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could have an adverse effect on our business, financial condition and results of operations. In addition, our results of operations could be adversely affected if any such tensions or unfavorable government trade policies harm the Chinese economy or the global economy in general.

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

In the future, we may explore market opportunities overseas, where we believe there is substantial demand for our products, and we may identify and collaborate with reputable local partners or global MNCs that have proven track record to maximize the global value of our drugs and drug candidates.

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

- efforts to enter into collaboration or licensing arrangements with third parties may increase our expenses or divert our management’s attention from the development of drug candidates;
- changes in a specific country’s or region’s political and cultural climate or economic condition;
- differing regulatory requirements for drug approvals and marketing internationally;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potentially reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

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

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

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

The occurrence of a disaster or a prolonged outbreak of an epidemic illness, including the COVID-19 pandemic, or other adverse public health developments in which we operate our business could materially disrupt our business and operations. These uncertain and unpredictable factors include, but are not limited to, adverse effects on the economy, potential delays of our ongoing and future clinical trials, and disruptions to the operations of our business partners and CROs.

Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of the foregoing events and other events beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial condition and results of operations.

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

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

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

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

Our risk management and internal control systems may not be thorough or effective in all respects.

We seek to establish risk management and internal control systems consisting of an organizational framework, policies, procedures and risk management methods that are appropriate for our business operations, and seek to continue to improve these systems. See “Business — Risk Management and Internal Control” for further details. However, due to the inherent limitations in the design and implementation of risk management and internal control systems, we cannot assure that our risk management and internal control systems will be able to identify, prevent and manage all risks. Our internal procedures are designed to monitor our operations and ensure their overall compliance. However, our internal control procedures may be unable to identify all non-compliance incidents in a timely manner or at all. It is not always possible to timely detect and prevent fraud and other misconduct committed by our employees or third parties, and the precautions we take to prevent and detect such activities may not be effective.

Furthermore, we cannot assure you that our risk management and internal control systems will be effectively implemented. Since our risk management and internal control systems depend on their implementation by our employees, we cannot assure you that all of our employees will adhere to such policies and procedures, and the implementation of such policies and procedures may involve human errors or mistakes, which may materially and adversely affect our business and results of operations. Moreover, as we are likely to offer a broader and more diverse range of services and solutions in the future, the expansion and diversification of our service offerings will require us to continue to enhance our risk management capabilities. If we fail to adapt our risk management policies and procedures to our evolving business in a timely manner, our business, financial condition and results of operations could be materially and adversely affected.

RISK FACTORS

You may experience difficulties in effecting service of process upon or enforcing foreign judgments against us or our management.

Cross-border service of process presents inherent uncertainties. Most of our assets are situated in the PRC and most of our directors and officers reside in the PRC. Therefore, there remains the possibility that it may be difficult to effect service of process outside the PRC upon most of our directors and officers, including with respect to matters arising under applicable securities laws. The PRC does not have treaties providing for the reciprocal recognition and enforcement of civil case judgments of courts with the United States and many other countries. Consequently, you may experience difficulties in enforcing against us or our directors or officers in the PRC any judgments obtained from courts outside of the PRC.

On July 14, 2006, Hong Kong and China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》), or the Arrangement, pursuant to which a party with a final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with a final judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. On January 18, 2019, the Supreme People’s Court and the Hong Kong Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》), which has come into effect on January 29, 2024 and superseded the Arrangement, or the New Arrangement, which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong and the mainland. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. After the New Arrangement became effective, a judgment rendered by a Hong Kong court can generally be recognized and enforced in the PRC even if the parties in the dispute do not enter into a choice of court agreement in writing. However, we cannot guarantee that all judgments made by Hong Kong courts will be recognized and enforced in the PRC, as whether a specific judgment will be recognized and enforced is still subject to a case-by-case examination by the relevant court in accordance with the New Arrangement.

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RISKS RELATING TO THE [REDACTED]

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

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

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

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

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

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

Prior to the [REDACTED], there has not been a [REDACTED] for our H Shares. Future [REDACTED] or perceived [REDACTED] of significant amounts of our H Shares or [REDACTED] of the Unlisted Shares, if any, by specific Shareholders subject to certain regulatory requirements, after the [REDACTED] could result in a significant decrease in the prevailing [REDACTED] of our H Shares. Nevertheless, after these restrictions lapse or if they are waived, future [REDACTED] of significant amounts of our H Shares in the [REDACTED] or the perception that these [REDACTED], or [REDACTED] of existing Unlisted Shares, if any, may occur could significantly decrease the prevailing [REDACTED] of our H Shares and our ability to raise equity capital in the future.

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

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

There can be no assurance whether and when we will pay dividends in the future, and payment of dividends is subject to applicable PRC laws.

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

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

Our management may spend the [REDACTED] from the [REDACTED] in ways you may not agree with or that do not yield a favorable return to our Shareholders. For details of our intended [REDACTED], see the section headed “Future Plans and [REDACTED].” However, our management will have discretion as to the actual application of our [REDACTED]. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the [REDACTED] from the [REDACTED].

RISK FACTORS

The industry facts, statistics and forecasts in this document that were obtained from various government publications and the industry report have not been independently verified.

This document, particularly the section headed "Industry Overview," contains information and statistics relating to the healthcare market. Such information and statistics have been derived from third-party reports, either commissioned by us or publicly accessible, and other publicly available sources. The information and statistics from such sources have not been independently verified by us, the Sole Sponsor, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED] and other [REDACTED], any of our or their respective directors, officers or representatives or any other party, other than CIC, involved in the [REDACTED] and no representation is given as to its accuracy. Collection methods of such information may be flawed or ineffective, or there may be discrepancies between published information and market practice, which may result in the statistics being inaccurate. You should therefore not place undue reliance on such information. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. In any event, you should consider carefully the importance placed on such information or statistics.

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

This document contains certain future plans and forward-looking statements about us that are made based on the information currently available to our management. The forward-looking information contained in this document is subject to certain risk and uncertainties. Whether we implement those plans, or whether we can achieve the objectives described in this document, will depend on various factors including the market conditions, our business prospects, actions by our competitors and the global financial situations.

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].

We strongly caution you not to rely on any information contained in press articles or other media regarding us and the [REDACTED]. Prior to the publication of this document, there has been press and media coverage regarding us. Such press and media coverage may include references to certain information that does not appear in this document, including certain operating and financial information and projections, valuations and other information. We have not authorized the disclosure of any such information in the press or media and do not accept any responsibility for any such press or media coverage or the accuracy or completeness of any such information or publication. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such information or publication. To the extent that any such information is inconsistent or conflicts with the information contained in this document, we disclaim responsibility for it and you should not rely on such information.

WAIVERS AND EXEMPTION

In preparation for the [REDACTED], we have sought the following waivers from strict compliance with the relevant provisions of the Listing Rules and a certificate of exemption from strict compliance with the relevant provisions of the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

MANAGEMENT PRESENCE IN HONG KONG

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

Since all our business operations are not principally located, managed or conducted in Hong Kong, and our Directors consider that the relocation of our executive Directors to Hong Kong or the appointment of additional executive Directors who will be ordinarily resident in Hong Kong would not be beneficial to, or appropriate for, our Company and therefore would not be in the best interests of our Company and our Shareholders as a whole, our Company does not, and, for the foreseeable future, will not, have two executive Directors who are ordinarily resident in Hong Kong for the purpose of satisfying the requirements under Rules 8.12 and 19A.15 of the Listing Rules.

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

- (i) **Authorized representatives:** both of our Company’s authorized representatives, Ms. Xu Yanjun (徐艷君) and Mr. Ng Tung Ching Raphael (吳東澄), will act as our Company’s principal channels of communication with the Stock Exchange. Accordingly, the authorized representatives of our Company will be able to meet with the relevant members of the Stock Exchange on reasonable notice and will be readily contactable by telephone, facsimile (if any) and/or email.

Each of the authorized representatives of our Company has means of contacting all Directors (including our independent non-executive Directors) promptly at all times as and when the Stock Exchange proposes to contact a Director with respect to any matter;

- (ii) **Directors:** each Director has provided their mobile phone number, office phone number, fax number, if any, and e-mail address to the authorized representatives of our Company and the Stock Exchange, and in the event that any Director expects to travel or otherwise be out of the office, they will provide the phone number of the place of their accommodation to the authorized representatives.

Each of our Directors not ordinarily residing in Hong Kong possesses or can apply for valid travel documents to visit Hong Kong and will be able to meet with the relevant members of the Stock Exchange within a reasonable period of time;

WAIVERS AND EXEMPTION

- (iii) **Compliance advisor:** we have appointed First Shanghai Capital Limited as our Compliance Advisor, in compliance with Rule 3A.19 of the Listing Rules, who will, among other things and in addition to the authorized representatives and our Directors, also act as an additional channel of communication with the Stock Exchange from the [REDACTED] to the date when our Company complies with Rule 13.46 of the Listing Rules in respect of its financial results for the first full financial year immediately following the [REDACTED]. Pursuant to the Note of Rule 3A.23, the Compliance Advisor will have access at all times to our authorized representatives, our Directors and other officers. We shall also ensure that our authorized representatives, Directors and other officers will promptly provide such information and assistance as the Compliance Advisor may need or may reasonably require in connection with the performance of the Compliance Advisor’s duties as set forth in Chapter 3A of the Listing Rules. We shall ensure that there are adequate and efficient means of communication among our Company, our authorized representatives, our Directors, other officers and the Compliance Advisor, and will keep the Compliance Advisor fully informed of all communications and dealings between the Stock Exchange and us.

Any meeting between the Stock Exchange and our Directors will be arranged through the authorized representatives or the Compliance Advisor or directly with our Directors within a reasonable time frame. We will inform the Stock Exchange promptly in respect of any changes in our authorized representatives and/or our Compliance Advisor; and

- (iv) **Legal advisors:** we will also retain legal advisors to advise on on-going compliance requirements as well as other issues arising under the Listing Rules and other applicable laws and regulations of Hong Kong after the [REDACTED].

JOINT COMPANY SECRETARIES

Pursuant to Rules 3.28 and 8.17 of the Listing Rules, the company secretary must be an individual who, by virtue of their academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of the company secretary. The Stock Exchange considers the following academic or professional qualifications to be acceptable:

- (i) a member of The Hong Kong Chartered Governance Institute;
- (ii) a solicitor or barrister (as defined in the Legal Practitioners Ordinance); and
- (iii) a certified public accountant (as defined in the Professional Accountants Ordinance).

Pursuant to Note 2 to Rule 3.28 of the Listing Rules, in assessing “relevant experience,” the Stock Exchange will consider the individual’s:

- (i) length of employment with the issuer and other issuers and the roles they played;

WAIVERS AND EXEMPTION

- (ii) familiarity with the Listing Rules and other relevant law and regulations including the Securities and Futures Ordinance, the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code;
- (iii) relevant training taken and/or to be taken in addition to the minimum requirement of taking not less than 15 hours of relevant professional training in each financial year under Rule 3.29 of the Listing Rules; and
- (iv) professional qualifications in other jurisdictions.

Pursuant to paragraph 13 of Chapter 3.10 of the Guide for New Listing Applicants, the Stock Exchange will consider a waiver application by an issuer in relation to Rules 3.28 and 8.17 of the Listing Rules based on the specific facts and circumstances. Factors that will be considered by the Stock Exchange include:

- (a) whether the issuer has principal business activities primarily outside Hong Kong;
- (b) whether the issuer was able to demonstrate the need to appoint a person who does not have the Acceptable Qualification (as defined under paragraph 11 of Chapter 3.10 of the Guide for New Listing Applicants) nor Relevant Experience (as defined under paragraph 11 of Chapter 3.10 of the Guide for New Listing Applicants) as a company secretary; and
- (c) why the directors consider the individual to be suitable to act as the issuer’s company secretary.

Further, pursuant to paragraph 13 of Chapter 3.10 of the Guide for New Listing Applicants, such waiver, if granted, will be for a fixed period of time (the “**Waiver Period**”) and on the following conditions:

- (a) the proposed company secretary must be assisted by a person who possesses the qualifications or experience as required under Rule 3.28 of the Listing Rules and is appointed as a joint company secretary throughout the Waiver Period; and
- (b) the waiver will be revoked if there are material breaches of the Listing Rules by the issuer.

Our Company considers that while it is important for the company secretary to be familiar with the relevant securities regulation in Hong Kong, they also need to have experience relevant to our Company’s operations, nexus to the Board and close working relationship with the management of our Company in order to perform the function of a company secretary and to take the necessary actions in the most effective and efficient manner. It is for the benefit of our Company to appoint a person who is familiar with our Company’s business and affairs as company secretary.

WAIVERS AND EXEMPTION

We have appointed Mr. He Chengming (何成明) (“**Mr. He**”) and Mr. Ng Tung Ching Raphael (吳東澄) (“**Mr. Ng**”) as our joint company secretaries. Since Mr. He does not possess a qualification stipulated in Rule 3.28 of the Listing Rules, he is not able to solely fulfill the requirements as a company secretary of a listed issuer stipulated under Rules 3.28 and 8.17 of the Listing Rules. To support Mr. He, we have appointed Mr. Ng, an associate member of both The Hong Kong Chartered Governance Institute (formerly known as the Hong Kong Institute of Chartered Secretaries) and The Chartered Governance Institute in the United Kingdom, who meets the requirements under Rules 3.28 and 8.17 of the Listing Rules, as a joint company secretary to provide assistance, for a three-year period from the [REDACTED] so as to enable Mr. He to acquire the relevant experience (as required under Rule 3.28(2) of the Listing Rules) to duly discharge his duties.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules in relation to the appointment of Mr. Ng as our joint company secretary. Pursuant to Chapter 3.10 of the Guide for New Listing Applicants, such waiver [has been] granted on the conditions that:

- (i) Mr. Ng is appointed as a joint company secretary to assist Mr. He in discharging his functions as a company secretary and in gaining the relevant experience under Rule 3.28 of the Listing Rules;
- (ii) our Company will further ensure that Mr. He has access to the relevant training and support to enable him to familiarize himself with the Listing Rules and the duties required of a company secretary of an issuer listed on the Stock Exchange. Our Hong Kong legal advisors have provided training to Mr. He on the principal requirements of the Listing Rules and the Hong Kong laws and regulations applicable to our Company after the [REDACTED]. In addition, Mr. He will endeavor to familiarize himself with the Listing Rules, including any updates thereto, during the three-year period from the [REDACTED];
- (iii) Mr. He has confirmed that he will attend no less than 15 hours of training courses on the Listing Rules, corporate governance, information disclosure, investor relations as well as the functions and duties of a company secretary of a Hong Kong listed issuer during each financial year as required under Rule 3.29 of the Listing Rules;
- (iv) before the expiry of Mr. He’s initial term of appointment as the company secretary of our Company, our Company will evaluate his experience in order to determine if he has acquired the qualifications required under Rule 3.28 of the Listing Rules; and
- (v) this waiver will be revoked immediately if and when Mr. Ng ceases to provide such assistance during the three-year period, and we undertake to re-apply to the Stock Exchange for a waiver in the event that Mr. Ng ceases to meet the requirements under Rule 3.28 of the Listing Rules or otherwise ceases to serve as a joint company secretary of our Company. In addition, this waiver is subject to revocation in the event of any material breaches of the Listing Rules by our Company.

WAIVERS AND EXEMPTION

For biographical information of Mr. He and Mr. Ng, see the section headed “Directors, Supervisors and Senior Management.”

WAIVER FROM STRICT COMPLIANCE WITH RULE 4.04(1) OF THE LISTING RULES AND EXEMPTION FROM STRICT COMPLIANCE WITH SECTION 342(1) IN RELATION TO PARAGRAPH 27 OF PART I AND PARAGRAPH 31 OF PART II OF THE THIRD SCHEDULE TO THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

Requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Section 342(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires, subject to section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, all prospectuses to state the matters specified in Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance and set out the reports specified in Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

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

According to paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, a listing applicant is required to include in its prospectus a report by the auditors of the listing applicant with respect to profits and losses and assets and liabilities in respect of each of the three financial years immediately preceding the issue of the prospectus.

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

WAIVERS AND EXEMPTION

Requirements under the Listing Rules

Rule 4.04(1) of the Listing Rules requires that the consolidated results of the listing applicant and its subsidiaries in respect of each of the three financial years immediately preceding the issue of the prospectus of the listing applicant, or such shorter period as may be acceptable to the Stock Exchange, be included in the accountants’ report of the prospectus.

Rule 13.49(1) of the Listing Rules requires issuers to publish preliminary financial results not later than three months after the end of each financial year.

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

Requirements under the Guide for New Listing Applicants

[REDACTED]

Grounds for waiver and exemption application

The financial year of our Company ends on December 31. This document [contains] the consolidated results of our Group for the two years ended December 31, 2023 and the [REDACTED], but does not include the consolidated results of our Group as required under Rule 4.04(1) of the Listing Rules, paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

WAIVERS AND EXEMPTION

The strict compliance with the requirements under Rule 4.04(1) of the Listing Rules, paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance would be unduly burdensome for the following reasons:

- (i) our Company is an innovation-driven biopharmaceutical company committed to the R&D and commercialization of novel drugs to address clinical needs in China and globally, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules;
- (ii) there would not be sufficient time for our Company and the reporting accountants of our Company (the “**Reporting Accountants**”) to finalize the audited consolidated financial statements of our Group for the year [ended] December 31, 2024 for inclusion in this document. It would be unduly burdensome for our Company and the Reporting Accountants to undertake the considerable amount of work required to prepare, update and finalize the Accountants’ Report to cover such additional period within a short period of time. If the results for the full year ended December 31, 2024 are to be included in this document, there would be a significant delay in the [REDACTED] timetable;
- (iii) our Company [has included] in this document (a) the Accountant’s Report covering the two years ended December 31, 2023 and the [REDACTED] in accordance with Rule 18A.06 of the Listing Rules, (b) the unaudited preliminary financial information of our Group for the year ended December 31, 2024 and a commentary on the results for the year, which has been agreed with our Group’s Reporting Accountants, following their review under Practice Note 730 “Guidance for Auditors Regarding Preliminary Announcements of Annual Results” issued by the Hong Kong Institute of Certified Public Accountants, and such disclosure is no less than the content requirements for a preliminary results announcement under Rule 13.49 of the Listing Rules, and (c) the information regarding the recent development of our Group subsequent to the Track Record Period and up to the Latest Practicable Date;
- (iv) notwithstanding that the financial results set out in this document are only for the two years ended December 31, 2023 and the [REDACTED] in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and requirements under the Companies (Winding up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements;
- (v) furthermore, as Chapter 18A of the Listing Rules provides track record period of two years for biotech companies in terms of financial disclosure, strict compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance would be unduly burdensome for our Company as this would require additional work to be performed by us and our Reporting Accountants;

WAIVERS AND EXEMPTION

- (vi) our Directors and the Sole Sponsor [confirm] that after performing all due diligence work which they consider appropriate, up to the date of this document, there has been no material adverse change to the financial and trading positions or prospects of our Company since [REDACTED] (immediately following the date of the latest audited statement of financial position in the accountant's report set out in Appendix I to this document) to the date of this document and there has been no event which would materially affect the information shown in the Accountants' Report as set out in Appendix I to this document since [REDACTED];

[REDACTED]

WAIVERS AND EXEMPTION

The waiver and exemption application

[REDACTED]

We have also applied for, and the SFC [has granted] us, a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance from strict compliance with the requirements under paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance on the conditions that:

- (i) the particulars of this exemption are set out in this document; and
- (ii) this document will be issued on or before [REDACTED] and the Company’s H Shares will be [REDACTED] on or before [REDACTED].

WAIVERS AND EXEMPTION

NON-EXEMPT CONTINUING CONNECTED TRANSACTION

We have entered into, and are expected to continue to engage in a transaction which will constitute non-exempt continuing connected transaction of our Company under the Listing Rules upon the [REDACTED]. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted,] waivers from strict compliance with (i) the announcement, circular and independent Shareholders’ approval requirements under Rule 14A.105 of the Listing Rules; (ii) the requirement of limiting the term of continuing connected transaction to three years or less under Rule 14A.52 of the Listing Rules; and (iii) the requirement of setting a monetary annual cap set out in Rule 14A.53 of the Listing Rules. For further details, see the section headed “Connected Transaction” in this document.

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]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
Executive Directors		
Ms. Xu Yanjun (徐艷君)	Room 7-3-1005 Evergrande Oasis Hi-Tech District Changchun, Jilin Province PRC	Chinese
Dr. Li Jia Kui (李嘉逵)	Room 1-2412, Building 2 No. 88, Huizhan West Road Hi-tech District Jinan, Shandong Province PRC	American
Dr. Shih Cheng-Kon (史澂空)	6 Tom Thumb Ln Danbury CT 06811 USA	American
Non-executive Directors		
Ms. Li Huiying (李惠英)	Room 5007 Sihuan Pharm Living Area No. 13, Guangyuan West Street Zhangjiawan Town Tongzhou District, Beijing PRC	Chinese
Mr. Yu Lifeng (尉麗峰)	Room 5-1-1402 Zhongyang Xinhe Waterfront No. 375, Youyi North Street Xinhua District Shijiazhuang, Hebei Province PRC	Chinese
Ms. Chen Yanling (陳燕玲)	Flat C, 8/F, Block 10 No. 1, Beacon Hill Road One Beacon Hill, Kowloon Tong Kowloon Hong Kong	Chinese

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
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Independent Non-executive Directors

Mr. Liu Shuo (劉碩)	Room 805, Building 3 New City International Apartment No. 6, Chaowai Street Chaoyang District, Beijing PRC	Chinese
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Ms. Wang Yu (王宇)	Room 101, Building 12 No. 1, Lincui East Road Chaoyang District, Beijing PRC	Chinese
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Mr. Fan Chi Chiu (范智超)	Room 408, 4/F Block E, Kam Wei House Kam Tai Court Sha Tin Hong Kong	Chinese
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SUPERVISORS

Name	Address	Nationality
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Mr. Lu Benyu (盧本玉)	Room 372, 7/F Building 68, Dongguoyuan Tongzhou District, Beijing PRC	Chinese
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Mr. Wang Xiaoping (王曉平)	Room 2104, Unit 2 Building 36, Hou Nan Cang Tongzhou District, Beijing PRC	Chinese
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Ms. Yue Xin (岳鑫)	No. 268 Qianying Village Taihu Town Tongzhou District, Beijing PRC	Chinese
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For further details regarding our Directors and Supervisors, please see the section headed "Directors, Supervisors and Senior Management" in this document.

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

Sole Sponsor [REDACTED]

**China International Capital Corporation
Hong Kong Securities Limited**
29/F, One International Finance Centre
1 Harbour View Street
Central
Hong Kong

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Legal Advisors to our Company

as to Hong Kong and U.S. laws:

Kirkland & Ellis

26/F, Gloucester Tower
The Landmark
15 Queen’s Road Central
Hong Kong

as to PRC law:

Fangda Partners

24/F, HKRI Centre Two
HKRI Taikoo Hui
288 Shi Men Yi Road
Shanghai
PRC

Legal Advisors to the Sole Sponsor

as to Hong Kong and U.S. laws:

DLA Piper Hong Kong

25/F, Three Exchange Square
8 Connaught Place
Central
Hong Kong

as to PRC law:

Jingtian & Gongcheng

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

Auditor and Reporting Accountants

Ernst & Young

*Certified Public Accountants
Registered Public Interest Entity Auditor*
27/F, One Taikoo Place
979 King’s Road
Quarry Bay
Hong Kong

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Industry Consultant

China Insights Industry Consultancy

Limited

10/F, Block B

Jing’an International Center

88 Puji Road

Jing’an District, Shanghai

PRC

Compliance Advisor

First Shanghai Capital Limited

19/F, Wing On House

71 Des Voeux Road Central

Hong Kong

[REDACTED]

CORPORATE INFORMATION

Registered Office in PRC	203C507 Beijing-Tianjin-Hebei Collaborative Innovation Demonstration Park No. 769 Taihang Street, Hi-Tech District Shijiazhuang, Hebei Province PRC
Head Office and Principal Place of Business in PRC	9/F North Tower of CP Center No. 20 Jin He East Avenue Chaoyang District, Beijing PRC
Principal Place of Business in Hong Kong	46/F Hopewell Centre 183 Queen’s Road East Wan Chai Hong Kong
Company’s Website	<u>www.xuanzhubio.com</u> <i>(Information contained in this website does not form part of this document)</i>
Joint Company Secretaries	Mr. He Chengming (何成明) Room 2702, Building 12 Phase I, Shenhui Garden Danshui Street, Huiyang District Huizhou, Guangdong Province PRC Mr. Ng Tung Ching Raphael (吳東澄) <i>(ACG, HKACG)</i> FT C, 66/F, Tower 2 Grand Promenade Sai Wan Ho Hong Kong

CORPORATE INFORMATION

Authorized Representatives

Ms. Xu Yanjun (徐艷君)
Room 7-3-1005
Evergrande Oasis
Hi-Tech District
Changchun, Jilin Province
PRC

Mr. Ng Tung Ching Raphael (吳東澄)
FT C, 66/F, Tower 2
Grand Promenade
Sai Wan Ho
Hong Kong

Audit Committee

Mr. Fan Chi Chiu (范智超) (*Chairperson*)
Ms. Chen Yanling (陳燕玲)
Ms. Wang Yu (王宇)

Remuneration and Appraisal Committee

Ms. Wang Yu (王宇) (*Chairperson*)
Ms. Xu Yanjun (徐艷君)
Mr. Liu Shuo (劉碩)

Nomination Committee

Mr. Liu Shuo (劉碩) (*Chairperson*)
Ms. Xu Yanjun (徐艷君)
Ms. Wang Yu (王宇)

[REDACTED]

CORPORATE INFORMATION

Principal Banks

**Industrial and Commercial Bank of
China Limited, Haikou World Trade
Center Branch**

1/F, World Trade Center
No. 2 East World Trade Road
Longhua District, Haikou City
Hainan Province
PRC

**China Merchants Bank Co., Ltd.,
Shijiazhuang Hi-Tech District Branch**

No. 1 Building
Science and Technology Center
No. 136 Huanghe Avenue
Hi-Tech District, Shijiazhuang City
Hebei Province
PRC

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from different official government publications, available sources from public market research and other sources from independent suppliers, and from the independent industry report prepared by China Insights Consultancy (the “CIC Report”). We engaged China Insights Consultancy, an independent industry advisor, to prepare the CIC Report in connection with the [REDACTED]. The information from official government sources has not been independently verified by us, [the Sole Sponsor, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED]], any of the [REDACTED], any of their respective directors and advisors, or any other persons or parties involved in the [REDACTED], and no representation is given as to its accuracy.

GLOBAL AND CHINA PHARMACEUTICAL MARKETS

Pharmaceutical products can be categorized into (i) innovative drugs and (ii) generic drugs and biosimilars. Innovative drugs typically refer to pharmaceutical products that contain a novel active pharmaceutical ingredient (API) or combination of APIs that has not been previously approved for therapeutic use. Generic drugs are identical copies of innovative drugs and are marketed after the innovative drugs’ patents expire. Biosimilars are highly similar to the approved innovative drugs in terms of safety and efficacy in clinical use, but may not contain a molecular structure identical to such innovative drugs. Typically, innovative drugs have higher technical barriers and enjoy marketing exclusivity and significant pricing power, while generic drugs and biosimilars offer more affordability which could potentially lower healthcare costs for consumers.

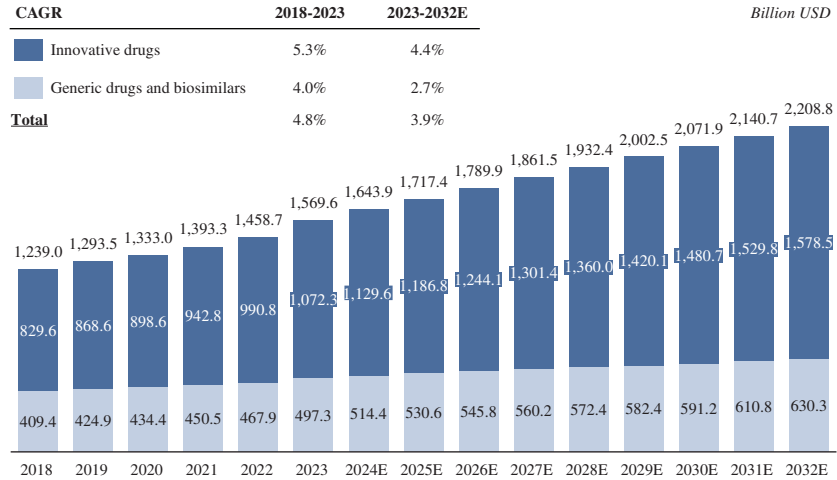
The pharmaceutical markets globally and in China have experienced significant growth in recent years, fueled by the expansion of both the innovative drugs and generic drugs (including biosimilars) sectors. The global pharmaceutical market rose from US\$1,239.0 billion in 2018 to US\$1,569.6 billion in 2023 at a CAGR of 4.8% and is expected to reach US\$2,208.8 billion in 2032 at a CAGR of 3.9% from 2023.

The pharmaceutical market in China is also poised for accelerated growth in the coming years. Robust healthcare needs, expanding aging populations, and the development of innovative drugs provide a strong foundation of expansion. Furthermore, supportive government policies, including systematic reforms to the pharmaceutical industry and the expansion of the national reimbursement drug list, are creating a favorable environment for sustained growth. As a result, the market is forecasted to reach RMB3,066.9 billion in 2032, representing a CAGR of 6.3% from 2023.

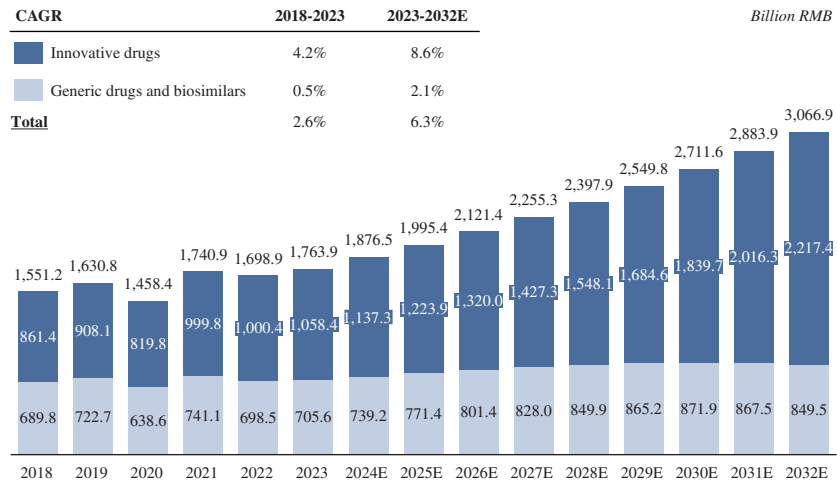
INDUSTRY OVERVIEW

The following charts set forth the market size of pharmaceutical markets globally and in China, categorized by drug types.

Global Pharmaceutical Market Size, 2018-2032E



China’s Pharmaceutical Market Size, 2018-2032E

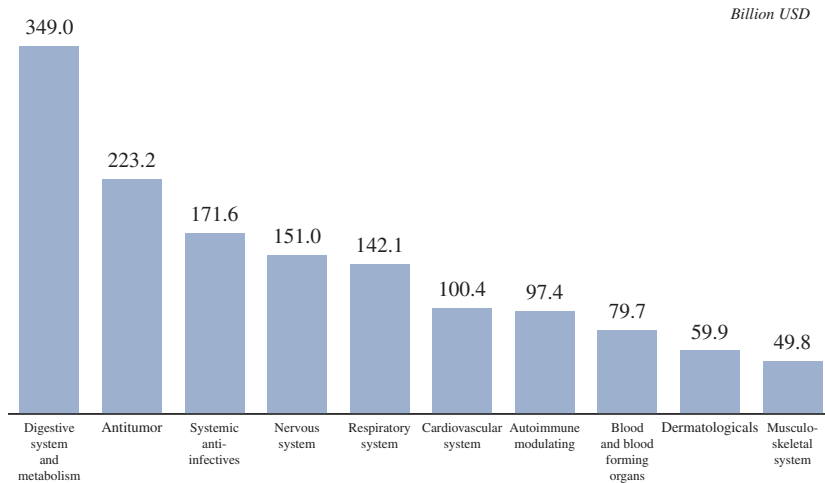


Source: WHO, National Bureau of Statistics, NHC, Annual reports, China Insights Consultancy

INDUSTRY OVERVIEW

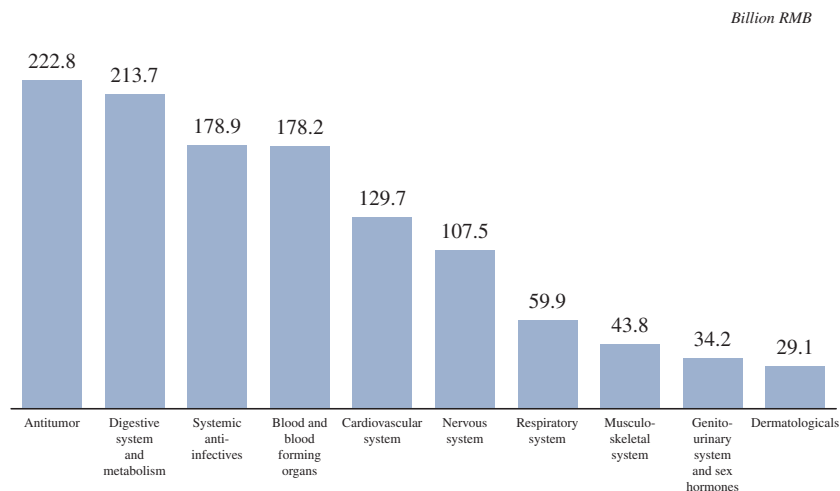
As illustrated in the charts below, anti-tumor and digestive system and metabolism therapeutics are the top two therapeutic areas that dominate the pharmaceutical markets globally and in China in 2023.

Top 10 Therapeutic Areas in terms of Revenue Globally



Source: WHO, IARC, Annual reports, China Insights Consultancy

Top 10 Therapeutic Areas in terms of Revenue in China



Source: National Bureau of Statistics, NHC, Annual reports, China Insights Consultancy

China’s Innovative Drug Market

Once dominated by generic drugs, China’s pharmaceutical landscape has undergone significant development with the innovative drug market expanding rapidly in recent years. Following the implementation of favorable government policies for drug innovation, China has witnessed a significant growth in NDAs granted by the NMPA for innovative drugs, from nine in 2018 to 40 in 2023. The pharmaceutical industry in China is gradually transitioning from

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sales-driven to R&D- and innovation-driven, with its focus being shifted from producing generic drugs to investing in the development of innovative drugs. Accordingly, China’s innovative drug market size has reached RMB1,058.4 billion in 2023, growing from RMB861.4 billion in 2018 at a CAGR of 4.2%. The innovative drug market size in China is expected to grow even faster in the near future, reaching RMB2,217.4 billion in 2032 at a CAGR of 8.6% from 2023.

Market Drivers and Entry Barriers

The growth of China’s innovative drug market is driven primarily by the following factors:

Expanding patient base with unmet needs. China’s aging population and evolving lifestyles are contributing to a larger patient pool grappling with chronic diseases and cancers. This fuels demand for innovative drugs. For example, although there are multiple types of proton pump inhibitors (PPIs) available for the treatment of peptic ulcers and reflux diseases, the current PPIs are primarily metabolized in the liver and excreted via urine, posing potential risks to patients with impaired liver or kidney function, particularly the elderly. This indicates the need for more innovative therapies to improve prognosis and outcome.

Emergence of new modalities and technologies. The innovative drug market in China is driven by ongoing technological advancements that enhance drug efficacy and safety. Breakthroughs such as antibody-drug conjugates (ADCs) and a wider selection of targets are boosting the therapeutic potential of targeted anti-cancer drugs. Small molecule drugs such as kinase inhibitors, epigenetic inhibitors, and proteasome inhibitors remain at the forefront. With the emergence of artificial intelligence and computer-assisted drug development, new technologies like antibody design tools leveraging artificial intelligence and computer-assisted drug development, are further reshaping the landscape and accelerating the discovery and production of innovative medications.

Growing R&D investment and collaboration. A surge in R&D investments from pharmaceutical and biotechnology companies is propelling the market. These investments target novel therapeutic targets and enhancement of existing treatments, driving the development of groundbreaking drugs. Collaborations between pharmaceutical companies and academic institutions are also crucial. These strategic alliances capitalize on complementary expertise and resource sharing, accelerating the drug discovery and development processes, ultimately contributing to the growth of China’s cutting-edge pharmaceutical landscape.

Favorable government policies. Government support remains a key driver of innovative drug research and development. China aims to shift its pharmaceutical industry away from developing “me too” or “me better” drugs and relying on drug in-licensing and towards fostering end-to-end innovation. The “Fourteenth Five-Year Plan for National Economic and Social Development of the PRC and the Outline of Vision Goals for 2035 (《中華人民共和國國民經濟和社會發展第十四個五年規劃和2035年遠景目標綱要》)” released in 2021 reinforces the central role of innovation in China’s modernization and prioritizes R&D

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breakthroughs in medical science. The NMPA’s streamlined NDA review procedures have further contributed to significant growth in approvals for Class 1 innovative drugs. For more details on China’s recent healthcare reform, see the section headed “Regulatory Overview.”

Significant entry barriers remain in China’s innovative drug market, which include regulatory, technological, capital, and talent-related challenges. The highly regulated nature of the market demands extensive experience and familiarity with compliance requirements. Technological hurdles arise from the need to discover novel mechanisms of action and navigate a complex and multi-stage development process, which requires specialized expertise and resources. The capital-intensive and time-consuming nature of innovative drug development creates financial barriers, particularly for smaller companies. Additionally, the industry’s demand for highly skilled professionals with multidisciplinary expertise in areas such as biochemistry, medicine, business development, and marketing, poses a significant talent barrier. These combined factors make it difficult for new entrants to compete effectively in China’s innovative drug market.

CHINA’S DIGESTIVE DISEASE DRUG MARKET

Digestive diseases are those that affect the gastrointestinal tract, liver, pancreas, and gallbladder. Peptic ulcers, reflux esophagitis, inflammatory bowel disease, among others, are some of the most common digestive diseases in China, each affecting a significant patient population.

Peptic Ulcers

Peptic ulcer (PU), a common digestive ailment affecting millions worldwide, is a defect or erosion in the lining of the stomach (gastric ulcer) or the first part of the small intestine (duodenal ulcer, or DU). These lesions occur when the protective mechanisms that prevent the acidic digestive fluids from damaging the stomach and intestinal lining are disrupted. PU is characterized by abdominal pain, which may be burning or gnawing in nature, and can be accompanied by other symptoms such as nausea, vomiting and loss of appetite.

PU represents a significant health concern in China. The prevalence of PU in China increased from 71.4 million in 2018 to 73.5 million in 2023 at a CAGR of 0.6%, and is expected to increase to 81.2 million in 2032 at a CAGR of 1.1% from 2023. Approximately 75% of PU cases were DU.

While lifestyle modifications such as quitting smoking, reducing alcohol consumption and modifying dietary habits, and, in some cases, surgical intervention, may be recommended, pharmaceutical treatment remains the mainstay of PU management. Medications commonly used include antisecretory drugs to reduce acid production, antibiotics to eradicate *Helicobacter pylori* infection, and medications to protect the gastric lining. H₂ receptor antagonists (H₂RAs) are a class of antisecretory drugs developed earliest but with mild antisecretory effect. Proton pump inhibitors (PPIs) are currently the most prevalent option for patients with PU, bringing stronger antisecretory effect compared to H₂RAs. More than 80%

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of gastric ulcers and 90% of DU can be healed within 4 weeks by using PPIs. Potassium-competitive acid blockers (P-CABs), while exhibiting strong antisecretory effects, are not the preferred treatment for PU and have limited adoption in clinical practice.

Reflux Esophagitis

Reflux esophagitis (RE), a type of gastroesophageal reflux disease (GERD), occurs when the contents of the stomach, including acidic gastric fluids and partially digested food, frequently flows back into the esophagus, causing inflammation and damage to the esophageal lining. Patients with RE have symptoms such as heartburn, chest pain, difficulty swallowing, and regurgitation of food or sour liquid. GERD also includes non-erosive reflux disease where patients experience reflux symptoms without obvious mucosal damage and may progress to RE, and approximately 35% of GERD cases are classified as RE. Long-term untreated RE may advance to serious complications such as gastrointestinal bleeding, esophageal stenosis and Barrett’s esophagus, which could increase the risk of esophageal cancer. In China, the prevalence of RE remains a high level, which increased from 36.7 million in 2018 to 37.8 million in 2023 and is expected to increase to 42.4 million in 2032.

RE is caused by a complex interplay of factors that lead to the dysfunction of the lower esophageal sphincter (LES) and the exposure of the esophagus to gastric contents. The LES, a circular band of muscle at the bottom of the esophagus, normally prevents the backflow. However, reduced LES tone and transient LES relaxations can result in acid reflux into the esophagus.

RE is typically treated with a similar approach to PU. Apart from lifestyle changes, the standard treatment involves 4-8 weeks of PPIs or P-CABs therapy, with or without H₂RA, antacid, or gastrointestinal stimulants drugs. If the initial medication is effective, patients may require long-term maintenance therapy to prevent relapse, including on-demand or intermittent therapy. If it is ineffective, changes to dosage or another antisecretory drug may be needed.

Proton Pump Inhibitor

Proton pump, also known as H⁺/K⁺ ATPase, is an enzyme located in the parietal cells of the stomach. This enzyme plays a crucial role in gastric acid production by actively transporting hydrogen ions (H⁺) into the stomach in exchange for potassium ions (K⁺). These hydrogen ions then combine with chloride ions (Cl⁻) to form hydrochloric acid (HCl), the primary component of gastric acid. This acidic environment is necessary for protein digestion and the activation of digestive enzymes. However, excessive gastric acid can lead to conditions like PU and GERD, necessitating treatments to reduce acid production.

PPIs are a class of drugs that effectively reduce gastric acid by irreversibly binding to and inactivating the proton pump, thereby inhibiting the secretion of HCl into the stomach lumen. PPIs are considered the most potent inhibitors of gastric acid secretion and are the standard of care for managing acid-related disorders.

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All PPIs share the same basic mechanism of action, but differ in their pharmacokinetic properties such as bioavailability and metabolic pathway, safety profile, and duration of action, among other things. PPIs that can address unmet medical needs are generally those that have low risk of drug-drug interactions, can be used across major populations such as the elderly and those with renal impairment, have fast onset of action and long-lasting effects. The table below sets forth features of approved PPIs in China in terms of safety profile.

Safety Profile Comparison of Oral PPIs

PPIs	Anaprazole	Omeprazole	Lansoprazole	Pantoprazole	Rabeprazole	Esomeprazole	Ilaprazole
Metabolic pathways ⁽¹⁾	Non-enzyme; multiple CYP450 (3.5% CYP2C19)	CYP2C19	CYP2C19	CYP2C19	Non-enzyme; CYP2C19/CYP3A4	CYP2C19	CYP3A4
Genetic polymorphism-based risk ⁽²⁾	Low	High	High	High	Moderate	High	Low
Metabolism-induced DDI risk ⁽³⁾	Low	High	High	High	Moderate	High	Low
Renal clearance	40-50%	≥80%	~15%	≥80%	≥80%	≥80%	/
Renal burden	Low	High	Low	High	High	High	/

Notes:

- (1) Representing major metabolic pathways of underlying PPIs.
- (2) CYP2C19 genetic polymorphisms significantly influence the metabolism of PPIs. Patients who are CYP2C19 poor metabolizers may experience higher drug exposure when treated with PPIs that are primarily metabolized by CYP2C19, potentially leading to increased risk of adverse events. Conversely, rapid metabolizers may show inadequate therapeutic response due to reduced drug exposure.
- (3) PPIs with metabolic pathways primarily through CYP2C19 may face risk of drug-drug interactions with other medications that metabolize through CYP2C19, such as clopidogrel, because the inhibition of CYP2C19 would interfere with the plasma concentration of these medications.

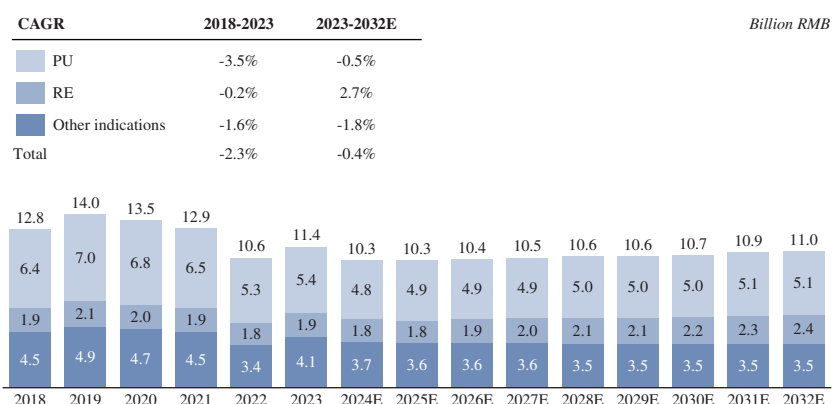
Source: Expert Opinion on Drug Metabolism & Toxicology, Clinical Pharmacokinetics, Drug labels, China Insights Consultancy

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Addressable Market Size of PPIs in China

Oral PPIs had a market size consistently over RMB10.0 billion for years in China. Although demand continued to be strong, the market size of oral PPIs historically fluctuated due to the implementation of VBP Scheme and Key Supervision List on a number of marketed generic PPIs. For example, pantoprazole, esomeprazole and lansoprazole were included in the VBP Scheme in 2021 and rabeprazole was included in the VBP Scheme in 2023. While sales volume remained high, prices were reduced as a result and therefore the market size decreased in 2022 and is expected to decrease in 2024. However, driven by the high prevalence of the targeted indications, such as PU and RE, and the anticipated launch of more innovative PPIs, the market size of oral PPIs will gradually grow to RMB11.0 billion by 2032. The following chart sets forth the addressable market size of oral PPIs in China.

Market Size of Oral PPIs in China, 2018-2032E



Source: NRDL, NHSA, NHC, Annual reports, China Insights Consultancy

Competitive Landscape of PPIs in China

As of the Latest Practicable Date, there were seven PPIs approved for marketing in China, among which, five were generics, namely lansoprazole, pantoprazole, omeprazole, rabeprazole and esomeprazole. All of the marketed generic PPIs are included in the VBP Scheme and Key Supervision List, leading to a reduction in their prices and market size. In addition, ilaprazole, one of the two currently marketed innovative PPIs, has become subject to competition from generic PPIs and may be included in the VBP Scheme. Our Company’s anaprazole (KBP-3571) is the only other marketed innovative PPI, which was approved in 2023 and is not subject to either regulation.

As of the Latest Practicable Date, six marketed PPIs were approved for the treatment of PU and GERD/RE. Our Company’s anaprazole (KBP-3571) was approved for DU in June 2023, and the phase 2 clinical trial for RE as the second indication has been completed. As of the same date, according to CIC, there were a total of 72 generic PPI candidates which were

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in the bioequivalence stage and our Company’s anaprazole (KBP-3571) was the only innovative PPI candidate under clinical development in China for the treatment of RE. The following table illustrates the competitive landscape of the marketed PPIs in China.

Marketed PPIs in China

Drug Name	Initial Approval	Original Manufacturer	Generic	Covered by VBP Scheme	Covered by Key Supervision List	Price Change: 2018-2023 CAGR	Market Size Change: 2018-2023 CAGR
Lansoprazole	1994	Takeda Pharma	Yes	2021 (injectable)	2023	Oral (15 mg): -14.9% Injectable (30 mg): -46.3%	-24.8%
Pantoprazole	1997	Takeda Pharma	Yes	2021 (oral & injectable)	2023	Oral (20 mg): -32.5% Injectable (40 mg): -38.5%	-34.2%
Omeprazole	2000	AstraZeneca	Yes	2020 (oral); 2022 (injectable)	2023	Oral (20 mg): -36.5% Injectable (40 mg): -31.0%	-21.0%
Rabeprazole	2000	Eisai	Yes	2023 (oral)	2023	Oral (10 mg): -48.8% Injectable (20 mg): -16.6%	-5.7%
Esomeprazole	2002	AstraZeneca	Yes	2021 (oral & injectable)	2023	Oral (20 mg): -26.9% Injectable (20 mg): -44.4%	-12.5%
Elaprazole	2007	Livzon Pharma	No	No	No	Oral (5 mg): -5.0% Injectable (10 mg): -22.7%	39.4%
Anaprazole	2023	Our Company	No	No	No	N/A ⁽¹⁾	N/A ⁽¹⁾

Note:

- (1) Anaprazole was approved for the treatment of DU in June 2023, price change and market size change of which are not applicable.

Source: NRDL, NHSA, Drug labels, China Insights Consultancy

CHINA’S BREAST CANCER DRUG MARKET

Breast Cancer

Breast cancer (BC) is the most commonly diagnosed malignant tumor in women worldwide, and a leading cause of cancer-related deaths. In China, the number of new BC cases increased from 322.2 thousand in 2018 to 366.1 thousand in 2023, and it is expected to reach 435.0 thousand in 2032. Several factors can increase the risk of developing BC, including genetic predisposition (BRCA1 or BRCA2 mutations), exposure to estrogen and progesterone, and lifestyle factors such as weight, diet or alcohol consumption.

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BC is typically classified into three main subtypes, namely, HR+/HER2- BC, HER2+ BC and TNBC:

HR+/HER2- BC is the most prevalent subtype in China, accounting for approximately 75% of all cases. HR+/HER2- BC is characterized by estrogen receptor (ER) and/or progesterone receptor (PR) levels without overexpression of human epidermal growth factor 2 (HER2) protein and has been associated with better prognosis and improved survival compared to other subtypes in the metastatic setting. About 30% of HR+/HER2- BC patients are diagnosed with advanced BC. The five-year survival rate for advanced HR+/HER2- BC in China is approximately 20%, highlighting the urgent need for more effective treatment strategies. The standard first-line treatment for advanced HR+/HER2- BC in China involves endocrine therapies, such as aromatase inhibitors (AIs) and a selective ER degrader (SERD) like fulvestrant, in combination with CDK4/6 inhibitors. In addition, endocrine therapies combined with CDK4/6 inhibitor abemaciclib is recommended as the post-operative adjuvant therapy for the treatment of HR+/HER2- early BC.

HER2+ BC accounts for approximately 15% of total BC cases. HER2+ BC is characterized by the overexpression of HER2 protein and is typically more aggressive and fast-growing than HR+/HER2 type. The standard treatments of advanced HER2+ BC in China primarily comprise chemotherapy, targeted therapy such as HER2 monoclonal antibodies, tyrosine kinase inhibitors (TKIs) and HER2 ADC.

TNBC is the most malignant BC subtype, which grows and spreads faster, has fewer treatment options, and tends to have a worse prognosis. TNBC, i.e., triple-negative breast cancer, is characterized by the absence of ER, PR and HER2 proteins, a particularly aggressive subtype known for its extremely high drug resistance, progression, and poor prognosis. In China, the current first line treatments for advanced TNBC involve either single-agent or doublet chemotherapy.

The treatment paradigm of BC in China is set forth below.

Classification		Postoperative adjuvant treatment	Salvage treatment for advanced breast cancer		
			Grade I	Grade II	Grade III
Breast cancer	HR+/HER2-	Adjuvant chemotherapy (Grade I): <ul style="list-style-type: none"> 1–3 positive lymph nodes: TC × 4; AC ≥4 positive lymph nodes: AC-T; ddAC-ddT Adjuvant endocrine treatment: <ul style="list-style-type: none"> Primary therapy for post-menopausal patients (Grade I): AI ± Abemaciclib Primary therapy for pre-menopausal patients (Grade I): OFS + AI/TAM ± Abemaciclib 	<ul style="list-style-type: none"> ET-naïve/Failed to TAM: AI + CDK4/6 i Failed to non-steroidal AIs/Failed to steroidal AI: Fulvestrant + CDK4/6 i HR+/HER2-low: Endocrine therapy + CDK4/6 i if CDK4/6 inhibitor naïve 	<ul style="list-style-type: none"> ET-naïve: Fulvestrant + CDK4/6 i; AI Failed to TAM: AI + chidamide/everolimus; Fulvestrant + CDK4/6 i Failed to non-steroidal AIs: Steroidal AI + chidamide/everolimus Failed to steroidal AI: Fulvestrant + everolimus; Non-steroid AI + CDK4/6 i HR+/HER2-low: Chemotherapy; T-Dxd 	<ul style="list-style-type: none"> ET-naïve: TAM Failed to TAM: AI; Fulvestrant Failed to non-steroidal AIs: Fulvestrant; Steroidal AI Failed to steroidal AI: Fulvestrant HR+/HER2-low: Sacituzumab govitecan
	HER2+	Primary treatment (Grade I): <ul style="list-style-type: none"> Positive axillary lymph nodes: AC-THP; TCbHP Negative axillary lymph nodes, tumor sized >2 cm: AC-TH; TCbH; TC + H 	<ul style="list-style-type: none"> Trastuzumab sensitive: THP;TH + pyrotinib Trastuzumab-resistant: Pyrotinib + capecitabine; T-Dxd 	<ul style="list-style-type: none"> Trastuzumab-sensitive: TXH; H + chemotherapy Trastuzumab-resistant: T-DM1 Pyrotinib-resistant: T-Dxd; HP + other chemotherapy; T-DM1 	<ul style="list-style-type: none"> Trastuzumab-sensitive: Pyrotinib + capecitabine Trastuzumab-resistant: Neratinib + capecitabine
	TNBC	Primary treatment (Grade I): <ul style="list-style-type: none"> Positive lymph nodes, tumor sized >2 cm: AC-T; ddAC-ddT (Olaparib for extended therapy, with BRCA mutation type, Grade II) Tumor sized ≤2 cm and with negative lymph nodes: TC × 4; AC 	<ul style="list-style-type: none"> Chemotherapy Chemotherapy + PD-1 inhibitors: Albumin-bound paclitaxel/GP + PD-1 inhibitors 	<ul style="list-style-type: none"> Other chemotherapy Chemotherapy + PD-1 inhibitors: Albumin-bound paclitaxel/GP + PD-1 inhibitors 	<ul style="list-style-type: none"> Olaparib for the presence of BRCA mutation Other chemotherapy

Note: ET: Endocrine therapy; TAM: Tamoxifen; AI: Aromatase inhibitor; CDK4/6 i: CDK4/6 inhibitor; T-DM1: Trastuzumab emtansine; T-Dxd: Trastuzumab deruxtecan; A, Anthracyclines; T, Taxanes; C, Cyclophosphamide; G, Gemcitabine; X, Capecitabine; Cb, Carboplatin; H/P, Trastuzumab/pertuzumab; OFS, Ovarian function suppression

Source: CSCO (2024), China Insights Consultancy

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CDK4/6 Inhibitor

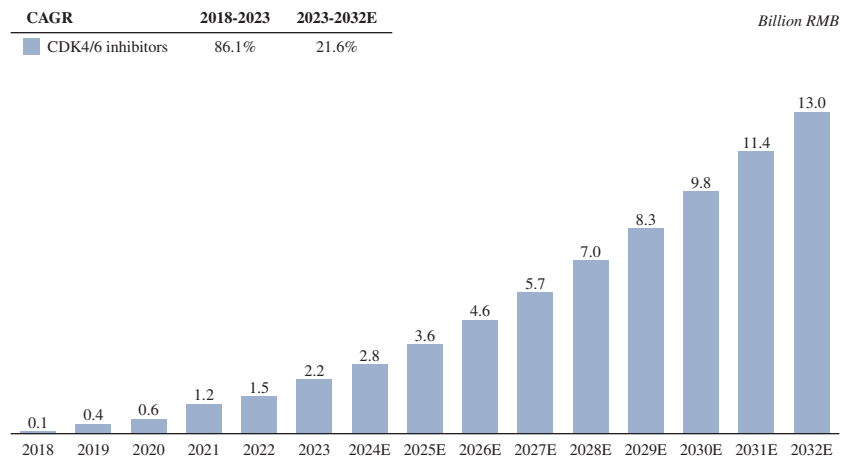
Cyclin-dependent kinases (CDKs) are a family of enzymes that play a crucial role in regulating the cell cycle — the process by which cells divide and replicate. CDKs are activated by binding to regulatory proteins called cyclins, forming cyclin-CDK complexes. Two specific members of the CDK family, CDK4 and CDK6, are essential for the G1 phase of the cell cycle. In this phase, cells prepare for DNA synthesis and eventual division. When binding to cyclin D proteins, these kinases (cyclin D-CDK4/6 complexes) can inactivate tumor suppressor proteins, ultimately promoting cell cycle progression. However, in many cancers, including BC, the CDK4/6 pathway becomes dysregulated, leading to uncontrolled cell proliferation and tumor growth. This has made CDK4 and CDK6 attractive targets for cancer therapies.

Targeting this dysregulated pathway, CDK4/6 inhibitors are a class of drugs designed to selectively inhibit the activity of CDK4 and CDK6 enzymes. By blocking these kinases, CDK4/6 inhibitors can induce cell cycle arrest in the G1 phase, preventing cancer cells from dividing and proliferating. This mechanism of action is particularly effective in cancers driven by CDK4/6 pathway dysregulation, such as HR+/HER2- BC. As a standard treatment option for advanced HR+/HER2- BC, CDK4/6 inhibitors in combination with endocrine therapies have significantly improved progression-free survival (PFS) among BC patients and are well tolerated, compared to traditional endocrine therapy alone.

Addressable Market Size of CDK4/6 Inhibitors for BC in China

Since the first CDK4/6 inhibitor received approval from the NMPA in 2018, the market of these drugs has experienced steady growth. Driven by a wave of new CDK4/6 inhibitors entering the market and gaining coverage on the NRDL, the CDK4/6 inhibitor market in China grew from RMB0.1 billion in 2018 to RMB2.2 billion in 2023 at a CAGR of 86.1%, and is expected to reach RMB13.0 billion in 2032 at a CAGR of 21.6% from 2023 to 2032. The following chart sets forth the addressable market size of CDK4/6 inhibitors in China for treating BC.

Market Size of CDK4/6 Inhibitors for BC in China, 2018-2032E



Source: Annual reports, China Insights Consultancy

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Competitive Landscape of CDK4/6 Inhibitors in China

As of the Latest Practicable Date, there were four innovative CDK4/6 inhibitors approved for the treatment of BC in China. None of the four CDK4/6 inhibitors has been approved as monotherapy. As of the same date, there were seven CDK4/6 inhibitor candidates in phase 3 or beyond in China. The following tables illustrate the competitive landscape of the marketed CDK4/6 inhibitors and the CDK4/6 inhibitor candidates for treating BC in phase 3 or beyond in China.

Marketed CDK4/6 Inhibitors for BC in China

Drug Name	Company	Indication	Treatment Line	First Approval	NRDL Year
Palbociclib	Pfizer	HR+/HER2- 1a/mBC (Combo: AIs)	1L	July 2018	2023
Abemaciclib	Lilly	HR+/HER2- 1a/mBC (Combo: AIs or fulvestrant)	1L (combo: AIs) ≥2L (combo: fulvestrant)	March 2021	2022
		HR+/HER2- early BC (Combo: endocrine therapy, ET)	/	December 2021	2024
Dalpiciclib	Hengrui	HR+/HER2- 1a/mBC that progressed after ET (Combo: fulvestrant)	≥2L	December 2021	2023
		HR+/HER2- 1a/mBC (Combo: AIs)	1L	June 2023	2024
Ribociclib	Novartis	HR+/HER2- 1a/mBC (Combo: AIs)	1L	January 2023	2024

Source: NRDL, NHSA, Drug labels, China Insights Consultancy

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CDK4/6 Inhibitor Candidates for BC in Phase 3 or Beyond in China

Drug Name/Code	Company	Indication	Phase	Treatment Line	First Posted Date/ NDA Acceptance Date
Ribociclib	Novartis	HR+/HER2- early BC with or without PgR+	NDA	Post-operative adjuvant therapy	2023-12-19
Dalpiciclib	Hengrui Pharmaceuticals	HR+/HER2- BC	3	Post-operative adjuvant therapy	2021-04-13
GB491 (Lerociclib)	G1/Genor BioPharma	HR+/HER2- la/mBC after ET (Combo: fulvestrant)	NDA	≥2L	2023-03-28
		HR+/HER2- la/mBC (Combo: AIs)	NDA	1L	2024-03-13
XZP-3287	Our Company	HR+/HER2- aBC after ET (Combo: fulvestrant)	NDA	≥2L	2023-08-30
		HR+/HER2- la/mBC after ET and CT (Mono)	NDA	>3L	2023-10-11
		HR+/HER2- aBC (Combo: AIs)	3	1L	2022-02-09
Tibremciclib	Betta Pharmaceutical	HR+/HER2- la/r/mBC (Combo: fulvestrant)	NDA	2L	2024-05-01
FCN-437c	Fochon Pharmaceuticals	HR+/HER2- aBC (Combo: fulvestrant)	NDA	≥2L	2023-11-21
		HR+/HER2- aBC (Combo: AIs)	3	1L	2021-12-17
BEET-209	BeBetter Med	HR+/HER2- aBC after ET (Combo: fulvestrant)	3	≥2L	2022-02-28

Note: la/mBC stands for locally advanced/metastatic BC; la/r/mBC stands for locally advanced/recurrent/metastatic BC; ET stands for endocrine therapy; CT stands for chemotherapy.

Source: CDE, China Insights Consultancy

CHINA'S LUNG CANCER DRUG MARKET

Lung Cancer

Lung cancer (LC) is one of the leading causes of cancer-related mortality in China and worldwide. While smoking and tobacco use are responsible for about 80% of LC cases, other factors, such as air pollution exposures and chronic infections, can also increase the risk of developing this disease. In 2023, LC emerged as the most frequently diagnosed cancer in China, with the number of new cases increasing from 899.3 thousand in 2018 to 1,103.1 thousand in 2023 at a CAGR of 4.2%. It is expected that this number will reach 1,454.6 thousand in 2032 at a CAGR of 3.1% from 2023.

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LC can be classified into two primary subtypes, small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC), based on the pathologic and histomorphological features. SCLC is an aggressive form of LC characterized by small, round cancer cells exhibiting a distinct “oat-like” morphology under microscopic examination. In contrast to NSCLC, SCLC grows and spreads more rapidly, often involving distant metastases at the time of diagnosis. NSCLC is any type of epithelial LC other than SCLC. NSCLC is the most common subtype of LC and represents over 85% of all LC cases in China. NSCLC is further divided into several subtypes, with adenocarcinoma being the most prevalent, representing approximately 71% of all NSCLC cases in China. The number of new NSCLC cases in China has been steadily increasing, rising from 764.4 thousand in 2018 to 937.6 thousand in 2023 at a CAGR of 4.2%. It is estimated that the number of new NSCLC cases will reach 1,236.4 thousand in 2032 at a CAGR of 3.1% from 2023.

Treatment for NSCLC is determined by the histology subtype, disease stage and the patient’s overall health and comorbidities. Accurately staging NSCLC is crucial, as it directly impacts treatment decisions and provides valuable insights into the likely course of the disease. Approximately 24% of patients with NSCLC in China are in stage I or II at the time of initial diagnosis, 13% in stage III, and the remaining approximately 64% have advanced disease (stage IV). The all seer stage combined five-year survival rates of NSCLC can be 19.7%, with a low five-year survival rate of 5.8% for advanced NSCLC.

For patients diagnosed with stage I to III NSCLC who are eligible for surgery, the primary treatment approach involves surgically removing the tumor and any affected lymph nodes. This is often followed by adjuvant therapies such as chemotherapy, immune checkpoint inhibitors, or targeted therapy to reduce the risk of recurrence. For example, ALK inhibitor alectinib has been approved for the post-operative adjuvant therapy of ALK-positive NSCLC. In cases where surgical intervention is not feasible due to the location or extent of the tumor, patients with stage I to III NSCLC may receive radiotherapy and/or chemotherapy. For patients with advanced (stage IV) NSCLC harboring known gene alterations, such as mutations in EGFR, ALK, ROS1 or NTRK gene rearrangements, targeted therapy directed the specific genetic aberration is recommended as the first-line treatment.

Among NSCLC patients in China, the most common driver mutations are EGFR (28.2%), followed by KRAS (6.0%) and ALK (5.6%). For patients with EGFR mutations, small molecule targeted drugs known as EGFR-TKIs, such as gefitinib and osimertinib, are primarily recommended throughout the treatment process. For KRAS-mutant patients, immunotherapy is the first-line treatment option and KRAS G12C inhibitors, such as sotorasib and adagrasib are used in the second-line setting. For ALK-positive NSCLC patients, ALK inhibitors, such as alectinib, brigatinib and lorlatinib, are the preferred first-line treatment. The treatment paradigm of ALK-positive NSCLC in China is set forth below.

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Stage I-III ALK fusion NSCLC	Ineligible for surgery	Eligible for surgery	Adjuvant therapy for postoperative stage II-III patients:		
	<ul style="list-style-type: none"> Radiotherapy ± Chemotherapy 	<ul style="list-style-type: none"> Surgical resection + Mediastinal lymph node dissection 	<ul style="list-style-type: none"> Atezolizumab following curative surgery (Restricted to PD-L1 TC ≥ 1%, Grade I) Platinum-based doublet chemotherapy (Stage IIB, Grade I) Platinum-based chemotherapy combined with toripalimab (Stage III, Grade I) Alectinib for ALK-positive patients (Grade II) 		
Stage IV ALK fusion NSCLC	Grade I			Grade II	Grade III
	First line therapy	<ul style="list-style-type: none"> Preferred: Alectinib, Brigatinib, Lorlatinib Ceritinib, Crizotinib, Iruplinalkib 		<ul style="list-style-type: none"> Platinum-based doublet chemotherapy ± Bevacizumab (Non-squamous carcinoma) 	• N/A
	Subsequent targeted therapy	<ul style="list-style-type: none"> Oligoprogress/CNS metastasis: <ul style="list-style-type: none"> Initial ALK-TKI ± local therapy Alectinib, Ceritinib, Brigatinib, Lorlatinib, Lorlatinib (Restricted to post-Crizotinib treatment) Extensive progression: <ul style="list-style-type: none"> Next-generation ALK-TKI Platinum-based doublet chemotherapy ± Bevacizumab (Non-squamous carcinoma) 		<ul style="list-style-type: none"> Extensive progression: <ul style="list-style-type: none"> Platinum-based doublet chemotherapy ± Bevacizumab, biopsy to assess resistance mechanisms 	• N/A
	Post-failure therapy	<ul style="list-style-type: none"> PS=0-2: <ul style="list-style-type: none"> Single-agent chemotherapy 		<ul style="list-style-type: none"> PS=0-2: <ul style="list-style-type: none"> Single-agent chemotherapy + Bevacizumab (Non-squamous carcinoma) 	<ul style="list-style-type: none"> PS=0-2: <ul style="list-style-type: none"> Anlotinib

Source: CSCO (2024), China Insights Consultancy

ALK Inhibitor

Anaplastic lymphoma kinase (ALK) is a receptor tyrosine kinase with a crucial role in normal cell signaling and development. In healthy cells, ALK is involved in regulating the growth, survival, and specialization of neurons. However, in certain types of cancer, particularly NSCLC, genetic alterations can lead to the abnormal activation or rearrangement of the ALK protein. ALK rearrangements have been identified in 5-6% of NSCLC cases. These oncogenic changes in ALK drive the uncontrolled proliferation and survival of cancer cells, making it an important therapeutic target.

ALK inhibitors are a class of drugs designed to specifically block the activity of the ALK protein, effectively disrupting the signals that drive cancer cell growth and survival. In ALK-positive NSCLC patients, ALK inhibitors have demonstrated improved objective response rate (ORR), prolonged PFS, and better tolerability compared to standard chemotherapy. Despite the success of ALK inhibitors, resistance to ALK inhibitors can arise through several mechanisms, including genetic mutations within the ALK gene that reduce the binding affinity of the inhibitor, and the activation of alternative signaling pathways that bypass the inhibition of the ALK pathway.

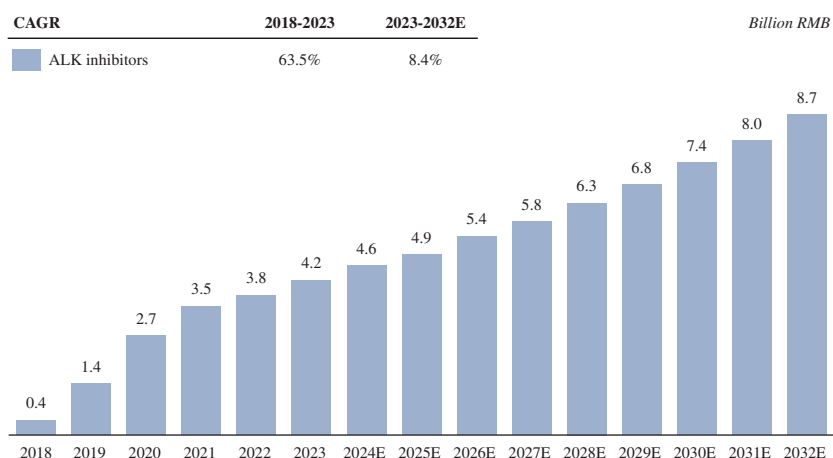
Since the launch of the first ALK inhibitor crizotinib in China in 2013, several newer ALK inhibitors have been developed or are being developed, including our Company’s XZP-3621 which is at NDA stage. These newer inhibitors are more potent and selective for ALK compared to crizotinib. They are designed to overcome resistance mechanisms that can develop with crizotinib treatment, and they have also demonstrated improved activity against brain metastases and efficacy in patients who have progressed on previous ALK inhibitor therapies.

INDUSTRY OVERVIEW

Addressable Market Size of ALK Inhibitors for NSCLC in China

The first ALK inhibitor for NSCLC received NDA approval from the NMPA in 2013. With a growing array of ALK inhibitors entering the market and being included in the NRDL, the ALK inhibitor market in China grew from RMB0.4 billion in 2018 to RMB4.2 billion in 2023 at a CAGR of 63.5%, and is forecasted to increase to RMB8.7 billion in 2032, representing a CAGR of 8.4% from 2023. The following chart sets forth the addressable market size of China’s ALK inhibitor markets for treating NSCLC.

Market Size of ALK Inhibitors for NSCLC in China, 2018-2032E



Source: NHSA, Annual reports, China Insights Consultancy

Competitive Landscape of ALK Inhibitors for NSCLC in China

As of the Latest Practicable Date, there were eight innovative ALK inhibitors approved for treating NSCLC in China. As of the same date, our Company’s XZP-3621 was the only ALK inhibitor candidate for NSCLC at NDA stage in China. The following tables illustrate the competitive landscape of marketed ALK inhibitors and the ALK inhibitor candidate at NDA stage for NSCLC in China.

Marketed ALK Inhibitors for NSCLC in China

Drug Name	Company	Indication	Treatment Line	First Approval	NRDL
Alectinib	Roche	ALK-positive stage IB to stage IIIA NSCLC	Post-operative adjuvant therapy	June 2024	No
Crizotinib	Pfizer	ALK-positive la/mNSCLC	1L	January 2013	Yes
Ceritinib	Novartis	ALK-positive la/mNSCLC	≥1L	May 2018	
Alectinib	Roche	ALK-positive la/mNSCLC	1L	August 2018	
Ensartinib	Betta	ALK-positive la/mNSCLC	≥1L	November 2020	
Brigatinib	Takeda	ALK-positive la/mNSCLC	1L	March 2022	Yes
Lorlatinib	Pfizer	ALK-positive la/mNSCLC	1L	April 2022	
Iruplinalkib	Qilu	ALK-positive la/mNSCLC	≥1L	June 2023	
Envonalkib	CTTQ	ALK-positive la/mNSCLC	1L	June 2024	No

Note: la/m stands for locally advanced or metastatic

Source: Drug labels, NMPA, CDE, China Insights Consultancy

INDUSTRY OVERVIEW

ALK Inhibitor Candidate for NSCLC at NDA Stage in China

Drug Name/Code	Company	Indication	Phase	Treatment Line	NDA Acceptance Date
XZP-3621	Our Company	ALK-positive NSCLC	NDA	1L	2024-04-25

Source: CDE, China Insights Consultancy

OTHER SELECT ONCOLOGY DRUG MARKETS IN CHINA

CD80-Fc Fusion Protein

CD80-Fc is a recombinant fusion protein engineered to boost the immune system's ability to fight cancer. It combines the extracellular domain of the cluster of differentiation (CD) 80, a costimulatory molecule, with the fragment crystallizable (Fc) region of an immunoglobulin G (IgG) antibody. CD80 is a cell surface protein expressed on antigen-presenting cells, such as dendritic cells and B cells.

CD80-Fc fusion proteins enhance cancer immunotherapy by modulating T cell activity. They provide co-stimulation by binding to CD28 on T cells, which is crucial for their activation and proliferation. Additionally, CD80-Fc can block cytotoxic T-lymphocyte-associated protein 4 (CTLA-4), a checkpoint inhibitor, preventing the downregulation of T cell responses. Moreover, CD80-Fc has been reported to bind to programmed cell death ligand 1 (PD-L1), potentially competing with the PD-1/PD-L1 interaction and counteracting the inhibitory signal. The ability of CD80-Fc fusion proteins to engage multiple receptors, both activating and inhibitory, contributes to its potential to modulate the immune system and enhance anti-tumor immune responses in cancer therapy.

Market Opportunity of CD80-Fc Fusion Protein Drugs

While research on CD80-Fc fusion proteins is still in early stage, these molecules hold significant potential for activating and potentiating the immune system's response against various types of cancer. Given the broad applicability of CD80-Fc fusion proteins in cancer immunotherapy across multiple malignancies, the addressable market for CD80-Fc fusion proteins can potentially extend to the entire cancer immunotherapy market according to CIC. The global cancer immunotherapy market increased from US\$18.6 billion in 2018 to US\$59.3 billion in 2023 at a CAGR of 26.1%, and is expected to reach US\$185.6 billion in 2032 at a CAGR of 14.6% from 2023. The cancer immunotherapy market in China grew from RMB0.8 billion in 2018 to RMB22.0 billion in 2023 at a CAGR of 94.5% and is forecasted to reach RMB155.9 billion in 2032 at a CAGR of 24.3% from 2023.

INDUSTRY OVERVIEW

Competitive Landscape of CD80-Fc Fusion Protein Drugs

As of the Latest Practicable Date, there were no CD80-Fc fusion protein drugs approved for marketing globally and in China. As of the same date, our Company’s KM602, was the only one CD80-Fc fusion protein drug candidate under clinical development in China.

HER2/HER2 Bispecific ADC

HER2, a cell surface receptor protein within the HER family, plays a key role in regulating cellular growth, division and survival. When activated by ligand binding or overexpression, HER2 forms pairs (dimerizes) with other HER family members, triggering downstream signaling cascades, such as the PI3K/AKT and MAPK/ERK pathways. These pathways promote cell proliferation, inhibit apoptosis, and enhance cell migration and invasion. While HER2 is expressed at low levels in normal tissues, its aberrant activation through overexpression in tumor cells promote their growth and survival, driving the development of various types of cancers. The table below highlights the major cancers where HER2 is frequently expressed.

Cancer Type	IHC 1+	IHC 2+	IHC 3+
BC	27.8%	19.3%	10.3%
LC	32.2%	14.7%	2.8%
Gastric cancer	21.2%	13.5%	13.9%
Biliary tract cancer	27.3%	14.9%	5.0%
Ovarian cancer	12.9%	20.0%	4.7%
Cervical cancer	7.1%	14.3%	14.3%
Pancreatic cancer	23.9%	7.5%	1.5%
Colorectal cancer	20.5%	8.0%	3.3%
Head and neck squamous cell carcinoma	17.4%	4.3%	8.7%

Note: According to NCCN, HER2+ refers to IHC 3+ or IHC 2+ with FISH (fluorescence *in situ* hybridization) positive. HER2-low refers to IHC 1+ or IHC 2+ with FISH equivocal or negative.

Source: ESMO, *The Oncologist*, *Annals of Oncology*, *China Insights Consultancy*

HER2/HER2 bispecific ADCs are a novel class of targeted cancer therapies that combine two distinct anti-HER2 antibody fragments within a single molecule. These bispecific ADCs are designed to simultaneously bind to two different epitopes on the HER2 receptor, triggering enhanced internalization and trafficking of the HER2-ADC complex into the cancer cell. Once inside the cell, the cytotoxic payload — typically a potent microtubule-disrupting agent — is released, leading to targeted cell death.

The key benefits of HER2/HER2 bispecific ADCs are their improved anti-tumor efficacy due to more efficient internalization and higher intracellular concentrations of the cytotoxic payload, the enhanced selectivity and delivery to HER2-expressing tumor cells, and the potential to overcome resistance mechanisms by targeting multiple HER2 epitopes, all of which can translate to better treatment outcomes for patients with HER2-expressing cancers, particularly those who have developed resistance to other HER2-targeted therapies.

INDUSTRY OVERVIEW

Market Opportunity of HER2/HER2 Bispecific ADCs in China

The addressable market for HER2/HER2 bispecific ADCs primarily includes patients with HER2+ and HER2-low cancers. According to CIC, the incidence of major cancers where HER2 is frequently expressed, such as BC, gastric cancer, biliary cancer, and NSCLC, in China grew from 808.9 thousand in 2018 to 895.5 thousand in 2023 at a CAGR of 2.1%, and is forecasted to reach 1,057.1 thousand in 2032 at a CAGR of 1.9% from 2023. For more details regarding BC and NSCLC, see in this section “— China’s Breast Cancer Drug Market — Breast Cancer” and “— China’s Lung Cancer Drug Market — Lung Cancer,” respectively.

Competitive Landscape of HER2/HER2 Bispecific ADCs in China

As of the Latest Practicable Date, there were no HER2/HER2 bispecific ADCs approved for marketing in China. As of the same date, there were three HER2/HER2 bispecific ADC candidates under clinical development in China as shown in the table below.

HER2/HER2 Bispecific ADC Candidates under Clinical Development in China

Drug Name/Code	Company	Indication	Phase	Treatment Line	First Posted Date
JSKN003	Alphamab Oncology	HER2 low expression recurrent/metastatic BC	3	2L&3L	2023-10-07
		Advanced malignant solid tumors	1/2	≥2L	2023-01-18
TQB2102	Chiatai Tianqing Pharmaceutical Group	HER2-positive BC	2	1L	2024-01-11
		HER2-negative recurrent/metastatic BC	2	≥2L	2024-03-25
		HER2 genetic aberration locally advanced or metastatic NSCLC	2	/	2024-06-11
		HER2-positive locally advanced or metastatic biliary tract cancer	1b/2	/	2024-05-22
		Advanced malignant tumors	1	≥1L	2023-02-10
		HER2-expressing recurrent/metastatic BC	1	2L	2023-10-31
KM501	Our Company	Advanced solid tumors with HER2 expression, amplification, or mutation	1	≥2L	2023-03-10

Source: CDE, China Insights Consultancy

PARP1 Inhibitor

Poly ADP-ribose polymerase 1 (PARP1) is an enzyme with a critical role in maintaining the integrity of DNA, primarily through its involvement in DNA repair and gene transcription. Once activated, it facilitates the recruitment of DNA repair proteins to the damage site, primarily through the base excision repair (BER) pathway. By adding poly ADP-ribose chains, PARP1 modifies itself and other proteins to signal and coordinate the repair process, maintaining genomic stability. In addition, PARP1 influences gene transcription by interacting with transcription factors, transcription machinery, and chromatin modulators. It can modify chromatin structure and regulate the accessibility of transcriptional machinery to DNA, thereby impacting gene expression. Hyperactivation of PARP1 can lead to the upregulation of inflammatory signaling factors, which may contribute to tumor development.

INDUSTRY OVERVIEW

PARP1 inhibitors are designed to block the activity of PARP1, primarily focused on preventing cancer cells from repairing their DNA. This leads to the accumulation of DNA damage, ultimately causing cell death. This is particularly effective in cancers with existing DNA repair deficiencies, such as BRCA1 or BRCA2 mutations. PARP1 inhibitors are used in treating certain types of breast, ovarian, and prostate cancers, exploiting the concept of synthetic lethality to selectively target cancer cells while sparing normal cells.

All of marketed PARP inhibitors target both PARP1 and PARP2. Compared to these PARP1/2 inhibitors which have certain limitations such as adverse reactions related to hematological toxicity due to the inhibition of PARP2, selective PARP1 inhibitors can not only potentially reduce side effects associated with broad inhibition of both PARP1 and PARP2, but also drive synthetic lethality in tumors with BRCA mutations.

Addressable Market Size of PARP1 Inhibitors in China

Following the approval of the first PARP1/2 inhibitor in 2018, PARP1 inhibitor market in China surged from RMB19.9 million in 2018 to RMB2.9 billion in 2023, at a CAGR of 171.1%. It is forecasted to reach RMB5.0 billion in 2032, at a CAGR of 6.3% from 2023. The chart below sets forth the addressable market size of PARP1 inhibitors in China.



Source: NHSA, CSCO, Annual reports, Drug labels, China Insights Consultancy

Competitive Landscape of PARP1 Inhibitors in China

As of the Latest Practicable Date, five PARP1/2 inhibitors had received approval for marketing in China. As of the same date, there were nine PARP inhibitor candidates under clinical development in China, three of which were selective PARP1 inhibitor candidates and six were PARP1/2 inhibitor candidates. Two of the three selective PARP1 inhibitor candidates have only recently initiated clinical development. The tables below set forth the competitive landscape of marketed PARP1/2 inhibitors and PARP inhibitor candidates at clinical stage in China.

INDUSTRY OVERVIEW

Marketed PARP1/2 Inhibitors in China

Drug Name	Company	Indication	Treatment Line	First Approval	NRDL Year
Olaparib (Lynparza®)	AstraZeneca	HRD+/BRCA mutations advanced or recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer who are in complete or partial response to ≥1L platinum-based chemotherapy	Maintenance therapy	August 2018	2019
		Metastatic castration-resistant prostate cancer carrying germline or somatic BRCA mutations	≥2L	June 2021	2022
Niraparib (Zejula®)	MSD/GSK	Advanced or recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer who are in complete or partial response to ≥1L platinum-based chemotherapy	Maintenance therapy	December 2019	2020
Fluzoparib (AiRuiYi®)	Hengrui	Platinum-sensitive recurrent ovarian cancer, fallopian tube cancer, or primary peritoneal cancer who have undergone chemotherapy and have gBRCA mutations	≥3L	November 2020	2021
		Platinum-sensitive advanced or recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer who are in complete or partial response to ≥1L platinum-based chemotherapy	Maintenance therapy	June 2021	2021
Pamiparib (Partruvix®)	Beone	Recurrent ovarian cancer, fallopian tube cancer, or primary peritoneal cancer who have undergone chemotherapy and have gBRCA mutations	≥3L	April 2021	2021
Talazoparib (Talzenna™)	Pfizer	Male patients of mCSPC with DDR-mutation	≥1L	October 2024	N/A

Source: NHSA, Drug labels, China Insights Consultancy

INDUSTRY OVERVIEW

PARP Inhibitor Candidates under Clinical Development in China

Drug Name/Code	Company	Indication	Target	Phase	Treatment Line	First Posted Date /NDA Acceptance Date
Senaparib	IMPACT	Advanced ovarian cancer	PARP1/2	NDA	1L (Maintenance therapy)	2023-08-26
		Advanced ovarian cancer, fallopian tube cancer, or primary peritoneal cancer		3	≥3L	2019-04-04
		Advanced SCLC		2	2L	2022-05-23
Saruparib	AstraZeneca	Metastatic castration-sensitive prostate cancer	PARP1	3	≥2L	2024-04-15
		Advanced solid tumors		1/2	/	2022-03-03
TQB-3823	Chia Tai Tianqing	Advanced ovarian cancer, fallopian tube cancer, and primary peritoneal cancer	PARP1/2	1b/3	1L (Maintenance therapy)	2023-06-05
HTMC-0435	Huilun	Advanced pancreatic cancer	PARP1/2	2	≥2L	2023-03-14
		Advanced cholangiocarcinoma		2	≥2L	2023-03-06
		Advanced small cell lung cancer and other solid tumors		1b/2	2L&3L	2022-10-11
		Advanced solid tumors		1/2	≥1L	2020-04-14
HWH-340	Humanwell	Prostate cancer	PARP1/2	2	≥2L	2022-12-22
		solid tumors with BRCA mutations or deletions and overexpression of PARP		1	≥1L	2018-01-02
HRS-1167	Hengrui	Recurrent ovarian cancer	PARP1	1b/2	2L&3L	2024-02-26
IMP-1734	IMPACT	Advanced solid tumors	PARP1	1/2	/	2024-02-26
Venadaparib	Idience	Advanced gastric cancer	PARP1/2	1b	1L&≥3L	2022-06-09
Simmiparib	Shanghai Institute of Materia Medica	HER-2 negative advanced breast cancer with gBRCA1/2 mutations	PARP1/2	1b	≥2L	2023-07-17

Source: CDE, China Insights Consultancy

INDUSTRY OVERVIEW

USP1 Inhibitor

Ubiquitin-Specific Protease 1 (USP1) is an enzyme that belongs to the family of deubiquitinating enzymes, and functions by removing ubiquitin molecules from specific protein substrates critical in DNA repair, thereby regulating their stability, function, or localization within the cell. It plays a crucial role for DNA damage response (DDR) by involving in various cellular processes, including the Fanconi anemia pathway and the trans-lesion DNA synthesis pathway.

USP1 inhibitors are a class of compounds designed to block the activity of USP1 enzyme. By inhibiting USP1, these drugs aim to disrupt the DDR mechanisms in cancer cells, potentially making them more susceptible to DNA-damaging therapies like chemotherapy or radiation. USP1 inhibitors are thought to be particularly promising for cancers with defects in DNA repair pathways, such as those with BRCA mutations. They may also enhance the effectiveness of PARP inhibitors by overcoming their resistance and improving the effect of synthetic lethality.

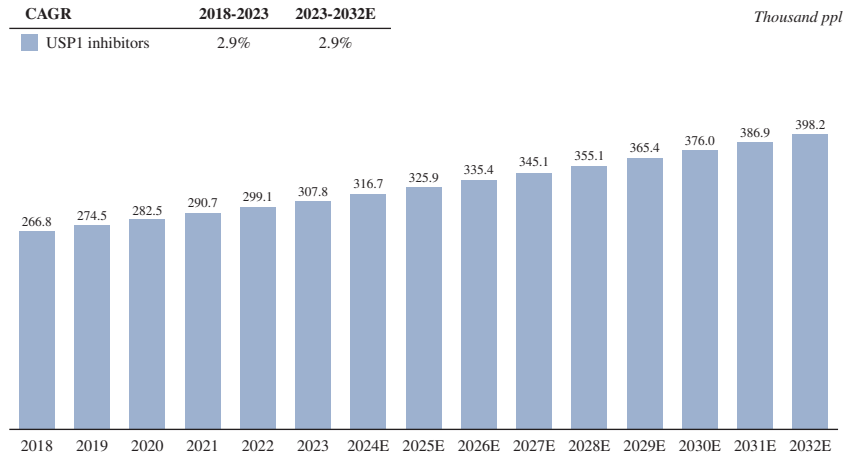
Several USP1 inhibitors are currently in preclinical development and early-phase clinical trials, being studied both as monotherapies and in combination with other cancer treatments. While still in the early stages of research, USP1 inhibitors represent a novel approach in targeted cancer therapy, potentially offering new options for patients with hard-to-treat cancers.

Market Opportunity of USP1 Inhibitors in China

Eligible patients for USP1 inhibitors primarily include patients with BRCA mutations. In China, the number of patients eligible for USP1 inhibitors increased from 266.8 thousand in 2018 to 307.8 thousand in 2023, and is expected to reach 398.2 thousand in 2032 at a CAGR of 2.9% from 2023. The chart below sets forth the eligible patients of USP1 inhibitors in China.

INDUSTRY OVERVIEW

Eligible Patients of USP1 Inhibitors in China, 2018-2032E



Source: National Central Cancer Registry of China (NCCR), Nature communications, China Insights Consultancy

Competitive Landscape of USP1 Inhibitors in China

As of the Latest Practicable Date, there were no USP1 inhibitors approved for marketing in China. As of the same date, there were three USP1 inhibitor candidates under clinical development in China as shown in the table below. Our Company’s XZP-6924 had obtained IND approval as of the Latest Practicable Date.

USP1 Inhibitor Candidates under Clinical Development in China

Drug Name/Code	Company	Indication	Phase	Treatment Line	First Posted Date
HSK39775	Haisco	Advanced solid tumors	1/2	≥2L	2024-02-27
SIM-0501	Simcere	Advanced solid tumors	1	≥2L	2024-02-26
ISM-3091	InSilico	Advanced solid tumors	1	≥2L	N/A

Source: CDE, China Insights Consultancy

AXL Inhibitor

Anexelekt (AXL) is a receptor tyrosine kinase that is vital in various cellular processes, including cell survival, proliferation, migration, and invasion. When activated by its ligands, such as Gas6, AXL undergoes autophosphorylation, which triggers the activation of downstream signaling pathways. These signaling cascades regulate gene expression and cellular functions essential for normal physiological processes like immune response, blood clotting, and tissue repair. However, dysregulation of AXL signaling, often caused by overexpression or mutation, can contribute to the development and progression of various hematological and solid cancers.

INDUSTRY OVERVIEW

AXL inhibitors are typically small molecule compounds that bind to AXL’s binding site, blocking its kinase activity and disrupting key signaling pathways. This can lead to reduced tumor growth, decreased metastasis, and enhanced sensitivity to other cancer treatments. Preclinical and clinical studies are exploring the efficacy of AXL inhibitors both as monotherapies and in combination with other treatments, aiming to enhance therapeutic responses and overcome drug resistance.

Notably, according to CIC, AXL overexpression has been reported in 30%-60% of NSCLC patients, where it promotes tumor cell survival and metastasis through multiple mechanisms, including EMT activation and immune suppression. AXL inhibition has demonstrated anti-tumor activity in preclinical models, suggesting its potential as a therapeutic target in NSCLC.

Competitive Landscape of AXL Inhibitors in China

As of the Latest Practicable Date, there were no AXL inhibitors approved for marketing in China. As of the same date, there were three highly selective AXL inhibitor candidates under clinical development in China as shown in the table below.

Highly Selective AXL Inhibitor Candidates under Clinical Development in China

Drug Name/Code	Company	Indication	Phase	Treatment Line	First Posted Date
XZB-0004	Our Company	Hematologic malignancies	1	≥1L	2023-02-15
		Advanced solid tumors	1	≥1L	2023-02-24
FC-084-CSA	Medical Novishen	Advanced solid tumors	1	≥1L	2023-02-23
NTQ-2494	Chia Tai Tianqing	Hematologic malignancies	1	N/A	2023-04-12

Source: CDE, China Insights Consultancy

DNA-PK Inhibitor

DNA-dependent protein kinase (DNA-PK) is a crucial nuclear serine/threonine protein kinase involved in DNA repair, particularly in the non-homologous end joining (NHEJ) pathway. Composed of a catalytic subunit (DNA-PKcs) and a regulatory component (Ku70/Ku80 heterodimer), DNA-PK plays a vital role in recognizing and repairing DNA double-strand breaks (DSB), thus maintaining genomic stability. While essential for normal cellular function, DNA-PK can also contribute to cancer cell survival by repairing DNA damage caused by radiation or chemotherapy.

DNA-PK inhibitors are a class of compounds designed to block the activity of DNA-PK, thereby preventing the DSB repair. These inhibitors are being developed as potential cancer treatments, particularly as radio- and chemo-sensitizers, which can improve the sensitivity of tumor cells to radiotherapy and chemotherapy.

INDUSTRY OVERVIEW

Competitive Landscape of DNA-PK Inhibitors in China

As of the Latest Practicable Date, there were no DNA-PK inhibitors approved for marketing in China. As of the same date, there was only one DNA-PK inhibitor candidate under clinical development and our Company’s XZP-6877 had obtained IND approval in China.

CHINA’S NASH DRUG MARKET

NASH

Non-alcoholic steatohepatitis (NASH), or metabolic dysfunction-associated steatohepatitis (MASH), is a severe form of non-alcoholic fatty liver disease (NAFLD), or metabolic dysfunction-associated steatotic liver disease (MASLD), characterized by excessive fat accumulation in the liver (steatosis) and accompanied by inflammation and hepatocyte injury. The primary pathogenesis of NASH is linked to metabolic disorders like obesity, insulin resistance, and dyslipidemia, which can lead to increased free fatty acid influx, lipotoxicity, oxidative stress, and inflammation within the liver. Severe NASH can progress to liver fibrosis, cirrhosis and even liver cancer.

NASH is one of the most common hepatic diseases. In China, the prevalence of NASH increased from 36.0 million in 2018 to 41.5 million in 2023 at a CAGR of 2.9%. The number is expected to grow to 50.8 million in 2032 at a CAGR of 2.3% from 2023. In addition, over 80% of patients with NASH are also suffering from other metabolic disorders, such as obesity, diabetes, and cardiovascular disease.

The current treatment approach for NASH involves lifestyle modifications such as diet and regular exercise, management of comorbidities such as metabolic syndrome or type 2 diabetes, and emerging drug therapies. In March 2024, the FDA approved Rezdiffra (resmetirom) for the treatment of adults with NASH with moderate to advanced liver fibrosis, which was the first approved medication directly for NASH. To date, there has been no NMPA approval of any specifically treatment for NASH. The current medications for the treatment of NASH in China are those for weight loss, hypertension and diabetes. Given NASH’s high prevalence, associated morbidity, growing burden of end-stage liver disease, and limited medication availability, identifying therapies that can halt or reverse NASH progression remains an urgent unmet medical need.

FXR Agonist

Farnesoid X receptor (FXR) is a nuclear receptor that acts as a bile acid sensor, regulating bile acid homeostasis and metabolism. Additionally, FXR plays a crucial role in lipid and glucose metabolism, exhibiting anti-inflammatory and anti-fibrotic properties, making it an attractive therapeutic target for metabolic and liver disorders.

INDUSTRY OVERVIEW

Low expression or reduced activity of FXR can result in multiple health problems, such as excessive bile acid accumulation and potential liver toxicity, impaired lipid and glucose metabolism contributing to dyslipidemia and insulin resistance, and exacerbated liver inflammation which may progress to liver fibrosis and cirrhosis. FXR agonists are synthetic compounds that selectively activate the FXR, which can improve the metabolic homeostasis and reverse the progress of hepatic damage.

FXR agonists have shown promising therapeutic potential in various conditions, including NASH, primary biliary cholangitis (PBC), and other chronic liver diseases. By modulating bile acid homeostasis and exerting beneficial metabolic, anti-inflammatory and anti-fibrotic effects, FXR agonists represent a promising therapeutic approach for various metabolic and chronic liver disorders.

Competitive Landscape of FXR Agonists for NASH in China

As of the Latest Practicable Date, there were no FXR agonists approved for treating NASH in China. As of the same date, seven FXR agonist candidates were undergoing clinical development for NASH in China as shown in the table below.

FXR Agonist Candidates under Clinical Development for NASH in China

Drug Name/Code	Company	Indication	Phase	First Posted Date
TQA3526	Chia Tai Tianqing	NASH; PBC	2	2020-01-10
HEC96719	HEC Pharma	NASH	2	2021-07-27
CS0159	Cascade Pharma	NASH; PBC; PSC; IBD	2	2023-05-12
MT2004	Aolitai Pharma	NASH; cholestatic and drug-induced hepatic damage	2	2023-07-07
XZP-5610	Our Company	NASH	1	2021-04-14
SYHA1805	CSPC	NASH	1	2021-06-29
HPG1860	Hepagene Therapeutics	NASH (MASH); IBD; PBS/PSC	1	2021-11-18

Source: CDE, China Insights Consultancy

KHK Inhibitor

Ketohexokinase (KHK) is an enzyme that plays a crucial role in the metabolism of fructose. It catalyzes the first step in the fructose metabolic pathway by phosphorylating fructose to fructose-1-phosphate. This reaction is considered the rate-limiting step in hepatic fructose metabolism. Increased KHK activity and fructose metabolism have been implicated in the development of NAFLD and NASH. Excessive fructose metabolism can lead to the accumulation of lipids in the liver, oxidative stress, and inflammation, contributing to the pathogenesis of these conditions.

INDUSTRY OVERVIEW

KHK inhibitors are small molecule compounds designed to specifically inhibit the activity of the KHK enzyme, thereby reducing the metabolism of fructose in the liver. By inhibiting KHK, these compounds aim to prevent or reduce the accumulation of lipids, oxidative stress, and inflammation associated with excessive fructose metabolism. This approach has emerged as a potential therapeutic strategy for NAFLD and NASH, as well as other metabolic disorders linked to fructose metabolism.

Competitive Landscape of KHK Inhibitors in China

As of the Latest Practicable Date, there were no KHK inhibitors approved for marketing in China. As of the same date, our Company’s XZP-6019 was the only KHK inhibitor candidate that had obtained IND approval in China.

REPORT COMMISSIONED BY CHINA INSIGHTS CONSULTANCY

In connection with the [REDACTED], we have engaged China Insights Consultancy to conduct a detailed analysis and prepare an industry report on the major markets for which our drug candidates are positioned. China Insights Consultancy is an independent global market research and consulting company that provides market research on a variety of industries including biotechnology. We have agreed to pay China Insights Consultancy a total fee of RMB1,500,000 for the preparation of the CIC Report, and we believe that such fees are consistent with the market rate. The payment of such amount was not contingent upon our successful [REDACTED] or on the results of the CIC Report. Except for the CIC Report, we did not commission any other industry report in connection with the [REDACTED].

REGULATORY OVERVIEW

This section summarizes the principal PRC laws, regulations, rules and policies that may have a material impact on our business and operations.

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 (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, under and supervised by the State Administration for Market Regulation (國家市場監督管理總局) (the “SAMR”), is the primary regulatory agency in the PRC for the supervision and management of the pharmaceutical products and related businesses, and regulates almost all the key stages of the life-cycle of pharmaceutical products, including non-clinical research, clinical trial, marketing approval, production, circulation, etc. The Center for Drug Evaluation (藥品審評中心) (the “CDE”), which is a subsidiary under the NMPA, conducts the technical evaluation on each drug and biologic application to assess the safety and efficacy of each candidate.

The NHC is a 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 PRC 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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PRC LAWS AND REGULATIONS

Laws and Regulations in Relation to New Drugs

Drug Registration Administration

Pursuant to the provisions of the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) promulgated by the SAMR on January 22, 2020 and taking effect from July 1, 2020, the Measures for the Administration of Drug Registration shall apply to the development, registration, supervision and management activities carried out in the territory of the PRC for marketing of drugs. In accordance with the Measures for the Administration of Drug Registration, drug registration refers to activities that a drug registration applicant files an application and other supplementary applications for clinical drug trial, approval for drug marketing, and re-registration, among others, under the legal procedures and according to the relevant requirements, and that the medical products administrative department examines the safety, effectiveness, and quality controllability based on the laws and regulations, and the existing scientific cognitions, to decide whether to agree with the activities applied for. Drug registration is categorized and managed according to Traditional Chinese Medicine, Chemical Drugs, and Biological Products. The registration of chemical drugs is classified into Innovative Chemical Drugs, Improved New Chemical Drugs, and Generic Chemical Drugs. The registration of biological products is categorized into Innovative Biological Drugs, Improved New Biological Drugs, and Marketed Biological Products (including Biosimilars). Prior to applying for registration of drug marketing, the applicant shall complete study work relating to pharmacy, pharmacology and toxicology, clinical trial of drugs etc. Non-clinical safety evaluation and study for drugs shall be carried out by institutions with Certification of the Good Laboratory Practice for Non-clinical Laboratory Studies and comply with the Good Laboratory Practice for Non-clinical Laboratory Studies. The clinical trial of a drug shall be subject to approval, among which the bioequivalence trial shall be subject to record-filing; the clinical trial of a drug shall be carried out in the clinical trial institutions meeting the relevant provisions and comply with the Good Clinical Practice of Drug Trials (the “GCP”). The administration of drug registration shall follow the principles of openness, fairness and justice, take clinical value as orientation, encourage the research and development of new drugs, and actively promote the development of generic drugs.

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.

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Non-clinical Research and Animal Testing

The institutions for non-clinical safety evaluation and study shall implement the Good Laboratory Practice for Non-Clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) (the “GLP”), which was promulgated by the China Food and Drug Administration (the “CFDA”) on August 6, 2003, last amended on July 27, 2017 and came into effect from September 1, 2017. (Note: The CFDA was abolished in March 2018, and its functions were succeeded by the newly established SAMR.) The GLP contains a set of rules and criteria for the quality system concerned with the organizational process and conditions under which non-clinical laboratory studies are planned, performed, monitored, recorded, achieved and reported. Other preclinical related research activities for the purpose of drug registration shall be carried out with reference to the GLP. The Measures for Administration of Certification of the Good Laboratory Practice 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 was last amended by the NMPA on January 19, 2023 and came into effect from July 1, 2023, set out the requirements for organizations to apply for GLP certification to conduct non-clinical drug studies.

According to the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) promulgated by the State Science and Technology Commission on November 14, 1988 and last amended on March 1, 2017 by the State Council, the Administration Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) jointly promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997, and the Administrative Measures on the Certificate for Experimental Animals (For Trial Implementation) (《實驗動物許可證管理辦法(試行)》) promulgated by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001 and taking effect from January 1, 2002, using experimental animals and related products requires a Certificate for Use of Laboratory Animals. A Certificate for Use 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.

Clinical Trial Application and Approval

Clinical trials should be conducted when applying for registration of a new drug. 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 taking effect from 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.

According to the Announcement of Several Policies on the Evaluation and Examination for Drug Registration (《關於藥品註冊審評審批若干政策的公告》) promulgated by the CFDA on November 11, 2015, the INDs of new drugs are subject to one-off umbrella approval instead of declaration, evaluation and approval by stages. Provided by the Announcement of the Adjustment of Procedures of the Evaluation and Examination for Drug Clinical Trial (《關於調整藥物臨床試驗審評審批程序的公告》) issued by the NMPA on July 24, 2018, applicants

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could proceed with their clinical trials if they have not received any denial or query from the CDE within 60 business days after the application has been accepted and the relevant application fees have been paid. The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”), which was promulgated by the Standing Committee of the National People’s Congress (全國人民代表大會常務委員會) (the “**SCNPC**”) in September 1984, last amended on August 26, 2019, and came into effect on December 1, 2019, further confirms that the drug regulatory department under the State Council shall, within 60 working days from the date on which the application for a clinical trial is accepted, decide on whether to approve it and then notify the clinical trial applicant. In the case of failure to notify the applicant within the prescribed time limit, it shall be deemed as approved. For bioequivalence studies, they shall be filed for record on the website of the CDE as required.

Clinical Trial Registration

Pursuant to the Measures for the Administration of Drug Registration, upon obtaining the clinical trial approval and before commencing a clinical trial, the sponsor shall register the scheme of the clinical trial and other information on the Drug Clinical Trial Registration and Information Platform for clinical trials of drugs. During the clinical trial of drugs, the sponsor shall update registration information continuously, and register information on the outcome of the clinical trial of drugs upon completion of the clinical trial of drugs. The registration information shall be published on the platform and the sponsor shall be responsible for the veracity of such information. More details are provided in the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) released by the CFDA on September 6, 2013, providing that for all clinical trials approved by the CFDA and conducted in China shall be published through the Drug Clinical Trial Registration and Information Platform. The applicant shall complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial’s unique registration number and shall complete certain follow-up information and first submission for publication before the first subject’s enrollment in the trial. If the foregoing first time of publication has not been submitted within one year after obtaining the clinical trial approval, the applicant shall submit an explanation, and if the procedure is not completed within three years, the clinical trial approval shall automatically be annulled.

Phases of Clinical Trials

According to the Measures for the Administration of Drug Registration, a clinical drug trial consists of Phases I, II, III, IV and bioequivalence trial. Pursuant to the characteristics of a drug and the research purpose, the research contents shall include clinical pharmacological research, exploratory clinical trial, confirmatory clinical trial and post-marketing research.

According to the Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》) promulgated by the NMPA and NHC on November 29, 2019 and taking effect from December 1, 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 PRC territory, they shall be conducted in drug clinical trial institutions. Drug clinical trial institutions shall be subject to filing administration.

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A clinical drug trial to be carried out shall be examined and approved by the ethics committee, and comply with the relevant requirements of the GCP. The sponsor shall submit safety update reports on the CDE website regularly during the research and development period. The sponsor shall promptly report to the CDE regarding suspicious and unexpected serious adverse reaction and other potential serious safety risks arising in the course of the clinical trial. Based on the severity of the safety risks, the sponsor may be required to adopt measures to strengthen risk control, and may be required to suspend or terminate the clinical trial of drugs where necessary.

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 I and Phase II clinical trials and before the implementation of Phase III 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 III clinical trials. The applicant can also apply for communication on key technical issues at different stages of clinical research and development.

According to the Technical Guiding Principles for Clinical Trials of Anti-tumor Drugs (《抗腫瘤藥物臨床試驗技術指導原則》) promulgated by the CFDA on May 15, 2012, the clinical study staging of anti-tumor drugs is not a fixed developmental sequence. The rapid development of anti-tumor drug research theories and technologies is likely to have an impact on future anti-tumor drug development models. Therefore, applicants can actively explore more scientific and rational research methods and promptly seek advice from the drug registration department under the NMPA. According to the Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》) promulgated by the CDE in November 2021, the fundamental purpose of the marketing market is to address the needs of patients, and drug research and development should be based on patient needs and clinical value.

Approval or Filing relating to Chinese Human Genetic Resources

According to the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the Ministry of Science and Technology (the “MOST”) on July 2, 2015, the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the China Human Genetic Resources Management Office. On October 26, 2017, the MOST promulgated the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》), simplifying the approval of sampling and collecting human genetic resources for the purpose of listing a drug in the PRC. According to the Notice on Updating the Services Guidelines, Filing, and Prior Reporting Scope and Procedures for Administrative Licensing of Human Genetic Resource Services

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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》) promulgated by the MOST on July 14, 2023, in order to obtain marketing authorization for relevant drugs in China, no approval is required in international clinical trial cooperation using China's human genetic resources at clinical institutions without export of human genetic resource materials, but certain conditions shall be satisfied and a record shall be filed with the MOST. For the exploratory research part involved in the clinical trials, an administrative license for international scientific research cooperation involving human genetic resources must be applied for.

According to the Administrative Regulations on Human Genetic Resources (《人類遺傳資源管理條例》) promulgated by the State Council on May 28, 2019, last amended on March 10, 2024, and taking effect from May 1, 2024, human genetic resource includes human genetic resource materials and information. Human genetic resource materials refer to organs, tissues, cells and other genetic materials containing human genome, genes and other genetic materials. Human genetic resource information refers to information, such as data, generated by human genetic resource materials. The Administrative Regulations on Human Genetic Resources further clarify that, in order to obtain marketing authorization for relevant drugs in China, no approval is required in international clinical trial cooperation using China's human genetic resources at clinical institutions without export of human genetic resource materials. However, the type, quantity and usage of the human genetic resource to be used shall be filed with the administrative department of health under the State Council before clinical trials. Foreign organizations, individuals and institutions established or actually controlled by foreign organizations and individuals are not allowed to collect or preserve human genetic resources in China or provide human genetic resources abroad.

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》), which was promulgated by the MOST on May 26, 2023, and took effect from July 1, 2023, further clarify the requirements for administrative licensing, record-keeping, and security review in relation to the collection, conservation, utilization, and external provision of China's human genetic resources, as well as detailing matters relating to the supervisory review and administrative penalties.

According to the Bio-security Law of the PRC (《中華人民共和國生物安全法》) promulgated by the SCNPC on October 17, 2020, and last amended with effect from April 26, 2024, where information on Chinese human genetic resources is to be provided or opened for use to foreign organizations, individuals or institutions established or actually controlled by foreign organizations and individuals, a report shall be filed in advance to the administrative department of health under the State Council and the information backup shall be submitted. It also provides that approvals are required to conduct international scientific research cooperation using Chinese biological resources. Furthermore, failure to comply with the requirements under the Bio-security Law of the PRC will result in penalties, including fines, suspension of related activities and confiscation of related human genetic resources and gains generated from conducting these activities.

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New Drug Application, Registration and Marketing Authorization

According to the Measures for the Administration of Drug Registration, an applicant may file an application for drug marketing authorization, after the completion of pharmaceutical, pharmacological and toxicological studies, clinical trials of drugs and other studies, determination of quality standards, the verification of commercial scale production process, and preparations to receive the check and inspection for drug registration. According to the Measures for the Administration of Drug Registration, drug marketing registration applications shall be subject to three categories, namely traditional Chinese drugs, chemical drugs and biological products. The CDE shall organize pharmacist, medical and other technical personnel to comprehensively review the application regarding the safety, effectiveness and quality control of the drug. Where the application is cleared by the comprehensive review, the drug shall be approved for marketing and a drug registration certificate shall be issued.

According to the Drug Administration Law, an applicant who has obtained a drug registration certificate shall be recognized as a drug marketing authorization holder, responsible for non-clinical laboratory studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals. The drug marketing authorization holder may engage in manufacturing or distribution on its own or to entrust a licensed third party.

Accelerated Approval for Clinical Trial and Registration

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》) promulgated and implemented by the State Council on August 9, 2015 established a framework for reforming the evaluation and approval system for drugs, and indicated enhancing the standard of approval for drugs and accelerating the evaluation and approval process for innovative drugs.

According to the Announcement of Several Policies on the Evaluation and Examination for Drug Registration promulgated by the CFDA on November 11, 2015, the INDs of new drugs are subject to one-off umbrella approval instead of declaration, evaluation and approval by stages.

According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs promulgated by the CFDA on March 17, 2017 and taking effect from 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.

The Opinion on Strengthening the Reform of the Drug and Medical Device Review and Approval Process to Encourage Drug and Medical Device Innovation, which was promulgated and implemented by the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council on October 8, 2017, further states that the evaluation and approval of drug marketing shall be accelerated and the approval procedure of drug clinical trials shall be optimized.

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The CFDA promulgated 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》) on December 21, 2017, which further clarify that a fast track clinical trial approval or drug marketing registration pathway will be available to innovative drugs. The Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation was replaced by the Announcement of the NMPA on Promulgating Three Documents including the Working Procedures for Evaluation of Breakthrough Therapy Designation Drugs (For Trial Implementation) (《國家藥監局關於發佈<突破性治療藥物審評工作程序(試行)>等三個文件的公告》), which was promulgated and implemented by the NMPA on July 7, 2020, refines the requirements and scope of the fast track, and the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation was repealed simultaneously.

According to the Announcement on Matters Concerning the Optimization of Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》) jointly promulgated by the NMPA and the NHC on May 17, 2018, the CDE will prioritize the allocation of resources for review, inspection, examination and approval of registration applications that have been included in the scope of fast track clinical trial approval.

The Announcement of the Adjustment of Procedures of the Evaluation and Examination for Drug Clinical Trial promulgated by the NMPA on July 24, 2018, stipulates that applicants could proceed with their clinical trials if they have not received any denial or query from the CDE within 60 business days after the application has been accepted and the relevant application fees have been paid.

The Measures for the Administration of Drug Registration provides more detailed standards, procedures and policy support for accelerating the marketing registration of different types of drugs such as procedures for breakthrough therapy designation, procedures for conditional approval, procedures for priority review and approval and procedures for special approval.

Regulations on the manufacture and distribution of pharmaceutical products

Drug Manufacturing License

According to the Drug Administration Law, a drug manufacturing enterprise is required to obtain a Drug Manufacturing License (藥品生產許可證) from the relevant provincial counterpart of the NMPA. According to the Measures for the Supervision and Administration of Drug Production (《藥品生產監督管理辦法》) promulgated by the SAMR on January 22, 2020 and taking effect on July 1, 2020, a Drug Manufacturing License is valid for five years and may be renewed upon the application by the holder of such Drug Manufacturing License at least six months prior to the expiration date and the approval by the provincial counterpart of the NMPA originally issues the Drug Manufacturing License.

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Good Manufacturing Practice

The Good Manufacturing Practices (《藥品生產質量管理規範》) (the “GMP”) last amended by the Ministry of Health of the PRC (the “MOH”, now known as the NHC) on January 17, 2011 and taking effect on March 1, 2011, provide guidance for the quality management, organization and staffing, production premises and facilities, equipment, materials 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.

Prior to December 1, 2019, a drug manufacturer shall apply for GMP certification to the drug supervision and administration department and obtain the GMP certificate in accordance with the relevant provisions. 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, the GMP and Good Supply Practice (GSP) certifications have been cancelled from December 1, 2019, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates are no longer issued. However, according to the Drug Administration Law, a manufacturer shall comply with the GMP and establish a sound GMP system, to ensure that the entire process of drug manufacturing maintains to meet the statutory requirements. The legal representative of and principal person in charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

On May 24, 2021, the NMPA promulgated the Administrative Measures for Drug Inspection (For Trial Implementation) (《藥品檢查管理辦法(試行)》) which was amended on July 19, 2023, and the Administrative Measures for the Certification of Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》) was repealed concurrently. The Administrative Measures for Drug Inspection (For Trial Implementation) provide that if a drug manufacturer applies for a drug manufacturing license for the first time, onsite inspections to be conducted in accordance with the GMP requirements is required, while for a drug manufacturer applying for the reissue of a drug manufacturing license, the review will be conducted based on the risk management principles, taking into account certain factors, including the drug manufacturer’s compliance with the laws and regulations of drug administration, the drug manufacturer’s operation of the GMP system and quality management system, and inspections on the drug manufacturer’s conformity to the GMP requirements may be conducted where necessary.

Contract Manufacturing of Drug

The Drug Administration Law specifies that a holder of drug sales approval may produce drugs by itself or may entrust other drug manufacturers. A holder of drug sales approval that intends to manufacture drugs on its own shall obtain a drug manufacturing permit, or if the holder intends to entrust a third-party to manufacture, it shall entrust a qualified drug manufacturer. The holder of drug sales approval and the commissioned manufacturer shall

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enter into an entrustment agreement and a quality agreement, and strictly perform the obligations pursuant to such agreements. Blood products, anesthetics, psychotropic pharmaceuticals, toxic pharmaceuticals for medical treatment, and pharmaceutical precursor chemicals may not be produced through entrustment, except as otherwise prescribed by the drug administrative department of the State Council.

According to the Provisions on the Supervision and Administration of Commissioned Production of Drugs (《藥品委託生產監督管理規定》) promulgated by the CFDA in August 2014, a drug manufacturer may commission its drugs to other domestic drug manufacturers to produce the drugs only when the production conditions are temporarily unavailable as a result of technical upgrading or the temporary inadequate capacity cannot guarantee the market supply. Such commissioning production arrangement shall be approved by the provincial branches of the CFDA.

Monitoring Periods for New Drugs

According to the Regulations for the Implementation of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》), the drug administrative department of the State Council may, for the purpose of protecting public health, provide for a monitoring period of not more than five years for new drugs manufactured by a drug manufacturer. During the monitoring period of a new drug, no approval shall be granted to any other manufacturer to produce or import the said drug.

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)》) (the “**Implementing Opinions on the Two-Invoice System**”) 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. Efforts shall be made to gradually promote the “Two-Invoice System” for the drug procurement among public medical institutions, and to encourage other medical institutions to promote the system for drug procurement. Pilot provinces (including autonomous regions and municipalities directly under

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the Central Government) for comprehensive medical reform and pilot cities for public hospital reform are required to take the lead in implementing the “Two-Invoice System”, while other regions are encouraged to implement the system, with the goal of having it implemented nationwide by 2018.

According to the Implementing Opinions on the “Two-Invoice System”, in areas where the “Two-Invoice System” is implemented for drug procurement in public medical institutions, the “Two-Invoice System” should be implemented as a prerequisite when centralized procurement agencies compile procurement documents. Pharmaceutical companies participating in centralized drug procurement must make a commitment to implement the “Two-Invoice System” in their bids; otherwise, the bids will be invalid. For drugs procured through other methods, the requirements of the “Two-Invoice System” must also be clearly stipulated in the procurement contracts.

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, pilot provinces (including autonomous regions and municipalities directly under the Central Government) for comprehensive medical reform and pilot cities for public hospital reform are required to take the lead in implementing the “Two-Invoice System”, while other regions are encouraged to implement the system, 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 medical institutions.

Drug Recall

According to the Administrative Measures for on Drug Recall (《藥品召回管理辦法》), which was promulgated on December 10, 2007, last amended in October 2022 and came into effect on November 1, 2022, Drug Recall refers to the activity whereby a drug marketing authorization holder (the “**Holder**”) recalls, in accordance with the prescribed procedures, any drugs that have been launched on the market but have quality problems or other potential safety hazards, and takes relevant measures to promptly control risks and eliminate potential hazards. The Holder shall establish and improve a drug recall system, collect relevant information on drug quality and safety, investigate and evaluate possible quality problems or other potential safety hazards, and timely recall drugs with quality problems or other potential safety hazards. The Holder shall formulate a drug recall information disclosure system, and voluntarily announce drug recall information pursuant to the law. Drug manufacturing enterprises, drug trading enterprises and drug users shall actively assist the Holder in investigation and evaluation of drugs which may have quality problems or other potential safety hazards, and voluntarily cooperate with the Holder in performing recall. Where a drug manufacturer, distributor or user discovers that the drug manufactured, sold or used by it may have quality problems or other potential safety hazards, it shall notify the Holder promptly, and where necessary, suspend manufacturing, release, sale and use of the drug, and report the matter to

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the government of the province, autonomous region or municipality directly under the Central Government where it is located. Information in the notice and report shall be truthful. The holders, drug manufacturers, drug trading enterprises and drug users shall, in accordance with relevant provisions, establish and implement a drug traceability system, and keep complete purchase and sales records to ensure the traceability of drugs launched on the market.

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 Basic Medical Insurance Coverage for Pharmaceutical Products for Urban Employees (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》) which was promulgated by the National Development and Reform Commission (the “NDRC”), the NMPA and other authorities and 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

According to the Tentative Measures for the Administration of the Scope of Basic Medical Insurance Coverage for Pharmaceutical Products for Urban Employees, the scope of basic medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Drug Catalogue for Basic Medical Insurance (《基本醫療保險藥品目錄》) (the “**Medical Insurance Catalogue**”). A pharmaceutical product listed in the Medical Insurance Catalogue must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements: it is set forth in the Pharmacopoeia of the PRC (current edition) (《中華人民共和國藥典》(現行版)); it meets the standards promulgated by the NMPA; and if imported, it is approved by the NMPA for import. The Medical Insurance Catalogue is divided into two parts of Part A and Part B. Patients purchasing medicines included in Part A of the Medical Insurance Catalogue are entitled to reimbursement in accordance with the regulations in respect of basic medical insurance.

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Patients purchasing medicines included in Part B of the Medical Insurance Catalogue are required to pay a certain percentage of the purchase price and the remainder shall be reimbursed in accordance with the regulations in respect of basic medical insurance. 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 Medical Insurance Catalogue in a strict manner, and shall not have the discretion to formulate the catalogue or increase the drugs in any form unless explicitly stipulated. After several adjustments, the currently effective Medical Insurance Catalogue is the National Reimbursement 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)》) which came into effect since January 1, 2024.

Drug Price

According to the Drug Administration Law, for drug products with market-regulated prices in accordance with the law, drug marketing authorization holders, drug manufacturers, drug trading enterprises and medical institutions 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. According 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 the NDRC, the NHC, the Ministry of Human Resources and Social Security, the Ministry of Industry and Information Technology (the “MIIT”), the Ministry of Finance (the “MOF”), the Ministry of Commerce (the “MOFCOM”) and the CFDA on May 4, 2015, from June 1, 2015, except for narcotic drugs and first-class psychotropic drugs, the price of drugs set by the government will be cancelled. On December 26, 2023, the NHSA issued the Notice on Promoting Fairness, Integrity, Transparency, and Balanced Prices Among Provinces for Drugs with the Same Generic Name and Manufacturer (《關於促進同通用名同廠牌藥品省際間價格公平誠信、透明均衡的通知》), requiring a comprehensive review and investigation of “Four-same Drugs” (referring to drugs with the same generic name, manufacturer, dosage form, and specifications) against the monitoring prices formed by the statistics of existing online drugs across the country. By the end of March 2024, it aims to essentially eliminate unfair high prices and discriminatory high prices among provinces for “Four-same Drugs”.

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Drug Technology Transfer

Drug technology transfer refers to the transfer of drug production technology by the owner to a drug manufacturer as the transferee and the application for drug registration by the drug manufacturer as the transferee pursuant to the laws and regulations in relation to drug technology transfer. The registration process of drug technology transfer, which includes application for, evaluation, review, approval and supervision of drug technology transfer registration, is regulated by the Measures for the Administration of 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 CFDA 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 CFDA will ultimately make an approval decision based on the comprehensive opinions of the CDE. Eligible applications will receive a letter of approval for the supplementary application and a drug approval number.

Administration of Pathogenic Microorganism Laboratories

According to the Regulations on Administration of Bio-safety in Pathogenic Microorganism Laboratories (《病原微生物實驗室生物安全管理條例》), which was promulgated by the PRC State Council on November 12, 2004 and last amended on March 19, 2018, the pathogenic microorganism laboratory is classified into four levels, namely Bio-safety Level 1, 2, 3 and 4 in terms of the national standard on bio-safety of the laboratory. A laboratory of Bio-safety Level 1 or 2 shall not conduct laboratory activities related to highly pathogenic microorganisms. The construction, alteration or expansion of a laboratory of Bio-safety Level 1 or 2 shall be reported for the record to competent health authorities. The establisher of a laboratory shall develop a scientific and strict management system, regularly inspect the implementation of the regulations on bio-safety, and regularly inspect, maintain and update the facilities, equipment and materials in the laboratory, to ensure its compliance with the national standards. The laboratories of Bio-safety Level 3 and Level 4 shall be subject to the state accreditation for laboratories. Laboratories passing accreditation will be granted with certificates for Bio-safety Laboratories at corresponding level. The certificate will be effective for five years.

Regulations on Company Establishment and Foreign Investment

The establishment, operation and management of corporate entities in China are governed by the Company Law of the PRC (《中華人民共和國公司法》) (the “**Company Law**”), which was promulgated by the SCNPC in December 1993 and further amended in December 1999, August 2004, October 2005, December 2013, October 2018 and December 2023, respectively. The Company Law also applies to foreign-invested joint stock limited companies.

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Investment activities in the PRC by foreign investors are governed by the Provisions on Guiding Foreign Investment Direction (《指導外商投資方向規定》), which was promulgated by the PRC State Council in February 2002 and came into effect in April 2002, the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2024 Version) (《外商投資准入特別管理措施(負面清單)(2024年版)》) (the “**Negative List**”), which was promulgated by the PRC MOFCOM and the NDRC in September 2024 and came into effect on November 1, 2024, and the Catalogue of Encouraged Industries for Foreign Investment (2022 Version) (《鼓勵外商投資產業目錄(2022年版)》) (the “**Encouraged Catalogue**”), which was promulgated by the MOFCOM and the NDRC in October 2022 and came into effect in January 2023. The Provisions on Guiding Foreign Investment Direction divides foreign investment projects into four categories, namely “encouraged”, “permitted”, “restricted” and “prohibited” categories. The Encouraged Catalogue lists the foreign investment projects of the encouraged category, while the Negative List sets out the foreign investment projects of the restricted and prohibited categories, and foreign investment projects which fall outside the encouraged, restricted and prohibited categories belong to the permitted category. The Negative List sets out the restrictive measures in a unified manner, such as the requirements on shareholding percentages and corporate governance, for the access of foreign investments, and the industries that are prohibited from receiving foreign investment. The Negative List covers 11 industries, and any field not falling under the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

The Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “**Foreign Investment Law**”) was promulgated by the National People’s Congress (the “**NPC**”) in March 2019 and came into effect in January 1, 2020. The Law on Wholly Foreign-owned Enterprises of the PRC (《中華人民共和國外資企業法》), the Law on Sino-foreign Equity Joint Ventures of the PRC (《中華人民共和國中外合資經營企業法》) and the Law on Sino-foreign Cooperative Joint Ventures of the PRC (《中華人民共和國中外合作經營企業法》) were repealed upon the Foreign Investment Law coming into effect. The investment activities of foreign natural persons, enterprises or other organizations (collectively, the “**Foreign Investors**”) directly or indirectly within the territory of China shall comply with and be governed by the Foreign Investment Law. Such activities include establishments by Foreign Investors of foreign invested enterprises in China alone or jointly with other investors; acquisitions by Foreign Investors of shares, equity, property shares, or other similar interests of Chinese domestic enterprises; investments by Foreign Investors in new projects in China alone or jointly with other investors; and other forms of investment prescribed by laws, administrative regulations or the State Council.

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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 Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》) jointly developed by the MOFCOM and the SAMR, which came into effect on January 1, 2020. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the relevant commerce administrative authorities in accordance with the Measures on Reporting of Foreign Investment Information.

The Measures on the Security Review of Foreign Investment (《外商投資安全審查辦法》) promulgated by the NDRC and MOFCOM on December 9, 2020 and taking effect on January 18, 2021 set forth provisions concerning the security review mechanism on foreign investment, including the types of investments subject to review, the scopes of review and procedures to review, among others.

Regulations on Self-Owned Real Properties

According to the Civil Code of the PRC (《中華人民共和國民法典》) (the “**Civil Code**”), which was promulgated by the NPC on May 28, 2020 and became effective from January 1, 2021, the creation, alteration, alienation, or extinguishment of the property right of a real property shall become effective upon registration in accordance with law. The certificate of ownership of real property shall be an evidence of the right holder’s entitlement in the real property.

According to the Land Administration Law of the PRC (《中華人民共和國土地管理法》) promulgated by the SCNPC on June 25, 1986, last amended on August 26, 2019 and taking effect from January 1, 2020, China implements socialist public ownership of land, that is, ownership by the whole people or collective ownership by the working masses. The State formulates an overall land utilization plan to stipulate land use, classifying land into agricultural land, construction land, or unused land. Entities or individuals using land must use the land strictly in accordance with the purposes of land use determined in the overall land utilization plan.

Regulations on Lease of Real Property

According to the Civil Code, a lease contract generally shall contain clauses specifying the name, quantity and purpose of use of the leased object, the term of the lease, rent, the schedule and method of its payment, the maintenance and repair of the leased object, etc. The lessee of a lease may, with the consent of the lessor, sublease the leased object to a third party.

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According to the Administrative Measures for Leasing of Commodity Housing (《商品房屋租賃管理辦法》) promulgated by the Ministry of Housing and Urban-Rural Development of the PRC (the “MOHURD”) on December 1, 2010 and became effective on February 1, 2011, a commodity housing lease contract should be registered and filed with the competent construction (real estate) departments of the municipalities directly under the central government, cities and counties where the house is located within 30 days after the execution of the lease contract. Those who fail to comply with the aforementioned filing regulations may be ordered by the competent authority to correct within a time limit. If the entity does not correct within the specified period, it may be subject to a fine ranging from 1,000 yuan to 10,000 yuan.

Regulations on Enterprise Investment Projects

According to the Regulations on the Administration of Approval and Record-Filing of Enterprise Investment Projects (《企業投資項目核准和備案管理條例》) which was promulgated by the PRC State Council on November 30, 2016 and became effective from February 1, 2017, pre-approval is required for projects that have national security concern or relate to major productivity distribution nationwide, strategic resource development and major public interests, and projects other than the aforesaid ones are subject to administration by way of filing. The Notice of the State Council on Issuing the Catalogue of Investment Projects Approved by the Government (2016 Version) (《國務院關於發佈政府核准的投資項目目錄(2016年本)的通知》) issued by the PRC State Council and taking effect from December 12, 2016 sets out projects required for pre-approval.

Regulations on Construction

Construction Work Planning Permit

In accordance with the Urban and Rural Planning Law of the PRC (《中華人民共和國城鄉規劃法》) promulgated by the SCNPC on October 28, 2007 and last amended with effect from April 23, 2019, where construction work is conducted in a city or town planning area, the relevant construction entity shall apply for a construction work planning permit (建設工程規劃許可證) from the competent administrative authority in charge of urban and rural planning.

Construction Work Commencement Permit

According to the Construction Law of the PRC (《中華人民共和國建築法》) promulgated by the SCNPC on November 1, 1997 and last amended with effect from April 23, 2019, a construction entity shall, prior to the commencement of a construction work, apply for a construction permit (施工許可證) from the competent construction administrative authority, except that certain small-scale projects that meet the requirements and conditions set by the competent construction administrative authority are exempted from obtaining a construction permit.

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According to the Administrative Measures for Construction Permits of Building Projects (《建築工程施工許可管理辦法》) promulgated by the MOHURD on October 15, 1999 and last amended with effect from March 30, 2021, any entity in China that carries out construction, fitting-out or decoration of a building and its ancillary facilities, installation of supporting lines, pipelines or equipment, as well as the construction of municipal infrastructure projects shall, prior to the commencement of the construction, apply for a construction permit. Construction works with a construction investment amount of less than RMB300,000 or a construction area of less than 300 square meters are not required for construction permits.

Acceptance on Completion of Construction

According to the Measures for the Administration of Completion Acceptance and Filing of Housing Construction and Municipal Infrastructure Projects (《房屋建築和市政基礎設施工程竣工驗收備案管理辦法》) promulgated by the MOHURD and taking effect from October 19, 2009, any entity in China that carries out construction works to build, expand or re-build real properties or municipal infrastructure projects shall, within 15 days after the acceptance of the relevant construction work, make a record-filing with the competent construction administration authority.

Regulations on Environmental Protection, Health and Safety

Environmental Protection

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, last amended on April 24, 2014 and taking effect from January 1, 2015, summarizes the rights and responsibilities of environmental protection regulatory authorities. The competent environmental protection administration authority under the State Council (currently is the Ministry of Ecology and Environment (the "MEE")) is authorized to promulgate national standards for environmental quality and discharge. At the same time, local environmental protection authorities may formulate local standards that are stricter than the national standards, in which case, the companies concerned shall comply with the national and local standards.

Environmental Impact Assessment

According to the Regulations on the Administration of Construction Project Environmental Protection (《建設項目環境保護管理條例》) promulgated by the PRC State Council on November 29, 1998, last amended on July 16, 2017 and taking effect from October 1, 2017, the construction entity shall submit an environmental impact report or an environmental impact statement, or fill in a registration form, as applicable, depending on the degree of impact the construction project has on the environment. For a construction project for which an environmental impact report or environmental impact statement shall be prepared, the construction entity shall submit the environmental impact report and environmental impact statement to the competent administrative authority of environmental protection for approval before the commencement of the construction. If the environmental impact assessment

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documents of a construction project have not been reviewed by the competent administrative authority in accordance with the law or have not been granted approval after the review, the construction entity shall be prohibited from commencing construction works of such project. Environmental protection facilities required for construction projects must be designed, constructed, and put into use simultaneously with the main project.

According to 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 last amended with effect from December 29, 2018, for construction projects that have an impact on the environment, entities shall prepare an environmental impact report, environmental impact statement or fill in an environmental impact registration form in accordance with the severity of the impact that the project may have on the environment.

Completion and Acceptance

According to the Regulations on the Administration of Construction Project Environmental Protection, for construction projects that involve the preparation of an environmental impact report or an environmental impact statement, the construction unit shall, after completion, conduct an acceptance inspection of the supporting environmental protection facilities in accordance with the standards and procedures stipulated by the State Council's environmental protection administrative department, and prepare an acceptance report. The Interim Measures for the Acceptance of Environmental Protection upon Completion of Construction Projects (《建設項目竣工環境保護驗收暫行辦法》), promulgated and implemented by the Ministry of Environmental Protection (now abolished) on November 20, 2017, regulate the procedures and standards for environmental protection acceptance by construction units after the completion of construction projects.

Pollutant Discharge

According to the Administrative Measures for Pollutant Discharge Licensing (《排污許可管理辦法》) promulgated by the MEE on April 1, 2024 and effective on July 1, 2024, enterprises, institutions and other producers and operators subject to the management of discharge permits shall apply for discharge permits and discharge pollutants in accordance with the requirements of the discharge permits; those who have not obtained discharge permits shall not discharge pollutants.

According to the Catalogue of Classified Management of Pollutant Discharge Permits for Stationary Pollution Sources (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》) promulgated by the MEE on December 20, 2019 and effective as of the same date, key management, simplified management and registration management of pollutant discharge permits are implemented based on factors such as the volume of pollutants generated, the amount of pollutants discharged and the degree of impact on the environment. The pollutant discharging entity subject to registration management does not need to apply for the pollutant discharge permit, but shall fill in the pollutant discharge registration form on the national pollutant discharge permit administration information platform.

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According to the Regulations on Urban Drainage and Sewage Treatment (《城鎮排水與污水處理條例》) promulgated by the PRC State Council on October 2, 2013 and with effect from January 1, 2014, urban entities and individuals shall dispose of sewage through urban drainage facilities covering their geographical area in accordance with the law. Companies or other entities engaging in medical activities shall apply for a sewage disposal drainage license (污水排入排水管網許可證) before disposing sewage into urban drainage facilities. Sewage-disposing entities and individuals shall pay sewage treatment fees in accordance with the law.

According to the Measures for the Bio-safety Environmental Management of Pathogenic Microbe Laboratories (《病原微生物實驗室生物安全環境管理辦法》) promulgated by the State Environmental Protection Administration (now abolished) on March 8, 2006 and with effect from May 1, 2006, where a laboratory intends to discharge waste water or waste gas, it shall comply with the relevant provisions issued by the State Environmental Protection Administration and implement the pollutant discharge declaration and registration system.

Production Safety

According to 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 last amended on June 10, 2021 and taking effect from September 1, 2021, 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 terms of production safety. Employees who fail the education and training programmes on production safety may not commence working in their positions. Safety facilities of new building, rebuilding or expanding project (the “**Construction Project**”) shall be designed, constructed and put into operation simultaneously with the main body of the project. Investment in safety facilities shall be included in the budget of the Construction Project.

According to the Regulation on the Administration of Precursor Chemicals (《易製毒化學品管理條例》) promulgated by the PRC State Council on August 26, 2005 and last amended and with effect from September 18, 2018, a classified administration and licensing system is applied to the production, distribution, purchase, transportation, and import and export of precursor chemicals. An enterprise shall report the variety and quantity in demand to the competent public security bureau for filing before purchasing any precursor chemicals in Category II and III.

On January 26, 2002, the State Council promulgated the Regulations on the Safety Management of Hazardous Chemicals (《危險化學品安全管理條例》) (the “**Hazardous Chemicals Regulations**”), which was last amended and effective on December 7, 2013. The Hazardous Chemicals Regulations set out supervision and administration provisions on the safe production, storage, use, operation and transport of hazardous chemicals. An enterprise that has

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obtained, in accordance with law, a license for safe production of hazardous chemicals, a license for safe use of hazardous chemicals or a license for operation of hazardous chemicals shall purchase highly toxic chemicals and hazardous chemicals liable to produce explosives based on the relevant licenses. The enterprises manufacturing explosives for civil use shall purchase hazardous chemicals liable to produce explosives with the licenses for manufacturing explosives for civil use. The units other than those stipulated in the preceding clause, for the purpose of purchasing highly toxic chemicals, shall apply to the public security authorities of the county-level government where they are located for the licenses for purchasing highly toxic chemicals. If any unit purchases hazardous chemicals liable to produce explosives, the statement on the legal use of hazardous chemicals liable to produce explosives issued by the relevant unit shall be submitted.

Fire Prevention

According to the Fire Prevention Law of the PRC (《中華人民共和國消防法》) (the “**Fire Prevention Law**”) promulgated by the SCNPC on April 29, 1998 and last amended with effect from April 29, 2021, design and construction of the fire control facilities for a construction work shall comply with the national fire control technical standards. The developer, designer, constructors and project supervisor of a construction project shall be responsible for the quality of the design and construction of the fire control facilities for the construction work according to the relevant laws.

According to the Fire Prevention Law and the Interim Provisions on the Administration of Design Inspection and Acceptance of Fire Protection of Construction Works (《建設工程消防設計審查驗收管理暫行規定》) (the “**Interim Provisions on Fire Protection**”) promulgated by the MOHURD on April 1, 2020, last amended on August 21, 2023 and taking effect from October 30, 2023, a special construction work as stipulated in the Interim Provisions on Fire Protection shall be subject to fire protection design review before the construction of such work is commenced and shall be subject to fire protection inspection before such work is put into use. Construction works other than a special construction work shall be subject to fire protection inspection filing, and the competent administrative authority in charge of the examination and acceptance of fire protection design shall conduct spot inspections. If a construction work fails to pass the spot inspection, the use of such construction work shall cease, and rectification actions must be taken with a view to applying for a re-inspection.

Prevention and Control of Occupational Diseases

According to the Law of the PRC on the Prevention and Control of Occupational Diseases (《中華人民共和國職業病防治法》), which was promulgated by the SCNPC on October 27, 2001 and last amended with effect from December 29, 2018, the Measures for the Supervision and Administration of “Three Simultaneities” for the Prevention and Control of Occupational Diseases Facilities of Construction Projects (《建設項目職業病防護設施“三同時”監督管理辦法》), which was promulgated by the State Administration of Work Safety (now abolished) on March 9, 2017 and became effective on May 1, 2017, and the Measures for the Declaration of Projects with Occupational Hazards (《職業病危害項目申報辦法》), which was promulgated

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by the State Administration of Work Safety (now abolished) on April 27, 2012 and became effective on June 1, 2012, the facilities for the prevention and control of occupational diseases of a construction project must be designed, constructed and put into operation simultaneously with the major construction works of the construction project. In addition, employers shall take required measures to prevent and control occupational diseases in work.

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》) (the “**Product Quality Law**”) promulgated by the SCNPC on February 22, 1993 and last amended with effect from December 29, 2018, is the principal law relating to the supervision and administration of product quality. The Product Quality Law clarifies liabilities of the manufacturers and sellers. Manufacturers shall be responsible for the quality of the products manufactured by them and sellers shall take measures to ensure the quality of the products sold by them.

If a defect in a product causes physical injury or damage to property other than the defective product, the manufacturer of the product shall be liable for compensation, unless the manufacturer is able to prove that: (1) the product has not been put into circulation; (2) the defects causing the physical injury or property damage did not exist at the time when the product was put into circulation; 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 for compensation if the physical injury or property damage of others is caused by defects due to the fault on the part of the seller. A seller shall also be liable for compensation if it can identify neither the manufacturer nor the supplier of the defective products. 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.

According to the Civil Code and the Product Quality Law, 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.

Regulations on Information Security and Data Protection

Personal Information Protection

According to the Civil Code, the personal information of an individual shall be protected by the law. Any organization or individual that needs to obtain personal information of others shall obtain such information legally and ensure the safety of such information, and shall not illegally collect, use, process or transmit personal information of others, or illegally purchase or sell, provide or publish personal information of others. In addition, the processing of personal information shall follow the principles of lawfulness, appropriateness and necessity.

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The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) (the “**Personal Information Protection Law**”), which was promulgated by the SCNPC on August 20, 2021 and became effective on November 1, 2021 requires that the processing of personal information should have a clear and reasonable purpose and should be limited to the minimum scope necessary to achieve the processing purpose, adopt a method that has the least impact on personal rights and interests, and shall not process personal information that is not related to the processing purpose.

The Interpretations of the Supreme People’s Court and the Supreme People’s Procuratorate on Several Issues Concerning the Application of Law in the Handling of Criminal Cases Involving Infringement of Citizens’ Personal Information (《最高人民法院、最高人民檢察院關於辦理侵犯公民個人信息刑事案件適用法律若干問題的解釋》) was promulgated on May 8, 2017 and became effective on June 1, 2017. The Interpretations clarify several concepts regarding the crime of “infringement of citizens’ personal information” stipulated by Article 253A of the Criminal Law of the PRC (《中華人民共和國刑法》), including “citizens’ personal information”, “violation of relevant national provisions”, “provision of citizens’ personal information” and “illegally obtaining any citizen’s personal information by other methods”. In addition, the Interpretations specify the standards for determining “serious circumstances” and “extraordinary serious circumstances” of this crime.

Information Security and Censorship

On June 10, 2021, the SCNPC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》) (the “**Data Security Law**”), which came into effect on September 1, 2021. The Data Security Law sets forth the regulatory framework and the responsibilities of the relevant administrative authorities in regulating data security. It provides that the central government shall establish a central data security work liaison system, which shall coordinate the relevant authorities covering different industries to formulate the catalogues of key data, and the special measures that shall be taken to protect the security of the key data.

On November 7, 2016, the SCNPC promulgated the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) (the “**Cyber Security Law**”), which became effective on June 1, 2017, according to which, network operators shall fulfill their obligations to safeguard the security of the network when conducting business and providing services. Those who provide services through networks shall take technical measures and other necessary measures according to laws, administrative regulations and compulsory national requirements to safeguard the safe and stable operation of the networks, respond to network security incidents effectively, prevent illegal and criminal activities, and maintain the integrity, confidentiality and usability of network data. The network operator shall not collect personal information irrelevant to the services it provides or collect or use the personal information in violation of the provisions of laws or agreements concluded with its users, and network operators of key information infrastructure shall store within the PRC all the personal information and important data collected and produced within the PRC. The purchase of network products and services that may affect national security shall be subject to national cybersecurity review.

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On July 30, 2021, the PRC State Council promulgated the Regulations on the Protection of the Security of Critical Information Infrastructure (《關鍵信息基礎設施安全保護條例》), which became effective on September 1, 2021. According to the Regulations on the Protection of the Security of Critical Information Infrastructure, a “critical information infrastructure” refers to an important network facility and information system in important industries such as, among others, public communications and information services, as well as other important network facilities and information systems that may seriously endanger national security, the national economy, the people’s livelihood, or the public interests in the event of damage, loss of function, or data leakage.

On December 28, 2021, the Cyberspace Administration of China (the “CAC”), jointly with 12 other administrative authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》), which became effective on February 15, 2022. According to the Measures for Cybersecurity Review, critical information infrastructure operators that purchase network products and services, and network platform operators engaging in data processing activities that affect or may affect national security are subject to cybersecurity review under the Measures for Cybersecurity Review. In addition, network platform operators with personal information of over one million users shall be subject to cybersecurity review before listing abroad (國外上市). The competent authorities may also initiate a cybersecurity review against the operators if the authorities believe that the network product or service or data processing activities of such operators affect or may affect national security.

On July 7, 2022, the CAC promulgated the Cross-border Data Transfer Security Assessment Measures (《數據出境安全評估辦法》), which became effective on September 1, 2022. It provides that, among others, data processors shall apply to competent authorities for security assessment when (1) the data processors transferring important data abroad; (2) a critical information infrastructure operator or a personal information processor that has processed personal information of more than one million people, transferring personal information abroad; (3) a data processor who has provided personal information of 100,000 individuals or sensitive personal information of 10,000 individuals abroad, in each case as calculated cumulatively, since January 1 of the last year, transferring personal information abroad, and (4) other circumstances where the security assessment of data cross-border transfer is required as prescribed by the CAC. In addition, on February 22, 2023, the Provisions on the Prescribed Agreement on Cross-border Data Transfer of Personal Information (《個人信息出境標準合同辦法》) (the “**Provisions on Prescribed Agreement**”) was promulgated by the CAC, which took effect on June 1, 2023. The Provisions on Prescribed Agreement attaches the prescribed template for cross-border data transfer agreement that could be used as an available option to satisfy the condition for cross-border transfer of personal information under Article 38 of the Personal Information Protection Law.

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》) promulgated by the CAC and came into effect on March 22, 2024, 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 January 1 of the current year.

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In September 2024, the State Council released the Regulation on Network Data Security Management (《網絡數據安全管理條例》), which shall come into force on January 1, 2025. The Regulation on Network Data Security Management is not only the first at the administrative regulation level specifically for network data security, but it also serves as a comprehensive implementing regulation for the compliance requirements set out by the Cybersecurity Law, the Data Security Law, and the Personal Information Protection Law. The Regulation on Network Data Security Management introduces several key obligations, including requiring network data handlers to specify the purpose and method of personal information processing, as well as the types of personal information involved, before any personal information is handled. It also clarifies definitions for important data, outlines the obligations of those handling important data, establishes broader contractual requirements for data sharing between data handlers, and introduces a new exemption for regulatory obligations regarding cross-border data transfers.

Regulations on Intellectual Property Rights

Trademark

Trademarks are 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 last amended on April 23, 2019 with effect from November 1, 2019, and the Implementation Regulation of the PRC Trademark Law (《中華人民共和國商標法實施條例》), which was promulgated by the State Council on August 3, 2002 and last amended on April 29, 2014 with effect from May 1, 2014. The Trademark Office of the China National Intellectual Property Administration is in charge of trademark registration and grants registered trademarks a validity term of 10 years which may be renewed for consecutive 10-year periods upon application by the owner of the registered trademark.

Patent

Patents are 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 last amended on October 17, 2020 with effect from June 1, 2021, and the Implementing Regulations of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), which was promulgated by the State Council on June 15, 2001 and last amended on December 11, 2023 with effect from January 20, 2024. The Patent Office of the China National Intellectual Property Administration is responsible for the patent work nationwide, and its counterparts at provincial level are responsible for the administration of patents within their respective administrative regions. An invention or utility model for which a patent is granted shall be novel, inventive and practically applicable. The protection period is 20 years for an invention patent, 10 years for a utility model patent, and 15 years for design patent, commencing from their respective application dates. Any entity or individual that intends to use a patent of another party must enter into a licensing agreement with the patent owner and pay patent royalties to the patent owner. Any use of a patent without the permission of the patent owner constitutes an infringement of the patent right.

REGULATORY OVERVIEW

The Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, and stipulates that the patent administration department under the State Council shall, upon request of the patentee, extend the patent term of relevant invention patents of the new drug that is approved to be listed on the market in China, to compensate for the time spent for the review and examination and approval of the listing of a new drug on the market. The compensated extension shall not exceed five years, and the total valid patent term after the new drug is approved for the market shall not exceed fourteen years.

Domain Names

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

Laws and Regulations Related to Tax

Enterprise Income Tax of the PRC

According to 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 and last amended and effective from December 29, 2018 by the SCNPC and its implementation rules, the EIT Law generally imposes a uniform income tax rate of 25% on all resident enterprises in China, including foreign-invested enterprises. The EIT Law and its implementation rules permit the enterprises qualified as “High and New Technologies Enterprises” to enjoy a reduced 15% enterprise income tax rate.

Value-added Tax of the PRC

According to the Provisional Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例》), which came into effect in January 1994, and was amended in November 2008, February 2016 and November 2017, and the Detailed Implementing Rules of the Provisional Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例實施細則》), which came into effect in December 1993 and was amended in December 2008 and October 2011, unless otherwise specified, taxpayers that sell goods, labor services, or tangible personal property leasing services or import goods in China shall pay VAT at a tax rate of 17%; the sales of transportation, postal services, basic telecommunications, construction, and real property leasing services, the sales of real property, and the transfer of land use rights shall be subject to VAT at a tax rate of 11%; the sales of services and intangible assets shall be subject to VAT at a tax rate of 6% unless otherwise provided.

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According to the Notice of the Ministry of Finance and the State Administration of Taxation on Adjusting Value-added Tax Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) issued in April 2018, from May 2018, the deduction rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively.

According to the Announcement on Relevant Policies for Deepening the Value-added Tax Reform (《關於深化增值稅改革有關政策的公告》) issued in March 2019, the previous applicable VAT rate of 16% and 10% will be adjusted to 13% and 9% respectively for VAT general taxpayers' taxable sales activities or imported goods.

Regulations on Foreign Exchange and Dividend Distribution

Foreign Exchange Control

The PRC Regulations for the Foreign Exchange Administration (《中華人民共和國外匯管理條例》), which was promulgated by the PRC State Council in January 1996 and amended in January 1997 and August 2008, established the regulatory framework of the administration on foreign currency exchange in China. Under the PRC Regulations for the Foreign Exchange Administration, payments of current account items, such as trade, services, benefits or current transfer-related transactions, in foreign currencies may be proceeded without prior approval from the State Administration of Foreign Exchange of the PRC (the “SAFE”) as long as certain procedural requirements are complied with. By contrast, approval from, or registration with, appropriate administrative authorities is required where RMB is to be converted into foreign currency and remitted out of China for items under the capital account such as repayment of foreign currency denominated loans or foreign currency is to be remitted into China under the capital account, such as a capital increase or foreign currency loans extended by an offshore entity to an entity in China.

The Provisions on the Administration of Foreign Exchange in Domestic Direct Investments by Foreign Investors (《外國投資者境內直接投資外匯管理規定》), which was promulgated by the SAFE in May 2013 and amended in October 2018 and December 2019, regulate and clarify the administration over foreign exchange administration in foreign investors' direct investments, and provide that the administration by the SAFE or its local branches over direct investment by foreign investors in China shall be conducted by way of registration and banks shall process foreign exchange business relating to the direct investment in China based on the information recorded with the SAFE and its branches.

According to the Circular of the State Administration of Foreign Exchange on Further Improving and Adjusting the 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》) and its appendices promulgated in November 2012 and amended in May 2015, October 2018 and December 2019 by the SAFE, the foreign exchange procedures are further simplified: (1) the opening of and payment into foreign exchange accounts under direct investment are no longer subject to approval by the SAFE; (2) reinvestment with legal income of foreign investors in China is no

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longer subject to approval by the SAFE; (3) the procedures for capital verification and confirmation that foreign-invested enterprises need to go through are simplified; (4) purchase and external payment of foreign exchange under direct investment are no longer subject to approval by the SAFE; (5) domestic transfer of foreign exchange under direct investment is no longer subject to approval by the SAFE; and (6) the administration over the settlement of foreign exchange capital of foreign-invested enterprises is improved. The SAFE issued the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of 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》) in February 2015 which became effective in June 2015 and was further amended in December 2019. It prescribes that the banks instead of the SAFE can directly handle foreign exchange registrations under foreign direct investment while the SAFE and its branches indirectly supervise the foreign exchange registration under foreign direct investment through the bank. On April 3, 2024, the SAFE promulgated the Guidelines on Foreign Exchange Operations for Capital Accounts (2024 Edition), which became effective on May 6, 2024, to provide guidelines on foreign exchange operations for capital accounts.

According to the Circular on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises (《關於改革外商投資企業外匯資本結匯管理方式的通知》) issued by the SAFE in March 2015 and amended in December 2019 and March 2023, and the Circular of the State Administration of Foreign Exchange on the Reform and Standardization of the Management Policy of the Settlement of Capital Accounts (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) issued by the SAFE on June 9, 2016 and amended in December 2023, discretionary settlement of foreign exchange receipts under capital accounts means that domestic institutions may settle their foreign exchange receipts under capital accounts (including foreign exchange capital, foreign debts, and repatriated funds raised through overseas listing) subject to discretionary settlement as explicitly prescribed in the relevant policies with banks according to their actual operation needs. Domestic institutions may, at their discretion, settle up to 100% of all foreign exchange receipts under capital accounts for the time being, and the SAFE may adjust the aforesaid proportion in due time according to the situation of international balance of payments. The Circular of the State Administration of Foreign Exchange on Further Deepening the Reform to Facilitate Cross-border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》) promulgated and implemented by the SAFE on December 4, 2023 further facilitates the payment and use of funds raised by foreign-invested enterprises through overseas listing. The asset realization account under the capital account shall be adjusted to the settlement account under the capital account. The foreign exchange funds raised by a domestic enterprise in overseas listing may be directly remitted to the settlement account under the capital account. The funds in the settlement account under the capital account may be settled and used on its own.

According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通 知》) issued by the SAFE in April 2020, eligible enterprises are allowed to make domestic payments by using their funds received by way of capital contribution, foreign debts and overseas listing, with no need to provide the evidentiary materials concerning authenticity of

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such payment to banks in advance, provided that their capital use shall be authentic and compliant, and conform with the prevailing administrative regulations on the use of income under capital accounts. The concerned bank shall conduct ex-post spot check and the local branches of the SAFE shall strengthen monitoring analysis and interim and ex-post regulation in accordance with the relevant requirements.

On April 28, 2013, the SAFE issued the Administrative Measures on Registration of Foreign Debt (《外債登記管理辦法》), which came into effect on May 13, 2013, and revised some of its contents in accordance with the Notice of the State Administration of Foreign Exchange on Nullified and Modified Regulatory Documents on the Reform of Registered Capital Registration System (《國家外匯管理局關於廢止和修改涉及註冊資本登記制度改革相關規範性文件的通知》). According to the Administrative Measures on Registration of Foreign Debt, debtors shall, after borrowing foreign debts in accordance with the provisions, register or submit contract conclusion, drawing, repayment, foreign exchange settlement and sale and other information in respect of foreign debts to the local foreign exchange bureaus in the prescribed manner.

According to the Notice of the State Administration of Foreign Exchange on Relevant Issue Concerning the Administration of Foreign Exchange for Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) issued by the SAFE on December 26, 2014, the domestic companies shall register the overseas listing with the foreign exchange bureaus located at their registered addresses in 15 working days after the completion of the overseas listing and issuance. The funds raised by the domestic companies through overseas listing may be repatriated to China or deposited overseas, provided that the intended use of the funds shall be consistent with the contents of the document and other public disclosure documents.

Dividend Distribution

The principal regulations governing distribution of dividends of foreign-invested enterprises include the Company Law. Under these regulations, joint stock limited companies (including foreign-invested enterprises) in the PRC may pay dividends only out of their accumulated profits, if any, determined in accordance with the PRC accounting standards and regulations. In addition, companies are required to allocate at least 10% of their accumulated profits each year, if any, to fund certain reserve funds unless these reserves have reached 50% of the registered capital of the enterprises.

The SAFE issued the Notice on Improving the Check of Authenticity and Compliance to Further Promote Foreign Exchange Administration Reform (《關於進一步推進外匯管理改革完善真實合規性審核的通知》) in January 2017, which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (1) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements for any remittance of profits of more than (not excluding) USD50,000; and (2) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall make detailed explanations of

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sources of capital and utilization arrangements, and provide board resolutions, contracts and other proof when completing the registration and outward remittance procedures in connection with an outbound direct investment.

Regulations on labor protection and social insurance

General Labor Contracts Rules

According to the Labor Law of the PRC (《中華人民共和國勞動法》) which was promulgated by the SCNPC on July 5, 1994, last amended and came into effect on December 29, 2018, the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) which was promulgated by the SCNPC on June 29, 2007, last amended on December 28, 2012 and came into effect on July 1, 2013, and the Implementing Regulations of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》) which was promulgated by the PRC State Council on September 18, 2008, a labor contract in writing is required to establish a labor relationship between an employee and his employer. Wages may not be lower than the local standards of minimum wages. Employers must establish their respective system of labor safety and sanitation, implement the rules and standards issued or imposed by the State from time to time, provide education regarding labor safety and sanitation to their employees, provide their employees with labor safety and sanitation conditions and necessary articles of labor protection conforming to the provisions of the State, and provide regular health examination for employees engaged in work involving occupational hazards.

Social Security and Housing Provident Fund

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) promulgated on October 28, 2010 and last amended with effect from December 29, 2018, employers in China are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, maternity insurance, occupational injury insurance and medical insurance, as well as a housing provident fund and other welfare plans. These payments are made to local competent administrative authorities, and any employer who fails to contribute may be ordered to correct the deficit within a stipulated time limit and be fined if it still fails to contribute after such stipulated time limit has passed.

On July 20, 2018, the General Office of the Communist Party of China and the General Office of the PRC State Council jointly issued 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》), under which, starting from January 1, 2019, tax authorities are responsible for the collection of social insurance contributions in China. 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》) issued by the SAT in 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》) issued by the

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General Office of the Ministry of Human Resources and Social Security in 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 Several 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》) issued by the SAT in November 2018, repeats that tax authorities at all levels may not organize self-collection of arrears of taxpayers including private enterprises in the previous years. The Notice on Issuing the Comprehensive Plan for the Reduction of Social Insurance Premium Rate (《關於印發降低社會保險費率綜合方案的通知》) promulgated by the General Office of the PRC State Council in April 2019, generally reduces the social insurance contribution burden of enterprises, underlines that the duties for collection of social insurances premium paid by the enterprises in any province shall not be transferred to tax authorities until the condition of the province is mature, and re-emphasizes that local authorities shall not conduct self-collection of historical unpaid social insurance contributions from enterprises.

Regulations on Overseas Listing

CSRC Filing Requirements for Overseas Offering and Listing

On February 17, 2023, the China Securities Regulatory Commission (the “CSRC”) released the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) and five supporting guidelines (together, the “**Trial Filing Measures**”), which came into effect on March 31, 2023. If a domestic company seeks for overseas securities issuance and listing, the issuer shall file with the CSRC in accordance with the Trial Filing Measures.

According to the Trial Filing Measures, the issuer shall submit the required filing documents to the CSRC within three working days after the overseas listing application is submitted to the relevant overseas regulator or listing venue. Once the filing documents are complete and in compliance with the stipulated requirements, the CSRC will, within 20 working days, conclude the review procedure and publish the filing results on the CSRC website. To the extent the filing documents are incomplete or do not conform to stipulated requirements, the CSRC will, within five working days upon receipt of filing documents, request supplementation and amendment to the filing. Then the issuer has 30 days to prepare any requested supplemented/amended filing. In addition, following the listing in an overseas market, the issuer shall submit a report to the CSRC within three working days after the occurrence and public disclosure of the following events involving the issuer: (1) change of control; (2) investigations or sanctions imposed by overseas regulators; (3) change of listing status or transfer of listing market; and (4) voluntary or involuntary delisting.

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The Trial Filing Measures also stipulate that following cases may be rejected by the CSRC: (1) offerings and listings are explicitly prohibited by laws and regulations; (2) offerings and listings may endanger national security as reviewed and determined by competent authorities under the PRC State Council in accordance with law; (3) domestic companies of the listing applicant or its controlling shareholder or actual controlling person are involved in criminal offenses in the last three years, such as corruption, bribery, embezzlement, misappropriation of property, or undermining the order of the socialist market economy; (4) domestic companies of the listing applicant are under investigations for suspicion of criminal offenses or are involved in major violations of laws and regulations and no conclusion of the investigation has yet been made; or (5) there are material ownership disputes over equity interests held by controlling shareholders or by shareholders who are controlled by the controlling shareholder or actual controlling person.

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

According to the Guidelines for the Application for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請“全流通”業務指引》) (the “**Guidelines for the ‘Full Circulation’**”) promulgated by the CSRC on November 14, 2019 and amended on August 10, 2023, “full circulation” means listing and circulating on the Hong Kong Stock Exchange of the domestic unlisted shares of an H-share listed company, including unlisted domestic shares held by domestic shareholders prior to overseas listing, unlisted domestic shares additionally issued after overseas listing, and unlisted shares held by foreign shareholders. Shareholders of domestic unlisted shares may determine by themselves through consultation the amount and proportion of shares, for which an application will be filed for circulation, provided that the requirements laid down in the relevant laws and regulations and set out in the policies for state-owned asset administration, foreign investment and industry regulation are met, and the corresponding H-share listed company may be entrusted to file with the CSRC for “Full Circulation”. After domestic unlisted shares are listed and circulated on the Hong Kong Stock Exchange, they may not be transferred back to China. Pursuant to Article 18 of the Trial Filing Measures, which came into effect on March 31, 2023, for a domestic enterprise seeking direct overseas listing, shareholders holding such enterprise’s domestic unlisted shares who apply for the conversion of its domestic unlisted shares into overseas listed shares shall comply with the relevant provisions of the CSRC and entrust such domestic enterprise to file with the CSRC.

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

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In order to fully promote the reform of H-share “Full Circulation” and clarify the business arrangement and procedures for the relevant shares’ registration, custody, settlement and delivery, the Guide to the Program for “Full Circulation” of H-shares of the Shenzhen Branch of China Securities Depository and Clearing Corporation Limited (《中國證券登記結算有限責任公司深圳分公司H股“全流通”業務指南》) was promulgated by the Shenzhen Branch of CSDC on September 20, 2024 and came into effect on September 23, 2024, which specifies the business preparation, cross-border transfer registration, overseas depository of shares and initial maintenance of domestic holding details, etc.

CSRC Requirements on Confidentiality and Archives Administration for Overseas Offering and Listing

On February 24, 2023, the CSRC, the MOF, the National Administration of State Secrets Protection and the National Archives Administration jointly released the revised Provisions on Strengthening the 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》) (the “**Archives Administration Provisions**”), which came into effect on March 31, 2023. According to the Archives Administration Provisions, the domestic companies shall establish and implement a solid confidentiality and archives administration system. If a domestic company decides to disclose any documents or materials containing state secrets, work secrets of state authorities or any information that may be detrimental to national security or public interest once leaked, proper governmental approval procedures should be followed. After obtaining the governmental clearance, the domestic company disclosing such information, as one party, and the securities companies and securities services providers receiving such information, as the other party, shall also enter into non-disclosure agreements, setting forth the confidentiality obligations of the securities companies and securities services providers. When providing the above information to the securities companies and securities services providers retained by it, the domestic companies are also required to issue a written statement outlining its compliance with the relevant regulatory requirements and procedures.

In terms of providing accounting archives or copies thereof to any other entities or persons (such as securities companies, securities services providers and overseas regulators), the Archives Administration Provisions stipulate that relevant governmental procedures should be complied with.

Any violation of the above regulations may subject the domestic companies to regulatory penalties under the Safeguarding State Secrets Law of the PRC (《中華人民共和國保守國家秘密法》) and the Archives Law of the PRC (《中華人民共和國檔案法》) and even criminal liabilities to the extent applicable.

HISTORY AND CORPORATE STRUCTURE

OVERVIEW

We are an innovation-driven biopharmaceutical company in China with a global vision, leveraging our deep understanding of China’s pharmaceutical industry and profound insights of its unique clinical needs to better patient health and life. Since our inception in 2008, we have built a comprehensive in-house R&D platform that has supported our development of a highly competitive and balanced pipeline. As of the Latest Practicable Date, we had over ten drug assets under active development covering digestive diseases, oncology and NASH. Our track record also includes the successful development of four drug candidates that were subsequently transferred and/or out-licensed to leading pharmaceutical companies. This achievement underscores our robust R&D capabilities and keen commercial instincts.

Our history can be traced back to 2008, when Sihuan Pharm, our Controlling Shareholder, acquired the majority interest in Shandong Xuanzhu with a view to advancing its research and development capabilities for innovative drugs. Prior to our establishment, our business activities were conducted through Shandong Xuanzhu, which is now a wholly-owned subsidiary of our Company. For details of the background information about our Controlling Shareholders, see the section headed “Relationship with Our Controlling Shareholders.”

Our Company was established in the PRC on September 5, 2018 by Xuanzhu Biopharma, a wholly-owned subsidiary of Sihuan Pharm, and was converted into a joint stock company under the name of Xuanzhu Biopharmaceutical Co., Ltd. (軒竹生物科技股份有限公司) on November 22, 2021. For further details of the establishment and major shareholding changes of our Company, see “— Our Corporate History” below.

MILESTONES

The following table summarizes various key milestones in our corporate and business development.

Year	Milestone
2008	<ul style="list-style-type: none">• We commenced our operations through Shandong Xuanzhu.• We initiated the business regarding the R&D of innovative drugs and started to build up our in-house small molecule drug R&D platform.
2012	<ul style="list-style-type: none">• Sihuan Pharm acquired the remaining equity interest in Shandong Xuanzhu and Shandong Xuanzhu became a wholly-owned subsidiary of Sihuan Pharm, mainly focusing on the R&D of innovative drugs.
2013	<ul style="list-style-type: none">• We obtained the IND approval of KBP-3571 (Anaprazole Sodium) for its phase 1 clinical trial.
2017	<ul style="list-style-type: none">• We obtained the IND approval of XZP-3287 (Bireociclib).

HISTORY AND CORPORATE STRUCTURE

Year	Milestone
2018	<ul style="list-style-type: none">• Our Company was established in Hainan Province, China and became the holding company of our Group upon completion of the intra-group restructuring.• We obtained the IND approval of XZP-3621.
2020	<ul style="list-style-type: none">• We commenced a phase 3 clinical trial of KBP-3571 (Anaprazole Sodium) for the treatment of DU in China.• We accelerated the development of our biological drug R&D platform by acquiring the biologics business of Beijing Combio Pharmaceutical Inc.
2021	<ul style="list-style-type: none">• We completed the Series A and Series B Financings.• Our Company was converted into a joint stock limited company under the name of Xuanzhu Biopharmaceutical Co., Ltd. (軒竹生物科技股份有限公司).• We commenced a phase 3 clinical trial of XZP-3287 (Bireociclib) in China in combination with fulvestrant in treating HR+/HER2-advanced BC.• We obtained approval from the NMPA for conducting phase 3 clinical trial of XZP-3621 in China for the first-line treatment of patients with ALK-positive advanced NSCLC.• We commenced a phase 3 clinical trial of XZP-3287 (Bireociclib) in China in combination with aromatase inhibitor in treating advanced HR+/HER2- BC.
2022	<ul style="list-style-type: none">• We commenced a phase 2 clinical trial of KBP-3571 (Anaprazole Sodium) for RE in adults in China.• We entered into two out-licensing and collaboration agreements with Shanghai SPH New Asia Pharmaceutical Co., Ltd., to out-license certain patents and know-how owned by us relating to KBP-5081, a Class 1 innovative benapenem candidate, and XZP-P803, a plazomicin candidate.

HISTORY AND CORPORATE STRUCTURE

Year	Milestone
2023	<ul style="list-style-type: none"> • KBP-3571 (Anaprazole Sodium) obtained drug registration approval from the NMPA for the treatment of DU, becoming our first commercialized product, which was subsequently included in the NRDL. • The NDA applications of XZP-3287 (Bireociclib)’s monotherapy and combinational therapy with fulvestrant in the treatment of advanced BC were filed and accepted by the NMPA.
2024	<ul style="list-style-type: none"> • The NDA application of XZP-3621 in the first-line treatment of patients with ALK- positive advanced NSCLC was filed and accepted by the NMPA. • We entered into an out-licensing and technology transfer agreement with Livzon Group Livzon Pharmaceutical Factory to grant certain patents, know-how and interests related to XZP-5849, a PDE5 inhibitor candidate.

OUR SUBSIDIARIES

As of the Latest Practicable Date, we had six subsidiaries which are all wholly-owned by our Company. Detailed information of our subsidiaries is set out below:

Company Name	Place of Incorporation	Principal Business	Date of Incorporation and Commencement of Business
Beijing Xuanzhu	PRC	R&D, clinical development and registration of innovative drugs, and sales of pharmaceutical products	December 10, 2018
Shandong Xuanzhu	PRC	R&D, clinical development and registration of innovative drugs	April 23, 2002
Xuanzhu Combio	PRC	R&D, clinical development and registration of innovative drugs	March 24, 2021
Xuanzhu HK	Hong Kong	Investment holding	June 3, 2021

HISTORY AND CORPORATE STRUCTURE

<u>Company Name</u>	<u>Place of Incorporation</u>	<u>Principal Business</u>	<u>Date of Incorporation and Commencement of Business</u>
Xuanzhu US	US	Overseas business development	June 18, 2021
Hainan Huixuan	PRC	No substantial business operations	August 10, 2020 ^{Note}

Note: Hainan Huixuan had not conducted any substantial business operations as of the Latest Practicable Date.

OUR CORPORATE HISTORY

Early Development

Our history can be traced back to 2008, when Sihuan Pharm, our Controlling Shareholder, acquired the majority interest in Shandong Xuanzhu with a view to advancing its R&D capabilities for innovative drugs. In 2012, Sihuan Pharm acquired the remaining equity interest in Shandong Xuanzhu and Shandong Xuanzhu became a wholly-owned subsidiary of Sihuan Pharm.

Prior to our establishment, our business activities were conducted through Shandong Xuanzhu, which is currently a wholly-owned subsidiary of our Company.

Establishment and Major Shareholding Changes of Our Company

Establishment in 2018

Our Company was established as a limited liability company in the PRC on September 5, 2018 with an initial registered capital of RMB1,000,000. At the time of our establishment, our Company was known as Hainan Xuanzhu Pharmaceutical Technology Co., Ltd. (海南軒竹醫藥科技有限公司) and wholly owned by Xuanzhu Biopharma. After our establishment, through a series of capital increases from December 2018 to December 2019, our registered capital was increased from RMB1,000,000 to RMB1,150,000,000, while remaining wholly owned by Xuanzhu Biopharma.

Subsequently, our Company has undertaken a series of equity transfers and capital increases to, amongst others, raise funds for the development of our business and diversify our Shareholders base. The major shareholding changes of our Company are set out below.

HISTORY AND CORPORATE STRUCTURE

Equity Incentive in 2020

On August 18, 2020, Xuanzhu Biopharma entered into two equity transfer agreements (as amended on September 10, 2021) with (i) our Directors, namely Ms. Xu Yanjun (徐艷君) (“**Ms. Xu**”), Dr. Li Jia Kui (李嘉逵) (“**Dr. Li**”) and Dr. Shih Cheng-Kon (史澂空) (“**Dr. Shih**”) and (ii) our Incentive Platforms, namely Tianjin Hongzekang, Tianjin Xuansheng, Tianjin Hongteng, Tianjin Zhenxuan, Tianjin Pusheng, Tianjin Guoding and Tianjin Huize, respectively. Pursuant to such agreements, Xuanzhu Biopharma agreed to transfer approximately 6.93% equity interest in our Company held by it to the aforesaid ten transferees for incentive purposes at a total consideration of RMB20,959,785. Upon completion of the above equity transfers, our Company was owned as to approximately 93.07% by Xuanzhu Biopharma, 3.83% collectively by our seven Incentive Platforms, 1.30% by Dr. Shih, 1.00% by Dr. Li, and 0.80% by Ms. Xu. For further details of our Incentive Platforms, see “— Incentive Platforms” below.

Details of the aforementioned equity transfers are set out below:

Transferee	Consideration	Registered capital transferred
	(RMB)	(RMB)
Tianjin Hongzekang	2,973,084	11,304,500
Tianjin Xuansheng	2,488,861	9,463,350
Tianjin Hongteng	1,922,070	7,308,250
Tianjin Zhenxuan	1,583,628	6,021,400
Tianjin Pusheng	1,000,505	3,804,200
Tianjin Guoding	959,069	3,646,650
Tianjin Huize	656,619	2,496,650
Subtotal	<u>11,583,835</u>	<u>44,045,000</u>
Ms. Xu	2,419,600	9,200,000
Dr. Shih	3,931,850	14,950,000 ^{Note}
Dr. Li	3,024,500	11,500,000
Subtotal	<u>9,375,950</u>	<u>35,650,000</u>
Total	<u>20,959,785</u>	<u>79,695,000</u>

Note: To facilitate incentives for other employees of our Group, Dr. Shih transferred registered capital to redistribute equity incentives previously granted to him recognizing their future contributions and responsibilities in our Group’s development. Pursuant to an equity transfer agreement dated July 26, 2021 (as amended on July 31, 2021), Dr. Shih transferred the registered capital of our Company of RMB5.75 million (representing approximately 0.38% of the then equity interest in our Company) to Beihai Jixin, an Incentive Platform, at the consideration of RMB1,512,250. Such transfers had been properly completed as of the Latest Practicable Date.

HISTORY AND CORPORATE STRUCTURE

Series A-1 Financing

Pursuant to the investment agreements entered into by our Company and Metropolitan Industrial Investment Fund (京津冀產業協同發展投資基金(有限合夥)) (“**MIIF**”), Future Industry Investment Fund II (先進製造產業投資基金二期(有限合夥)) (“**FIIF II**”), Shijiazhuang Keshuo Investment Centre (Limited Partnership) (石家莊科碩投資中心(有限合夥)), formerly known as Shijiazhuang Keshuo Equity Investment Centre (Limited Partnership) (石家莊科碩股權投資中心(有限合夥)) (“**Shijiazhuang Keshuo**”) and Beijing Tonghe Yinxing Innovative Asset Management Centre (Limited Partnership) (北京同合銀杏創新資產管理中心(有限合夥)) (“**Beijing Tonghe**”) dated August 8, 2020 and December 8, 2020, the Series A-1 Investors agreed to subscribe for the increased registered capital of our Company of RMB316,414,285.72 at a total consideration of RMB963 million (the “**Series A-1 Financing**”), details of which are set out below:

<u>Series A-1 Investors</u>	<u>Consideration</u>	<u>Registered capital subscribed for</u>	<u>Corresponding equity interest in our Company (upon completion of the capital increase)</u>
	<i>(RMB)</i>	<i>(RMB)</i>	
MIIF	600,000,000	197,142,857.14	13.44%
FIIF II	200,000,000	65,714,285.72	4.48%
Shijiazhuang Keshuo	100,000,000	32,857,142.86	2.24%
Beijing Tonghe	63,000,000	20,700,000	1.41%
Total	<u>963,000,000</u>	<u>316,414,285.72</u>	<u>21.58%</u>

The relevant considerations were determined based on arm’s length negotiations between the parties primarily taking into account our business prospects and the R&D progress of our drug candidates at the time of the investment, as well as the prevailing valuations of comparable companies within the industry. For further details of the Series A-1 Financing, see “— Pre-[REDACTED] Investments” below.

HISTORY AND CORPORATE STRUCTURE

Upon completion of the Series A-1 Financing, our registered capital was increased to RMB1,466,414,285.72 and the shareholding structure of our Company was as follows:

Shareholder	Registered capital (RMB)	Equity Interest
Xuanzhu Biopharma	1,070,305,000	72.99%
MIIF	197,142,857.14	13.44%
FIIF II	65,714,285.72	4.48%
Shijiazhuang Keshuo	32,857,142.86	2.24%
Beijing Tonghe	20,700,000	1.41%
Dr. Shih	14,950,000	1.02%
Dr. Li	11,500,000	0.78%
Tianjin Hongzekang	11,304,500	0.77%
Tianjin Xuansheng	9,463,350	0.65%
Ms. Xu	9,200,000	0.63%
Tianjin Hongteng	7,308,250	0.50%
Tianjin Zhenxuan	6,021,400	0.41%
Tianjin Pusheng	3,804,200	0.26%
Tianjin Guoding	3,646,650	0.25%
Tianjin Huize	2,496,650	0.17%
Total	<u>1,466,414,285.72</u>	<u>100.00%</u>

First Equity Incentive in 2021

On April 16, 2021, for incentive purpose, our then Shareholders passed a resolution to increase our registered capital to RMB1,516,056,593.10. The increased registered capital of RMB49,642,307.38 (representing 3.27% of our equity interest upon completion of the capital increase) was subscribed for by Beihai Baimei’en, our Incentive Platform, at a consideration of RMB61,273,500. For details of Beihai Baimei’en, see “— Incentive Platforms” below.

Series A-2 Financing

Pursuant to a capital increase agreement dated July 12, 2021 entered into between our Company and the Series A-2 Investor, namely Beijing SL Pharmaceutical Co., Ltd. (北京雙鷺藥業股份有限公司) (“**Beijing SL**”), the Series A-2 Investor agreed to subscribe for RMB6,779,891.57 increased registered capital of our Company at a consideration of RMB20,634,600 (the “**Series A-2 Financing**” together with the Series A-1 Financing, collectively, the “**Series A Financing**”). Such consideration was determined based on arm’s length negotiations between the parties primarily taking into account our business prospects and the R&D progress of our drug candidates at the time of the investment, as well as the prevailing valuations of comparable companies within the industry. For further details of the Series A-2 Financing, see “— Pre-[REDACTED] Investments” below.

HISTORY AND CORPORATE STRUCTURE

Upon completion of the Series A-2 Financing, our registered capital increased to RMB1,522,836,484.67 and the shareholding structure of our Company was as follows:

Shareholder	Registered capital	Equity interest
	(RMB)	
Xuanzhu Biopharma	1,070,305,000	70.28%
MIF	197,142,857.14	12.95%
FIIF II	65,714,285.72	4.32%
Beihai Baimei'en	49,642,307.38	3.26%
Shijiazhuang Keshuo	32,857,142.86	2.16%
Beijing Tonghe	20,700,000	1.36%
Dr. Shih	14,950,000	0.98%
Dr. Li	11,500,000	0.76%
Tianjin Hongzekang	11,304,500	0.74%
Tianjin Xuansheng	9,463,350	0.62%
Ms. Xu	9,200,000	0.60%
Tianjin Hongteng	7,308,250	0.48%
Beijing SL	6,779,892	0.45%
Tianjin Zhenxuan	6,021,400	0.40%
Tianjin Pusheng	3,804,200	0.25%
Tianjin Guoding	3,646,650	0.24%
Tianjin Huize	2,496,650	0.16%
Total	<u>1,522,836,484.67</u>	<u>100.00%</u>

Conversion into a Joint Stock Company

On August 5, 2021, our then Shareholders passed a resolution to reduce our Company’s registered capital from RMB1,522,836,484.67 to RMB400,000,000. Each Shareholder’s equity interest of the registered capital was reduced proportionally, and the shareholding structure of our Company remained unchanged upon completion of the capital decrease.

Pursuant to the Shareholders’ resolutions and the promoters’ agreement dated November 16, 2021, the then Shareholders of our Company agreed to convert our Company from a limited liability company into a joint stock company under the name of Xuanzhu Biopharmaceutical Co., Ltd. (軒竹生物科技股份有限公司). Upon completion of the conversion, the share capital of our Company was RMB400,000,000 divided into 400,000,000 Shares with a nominal value of RMB1.00 per Share, which were subscribed for by our then Shareholders in proportion to their respective equity interest in our Company immediately before the conversion.

Second Equity Incentive in 2021

On December 1, 2021, for incentive purpose, our then Shareholders passed a resolution to issue 3,849,190 Shares and 6,956,110 Shares to Beihai Keya and Beihai Jixin, our Incentive Platforms, at the consideration of RMB3,849,190 and RMB6,956,110, respectively. For details of Beihai Keya and Beihai Jixin, see “— Incentive Platforms” below. Upon completion of the Second Equity Incentive in 2021, our share capital increased to 410,805,300 Shares.

HISTORY AND CORPORATE STRUCTURE

Series B Financing

Pursuant to a share subscription agreement dated December 28, 2021 entered into among our Company, the then Shareholders, Sunshine Life Insurance Co., Ltd. (陽光人壽保險股份有限公司) (“**Sunshine Life Insurance**”), Jinjiang Xuanhong No. 3 Equity Investment Partnership (Limited Partnership) (晉江軒弘叁號股權投資合夥企業(有限合夥)) (“**Jinjiang Xuanhong**”), Shaanxi Jinou Investment Fund Partnership (Limited Partnership) (陝西金甌投資基金合夥企業(有限合夥)) (“**Shaanxi Jinou**”), Jiangmen Efung Yihe Venture Capital Partnership Enterprise (Limited Partnership) (江門市倚鋒邑和創業投資合夥企業(有限合夥)) (“**Jiangmen Efung**”), Hebei Zhongjicai Industrial Advancement Equity Investment Fund (Limited Partnership) (河北中冀財工業升級股權投資基金合夥企業(有限合夥)) (“**Hebei Zhongjicai**”), Shanghai Yunxin Venture Capital Partnership (Limited Partnership) (上海雲錚創業投資合夥企業(有限合夥)) (“**Shanghai Yunxin**”), Shanghai Chuangfeng Xinwen Venture Capital Partnership (Limited Partnership) (上海創豐昕文創業投資合夥企業(有限合夥)) (“**Shanghai Chuangfeng**”), Suzhou Taijin No. 1 Equity Investment Partnership (Limited Partnership) (蘇州太金壹號股權投資合夥企業(有限合夥)) (“**Suzhou Taijin**”), BOC Capital Investment Holding (China) Co., Ltd (中銀資本投資控股有限公司) (“**BOC Capital**”), Tianjin Baichuan Gongying Enterprise Management Partnership (Limited Partnership) (天津百川共贏企業管理合夥企業(有限合夥)) (“**Tianjin Baichuan**”), Shenzhen Denov No. 1 Investment Partnership (Limited Partnership) (深圳市德諾維一號投資合夥企業(有限合夥)) (“**Shenzhen Denov**”), Yantai Boyuan Development Investment Partnership (Limited Partnership) (煙台伯元發展投資合夥企業(有限合夥)) (“**Yantai Boyuan**”) and Wintrust Qifu (Shenzhen) Venture Capital Centre (Limited Partnership) (灣信啟富(深圳)創業投資中心(有限合夥)) (“**Wintrust Qifu**”), the Series B Investors agreed to acquire, and our Company agreed to issue, an aggregate of 39,808,990 Shares at a total consideration of RMB610,500,000 (the “**Series B Financing**”), details of which are as follows:

Series B Investors	Consideration	Number of Shares acquired	Corresponding equity interest in our Company (upon completion of the share issuance)
	<i>(RMB)</i>		
Sunshine Life Insurance	250,000,000	16,301,800	3.62%
Hebei Zhongjicai	70,000,000	4,564,500	1.01%
Suzhou Taijin	65,000,000	4,238,470	0.94%
Shanghai Chuangfeng	50,000,000	3,260,360	0.72%
Tianjin Baichuan	40,000,000	2,608,290	0.58%
Jiangmen Efung	35,000,000	2,282,250	0.51%
BOC Capital	30,000,000	1,956,220	0.43%
Jinjiang Xuanhong	18,000,000	1,173,730	0.26%
Wintrust Qifu	12,500,000	815,090	0.18%
Shaanxi Jinou	10,000,000	652,070	0.14%
Shanghai Yunxin	10,000,000	652,070	0.14%
Shenzhen Denov	10,000,000	652,070	0.14%
Yantai Boyuan	10,000,000	652,070	0.14%
Total	610,500,000	39,808,990	8.83%

HISTORY AND CORPORATE STRUCTURE

The relevant considerations were determined based on arm’s length negotiations between the parties primarily taking into account our business prospects and the R&D progress of our drug candidates at the time of the investment, as well as the prevailing valuations of comparable companies within the industry. The post-money valuation of our Company increased during the period between the Series A Financing and the Series B Financing primarily due to (i) the establishment and further development of our biological drug R&D platform through the acquisition of the biologics business of Beijing Combio Pharmaceutical Inc., (ii) the significant progress we made in the clinical development of our Core Products, and (iii) the capital contribution made by the Series B Investors. For further details of the Series B Financing, see “— Pre-[REDACTED] Investments” below.

Series B Repurchase

Due to our Controlling Shareholders’ strong confidence in the prospects of our business, from October 21, 2024 to November 15, 2024 each of the Series B Investors (except for Shanghai Yunxin) entered into a separate equity transfer agreement with Hainan Sihuan, our Controlling Shareholder, pursuant to which they agreed to transfer their respective Shares in our Company to Hainan Sihuan for an aggregate consideration of approximately RMB754.60 million (the “**Series B Repurchase**”). The relevant considerations were determined based on the investment amount of the Series B Investor and an annual rate of return of 8%, which was arrived after arm’s length negotiation between the parties with reference to the redemption provision set out in the share subscription agreement for the Series B Financing. The considerations were fully settled by November 15, 2024.

Pre-[REDACTED] Investment Adjustment

To provide a fair treatment to our investors after taking into consideration the prevailing market conditions and to reward them for their long-term commitment to our Company, subsequent to the Series B Repurchase, in November 2024, Xuanzhu Biopharma, our Controlling Shareholder entered into equity transfer agreements with certain Pre-[REDACTED] Investors, pursuant to which, Xuanzhu Biopharma agreed to transfer 18,249,655 Shares, 6,083,265 Shares, 3,041,743 Shares, 1,916,250 Shares and 500,249 Shares to MIIF, FIIF II, Shijiazhuang Keshuo, Beijing Tonghe and Shanghai Yunxin respectively, for nil consideration (the “**Pre-[REDACTED] Investment Adjustment**”). Such transfers had been completed prior to the first submission of the [REDACTED] to the Stock Exchange.

Equity Incentive in 2024

In recognition of the contributions of our employees and to incentivize them to further promote our development, pursuant to the equity transfer agreement entered into by Xuanzhu Biopharma, our Controlling Shareholder, and two of our Incentive Platforms, namely Tianjin Zhenxuan and Tianjin Guoding in November 2024, Xuanzhu Biopharma agreed to transfer 34,467,544 Shares and 1,581,600 Shares to Tianjin Zhenxuan and Tianjin Guoding for share incentive purposes at consideration of RMB34,467,544 and RMB1,581,600, respectively.

HISTORY AND CORPORATE STRUCTURE

In order to redistribute share incentives to recognize Ms. Xu’s significant contributions since her joining our Group, her extensive experience in the healthcare industry, and her sophisticated management skills, which are critical to our Group’s development and growth, pursuant to the equity transfer agreements dated November 1, 2024, Tianjin Guoding and Dr. Shih agreed to transfer 1,581,600 Shares and 716,400 Shares to Ms. Xu, at the consideration of RMB1,581,600 and RMB716,400, respectively. The considerations were determined based on the original cost for such incentives.

The transfers above had been completed prior to the first submission of the [REDACTED] to the Stock Exchange.

For the shareholding structure of our Company upon completion of the above equity transfers and as of the Latest Practicable Date, see “— Our Capitalization” below.

INCENTIVE PLATFORMS

In recognition of the contributions of, the employees and other key stakeholders of our Group, and to incentivize them to further promote our development, we adopted the Share Incentive Scheme and granted awards to eligible grantees under the Share Incentive Scheme directly or indirectly through the partnership interest in the Incentive Platforms. For further details of the Share Incentive Scheme, please refer to “Appendix VI — Statutory and General Information — Further Information about Our Directors, Supervisors, Chief Executive and Substantial Shareholders — Share Incentive Scheme” to this document.

To streamline the management of share incentives and effectively segregate different batches granted to eligible participants, and after considering the restriction on the number of limited partners of a limited partnership under the relevant PRC law, we established ten limited partnerships in the PRC as our Incentive Platforms, namely Beihai Baimei’en, Beihai Jixin, Beihai Keya, Tianjin Hongzekang, Tianjin Xuansheng, Tianjin Hongteng, Tianjin Zhenxuan, Tianjin Pusheng, Tianjin Guoding and Tianjin Huize.

Details of the Incentive Platforms are set out below:

(1) **Beihai Baimei’en**

Beihai Baimei’en was established in the PRC as a limited partnership on April 22, 2021, the general partner of which is Mr. Zhu Xiaodong (朱曉東) (“**Mr. Zhu**”), a former employee of our Group. The sole limited partner of Beihai Baimei’en is Beihai Maibo Investment Partnership Enterprise (Limited Partnership) (北海邁鉞投資合夥企業(有限合夥)) (“**Beihai Maibo**”). As of the Latest Practicable Date, the general partner of Beihai Maibo was also Mr. Zhu and Beihai Maibo had 13 limited partners, which include one employee and 12 former employees of our Group.

The voting rights attached to the Shares held by Beihai Baimei’en are controlled by Mr. Zhu, its general partner.

HISTORY AND CORPORATE STRUCTURE

(2) Beihai Jixin

Beihai Jixin was established in the PRC as a limited partnership on July 6, 2021, the general partner of which is Mr. Hou Deyan (侯德岩) (“**Mr. Hou**”), the senior manager of business development of our Company. The sole limited partner of Beihai Jixin is Beihai Sheng’an Xuanzhu Investment Partnership Enterprise (Limited Partnership) (北海盛安軒竹投資合夥企業(有限合夥)) (“**Beihai Sheng’an**”). As of the Latest Practicable Date, the general partner of Beihai Sheng’an was Mr. He Chengming (何成明) (“**Mr. He**”), a deputy general manager of our Company. It had 12 limited partners including Ms. Xu (our executive Director), Ms. Li Huiying (李惠英) (“**Ms. Li**”) (our non-executive Director), Ms. Chen Yanling (陳燕玲) (“**Ms. Chen**”) (our non-executive Director) and Dr. Wang Li (王莉) (“**Dr. Wang**”) (our deputy general manager, the director of Xuanzhu Combio and the general manager of Beijing Xuanzhu), holding approximately 6.30%, 6.45%, 4.72% and 4.13% of the partnership interest, respectively. The remaining eight limited partners of Beihai Sheng’an include seven employees and an external consultant of our Group.

The voting rights attached to the Shares held by Beihai Jixin are controlled by Mr. Hou, its general partner.

(3) Beihai Keya

Beihai Keya was established in the PRC as a limited partnership on July 6, 2021, the general partner of which is Mr. Hou. The sole limited partner of Beihai Keya is Beihai Enkang Xuanzhu Investment Partnership Enterprise (Limited Partnership) (北海恩康軒竹投資合夥企業(有限合夥)) (“**Beihai Enkang**”). As of the Latest Practicable Date, the general partner of Beihai Enkang was Mr. Zheng Shaojun (鄭少君) (“**Mr. Zheng**”), the deputy general manager of IP & government affairs of our Group and Beihai Enkang had seven limited partners, including Dr. Wang holding approximately 23.38% of the partnership interest) and six employees of our Group.

The voting rights attached to the Shares held by Beihai Keya are controlled by Mr. Hou, its general partner.

(4) Tianjin Hongzekang

Tianjin Hongzekang was established in the PRC as a limited partnership on August 4, 2020. The general partner of Tianjin Hongzekang is Mr. Li Zhuofu (李卓夫) (“**Mr. Li**”), the deputy general manager of operational management of our Group. As of the Latest Practicable Date, Tianjin Hongzekang had four limited partners, including Ms. Xu holding approximately 21.89% of the partnership interest, and three employees of our Group.

The voting rights attached to the Shares held by Tianjin Hongzekang are controlled by Mr. Li, its general partner.

HISTORY AND CORPORATE STRUCTURE

(5) Tianjin Xuansheng

Tianjin Xuansheng was established in the PRC as a limited partnership on August 3, 2020, the general partner of which is Mr. He. As of the Latest Practicable Date, Tianjin Xuansheng had five limited partners, including Mr. Lu Benyu (盧本玉) (“**Mr. Lu**”) (our Supervisor), Dr. Wang and Mr. Wang Xiaoping (王曉平) (“**Mr. Wang**”) (our Supervisor), holding approximately 3.47%, 10.06% and 3.47% of the partnership interest, respectively. The remaining limited partners of Tianjin Xuansheng were two employees.

The voting rights attached to the Shares held by Tianjin Xuansheng are controlled by Mr. He, its general partner.

(6) Tianjin Hongteng

Tianjin Hongteng was established in the PRC as a limited partnership on August 5, 2020, the general partner of which is Ms. Fan Xingming (范興明) (“**Ms. Fan**”), the deputy director of clinical research projects of our Group. As of the Latest Practicable Date, Tianjin Hongteng had nine limited partners, including Ms. Li holding approximately 18.75% of the partnership interest, seven employees and one former employee of our Group.

The voting rights attached to the Shares held by Tianjin Hongteng are controlled by Ms. Fan, its general partner.

(7) Tianjin Zhenxuan

Tianjin Zhenxuan was established in the PRC as a limited partnership on August 4, 2020, the general partner of which is Mr. Che Yuxuan (車雨軒) (“**Mr. Che**”), the assistant to the chairperson of our Group and the son of Dr. Che Fengsheng, our Controlling Shareholder. As of the Latest Practicable Date, Tianjin Zhenxuan had 11 limited partners, including Ms. Xu, Ms. Chen, Mr. Lu and Mr. Wang, holding approximately 9.40%, 5.03%, 5.03% and 5.03% of the partnership interest, respectively, and seven employees of our Group.

The voting rights attached to the Shares held by Tianjin Zhenxuan are controlled by Mr. Che, its general partner.

(8) Tianjin Pusheng

Tianjin Pusheng was established in the PRC as a limited partnership on August 4, 2020, the general partner of which is Mr. Liang Xiaodong (梁曉東) (“**Mr. Liang**”), the deputy general manager of resource management of our Group. As of the Latest Practicable Date, Tianjin Pusheng had four limited partners. Save for Ms. Chen holding approximately 20.02% of the partnership interest and an external consultant of our Group, the other limited partners were two employees and one former employee of our Group.

The voting rights attached to the Shares held by Tianjin Pusheng are controlled by Mr. Liang, its general partner.

HISTORY AND CORPORATE STRUCTURE

(9) Tianjin Guoding

Tianjin Guoding was established in the PRC as a limited partnership on August 5, 2020, the general partner of which is Mr. Duan Xiaobo (段曉波) (“**Mr. Duan**”), the sales director our Group. As of the Latest Practicable Date, Tianjin Guoding had six limited partners, consisting of Ms. Xu holding approximately 10.65% of the partnership interest and five employees of our Group.

The voting rights attached to the Shares held by Tianjin Guoding are controlled by Mr. Duan, its general partner.

(10) Tianjin Huize

Tianjin Huize was established in the PRC as a limited partnership on August 14, 2020, the general partner of which is Ms. Yu Zhuo (于卓) (“**Ms. Yu**”), the deputy director of quality systems and clinical quality assurance of our Group. As of the Latest Practicable Date, Tianjin Huize had two limited partners, both of whom were employees of our Group.

The voting rights attached to the Shares held by Tianjin Huize are controlled by Ms. Yu, its general partner.

Save as disclosed above, none of the limited partners or ultimate beneficial owners of the Incentive Platforms was a Director, a Supervisor, a core connected person of our Company or their close associate as of the Latest Practicable Date.

PRE-[REDACTED] INVESTMENTS

The following table summarizes the key terms of the Pre-[REDACTED] Investments⁽¹⁾:

	<u>Series A-1 Financing</u>	<u>Series A-2 Financing</u>	<u>Series B Financing</u>
Date of settlement	February 3, 2021	July 27, 2021	December 31, 2021 and November 15, 2024 (with respect to the Series B Repurchase)
Cost per Share ⁽²⁾	RMB8.57	RMB11.59	RMB8.68
Discount/(premium) to the [REDACTED] ⁽²⁾⁽³⁾	[REDACTED]	[REDACTED]	[REDACTED]
Post-money valuation of our Company ⁽⁴⁾	Approximately RMB3.3 billion	Approximately RMB4.6 billion	Approximately RMB3.9 billion
Use of proceeds	We utilized the proceeds to finance our R&D activities and to support the working capital needs of our Group. As of the Latest Practicable Date, approximately 77% of the net proceeds from the Pre-[REDACTED] Investments had been utilized for the aforementioned purposes. We expect to utilize the remaining proceeds from the Pre-[REDACTED] Investments for the same purposes.		

HISTORY AND CORPORATE STRUCTURE

	Series A-1 Financing	Series A-2 Financing	Series B Financing
Basis of determination of the consideration	The consideration for each Pre-[REDACTED] Investments were determined through arm’s length negotiation between the respective pre-[REDACTED] investor and our Group or the then existing Shareholders with reference to, among others, the status and continuous development of our business and the progress in the R&D of our pipeline products, as well as the prevailing valuations of comparable companies within the industry.		
Lock-up period	Pursuant to the applicable PRC laws, within the 12 months following the [REDACTED], all existing Shareholders (including the Pre-[REDACTED] Investors) of our Company could not dispose of any of the Shares held by them.		
Strategic benefits	Our Group would benefit from the additional capital injected by the Pre-[REDACTED] Investors in our Group, their business resources, knowledge and experience, potential business opportunities and benefits that may be provided by them. Our Pre-[REDACTED] Investors include institutional investors, some of which are highly experienced in investing in the healthcare industry. Our Directors believed that our Company could benefit from their industry insights and guidance. Our Directors were also of the view that the Pre-[REDACTED] Investments demonstrate the Pre-[REDACTED] Investors’ commitment and confidence in the business performance and operations, strengths and long-term prospects of our Group.		
Special rights of the Pre-[REDACTED] Investors	Pursuant to the Pre-[REDACTED] Investment agreements, certain Pre-[REDACTED] Investors had been granted certain special rights, including, among others, (i) pre-emptive right; (ii) guarantees of value and anti-dilution adjustment rights; (iii) redemption rights; (iv) tag-along rights; (v) liquidation preferences; (vi) rights of first refusal; (vii) co-sale rights; (viii) information and inspection rights; (ix) director nomination rights and (x) prohibitions on transfers. The redemption rights of our Pre-[REDACTED] Investors shall cease to be exercisable immediately upon the first filing of the application for the [REDACTED]. All other special rights of the Pre-[REDACTED] Investors will be terminated upon the [REDACTED].		

Notes:

- (1) For the dates of the relevant investment agreements, the number of registered capital or Shares subscribed for by the Pre-[REDACTED] Investors, and the amount of consideration paid by each Pre-[REDACTED] Investor, please refer to the section headed “— Our Corporate History — Establishment and Major Shareholding Changes of Our Company” above.
- (2) The cost per Share is adjusted to reflect subsequent capital injections or share conversions and the Pre-[REDACTED] Investment Adjustment, as applicable.
- (3) The discount to the [REDACTED] is calculated based on the foreign exchange rate as of the Latest Practicable Date and the assumption that the [REDACTED] is HK\$[REDACTED] per H Share (being the [REDACTED] of the indicative [REDACTED] range).
- (4) Post-money valuation is calculated on the basis of (a) cost per Share (after taking into account the Pre-[REDACTED] Investment Adjustment, if applicable); and (b) the total number of Shares of our Company upon completion of the relevant round of the Pre-[REDACTED] Investment.

HISTORY AND CORPORATE STRUCTURE

Information about Our Pre-[REDACTED] Investors

Our Pre-[REDACTED] Investors include certain Sophisticated Investors, namely MIIF and FIIF II. Each Sophisticated Investor has made meaningful investment in our Company at least six months before the [REDACTED].

To the best of our Company’s knowledge, information and belief and having made all reasonable enquiries, save for MIIF and FIIF II, both of which controlled by CS Capital Co., Ltd. (國投招商投資管理有限公司) (“**CS Capital**”) and held 20.72% of our issued share capital in aggregate, as of the Latest Practicable Date, all the other Pre-[REDACTED] Investors were Independent Third Parties. The background information of our Pre-[REDACTED] Investors as of the Latest Practicable Date is set out below.

Pre-[REDACTED] Investors	Backgrounds
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MIIF and FIIF II	Each of Metropolitan Industrial Investment Fund (京津冀產業協同發展投資基金(有限合夥)) and Future Industry Investment Fund II (先進製造產業投資基金二期(有限合夥)) is a limited partnership formed under the laws of the PRC, the general partner and manager of which is CS Capital. CS Capital is an equity investment management institution with affluent investment experience in biotech and healthcare sectors, including but not limited to Innovent Biologics, a company listed on the Stock Exchange (stock code: 1801), Ascentage Pharma, a company listed on the Stock Exchange (stock code: 6855), CanSino Biologics, a company listed on the Stock Exchange (stock code: 6185) and the Shanghai Stock Exchange (stock code: 688185), Peijia Medical, a company listed on the Stock Exchange (stock code: 9996), Kelun-Biotech, a company listed on the Stock Exchange (stock code: 6990). As of the Latest Practicable Date, CS Capital and its affiliates managed nearly RMB100 billion of capital.
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As of the Latest Practicable Date, MIIF and FIIF had approximately 20 and over 30 limited partners, respectively, each of whom hold less than 30% partnership interest therein and was an Independent Third Party.

HISTORY AND CORPORATE STRUCTURE

Pre-[REDACTED] Investors

Backgrounds

- Shijiazhuang Keshuo Shijiazhuang Keshuo Investment Centre (Limited Partnership) (石家莊科碩投資中心(有限合夥)) (formerly known as Shijiazhuang Keshuo Equity Investment Fund Centre (Limited Partnership) (石家莊科碩股權投資基金中心(有限合夥))) is a limited partnership established in the PRC and mainly focuses on investment holding. As of the Latest Practicable Date, the general partner of Shijiazhuang Keshuo was Shijiazhuang Kehong Investment Management Co., Ltd. (石家莊科弘投資管理有限公司), which was ultimately owned by the Department of Finance of Shijiazhuang Hi-tech Industrial Development District (石家莊高新技術產業開發區財政局). The sole limited partner of Shijiazhuang Keshuo is Shijiazhuang Hi-tech District Technology Investment Co., Ltd. (石家莊高新區科發投資有限公司), which is also ultimately owned by the Department of Finance of Shijiazhuang Hi-tech Industrial Development District.
- Beijing Tonghe Beijing Tonghe Yinxing Innovative Asset Management Centre (Limited Partnership) (北京同合銀杏創新資產管理中心(有限合夥)) is a limited partnership established in the PRC engaged in investment holding. As of the Latest Practicable Date, the general partner of Beijing Tonghe was Beijing Tonghedingtai Capital Management Co., Ltd. (北京同合鼎泰資本管理有限公司), ultimately held by Xue Ming (薛明), Li Jidong (李繼東), Lian Kui (連燾) and Wang Yanwei (王硯偉), each an Independent Third Party. As of the Latest Practicable Date, except for Beijing Zhiliang Ecological Technology Co., Ltd. (北京致良生態科技有限公司), which is an Independent Third Party and also ultimately controlled by Lian Kui, none of the limited partners of Beijing Tonghe owned over 30% partnership interest and each of them was an Independent Third Party.
- Beijing SL Beijing SL Pharmaceutical Co., Ltd. (北京雙鷺藥業股份有限公司) is a pharmaceutical biotechnology company, integrating research and development, manufacturing, and operation services of drugs, the shares of which are listed on the Shenzhen Stock Exchange (stock code: 002038).
- Shanghai Yunxin Shanghai Yunxin Venture Capital Partnership (Limited Partnership) (上海雲鋅創業投資合夥企業(有限合夥)) is a limited partnership established in the PRC, focusing on the biotech investment. As of the Latest Practicable Date, the general partner of Shanghai Yunxin was Shanghai Yunzinc Enterprise Management Co., Ltd. (上海雲鋅企業管理有限公司), a company ultimately controlled by Mr. Liu Lingyun (劉凌雲), an Independent Third Party. As of the Latest Practicable Date, none of the limited partners of Shanghai Yunxin owned over 30% partnership interest and each limited partner was an Independent Third Party.

HISTORY AND CORPORATE STRUCTURE

COMPLIANCE WITH GUIDE FOR NEW LISTING APPLICANTS

On the bases that (i) the consideration for the Pre-[REDACTED] Investments was irrevocably settled more than 28 clear days before the date of our first submission of the [REDACTED] application to the Stock Exchange or no less than 120 clear days before the [REDACTED] (as the case may be); and (ii) no special rights of our Pre-[REDACTED] Investors will exist after the [REDACTED], the Sole Sponsor confirms that the Pre-[REDACTED] Investments are in compliance with Chapter 4.2 of the Guide for New Listing Applicants.

PUBLIC FLOAT

The 357,245,794 Shares held by our Shareholders as of the Latest Practicable Date, representing approximately 79.28% of our total issued Shares as of the Latest Practicable Date, will not be counted towards the public float as these Shares are Unlisted Shares which will not be converted into H Shares and listed following completion of the [REDACTED].

The 9,435,200 H Shares to be converted from Unlisted Shares held by Ms. Xu, Dr. Li and Dr. Shih, representing approximately 2.09% of our total issued Shares as of the Latest Practicable Date, will not be considered as part of the public float as the aforesaid Shareholders are core connected persons of our Group.

To the best of our Directors' knowledge, information and belief and having made all reasonable inquiries, save as disclosed above, no other Shareholders (including the Pre-[REDACTED] Investors) (i) is a core connected person of our Group; (ii) has been financed directly or indirectly by a core connected person of our Group for the subscription of Shares; or (iii) is accustomed to taking instructions from a core connected person of our Group in relation to the acquisition, disposal, voting or other disposition of the Shares registered in their name or otherwise held by them. Therefore, the 83,933,296 H Shares to be converted from the Unlisted Shares held by the other existing Shareholders, representing approximately 18.63% of our total issued Shares as of the Latest Practicable Date, will be treated as part of the public float of our Company following [REDACTED] for the purpose of Rule 8.08 of the Listing Rules.

Immediately following completion of the [REDACTED], assuming that (i) [REDACTED] H Shares are allotted and issued in the [REDACTED] and the [REDACTED] is not exercised; (ii) [REDACTED] Unlisted Shares are converted into H Shares; (iii) [REDACTED] Shares are issued and outstanding in the share capital of our Company upon completion of the [REDACTED], based on an [REDACTED] of HK\$[REDACTED] per Share (being the [REDACTED] of the indicative [REDACTED] range); and (iv) all of the [REDACTED] under the [REDACTED] are subscribed by the core connected persons of our Company or their close associates, [REDACTED] Shares, representing approximately [REDACTED]% of the total number of issued Shares of our Company will be counted towards the public float and our Company will have a market capitalization of at least HK\$375 million held by the public. Therefore, our Company will be able to meet the minimum public float requirement under Rules 8.08 and 18A.07 of the Listing Rules.

HISTORY AND CORPORATE STRUCTURE

MAJOR ACQUISITIONS AND DISPOSALS

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

PREVIOUS LISTING APPLICATIONS

In September 2022, our Company submitted an application (the “**A Share Listing Application**”) for listing (the “**A Share Listing**”) of our Shares on the Science and Technology Innovation Board of the Shanghai Stock Exchange (the “**Sci-Tech Innovation Board**”). The Shanghai Stock Exchange issued two rounds of comments while reviewing the A Share Listing Application, to which our Company provided responses. In accordance with the review results of the sixth review meeting of the listing committee for Sci-tech Innovation Board in 2023 held on March 8, 2023, the A Share Listing was temporarily suspended (暫緩審議).

In view of our business development and strategic planning considerations, and after a thorough analysis of the prevailing capital market conditions and other relevant factors, we decided to withdraw the A Share Listing Application. We applied for withdrawal of the A Shares Listing Application, and the Sci-Tech Innovation Board has accepted such withdrawal application and issued the Decision in relation to the Termination of the Review of the Initial Public Offering and Listing of Xuanzhu Biopharmaceutical Co., Ltd. on the Sci-tech Innovation Board (《關於終止對軒竹生物科技股份有限公司首次公開發行股票並在科創板上市審核的決定》) on May 24, 2024. We had addressed all comments raised by the Sci-Tech Innovation Board up to the date of the withdrawal of the A Share Listing Application.

To further expand our global business and considering that the Stock Exchange would provide our Company with an international platform to access foreign capital and attract diverse overseas investors, our Company decided to pursue a [REDACTED] of the H Shares on the Stock Exchange in order to provide further capital for our R&D, manufacturing and commercialization of our products to address medical needs in China and globally, as described in more details in “Future Plans and [REDACTED]” in this document. For the reasons of [REDACTED], please refer to “— [REDACTED] of Our Group from the Sihuan Group” below.

To the best of our Directors’ knowledge, our Directors are not aware of (a) any matters or findings from the A Share Listing Application which would have a material adverse implication on the [REDACTED] or the [REDACTED], (b) any disagreement or dispute between us and the professional parties involving in the A Share Listing Application, or (c) any matters that might materially and adversely affect our suitability for the [REDACTED] or the [REDACTED]. Our Directors further confirm that there is no other matter in relation to the A Share Listing Application that needs to be brought to the attention of the Stock Exchange or potential [REDACTED].

HISTORY AND CORPORATE STRUCTURE

[REDACTED] OF OUR GROUP FROM THE SIHUAN GROUP

We consider that the [REDACTED] and separate [REDACTED] of the H Shares of our Group will be commercially beneficial to the Sihuan Group, our Group and our Shareholders as a whole for the following reasons:

- (a) the [REDACTED] will enable more focused development and strategic planning, better allocation of resources for the respective businesses, and therefore, unlock value of our business which is at fast-growing stage and provide Sihuan Pharm and its shareholders an opportunity to realize the value of their [REDACTED] in our Group under a separate standalone [REDACTED] platform;
- (b) the [REDACTED] will enable our Group to obtain a separate [REDACTED] status and an independent fund-raising platform. After the [REDACTED], both our Group and the Remaining Sihuan Group will have separate fundraising platforms that have direct access to both equity and debt capital markets, thereby accelerating both groups’ existing operations and future expansion;
- (c) the [REDACTED] will separate our business from the Remaining Sihuan Group’s business. Such separation will enable shareholders and [REDACTED] to appraise the strategies, success factors, functional exposure, risks and returns of our Group and the Remaining Sihuan Group separately and to make or refine their [REDACTED] decisions accordingly;
- (d) the [REDACTED] will enable our Group to build the identity as a separately [REDACTED] group, to have a separate fund-raising platform and to broaden our [REDACTED] base. Given the nature of our business, the R&D costs are relatively high. Furthermore, it takes time for the drug candidates of our Group to complete clinical trials before they are commercialized and start to generate revenue, for further details of which, please refer to the section headed “Business” in this document. The [REDACTED] would allow our Group to gain direct access to capital markets for equity and/or debt financing to fund the R&D and commercialization of our drug candidates without reliance on Sihuan Pharm, thereby accelerating our expansion, improving our operating and financial management efficiencies, which in turn will provide better return to the Shareholders of our Group;
- (e) the [REDACTED] will enhance the corporate governance, management incentive mechanism and operational efficiency of our Group and provide [REDACTED], financial institutions and rating agencies with greater disclosures on the businesses and financial status of our Group and the Remaining Sihuan Group, on a stand-alone basis, and such disclosures are expected to enhance and further facilitate [REDACTED]’ informed [REDACTED] decisions and [REDACTED] in respective businesses based on their assessment of the performance, management, strategy, risks and returns of both our Group and the Remaining Sihuan Group;

HISTORY AND CORPORATE STRUCTURE

- (f) the [REDACTED] will strengthen the operational management ability of both our Group and the Remaining Sihuan Group where their respective management teams can focus more efficiently and effectively on each business and improve their abilities to recruit, motivate and retain key management personnel for each line of business as well as to expediently and effectively capitalize on any business opportunities that may arise, thereby improving its operating and financial performance, which in turn aiming to provide better returns to the shareholders of both our Company and Sihuan Pharm; and
- (g) the [REDACTED] will enable our Group to enhance the corporate profile, thereby increasing our ability to attract [REDACTED] for making [REDACTED] in our Group, which could further provide synergy for our Group, and the Remaining Sihuan Group will also benefit from such [REDACTED] without further capital commitment. The Remaining Sihuan Group will be able to focus on and deploy its financial resources towards the development of its business and to gain exposure to more specialized [REDACTED], thereby having better chances to obtain more targeted [REDACTED].

The proposal in relation to the [REDACTED] was submitted by Sihuan Pharm to the Stock Exchange for approval pursuant to Practice Note 15, and the Stock Exchange has confirmed that Sihuan Pharm may proceed with the [REDACTED]. Practice Note 15 requires Sihuan Pharm to have due regard to the interests of its existing shareholders by providing them with an [REDACTED] to the Shares, either by way of a distribution in specie of existing Shares or by way of a [REDACTED] in the [REDACTED] of existing or new Shares. Practice Note 15 provides that the respective minority shareholders of Sihuan Pharm may by resolution in general meeting resolve to waive the [REDACTED]. Sihuan Pharm will provide the [REDACTED] to the [REDACTED] by way of the [REDACTED]. See the section headed “Structure of the [REDACTED]” for further details of the [REDACTED].

HISTORY AND CORPORATE STRUCTURE

OUR CAPITALIZATION

The below table is a summary of the capitalization of our Company:

Shareholder	As of the Latest Practicable Date		Immediately upon completion of the [REDACTED] ⁽¹⁾		
	Number of Shares	% as to the total issued share capital of our Company	Number of Shares	Description of Shares ⁽¹⁾	% as to the total issued share capital of our Company ⁽²⁾
<i>Controlling Shareholders</i>					
Xuanzhu Biopharma . . .	215,294,494	47.78%	[REDACTED]	[REDACTED]	[REDACTED]
Hainan Sihuan.	39,156,920	8.69%	[REDACTED]	[REDACTED]	[REDACTED]
<i>Our Directors</i>					
Dr. Li.	3,020,800	0.67%	[REDACTED]	[REDACTED]	[REDACTED]
Ms. Xu	4,714,400	1.05%	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Shih	1,700,000	0.38%	[REDACTED]	[REDACTED]	[REDACTED]
<i>Incentive Platforms</i>					
Tianjin Zhenxuan	36,049,144	8.00%	[REDACTED]	[REDACTED]	[REDACTED]
Beihai Baimei'en	13,039,600	2.89%	[REDACTED]	[REDACTED]	[REDACTED]
Beihai Jixin	8,466,510	1.88%	[REDACTED]	[REDACTED]	[REDACTED]
Beihai Keya	3,849,190	0.85%	[REDACTED]	[REDACTED]	[REDACTED]
Tianjin Hongzekang . .	2,969,200	0.66%	[REDACTED]	[REDACTED]	[REDACTED]
Tianjin Xuansheng . . .	2,485,600	0.55%	[REDACTED]	[REDACTED]	[REDACTED]

HISTORY AND CORPORATE STRUCTURE

Shareholder	As of the Latest Practicable Date		Immediately upon completion of the [REDACTED] ⁽¹⁾		
	Number of Shares	% as to the total issued share capital of our Company	Number of Shares	Description of Shares ⁽¹⁾	% as to the total issued share capital of our Company ⁽²⁾
Tianjin Hongteng	1,919,600	0.43%	[REDACTED]	[REDACTED]	[REDACTED]
Tianjin Pusheng	999,200	0.22%	[REDACTED]	[REDACTED]	[REDACTED]
Tianjin Guoding	958,000	0.21%	[REDACTED]	[REDACTED]	[REDACTED]
Tianjin Huize	655,600	0.15%	[REDACTED]	[REDACTED]	[REDACTED]
<i>Pre-[REDACTED] Investors</i>					
MIIF	70,032,855	15.54%	[REDACTED]	[REDACTED]	[REDACTED]
FIIF II	23,344,465	5.18%	[REDACTED]	[REDACTED]	[REDACTED]
Shijiazhuang Keshuo . .	11,672,143	2.59%	[REDACTED]	[REDACTED]	[REDACTED]
Beijing Tonghe	7,353,450	1.63%	[REDACTED]	[REDACTED]	[REDACTED]
Beijing SL	1,780,800	0.40%	[REDACTED]	[REDACTED]	[REDACTED]
Shanghai Yunxin	1,152,319	0.26%	[REDACTED]	[REDACTED]	[REDACTED]
<i>Other investors taking part in the [REDACTED]</i>	–	–	[REDACTED]	[REDACTED]	[REDACTED]
Total	450,614,290	100.0%	[REDACTED]		100.0%

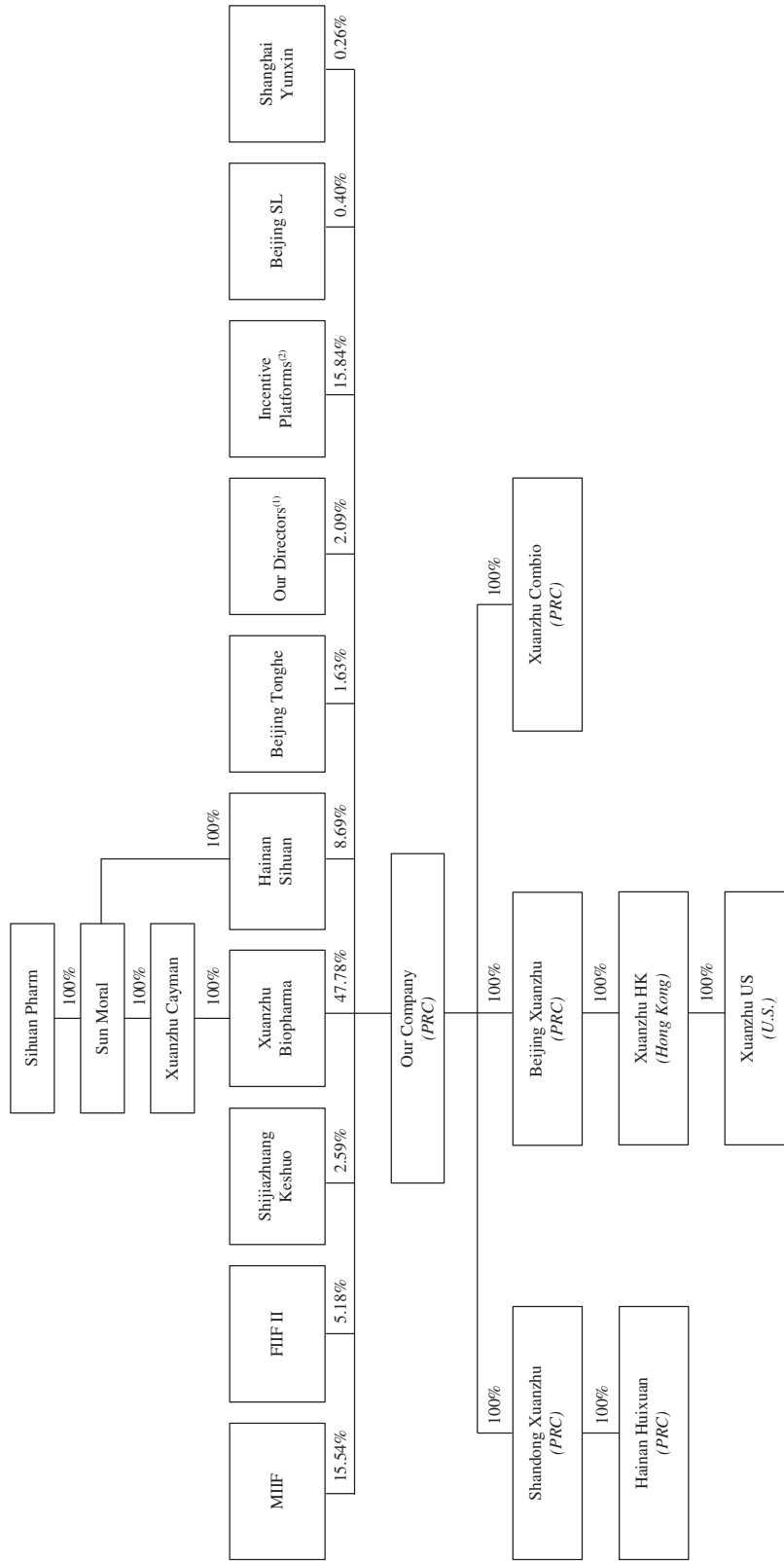
Notes:

- (1) Following the completion of the [REDACTED], [REDACTED] Unlisted Shares held by 17 existing Shareholders will be converted into H Shares on a one-for-one basis and [REDACTED] on the Stock Exchange for trading upon the [REDACTED]. For further details, see “Share Capital — Conversion of Unlisted Shares into H Shares.”
- (2) Assuming the [REDACTED] is not exercised.

HISTORY AND CORPORATE STRUCTURE

OUR SHAREHOLDING AND CORPORATE STRUCTURE Immediately Prior to the [REDACTED] and [REDACTED]

The following chart sets forth our corporate and shareholding structure of our Group as of the Latest Practicable Date:



Notes:

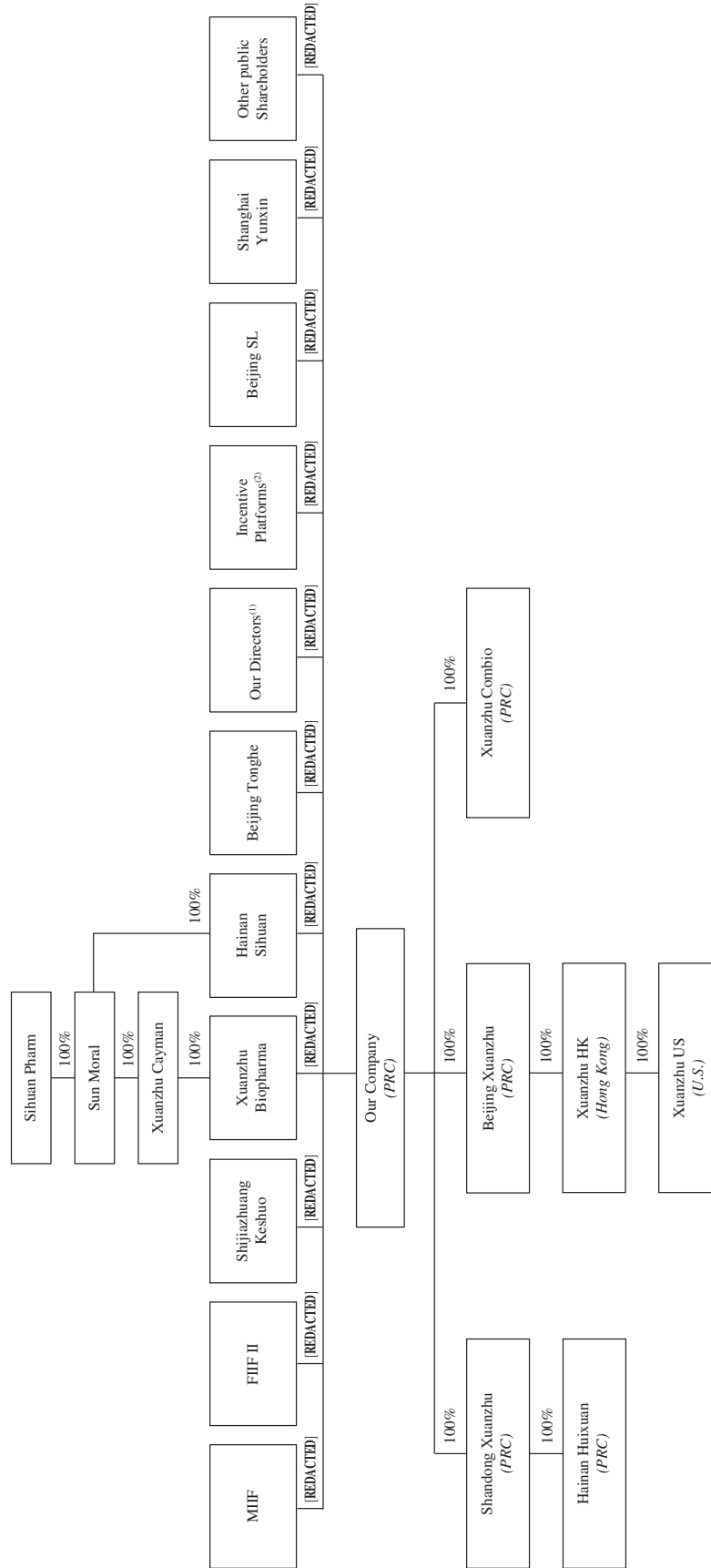
(1) Refer to Ms. Xu, Dr. Li and Dr. Shih, each a Director of our Company.

(2) Refer to Beihai Baimei'en, Beihai Jixin, Beihai Keya, Tianjin Guoding, Tianjin Hongteng, Tianjin Hongzekang, Tianjin Huize, Tianjin Pusheng, Tianjin Xuansheng and Tianjin Zhenxuan. For details, see “— Incentive Platforms” above.

HISTORY AND CORPORATE STRUCTURE

Immediately upon Completion of the [REDACTED] and the [REDACTED]

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



Note:

See the notes in “— Immediately Prior to the [REDACTED] and [REDACTED]” above.

BUSINESS

OVERVIEW

We are an innovation-driven biopharmaceutical company in China with a global vision, leveraging our deep understanding of China’s pharmaceutical industry and profound insights of its unique clinical needs to better patient health and life. Since our inception in 2008, we have built a comprehensive in-house R&D platform that has supported our development of a highly competitive and balanced pipeline. As of the Latest Practicable Date, we had over ten drug assets under active development covering digestive diseases, oncology and NASH. Our track record also includes the successful development of four drug candidates that were subsequently transferred and/or out-licensed to leading pharmaceutical companies. This achievement underscores our robust R&D capabilities and keen commercial instincts.

Our pipeline is staggered and complementary in structure, covering both validated targets with proven druggability as well as new mechanisms of action and drug modalities, established therapeutic areas such as oncology and high growth potential therapeutic areas such as NASH. As of the Latest Practicable Date, we had one NDA approved asset, two drug programs with four indications in pivotal trial or NDA registration-stage, four drug programs in phase 1 clinical trial and four at IND-enabling stage or IND-approved. This pipeline design strategically offers a balance in development risk and innovation, enabling our commercialized or late-stage assets to support the development of our early-stage innovative drugs.

We differentiate ourselves through driving drug development with speed and execution excellence, advancing at least one drug candidate on average to clinical trial every year since our inception, with a total of 18 IND approvals obtained as of the Latest Practicable Date. Within our pipeline are numerous industry firsts — KBP-3571, China’s first and only in-house developed PPI, KBP-5081, China’s first and only in-house developed carbapenem antibiotic (we out-licensed after the completion of phase 2 clinical trial), and XZP-5849, China’s first in-house developed PDE5 inhibitor (we out-licensed to a third party after the completion of phase 1 clinical trial), according to CIC. With a dual-track approach of in-house development and asset out-licensing, we have rapidly progressed these candidates towards the market, with five NDAs obtained or filed (including XZP-5695 that was transferred at phase 3 clinical trial stage).

We deeply understand that successful drug commercialization is fundamental to the long-term sustainability of innovative drug development. As a participant in China’s pharmaceutical industry for the past 15 years, we have shaped our commercialization strategy with profound insights into the industry’s evolving market dynamics and regulatory environment. We believe that these insights have enabled us to effectively navigate the complexities of this industry, developing the ability to formulate comprehensive and bespoke commercial strategies for each product that take into account differentiated product features, competitive landscape, sales channels, market education, pricing and regulatory policies. In addition, we have inherited valuable commercialization experience from our Controlling Shareholder, Sihuan Pharm, which has been crucial to our capability build-up. Our commercialization capabilities are evidenced by the initial success of our first approved product KBP-3571, which achieved RMB16.1 million in sales since its commercialization up until June 30, 2024.

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The pipeline chart below summarizes our commercialized drug and drug candidates as of the Latest Practicable Date:

Therapeutic Area	Drug Candidate	Target	Category	Internal/ External	Clinical Indications	Partner	Current Stage					Current Status/ Next Milestone	Commercialization Rights
							Preclinical R&D	IND-enabling	Clinical Phase 1	Clinical Phase 2	Clinical Phase 3		
Digestion	KBP-3571 Ampirozole Sodium	PPI	Innovative small molecule drug	In-house R&D	Duodenal ulcer Adult reflux esophagitis		█	█	█	█	█	Approved for marketing	Global
	XZP-3287 Birececlib	CDK4/6	Innovative small molecule drug	In-house R&D	HR+/HER2- advanced breast cancer (Combo: fulvestrant) HR+/HER2- advanced breast cancer (Combo: AI) HR+/HER2- locally advanced or metastatic breast cancer Adjuvant therapy for HR+/HER2- early breast cancer (Combo: endocrine) ¹		█	█	█	█	█	Enter clinical phase 3 in H2 2025 Obtain market approval in H1 2025 Submit NDA in H1 2025 Obtain market approval in H1 2025 Submit IND in H1 2025 Obtain market approval in H2 2025	Global
Oncology	XZP-3621	ALK	Innovative small molecule drug	In-house R&D	First-line treatment for patients with ALK-positive advanced non-small cell lung cancer Post-operative adjuvant therapy for patients with ALK-positive non-small cell lung cancer ²		█	█	█	█	█	Enter clinical phase 3 in H2 2025	Global
	KM602	CD80 Fusion Protein	Innovative biological drug	Acquisition ³	Solid tumors (melanoma, non-small cell lung cancer, etc.)	Beijing Xuanyi	█	█	█	█	█	Finish China clinical phase 1 in 2026 ⁴	Global
	KM501	HER2/HER 2-ADC	Innovative biological drug	In-house R&D	HER2+ and HER2-low solid tumors (breast cancer, gastric cancer, etc.)		█	█	█	█	█	Finish clinical phase 1 in 2026	Global
	XZP-7797	PARP1 Inhibitor	Innovative small molecule drug	In-house R&D	Solid tumors (breast cancer, ovarian cancer, prostate cancer, pancreatic cancer, etc.)		█	█	█	█	█	Submit IND in Q4 2024	Global
	XZP-6924	USP1 Inhibitor	Innovative small molecule drug	In-house R&D	Solid tumors (breast cancer, ovarian cancer, prostate cancer, pancreatic cancer, etc.)		█	█	█	█	█	Enter clinical phase 1 in H1 2026	Global
	XZB-0004	AXL	Innovative small molecule drug	License-in ¹	Solid tumors Myelodysplastic syndromes/ acute myeloid leukemia	SIGNALCHEM	█	█	█	█	█	Finish clinical phase 1 in 2025	Greater China
	XZP-6877	DNA-PK	Innovative small molecule drug	In-house R&D	Solid tumors		█	█	█	█	█	Enter clinical phase 1 in 2026	Global
	KM118	HER2	Biosimilar	In-house R&D Transfer ¹	Combine with trastuzumab and chemotherapy for HER2+ metastatic breast cancer (MBC)	康希诺	█	█	█	█	█	Enter clinical phase 1 in 2026	Commercialization rights transferred in full
	XZP-5610	FXR	Innovative small molecule drug	In-house R&D	Non-alcoholic steatohepatitis		█	█	█	█	█	Enter clinical phase 2 in 2026	Global
	XZP-6019	KHK	Innovative small molecule drug	In-house R&D	Non-alcoholic steatohepatitis		█	█	█	█	█	Enter clinical phase 1 in 2026	Global
Others	XZP-5695	SGLT-2 Inhibitor	Innovative small molecule drug	In-house R&D Transfer ¹	Type II diabetes	康科生物	█	█	█	█	█	Approved for marketing	Commercialization rights transferred in full
	KBP-5081	Camptoparom Antibiotic	Innovative small molecule drug	In-house R&D License-out ¹	Complicated urinary tract infection	康科生物	█	█	█	█	█	Enter clinical phase 1 in 2026	Regions other than Greater China
	XZP-5849	PDE-5	Innovative small molecule drug	In-house R&D License-out ¹	Erectile dysfunction Pulmonary arterial hypertension	康科生物	█	█	█	█	█	Enter clinical phase 1 in 2026	Europe, the U.S., Canada, Japan, South Korea, Australia, Brazil
							█	█	█	█	█	Enter clinical phase 1 in 2026	

Core Products: █ Key Products: █ Waived/Potentially Waived from this phase of clinical trial: █ R&D in the U.S.: █

Notes:

- We plan to submit an IND application with the NMPA for XZP-3287 as an adjuvant therapy for HR+/HER2- early breast cancer (combo: endocrine therapy), which, if approved, would enable us to proceed directly to phase 3 clinical trial; 2. We have filed an IND application with the NMPA for XZP-3621 as a post-operative adjuvant therapy for patients with ALK-positive NSCLC, which, if approved, would enable us to proceed directly to phase 3 clinical trial; 3. We expect to complete phase 1 clinical trial for KM602 in 2026 in China and our development plan for KM602 in the U.S. is pending our progress made in China; 4. For details of our acquisition of KM602, license-in of XZB-0004, transfer of KM118 and XZP-5695, and license-out of KBP-5081 and XZP-5849, see “Business — Our License and Asset Acquisition Arrangements” in this document.

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OUR COMPETITIVE STRENGTHS

Rich pipeline of differentiated drug candidates in commercial or late clinical stage development, supported by a comprehensive and systematic in-house R&D platform

We have built a comprehensive in-house R&D platform that serves as the cornerstone of our business and driver of our long-term growth. Leveraging our R&D platform, we have developed a pipeline of differentiated drug assets with speed and execution excellence, advancing at least one drug candidate on average to clinical trial every year since our inception, with a total of 18 IND approvals obtained as of the Latest Practicable Date. With a dual-track approach of in-house development and asset out-licensing, we have rapidly progressed these candidates towards the market, with five NDAs obtained or filed (including XZP-5695 that was transferred at phase 3 clinical trial stage). Within our pipeline are numerous industry firsts — KBP-3571, China’s first and only in-house developed PPI, KBP-5081, China’s first and only in-house developed carbapenem antibiotic (we out-licensed after the completion of phase 2 clinical trial), and XZP-5849, China’s first in-house developed PDE5 inhibitor (we out-licensed to a third party after the completion of phase 1 clinical trial), according to CIC. With our strong technological foundation, we are well-positioned to continuously deliver innovative results. In the next five years, we expect to advance one to two innovative drug candidates into the clinic each year.

We are one of the few in China with a comprehensive and integrated innovative drug R&D platform capable of both small molecule and biological drug discovery and development. With extensive capabilities across target validation, drug design and screening, preclinical evaluation, process development, to clinical development and regulatory affairs, we are able to increase R&D efficiency and achieve full-process risk control. Key features of our R&D platform are set out below:

- ***Small molecule drug R&D platform.*** We are able to discover and design innovative small molecule drugs with superior features, such as high potency, selectivity, good safety, as well as the ability to cross the blood-brain barrier and to overcome resistance. This is achieved through our expertise and know-how in the analysis of molecular and protein structures, supported by our use of computer aided drug design (CADD), and structure-based drug design (SBDD) methods. We have built a comprehensive drug evaluation system to assess and verify quality and developability, with fully fledged capabilities in pharmacology, ADME and safety evaluation. Moreover, we have mastered formulation development to optimize drug delivery and enhance bioavailability, including oral dosage forms, injectables and novel drug delivery systems. In addition to the late clinical stage candidates developed under this platform, we are also developing a number of innovative drug candidates such as XZP-7797, a next-generation PARP1 inhibitor with less hematologic toxicity and the capability to cross the blood-brain barrier, and XZP-6924, a potential first-in-class USP1 inhibitor with potential for combination therapies with PARP1 inhibitor.

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- ***Biological drug R&D platform.*** Our biological drug R&D platform is distinguished by its sophisticated drug design capabilities and robust antibody expression systems. We adhere to a Quality by Design (QbD) paradigm in antibody development, leveraging an extensive knowledge base in protein engineering and manipulation of antibody fragments and functional domains. This enables us to engineer antibody therapeutics with high binding affinity, improved endocytosis capability and increased cytotoxicity against tumor cells. Furthermore, we have developed proprietary Chinese Hamster Ovary (CHO) cell lines with a complete knockout of the FUT8 gene, facilitating the production of antibodies with nearly 100% absence of fucose in the Fc region. This modification significantly amplifies the binding of antibodies to natural killer cells and macrophages via FcγRIII, thereby enhancing ADCC and ADCP functions against tumor cells. Our clinical pipeline includes KM501, a bispecific HER2/HER2 ADC, which exemplifies the innovative design principles of our platform.
- ***Clinical development platform.*** We have built a robust and experienced clinical R&D team, with expertise covering medical science, translational medicine, pharmacology, biostatistics and statistical programming, clinical operation, and pharmacovigilance. As of June 30, 2024, our clinical research team consisting of over 50 members has managed and advanced over 30 clinical trials over the past five years. These team members bring a wealth of expertise in professional trial design, execution, and management, along with a deep understanding of communication and regulatory affairs crucial for drug registration processes. Our clinical development capabilities enable us to control the R&D process more efficiently and reliably, giving us more flexibility in designing and adjusting development strategies and advancing clinical development with speed and excellence. For example, by leveraging quantitative pharmacology to support our dose selection for phase 3 study of XZP-5695, we were able to implement a streamlined development pathway that enabled us to advance directly from phase 1 to phase 3 clinical trials.

By leveraging our comprehensive capabilities across the drug R&D lifecycle as well as our expertise in both small molecule drugs and biologics, we have been able to develop a synergistic pipeline for key indications of focus. For example, for breast cancer (BC) treatment, we have designed a robust pipeline of five self-developed assets to cover different patient populations, subtypes and lines of treatment. We have developed XZP-3287, a near-commercial CDK4/6 inhibitor for HR+/HER2- BC, KM501, a phase 1-stage bispecific ADC for HER2+ BC, XZP-7797, an IND-enabling stage PARP1 inhibitor for BRCA-mutated BC, and XZP-6924, an IND-approved USP1 inhibitor for combination therapies with PARP1 inhibitor. We are also exploring XZP-6877, a DNA-PK inhibitor, as a potential treatment for BC. We believe that our R&D platform affords us with critical optionality in optimizing our drug discovery and development, supporting our long-term sustainable growth.

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Solid drug development strategy balancing commercial potential and long- and short-term returns with deep understanding of the pharmaceutical industry in China

Since embarking on the innovative drug R&D journey in 2008, we have grown our business alongside the evolution of the pharmaceutical industry in China, witnessing the development of its regulatory framework and shift from generic drugs to innovative drugs. Our drug development strategy is rooted in our deep understanding of China’s pharmaceutical industry and profound insights of its unique clinical needs, based on which we have rationally developed a cohesive pipeline with complementary development arcs, synergistic value and returns on investment.

Our drug pipeline consists of over ten assets, representing two ‘waves’ of innovation. In the early years of our business, we focused on iterative innovation based on drugs with demonstrated clinical and commercial success, which provides us with higher development certainty. These drug programs have also been instrumental in our capability and experience build-up, as well as laying a sound financial foundation for continued innovative R&D. Representative assets in our first ‘wave’ of drug innovation include KBP-3571, XZP-3287 and XZP-3621, as well as transferred and/or out-licensed assets XZP-5695 and KBP-5081. Our KBP-3571 is a differentiated PPI drug targeting acid-related diseases, such as duodenum ulcers (DU) and reflux esophagitis (RE), in the vast digestive disease market in China, with a drug profile designed to address unmet clinical needs of the growing elderly patient population in China. In addition, we initiated the development of XZP-3287 and XZP-3621 close to program initiation of overseas competitors, reflecting our forward-looking vision in drug discovery and program selection.

With the rich experience we gained in the first innovation ‘wave’ and in line with the evolution of China’s pharmaceutical industry, we have increasingly directed our focus towards first-in-class drugs, including those with novel targets or mechanisms of action to address hard-to-treat diseases and conditions, and limitations of existing treatments. We have leveraged our R&D platform and systems to embark on this second ‘wave’ of drug innovation, while closely following scientific research both internationally and in China to identify candidates with strong potential and controlled R&D risk.

In line with our drug development strategies, our robust drug pipeline is centered in digestive diseases, oncology, and NASH, three significant therapeutic areas with large patient populations and imminent medical needs:

- ***Digestive diseases.*** Digestive diseases are increasingly prevalent as modern lifestyles with irregular diet, long working hours and nutritional imbalance become more common. According to the “China Health Statistical Yearbook 2022”, digestive diseases ranked among the top five in both two-week prevalence and chronic disease prevalence in China in 2018. In 2021, digestive diseases were the 7th highest contributor to mortality in China. The prevalence of peptic ulcer (PU) in China is expected to increase from approximately 73.5 million in 2023 to approximately 81.2 million in 2032, and that for RE is expected to grow from 37.8 million in 2023 to approximately 42.4 million in 2032. Oral PPI drugs are the mainstay treatment for these diseases, with a market size over RMB10.0 billion in China and projected to grow to RMB11.0 billion by 2032.

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- **Oncology.** According to CIC, cancer incidence in China increased from 4.3 million in 2018 to 4.96 million in 2023 at a 2.9% CAGR, and is expected to continue growing at a CAGR of 2.2% to reach 6.0 million by 2030. There is an underserved demand for patient-oriented innovative drugs that take into account the dynamic changes in treatment needs, according to the “Guidelines for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value” issued by the CDE in 2021. As such, the future direction of oncology drug development is towards anti-tumor treatments that are more precise, overcome drug resistance, and offer better safety profiles, thereby enhancing patient compliance, quality of life, and treatment effectiveness. We have five clinical-stage oncology drugs with diverse treatment modalities, including small molecule drugs, fusion proteins and ADCs, and tumor coverage, which we believe create a synergistic effect for patients and physicians. Several of our oncology drugs can address the limitations of existing tumor treatment regimens, solve problems such as drug resistance, and bring tangible clinical benefits to patients.
- **NASH.** NASH is a severe disease that is characterized by liver cirrhosis, fibrosis, and eventually failure and an increased risk of liver cancer. The global NASH patient population was 308.9 million in 2023, and is expected to grow to 333.3 million in 2032. In China, the patient population increased from 36.0 million in 2018 to 41.5 million in 2023, and is expected to reach 50.8 million by 2032, according to CIC. There is an urgent need for effective treatment as only one NASH drug has been approved globally to date. With major recent breakthroughs in NASH diagnosis and drug development, the treatment landscape for NASH is becoming more mature. We consider NASH to be an important growth area in our pipeline, with two drug assets under development, namely our non-steroidal FXR agonist XZP-5610 and KHK inhibitor XZP-6019.

Highly competitive and differentiated drug pipeline led by commercialized or near-commercial assets with high development visibility

We have developed a highly competitive and balanced pipeline of drug assets with differentiated features that, we believe, will address white space areas and unmet needs in the market. As of the Latest Practicable Date, we had one NDA approved asset, two drug programs with four indications in pivotal trial or NDA registration-stage, four drug programs in phase 1 clinical trial and four at IND-enabling stage or IND-approved. Our pipeline is staggered and complementary in structure, covering both validated targets with proven druggability as well as new mechanisms of action and drug modalities, established therapeutic areas such as oncology and high growth potential therapeutic areas such as NASH. This pipeline design strategically offers a balance in development risk and innovation, enabling our commercialized or late-stage assets to support the development of our early-stage innovative drugs.

Within our pipeline, we have three Core Products, namely, KBP-3571, an NDA-approved PPI for digestive diseases, XZP-3287, an NDA-filed CDK4/6 inhibitor targeting BC, and XZP-3621, an NDA-filed ALK inhibitor targeting NSCLC. We also have four key products, which represent the next wave in our staggered drug development, including three oncology assets for novel targets CD80, PARP1 and USP1, as well as a novel bispecific HER2/HER2 ADC. In addition, we have XZP-5610 and XZP-6019, our two assets for NASH.

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Details of these assets are set out below:

KBP-3571, a commercialized PPI for duodenum ulcers with phase 2 completed second indication in reflux esophagitis

PPIs are the mainstay treatment for DU and RE in China, which have a prevalence of 73.5 million and 37.8 million patients, respectively, in 2023. This significant prevalence is projected to persist due to the aging population, underscoring a substantial and ongoing demand for effective therapies. While PPIs have long been regarded as a generally effective drug class, unmet needs remain, particularly among elderly patients and those with hepatic or renal dysfunction, primarily attributed to the suboptimal metabolic profiles of existing PPIs. Our KBP-3571 is a PPI drug with a differentiated metabolic profile, which translates to lower risk of DDIs and reduced pressure on the renal function. Moreover, KBP-3571 is highlighted by potentially improved patient compliance with fast and long-lasting action and fewer side effects.

Importantly, according to CIC, among the seven PPIs approved in China as of the Latest Practicable Date, our KBP-3571 stands out as one of only two innovative drugs, with the other innovative PPI drug facing generic competition. This dynamic presents a crucial market opportunity for KBP-3571. Due to the government’s effort to increase drug accessibility, currently all generic PPI drugs are included in the VBP Scheme and the Key Supervision List, impacting their sales revenue. The only other innovative PPI, which has not yet been included in either program, has experienced a 79% increase in sales revenue between 2022 and 2023, according to CIC. However, generic competition is likely to alter its favorable market position. Given these market dynamics, we believe KBP-3571 is well-positioned to capture a significant market share. We obtained NDA approval for KBP-3571 for treatment of DU in June 2023, which was included in the NRDL since the beginning of 2024. We have also completed the phase 2 clinical trial for KBP-3571 for RE and expect to proceed to phase 3 trial in the second half of 2025. Our second indication in RE is expected to bring significant market upside given its large target patient population and bring synergies in commercialization.

Details of the competitive advantages of KBP-3571 are set out below:

- ***Lower risk of DDI.*** Many patients with DU and RE have underlying conditions that often require other medication, such as warfarin, clopidogrel, diazepam, and voriconazole. As such, the risk of drug-drug interaction (DDI) is a serious consideration when choosing PPI drugs. Many existing PPI drugs are primarily metabolized by CYP2C19 and CYP3A4 enzymes, suggesting a relatively high risk of DDIs, while KBP-3571 distinguishes itself through its unique metabolic profile. KBP-3571 is metabolized through non-enzymatic and multi-enzymatic pathways, with low CYP2C19 enzyme metabolism. Moreover, it does not significantly inhibit or induce CYP isozymes. These features result in a reduced DDI risk and positioning KBP-3571 as a preferred choice with high clinical value.

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- ***Low renal burden.*** Most PPIs are extensively metabolized by CYP2C19 and mainly excreted through the kidneys, which make them unsuitable for the large subset of elderly patients with compromised renal functions. Our KBP-3571 can be metabolized and excreted through both the intestinal tract and the kidney, and therefore can suit a wider patient population.
- ***Fast onset of action and lasting antisecretory effects.*** Many PPIs take several days to reach their maximum effectiveness, which does not meet the needs of patients seeking quick relief from symptoms. KBP-3571 is designed to have a higher pKa, which translates to faster onset antisecretory effect. In its phase 3 clinical trial, 81.2% of patients experienced significant symptom relief on the first day of treatment with KBP-3571. The rapid onset of action of KBP-3571 is coupled with its sustained antisecretory effects. Through binding to cysteine residue cys822, KBP-3571 can achieve a long-lasting antisecretory effect, which is crucial for many patients that would otherwise experience acid breakthrough at night. By controlling symptoms throughout the night, our KBP-3571 promotes patient compliance and broader clinical benefits.

XZP-3287, a near-commercial potential best-in-class CDK4/6 inhibitor for HR+/HER2- BC

Our XZP-3287 is a CDK4/6 inhibitor with NDA filed both as a monotherapy and in combination with fulvestrant for HR+/HER2- advanced BC, with a phase 3 clinical trial ongoing for XZP-3287 in combination with aromatase inhibitor (AI). BC is the most prevalent cancer in the world with approximately 2.4 million new cases in 2023, of which HR+/HER2- patients account for approximately 75%. CDK4/6 inhibitors have a market size of RMB2.2 billion in 2023 in China for the treatment of BC, which is expected to increase to RMB13.0 billion by 2032. CDK4/6 inhibitors are the standard treatment in combination with endocrine therapy for HR+/HER2- advanced BC, indicating significant market demand.

XZP-3287 can potentially cover a larger patient population with best-in-class potential, with demonstrated efficacy as a monotherapy in addition to combination therapy with AI for first-line and with fulvestrant for second-line endocrine treatment. To further expand patient coverage, we are also pursuing XZP-3287 as an adjuvant therapy for HR+/HER2- early BC in combination with endocrine therapy.

Key highlights of our XZP-3287 are set out below:

- ***Potentially the first and only CDK4/6-targeted monotherapy in China.*** Due to its strong efficacy profile, to date, our XZP-3287 is the only CDK4/6 inhibitor that has been investigated in phase 2 clinical trial as a monotherapy in China for HR+/HER2- locally advanced or metastatic BC. In its phase 2 clinical trial, XZP-3287 demonstrated good efficacy as of the data cut-off date (July 31, 2023) (ORR: 30.0%; mPFS: 9.17 months) in HR+/HER2- advanced BC patients with disease progression following prior endocrine therapies and chemotherapy in the metastatic setting. Abemaciclib, which is the only CDK4/6 inhibitor monotherapy approved in the

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world for HR+/HER2- locally advanced or metastatic BC, was reported to have an objective response rate (ORR) of 17.4% and mPFS of 5.9 months in its non-head-to-head phase 2 trial, according to CIC. In pre-treated HR+/HER2-low advanced BC population, XZP-3287 monotherapy demonstrated comparable efficacy to DS-8201, according to reported data from non-head-to-head trials.

- ***Broad patient coverage as a combination therapy.*** XZP-3287 combination therapy stands out as a comprehensive solution for early-stage, or locally advanced or metastatic HR+/HER2- BC across all treatment lines. We are exploring XZP-3287 in combination with fulvestrant for second-line endocrine treatment and with AI for first-line endocrine treatment. As a combination therapy with fulvestrant, XZP-3287 can significantly reduce tumor volume and demonstrated an ORR of 45.6% and 50.3% in intention-to-treat (ITT) population and in patients with measurable disease, respectively. Notably, XZP-3287 plus fulvestrant has shown significantly superior efficacy than control group in patients with prior chemotherapy, whereas abemaciclib and certain other CDK4/6 inhibitors have excluded such patients from clinical trials. We are also exploring XZP-3287 as an adjuvant therapy for early-stage BC in combination with endocrine therapy.
- ***Differentiated safety profile.*** XZP-3287 is differentiated by low hematological toxicity observed in clinical trials as a monotherapy and combination therapy, due to lower CDK6 inhibition compared to other major CDK4/6 inhibitors. XZP-3287 demonstrated the lowest discontinuation rate due to adverse events (AEs) among all approved CDK4/6 inhibitors according to reported non-head-to-head clinical data. Treatment with XZP-3287 plus fulvestrant was also associated with a low occurrence of grade 3 or higher AEs, most of which were reversible. Importantly, clinical data indicate that dose reductions of XZP-3287 did not significantly compromise its efficacy. This favorable safety profile positions XZP-3287 to potentially improve treatment adherence and quality of life for patients.
- ***Ability to treat cancer metastases.*** About 20%-30% of advanced BC patients develop metastases in the bone, liver and brain. Our XZP-3287 has shown promising potential, with preliminary efficacy observed. In a phase 3 trial of XZP-3287 plus fulvestrant, patients with liver metastases and bone-only metastases demonstrated significant risk reduction in disease progression (hazard ratios of 0.427 (95% CI, 0.271-0.674) and 0.184 (95% CI, 0.063-0.541), respectively) compared to the control group. Additionally, a phase 1 study of XZP-3287 showed stable disease (SD) in intracranial lesions for all patients with brain metastases, with a new brain metastasis incidence of just 2.1% — significantly lower than the typical 10-16% rate. These findings suggest that XZP-3287 has the potential to become a preferred treatment for BC patients with metastases.

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XZP-3621, a near-commercial differentiated ALK-targeted treatment for NSCLC

XZP-3621 is a differentiated ALK-targeted treatment with NDA filed in China for the treatment of NSCLC. 22% of all cancer incidences in China in 2022 were lung cancer cases, of which NSCLC is the most common subtype representing approximately 85% of all lung cancer cases. Approximately 64% of patients with NSCLC have stage IV disease at diagnosis. In China, NSCLC cases increased from 764.4 thousand cases in 2018 to 937.6 thousand cases in 2023, and are projected to reach 1,236.4 thousand cases by 2032.

ALK genetic mutations are detected in approximately 5-6% of NSCLC cases, for which treatments are specifically developed to treat this subtype of NSCLC more effectively. Our XZP-3621 is highlighted by its ability to offer strong anti-tumor effects and serve as an alternative to patients resistant to other ALK-targeted treatments. Moreover, XZP-3621 has demonstrated a good safety profile, which is crucial for patients on long-term treatment. With the interim data from the phase 3 clinical trial of XZP-3621, we have filed the NDA application of XZP-3621 in the first-line treatment of patients with ALK-positive advanced NSCLC in April 2024. We are also pursuing XZP-3621 as a post-operative adjuvant therapy for patients with ALK-positive NSCLC to further broaden the clinical and commercial value of our product.

Key features of XZP-3621 are set out below:

- ***Promising anti-tumor effects.*** XZP-3621 demonstrated a high ORR of 86.9% in ALK inhibitor treatment-naïve ALK+ advanced NSCLC patients in phase 3 clinical trial, higher than the reported ORR of approved ALK inhibitors in their non-head-to-head phase 3 clinical trials. Moreover, XZP-3621 demonstrated a statistically significant improvement in progression-free survival (PFS) compared to crizotinib, with a mPFS that was not reached at the time of data cutoff, underscoring its potential as a preferred treatment option.
- ***Effective in treating brain metastases.*** XZP-3621 has demonstrated exceptional efficacy in addressing brain metastases in ALK+ NSCLC. In a phase 3 clinical trial, XZP-3621 achieved a remarkable 92.3% intracranial objective response rate (IC-ORR) in patients with measurable intracranial lesions, significantly surpassing crizotinib’s 11.1% IC-ORR. Furthermore, XZP-3621 demonstrated a clinically meaningful improvement in mPFS compared to crizotinib in patients with baseline brain metastases, highlighting its potential to transform treatment paradigms in this challenging patient population.
- ***Promising for NSCLC patients resistant to other ALK-targeted treatments.*** XZP-3621 is a promising treatment for advanced NSCLC patients with prior treatment to other ALK inhibitors. In its phase 2 clinical trial, XZP-3621 demonstrated similar ORR as other ALK inhibitors for ALK+ advanced NSCLC patients who have received one prior line of treatment.

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- ***Good safety profile and patient compliance.*** Compared to other ALK-targeted treatments, XZP-3621 has a good safety profile with low incidence of grade 3 or higher AEs and lower incidence of treatment discontinuation due to AEs, with most common AEs being gastrointestinal disease. For therapies with extended duration of treatment, safety profile is a crucial factor for patient tolerability and compliance.

KM501, is a potential first-in-class HER2/HER2 bispecific antibody ADC in China. KM501 is designed with patented technology of knocking out fucose and with the ability to target both trastuzumab (anti-HER2 domain IV) and pertuzumab (anti-HER2 domain II) epitopes at the same time, potentially translating to better endocytosis of the ADC. This may contribute to KM501’s strong anti-tumor activity in HER2 low expression tumors. To date, DS-8201 is the only ADC approved for HER2 low expressing BC globally and there are no approved ADCs for other HER2 low expressing tumors. In preclinical mice tumor models, KM501 was superior to or non-inferior to DS-8201 in inhibiting tumors. We obtained IND approval for KM501 with the NMPA in February 2023 and are conducting a phase 1 clinical trial.

KM602, is the only clinical-stage anti-tumor CD80-Fc fusion protein drug in China, with first-in-class potential. CD80 plays an important role in T-cell activation and has become a promising approach for cancer immunotherapy. CD80 interacts with CD28 and PD-L1 to promote T-cell proliferation, differentiation and function. CD80 also interacts with CTLA-4 on the surface of T cells to suppress the response of specific effector T cells. Despite the availability of immune checkpoint inhibitors such as PD-1/PD-L1 drugs, many patients face low efficacy and drug resistance, which may be due to the lack of sufficient T cell co-stimulation in the tumor microenvironment. KM602 is designed to enhance the activation of T cells and has the potential to address the gap in this market. We obtained IND approval for KM602 with the NMPA and the FDA in February and September 2023, respectively, and are conducting a phase 1 clinical trial in China.

XZP-7797, is a potent, highly selective and brain-penetrating PARP1 inhibitor. First-generation PARP1/2 inhibitors have been approved for the treatment of a number of cancers, such as ovarian, prostate, pancreas, and breast cancers, with maximal activity against tumors harboring BRCA1/2 mutation or homologous recombination deficiency. However, PARP1/2 inhibitors have severe hematological toxicities due to the inhibition of PARP2, whereas data suggests that synthetic lethality with BRCA mutations is primarily caused by PARP1 inhibition. As such, we are developing XZP-7797 as a highly selective PARP1 inhibitor which is expected to reduce the hematological adverse effects associated with PARP2 inhibition while maintaining the required efficacy. Meanwhile, as approximately 20% of advanced cancer patients develop brain metastases, XZP-7797 also demonstrates an advantage over most first-generation PARP inhibitors with its ability to reach the brain lesions. We plan to submit an IND application for XZP-7797 to the NMPA by the end of 2024.

XZP-6924, is a potential first-in-class USP1 inhibitor. Research shows that inhibition of the DNA damage response (DDR) pathway can affect cancer cell replication and survival. Drugs targeting the DDR pathway are effective in the treatment of many types of cancers, such as PARP inhibitors, which, while demonstrating good clinical performance, is not effective in

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all patients and can be limited by treatment-related drug resistance. USP1 is involved in DNA damage repair processes, and in combination with PARP inhibitors, can synergistically target BRCA1/2 mutant cancers. XZP-6924 is a potent and highly selective USP1 inhibitor that has potential to be combined with PARP inhibitors to increase efficacy and overcome primary and acquired resistance to PARP inhibitors. We have observed a positive preclinical efficacy and safety profile for XZP-6924 and obtained IND approval from the NMPA in November 2024.

XZP-5610, is a novel, potential first-in-class, non-steroid FXR agonist poised to address the significant unmet medical needs in the treatment of NASH in China, a market currently lacking approved therapies. Preclinical studies have demonstrated XZP-5610’s potent FXR agonistic activity, effectively modulating downstream gene expression, reducing serum biomarkers, and improving key NASH histopathological features. Furthermore, XZP-5610 exhibits a favorable pharmacokinetic profile and a robust safety profile in preclinical models. We believe XZP-5610 has the potential to become a first-in-class therapy, offering a new and effective treatment option for patients with NASH. We are preparing the clinical study protocol for the phase 2 trial of XZP-5610.

XZP-6019, a novel, potential first-in-class KHK inhibitor, represents a promising therapeutic approach for the treatment of NASH. Preclinical studies have demonstrated XZP-6019’s potent KHK inhibitory activity, resulting in significant improvements in NASH-related parameters in animal models. Furthermore, XZP-6019 exhibits favorable pharmacokinetic and safety profiles, supporting its potential as a once-daily, well-tolerated treatment option. We are finalizing the clinical study protocol for the phase 1 trial of XZP-6019.

Effective commercialization strategy tailored to our drug pipeline, leveraging our deep understanding of China’s pharmaceutical industry and strengths of our commercialization partners

We deeply understand that successful drug commercialization is fundamental to the long-term sustainability of innovative drug development. As a participant in China’s pharmaceutical industry for the past 15 years, we have shaped our commercialization strategy with profound insights into the industry’s evolving market dynamics and regulatory environment. We believe that these insights have enabled us to effectively navigate the complexities of this industry, developing the ability to formulate comprehensive and bespoke commercial strategies for each product that take into account differentiated product features, competitive landscape, sales channels, market education, pricing and regulatory policies. In addition, we have inherited valuable commercialization experience from our Controlling Shareholder, Sihuan Pharm, which has been crucial to our capability build-up. Our commercialization capabilities are evidenced by the initial success of our first approved product KBP-3571, which achieved RMB16.1 million in sales since its commercialization up until June 30, 2024.

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With the approval and commercialization of KBP-3571 and in anticipation of the approval of other late-stage assets, we have established a solid commercialization system that will have synergistic benefits for other assets in our therapeutic areas of focus. We believe our tailored approach capitalizes on the unique characteristics of different markets, allowing us to optimize our resources to effectively deliver strong results.

- ***Digestive disease drugs.*** For our digestive disease pipeline, we have built a wide distribution network to mobilize the resources of experienced distributors and rapidly ramp up sales coverage, recognizing the importance of market coverage for the successful commercialization of chronic disease drugs in a relatively mature market. By leveraging our distributors’ channels, we are able to effectively capture market share while maintaining cost efficiency. Since the approval of KBP-3571 in June 2023, our lean in-house sales team consisting of over 30 members has built a 70+ distributor network to cover over 600 hospitals nationwide in China as of the Latest Practicable Date, with further growth expected as we ramp up sales. Moreover, with the specialized experience of our in-house commercialization team in digestive diseases, we have been able to successfully include KBP-3571 in the NRDL since the beginning of 2024, substantially increasing accessibility at scale. We are also developing KBP-3571 for RE, which is expected to bring significant market upside given its large target patient population and be synergistic in commercialization.
- ***Oncology drugs.*** For our rich oncology drug pipeline, we are adopting a dual-pronged “market + medical” strategy, focused on academic promotion to highlight the distinguishing features of our drugs and drug candidates that address unmet clinical needs. We are actively participating in academic conferences and publishing our findings and data in scientific journals, as well as conducting market education for our drugs candidates. In anticipation of commercialization of XZP-3287 in 2025, we are building and optimizing our commercialization team with a focus on market, medical science, distribution management and retail sales experience. We have also established detailed and tailored sales and marketing strategies for XZP-3287, including the selection of distributors across major hospitals. We are actively seeking and enhancing our cooperation with distributors nationwide, which we believe will actively drive our distribution network build-up nationwide going forward.

Visionary and experienced leadership with deep industry insights to guide and execute business strategies

Our strategic direction is guided by a visionary management team with a proven track record of success in China’s pharmaceutical industry. Their extensive experience in drug research and development, production, and commercialization enables the solid execution of our strategic initiatives.

Under the leadership of our chairperson of the Board, Ms. Xu Yanjun, we have become a competitive player in China’s pharmaceutical market. Ms. Xu is a highly accomplished pharmaceutical executive with over 29 years of experience in the industry. Prior to joining our Company in 2020, Ms. Xu held leadership positions at several prominent pharmaceutical

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companies across China. Ms. Xu was a core member of the founding team at Changchun BCHT Biotechnology Co., a leading Chinese vaccine developer and manufacturer. Prior to joining our Company, she assumed several managerial and leadership roles within Sihuan Group, including director and chairperson roles at several subsidiaries. Her experience also includes serving as chief project officer and director of the operation management center at Sihuan Pharm. Her comprehensive experience across major facets of drug development and project management, including drug registration pathways, manufacturing, quality control and corporate management has been instrumental in our success to date and will continue to ensure our enduring growth in the future.

Dr. Li Jia Kui, our Director and general manager, joined our Group in 2013. Dr. Li is a renowned scientist and surgeon whose career seamlessly blends clinical expertise and industry leadership. Following his clinical practice at a leading hospital in China, Dr. Li embarked on a distinguished career of nearly 14 years at Hoffmann-La Roche Ltd., steadily advancing to the position of principal scientist. Dr. Li brings exceptional academic and clinical experience in drug research and development in the fields of oncology, metabolism and infectious disease. He participated in the development of numerous novel drug candidates. As our head of small molecule drug research, Dr. Li leads a team responsible for advancing our pipeline of innovative therapeutics. Dr. Li’s leadership has been pivotal in driving the development of several commercialized and near-commercial drugs, including KBP-3571, which is the first and only PPI independently developed by a PRC-based biotech company.

Our deputy general manager, Dr. Wang Li, excels in clinical research and development, optimizing our clinical program design and developing differentiated drugs that can address limitations or unmet needs in strategic indications. Dr. Wang brings over two decades of multifaceted experience to our Company. Her career encompasses 18 years practicing as a physician oncologist at a leading Grade III Class A hospital, complemented by extensive expertise in biologics and small molecule drug development. Dr. Wang honed this expertise during her career leading research and development at several well-known biotech companies, including CStone Pharmaceuticals. Her unique background, seamlessly blending hands-on clinical practice with a strong foundation in academic research, makes her a significant asset to our Company.

Our deputy general manager, Mr. Yu Tao, brings over a decade of invaluable sales experience crucial to the successful commercialization of our drug candidates. Prior to joining our Company, Mr. Yu held key sales and marketing leadership roles at Sihuan Pharm for over 12 years. During his tenure as the general manager of the marketing center of Sihuan Pharm, he spearheaded the successful launch and commercialization of numerous drugs, notably demonstrated by his leadership in the highly successful launch of roxatidine.

Our deputy general manager, Mr. He Chengming strengthens our corporate governance with proficiency in operations, compliance, and financial management. Mr. He brings a wealth of legal and managerial expertise to his role, with a career spanning over two decades in the pharmaceutical industry. Prior to joining us in 2018, Mr. He honed his legal expertise at prominent pharmaceutical companies including Sihuan Pharm. This extensive experience, coupled with a strong academic background in law, positions Mr. He as a highly capable and well-rounded leader.

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OUR DEVELOPMENT STRATEGIES

Our mission is to drive the development of innovative drugs to treat underserved patient populations in China. Deeply rooted in China’s pharmaceutical industry, we are committed to leveraging both our local market insights and global perspectives to develop and commercialize innovative drugs in key therapeutic areas of digestive diseases, oncology and NASH.

Continue to implement sustainable and highly effective commercialization strategies

Our Core Products, all of which are approved or near-commercial, are the immediate drivers of our revenue growth in the short term, while the successful development and commercialization of our pipeline, particularly our key drug candidates, will fuel our long-term success. We will pursue a two-pronged commercialization strategy, combining the reach and resources of external partners with the strength of our internal teams.

- ***Expanding our sales reach.*** We will continue to focus on expanding our sales network and entering into strategic partnerships, prioritizing building a strong distribution network to set the groundwork for commercialization. This will allow us to optimize resource allocation and drive rapid market penetration, which is essential for us as more products reach the market. In selecting distributors, we will prioritize partnerships with established distributors with extensive resources and proven track records in innovative drug sales. We will provide comprehensive training to our distribution partners, emphasizing the unique advantages of our products to ensure efficient and effective commercialization. We will strategically engage external advisors to maximize the efficiency and impact of our business development activities.
- ***Building our in-house team.*** Internally, we are building a high-performing sales team with deep medical and scientific expertise to drive academic promotion endeavors and build business relationships with leading hospitals and KOLs. In particular, we will drive our “market + medical” strategy to increase awareness and knowledge of our drugs among physicians and hospitals in order to deliver clinical benefits to patients. In addition, we will strategically pursue NRDL inclusion for our drugs upon approval to increase their accessibility and affordability. While we will leverage the resources of external partners, we believe it is crucial to build relationships with key hospitals and physicians, as well as hands-on management of our distribution network.

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Continue to rapidly advance our pipeline

Through ongoing research and the anticipated launch of new products, we aim to broaden the therapeutic scope of our portfolio, addressing a wider range of diseases and improving the lives of more patients. We will diligently advance the development of our pipeline candidates through the design and execution of efficient and focused clinical development plans. We will expand our impact on patient care by:

- **Indication expansion.** We plan to actively pursue indication expansions for our Core Products to cover additional patient populations and indications.
 - o KBP-3571. We are currently working on finalizing the clinical trial design for a phase 3 study of KBP-3571 in adults with RE. We plan to commence the phase 3 clinical trial in the second half of 2025. We also plan to conduct post-marketing clinical studies of KBP-3571, including the exploratory studies investigating the potential of KBP-3571 for stress ulcer prevention and *Helicobacter pylori* eradication.
 - o XZP-3287. In addition to XZP-3287 monotherapy and combination therapy with fulvestrant in the treatment of advanced HR+/HER2- BC, we are also advancing a pivotal phase 3 clinical trial of XZP-3287 in combination with letrozole or anastrozole as first-line treatment of advanced HR+/HER2- BC. Pending positive results in an interim analysis, we anticipate submitting the NDA to the NMPA in the first half of 2025. We are also advancing the clinical development plan for XZP-3287 plus endocrine therapy as adjuvant therapy for the treatment of HR+/HER2- early BC.
 - o XZP-3621. With the interim data from the phase 3 clinical trial, we filed the NDA application of XZP-3621 in the first-line treatment of patients with ALK-positive advanced NSCLC in April 2024. We will supplement data based on regulatory feedback from the first to the third quarter of 2025. We are exploring the indication expansion of XZP-3621 in post-operative adjuvant therapy for ALK-positive early NSCLC. We submitted an IND application for such indication expansion to commence phase 3 clinical trial and received the acceptance notice to the IND application in November 2024.
- **Key product development.** We will focus our resources to drive development of our key products towards the market.
 - o KM602. We are currently conducting a phase 1 clinical trial of KM602 as monotherapy in patients with advanced solid tumors. We plan to complete patient enrollment for this clinical trial in 2025 with the full trial expected to conclude in 2026. In the second half of 2026, we plan to initiate a dose escalation study for combination therapy with a PD-1 antibody.

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- o KM501. We are currently conducting a phase 1 study of KM501 in subjects with advanced solid tumors that express, amplify, or mutate HER2. We plan to complete patient enrollment for this clinical trial in the second half of 2025 with the full trial expected to conclude in 2026. In the second half of 2026, we plan to initiate a dose escalation study for combination therapy with PD-1 antibody.
- o XZP-7797. We are currently completing IND-enabling studies for XZP-7797 and plan to submit an IND application by the end of 2024. We plan to initiate a phase 1 dose-escalation study in the second half of 2025, followed by a phase 1 expansion study in 2026.
- o XZP-6924. We obtained IND approval from the NMPA in November 2024. We plan to initiate a phase 1 study in the first half of 2026.

Refine and enhance our R&D capabilities

In an increasingly competitive industry landscape, we will focus on the in-house discovery and development of innovative drug candidates with the potential to be first-in-class or best-in-class therapies. We are committed to optimizing our drug development processes to accelerate drug development and clinical trials, bringing life-changing therapies to patients with expediency and quality. We will actively explore novel targets, drug combination strategies, cutting-edge technology platforms, and the application of artificial intelligence in drug discovery to drive the next generation of breakthrough therapies. We will also actively monitor emerging technologies and trends in the industry and seek strategic collaborations to complement our internal expertise and accelerate our business expansion.

Improve operational efficiency for sustainable growth

We are committed to continuous improvement across our operations to drive efficiency and support the development and commercialization of our products. Our focus is on optimizing organizational and management effectiveness, enhancing research and development productivity, driving commercialization efficiency, and strengthening risk management capabilities. This commitment to operational excellence provides a solid foundation for our long-term growth and success. We are dedicated to maintaining stable and scalable manufacturing capacity to meet market demand while upholding the highest standards of quality control. This commitment to operational excellence, combined with our dedication to leading-edge R&D, provides a solid foundation for sustained growth.

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Pursue strategic investment, licensing and acquisitions in China and overseas

We plan to pursue strategic investment, licensing, and acquisitions or asset purchases that align with our core competencies and offer compelling synergistic potential to further strengthen our market position and drive long-term sustainable growth. This includes actively evaluating potential acquisitions or in-licensing opportunities, particularly in areas such as oncolytic viruses, to enhance our product portfolio, broaden our technological capabilities, and accelerate our pipeline development. Moreover, in the future, we will also actively seek to identify synergistic assets and cutting-edge technologies and/or platforms, such as in the field of cell and gene therapies, in order to maintain our competitiveness. In addition, we will also pursue out-licensing opportunities for our innovative assets, particularly for global development in order to expedite their availability to patients worldwide and maximize their clinical and commercial value. We are committed to maintaining our position in key indications and will focus our resources and investments to further solidify our brand recognition and competitive advantage.

OUR PIPELINE

We are dedicated to the development and commercialization of innovative drugs for diseases with large patient populations and unmet medical needs, with a primary focus on digestive diseases, oncology and NASH. We have built a deep pipeline of drug programs with commercial visibility. As of the Latest Practicable Date, we had over ten drug assets under active development, including one NDA approved drugs and two drug programs with four indications in pivotal trial or NDA registration-stage. We also had four drug programs in phase 1 clinical trial and four at IND-enabling stage or IND-approved. In addition, we had transferred and/or out-licensed four self-developed drug candidates as of the Latest Practicable Date, demonstrating our robust research and development capabilities.

We pursue a staggered development strategy in each indication of focus. For digestive diseases, we obtained NDA approval from the NMPA for a Core Product, KBP-3571, for the treatment of DU, and are expanding indication coverage to RE, which has completed phase 2 clinical trial. For oncology, we have a robust drug franchise consisting of two NDA-filed innovative drugs, our Core Products XZP-3287 and XZP-3621, for BC and lung cancer, respectively. We are conducting further indication expansions for these Core Products, and also have a number of other oncology drug assets, including our four key products – KM602, KM501, XZP-7797 and XZP-6924, in phase 1 clinical trial or at IND-enabling stage. In addition, we are actively developing our NASH franchise with XZP-5610 in a phase 1 clinical trial and XZP-6019 at the IND stage.

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The pipeline chart below summarizes our commercialized drugs and drug candidates as of the Latest Practicable Date:

Therapeutic Area	Drug Candidate	Target	Category	Internal/ External	Clinical Indications	Partner	Current Stage					Current Status/ Next Milestone	Commercialization Rights
							Preclinical R&D	IND-enabling	Clinical Phase 1	Clinical Phase 2	Clinical Phase 3		
Digestion	KBP-3571 Ampirozole Sodium	PPI	Innovative small molecule drug	In-house R&D	Duodenal ulcer Adult reflux esophagitis		█	█	█	█	█	Approved for marketing	Global
	XZP-3287 Birececlib	CDK4/6	Innovative small molecule drug	In-house R&D	HR+/HER2- advanced breast cancer (Combo: fulvestrant) HR+/HER2- advanced breast cancer (Combo: AI) HR+/HER2- locally advanced or metastatic breast cancer Adjuvant therapy for HR+/HER2- early breast cancer (Combo: endocrine) ¹		█	█	█	█	█	Enter clinical phase 3 in H2 2025 Obtain market approval in H1 2025 Submit NDA in H1 2025 Obtain market approval in H1 2025 Submit IND in H1 2025 Obtain market approval in H2 2025	Global
Oncology	XZP-3621	ALK	Innovative small molecule drug	In-house R&D	First-line treatment for patients with ALK-positive advanced non-small cell lung cancer Post-operative adjuvant therapy for patients with ALK-positive non-small cell lung cancer ²		█	█	█	█	█	Enter clinical phase 3 in H2 2025	Global
	KM602	CD80 Fusion Protein	Innovative biological drug	Acquisition ³	Solid tumors (melanoma, non-small cell lung cancer, etc.)	Beijing Xuanyi	█	█	█	█	█	Finish China clinical phase 1 in 2026 ⁴	Global
	KM501	HER2/HER 2-ADC	Innovative biological drug	In-house R&D	HER2+ and HER2-low solid tumors (breast cancer, gastric cancer, etc.)		█	█	█	█	█	Finish clinical phase 1 in 2026	Global
	XZP-7797	PARP1 Inhibitor	Innovative small molecule drug	In-house R&D	Solid tumors (breast cancer, ovarian cancer, prostate cancer, pancreatic cancer, etc.)		█	█	█	█	█	Submit IND in Q4 2024	Global
	XZP-6924	USP1 Inhibitor	Innovative small molecule drug	In-house R&D	Solid tumors (breast cancer, ovarian cancer, prostate cancer, pancreatic cancer, etc.)		█	█	█	█	█	Enter clinical phase 1 in H1 2026	Global
	XZB-0004	AXL	Innovative small molecule drug	License-in ¹	Solid tumors Myelodysplastic syndromes/ acute myeloid leukemia	SIGNALCHEM	█	█	█	█	█	Finish clinical phase 1 in 2025	Greater China
	XZP-6877	DNA-PK	Innovative small molecule drug	In-house R&D	Solid tumors		█	█	█	█	█	Enter clinical phase 1 in 2026	Global
	KM118	HER2	Biosimilar	In-house R&D Transfer ¹	Combine with trastuzumab and chemotherapy for HER2+ metastatic breast cancer (MBC)	康希诺	█	█	█	█	█	Enter clinical phase 1 in 2026	Commercialization rights transferred in full
	XZP-5610	FXR	Innovative small molecule drug	In-house R&D	Non-alcoholic steatohepatitis		█	█	█	█	█	Enter clinical phase 2 in 2026	Global
	XZP-6019	KHK	Innovative small molecule drug	In-house R&D	Non-alcoholic steatohepatitis		█	█	█	█	█	Enter clinical phase 1 in 2026	Global
Others	XZP-5695	SGLT-2 Inhibitor	Innovative small molecule drug	In-house R&D Transfer ¹	Type II diabetes	康科生物 康科生物	█	█	█	█	█	Approved for marketing	Commercialization rights transferred in full
	KBP-5081	Camptoparom Antibiotic	Innovative small molecule drug	In-house R&D License-out ¹	Complicated urinary tract infection	康科生物	█	█	█	█	█	Enter clinical phase 1 in 2026	Regions other than Greater China
	XZP-5849	PDE-5	Innovative small molecule drug	In-house R&D License-out ¹	Erectile dysfunction Pulmonary arterial hypertension	康科生物 康科生物	█	█	█	█	█	Enter clinical phase 1 in 2026	Europe, the U.S., Canada, Japan, South Korea, Australia, Brazil
							█	█	█	█	█	Enter clinical phase 1 in 2026	

Core Products Key Products Waived/Potentially Waived from this phase of clinical trial R&D in the U.S.

Notes:

- We plan to submit an IND application with the NMPA for XZP-3287 as an adjuvant therapy for HR+/HER2- early breast cancer (combo: endocrine therapy), which, if approved, would enable us to proceed directly to phase 3 clinical trial; 2. We have filed an IND application with the NMPA for XZP-3621 as a post-operative adjuvant therapy for patients with ALK-positive NSCLC, which, if approved, would enable us to proceed directly to phase 3 clinical trial; 3. We expect to complete phase 1 clinical trial for KM602 in 2026 in China and our development plan for KM602 in the U.S. is pending our progress made in China; 4. For details of our acquisition of KM602, license-in of XZB-0004, transfer of KM118 and XZP-5695, and license-out of KBP-5081 and XZP-5849, see “Business — Our License and Asset Acquisition Arrangements” in this document.

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DIGESTIVE DISEASE DRUGS

KBP-3571, a Commercialized PPI for Duodenum Ulcers with Phase 2 Completed Second Indication in Reflux Esophagitis, a Core Product

Overview

KBP-3571 is an internally developed innovative drug for which we hold global IP rights, and the first and only PPI independently developed by a PRC domestic company. Since the first PPI was approved in China in 1994, this class of drugs has become the standard of care for DU and RE. In China, the prevalences of DU and RE are rising, and the size of the oral PPI drug market is expected to gradually grow to RMB11.0 billion by 2032.

Although PPIs are a relatively mature drug class with good effectiveness, there remains unmet needs for patients in China. Existing PPIs are faced with unpredictable metabolic profiles, high strain on hepatic and renal function, slow and short-lasting onset of action, which can significantly lower patient compliance especially when used as a long-term treatment. KBP-3571 has a differentiated metabolic profile that enables a reduced renal burden, a lowered risk of DDIs, and a rapid and long-lasting onset of antisecretory effects. This demonstrates strong potential to compete favorably within the PPI class and address current unmet medical needs.

In June 2023, KBP-3571 received NDA approval from the NMPA for the treatment of DU. We are also pursuing indication expansion for KBP-3571 to treat adult RE, for which we have completed a phase 2 clinical trial in May 2023. For further details, please see “— Digestive Disease Drugs — KBP-3571, a Commercialized PPI for Duodenum Ulcers with Phase 2 Completed Second Indication in Reflux Esophagitis, a Core Product — Summary of Clinical Trial Data” below. We plan to initiate phase 3 clinical trial in the second half of 2025.

Mechanism of Action

DU is an open sore that develops in the lining of the duodenum, which is the first part of the small intestine, just beyond the stomach. These ulcers typically develop due to an imbalance between the digestive fluids (stomach acid and pepsin) and the protective mucus layer that lines the duodenum. When the protective mucus layer is compromised, the digestive fluids can erode the duodenal lining, leading to the formation of an ulcer.

PPIs are designed to reduce stomach acid secretion by inhibiting the H⁺/K⁺ ATPase enzyme, also known as the proton pump, that resides on the luminal surface of the parietal cells in the stomach lining. The function of the proton pump is to pump out H⁺ (protons) into the gastric mucosal cavity, increasing the acidity of the stomach, and in exchange, pump K⁺ (potassium ions) into the parietal cells. PPIs can enter the parietal cells and form a disulfide covalent bond with the proton pump responsible for secreting gastric acid, effectively reducing and inhibiting gastric acid secretion, alleviating the symptoms of PU, and promoting the healing of ulcer lesions.

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Market Opportunity and Competition

PPIs are the mainstay treatment for PU and RE in China. The high prevalences of PU and RE in China represent a significant market opportunity for PPIs. The number of people suffering from PU in China is projected to rise from 73.5 million in 2023 to 81.2 million by 2032, demonstrating a consistent need for these medications. Approximately 75% of PU cases were DU. Similarly, RE affects a substantial portion of the population, with prevalence expected to climb from 37.8 million in 2023 to 42.4 million by 2032. This growing patient population underscores the substantial and expanding market potential for PPIs.

As of the Latest Practicable Date, there were seven PPIs approved for marketing in China, among which, five are generics, namely lansoprazole, pantoprazole, omeprazole, rabeprazole and esomeprazole. All of the marketed generic PPIs are included in the VBP Scheme and Key Supervision List, leading to a reduction in their prices and market size. Ilaprazole, one of the two currently marketed innovative PPIs, has become subject to competition from generic PPIs and may be included in the VBP Scheme. This highlights the unique positioning of our KBP-3571. As the only other innovative PPI approved in China and not included in either the VBP Scheme or Key Supervision List, KBP-3571 has a significant competitive advantage. Furthermore, according to CIC, KBP-3571 is currently the only innovative PPI candidate under clinical development in China for RE, further solidifying its potential in this large and underserved market.

For more details regarding the addressable market size and competitive landscape of PPIs, see “Industry Overview — China’s Digestive Disease Drug Market — Proton Pump Inhibitor.”

Competitive Advantages

Differentiated Metabolic Pathway. Most currently marketed PPIs are primarily metabolized by CYP2C19. Therefore, CYP2C19 genetic polymorphisms can significantly affect DDIs and clinical outcomes. Approximately 15% patients in China are poor metabolizers of CYP2C19, which may result in higher plasma concentrations of PPIs, increase the risk of DDIs and contribute to variable therapeutic outcomes. Unlike most marketed PPIs, KBP-3571 is metabolized differently due to its structure-based design. This design features a modified pyridine ring with the removal of the C5 methyl group, which could potentially interact with CYP2C19 through hydrogen bonding. As a result, KBP-3571 has shown significantly reduced reliance on CYP2C19 for its metabolism. An *in vitro* biotransformation study revealed that CYP2C19 contributes to only 3.5% of KBP-3571’s overall metabolism. Consequently, genetic variations in CYP2C19 are not expected to significantly impact the plasma concentration or clinical outcomes of KBP-3571.

Lower Risk of DDI. A significant proportion of patients with DU and RE have underlying conditions that often require other medication. KBP-3571 is metabolized through multiple routes, including both non-enzymatic pathways and various hepatic enzyme CYP450-mediated pathways, thereby decreasing the risk of DDI. In its phase 1f clinical trial, we evaluated the risk of DDI between KBP-3571 and amoxicillin, clarithromycin, and potassium bismuth

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citrate. The study demonstrated that, co-administration of KBP-3571 20 mg, amoxicillin 1 g, and clarithromycin 500 mg resulted in a modest increase of KBP-3571 exposure without any dose adjustment required, while the exposure of amoxicillin and clarithromycin remained unchanged compared to monotherapy. Similarly, the addition of potassium bismuth citrate 0.6 g to triple therapy did not significantly alter the exposure of KBP-3571, amoxicillin or clarithromycin. These findings underscore the low risk of DDI with KBP-3571, making it a safe option for patients taking multiple medications, particularly those undergoing *Helicobacter pylori* eradication therapy.

Reduced Renal Burden. Most drugs and their metabolites are processed in the liver and excreted through the kidneys. In elderly patients and those with impaired liver or kidney function, this process can be compromised, leading to drug accumulation, toxicity, and adverse reactions. Unlike other PPIs that primarily rely on renal excretion, KBP-3571 features a furan ring in its structure, resulting in lower polarity for some of its metabolites. High polarity metabolites are excreted through the kidneys, while low polarity metabolites are processed in the liver and excreted into the bile, eventually leaving the body via the intestines. Phase 1e clinical trial data show that 53.34% of the drug's metabolites are excreted in urine and 39.86% in feces. This dual excretion pathway, encompassing both renal and intestinal routes, makes KBP-3571 particularly advantageous for patients with compromised renal function.

Rapid Onset of Action. The effectiveness of PPIs depends on the electron behavior of their pyridine and benzimidazole rings, influenced by their acid dissociation constants (pKa1 and pKa2). pKa1 affects initial protonation and accumulation in parietal cells, while pKa2 influences activation speed. KBP-3571 is uniquely designed to raise its pKa1 to 5.03 and pKa2 to 0.79. This structural modification enhances its acid-binding capacity and accelerates activation. Phase 3 clinical trial data show that 81.2% of patients experienced relief from acid reflux symptoms on the first day of administration, highlighting its rapid and effective action.

Lasting Antisecretory Effects. PPIs function through two key processes in the body's acidic environment: acid accumulation and acid activation. The rate of acid activation hinges on the PPI's ability to bind to cysteine residues cys813 and cys822 at its target site, with deeper binding at cys822 offering a more prolonged acid-suppressing effect. KBP-3571's unique structural properties enable it to deeply bind to cys822, ensuring sustained acid suppression. KBP-3571, due to its lasting antisecretory effects, effectively controls nighttime symptoms. In the phase 3 clinical trial, KBP-3571 demonstrated effective control of nocturnal abdominal pain, with the median time for the disappearance of initial nighttime abdominal pain being only two days.

Clinical Development Plan

We obtained IND approval from the NMPA to investigate KBP-3571 for DU in June 2013 and commenced first phase 1 clinical trial in August 2014. Based on multiple phase 1 clinical trial results, we obtained approval from the NMPA in April 2018 and commenced phase 2 clinical trial for DU in October 2018. We commenced phase 3 clinical trial in January 2020 and filed for NDA in October 2021. We subsequently obtained NDA approval in June 2023.

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Leveraging the phase 1 clinical trial and phase 2 clinical trial conducted for DU, which covers the planned dosage and treatment for adult RE, we initiated a phase 2 clinical trial for KBP-3571 in adult RE in December 2022. As of the Latest Practicable Date, we were finalizing the phase 3 clinical trial design for KBP-3571 in RE. We plan to commence the phase 3 clinical trial in the second half of 2025.

Summary of Clinical Trial Data

As of the Latest Practicable Date, we had completed a total of nine clinical trials of KBP-3571, including a phase 2 and a phase 3 clinical trial for the treatment of DU, a phase 2 clinical trial for the treatment of RE, and six phase 1 clinical trials in healthy subjects.

Phase 3 Clinical Trial for the Treatment of DU

Trial Design. This was a multicenter, randomized, double-blind, double-dummy, positive-drug parallel-controlled, phase 3, non-inferiority study that compared the efficacy and safety of KBP-3571 with rabeprazole in Chinese patients with DU. A total of 448 patients with DU were expected to be enrolled in this clinical trial. Following the screening period, patients who met the predefined inclusion criteria were randomized in a 1:1 ratio to received 10 mg rabeprazole plus a placebo or 20 mg KBP-3571 plus a placebo once daily for four weeks.

Trial Objectives and Endpoints. The primary objective of this study was to evaluate the efficacy of KBP-3571 in the treatment of DU and to demonstrate non-inferiority compared to rabeprazole. The secondary objective is to investigate the safety and population pharmacokinetic characteristics of KBP-3571 in patients with DU. The primary efficacy endpoint of this study was the ulcer healing rate at week 4 assessed by a blinded independent central review (BICR). Secondary efficacy endpoints included the proportion of patients with improved severity of DU symptoms. Exploratory endpoints included the number of days to resolution of DU abdominal pain and nocturnal abdominal pain. AEs, vital signs, physical and laboratory examinations, and electrocardiograms were assessed as safety endpoints.

Trial Progress. The clinical trial was completed in December 2020. A total of 442 patients received at least one dose of study treatment and were included in the full analysis set (FAS). The per protocol set (PPS) consisted of 418 patients who completed the study per protocol. The safety analysis set (SS) included 439 patients.

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Efficacy Data. The ulcer healing rates of each treatment group at week 4 were as follows:

Treatments	Healing rates	
	FAS (nA = 220, nR = 222)	PPS (nA = 210, nR = 208)
Anaprazole, % (95% CI)	90.9 (87.1, 94.7)	93.3 (90.0, 96.7)
Rabeprazole, % (95% CI)	93.7 (90.5, 96.9)	96.6 (94.2, 99.1)
Difference in healing rates, % (anaprazole-rabeprazole, 95% CI)	-2.8 (-7.7, 2.2)	-3.3 (-7.5, 0.9)

CI: Confidence interval; FAS: Full analysis set; PPS: Per-protocol analysis set; nA: Number of anaprazole group; nR: Number of rabeprazole group.

95% CIs were estimated by the Wald asymptotic method.

Safety Data. Most treatment-emergent adverse events (TEAEs) were mild and there was a numerically lower proportion of TEAE incidences with KBP-3571 (32.7%) than with rabeprazole (38.4%). The safety data from this clinical trial are summarized in the table below.

Events	Anaprazole (n=220)	Rabeprazole (n=219)	Total (n=439)	χ^2 or Fisher	P
AEs	74 (33.6)	84 (38.4)	158 (36.0)	1.06	0.30
SAEs	3 (1.4)	1 (0.5)	4 (0.9)	Fisher	0.62
TEAEs	72 (32.7)	84 (38.4)	156 (35.5)	1.52	0.22
TESAE	3 (1.4)	1 (0.5)	4 (0.9)	Fisher	0.62
TEAEs leading to discontinuation . . .	3 (1.4)	0	3 (0.7)	Fisher	0.25
TEAEs leading to withdrawal	2 (0.9)	0	2 (0.5)	Fisher	0.50
TEAEs of special interest	3 (1.4)	4 (1.8)	7 (1.6)	Fisher	0.72
Treatment-related AEs	18 (8.2)	24 (11.0)	42 (9.6)	0.98	0.32
TRSAE	0 (0)	1 (0.5)	1 (0.2)	Fisher	0.50
Treatment-related AEs of special interest	2 (0.9)	3 (1.4)	5 (1.1)	Fisher	0.69
Severity of treatment- related AEs				Fisher	1.00
Mild	15 (6.8)	21 (9.6)	36 (8.2)		
Moderate	3 (1.4)	3 (1.4)	6 (1.4)		
Severe	0	0	0		

AE: Adverse event; SAE: Serious adverse event; SS: Safety analysis set; TEAE: Treatment-emergent adverse event. Data are presented as n(%).

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Conclusion. At four weeks of treatment, patients in both groups experienced substantial improvements in ulcer symptoms and had similar improvement rates. There were no statistically significant differences between treatments for time to elimination of ulcer-related or nocturnal abdominal pain. The safety and tolerability profiles were similar between treatments. However, KBP-3571 has a slightly lower frequency of AEs than rabeprazole.

Phase 2 Clinical Trial for the Treatment of DU

Trial Design. This was a multicenter, randomized, positive-controlled, double-blinded, parallel-group phase 2 clinical study that compared the efficacy and safety of KBP-3571 versus rabeprazole in patients with DU. A total of 150 patients with active DU were expected to be enrolled in this clinical trial. They were randomized 1:1:1 to receive rabeprazole 10 mg, KBP-3571 20 mg or KBP-3571 40 mg for four weeks. The ulcer healing rates after four weeks of treatment were compared between groups by BICR and investigator review. In addition, symptoms and safety were evaluated.

Trial Objectives and Endpoints. The primary objective of this trial was to compare the efficacy of KBP-3571 (20 mg and 40 mg) administered once daily to that of rabeprazole in the treatment of DU, and to identify the most effective dosage. A secondary objective was to assess the safety profile of KBP-3571 administered once daily in patients with DU. The primary endpoint was the ulcer healing rate at week 4 as assessed endoscopically by investigator review. The healing rate of the ulcer is described as the percentage of the number of patients who achieved a healing state among all patients in each group. The secondary endpoint included the time to achievement of complete epigastric pain relief and nocturnal epigastric pain relief and the percentage of patients who were free from epigastric pain or nocturnal epigastric pain at week 2 and week 4. Complete relief of epigastric pain was defined as the disappearance of epigastric pain without recurrence. Safety was assessed on the basis of adverse events (AEs) and common safety indexes at each visit.

Trial Progress. The clinical trial was completed in May 2019. A total of 145 patients received at least one dose of study treatment and were included in the FAS. The PPS consisted of 132 patients who completed the study per protocol. The SS included all 145 patients who received at least one administration.

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Efficacy Data. The ulcer healing rates of each treatment group in the FAS population at week 4 of follow-up were as follows:

Treatment	FAS population		PPS population	
	Independent central review	Investigator review	Independent central review	Investigator review
Healing rates				
Rabeprazole 10 mg [No.]				
[(%) (95% CI)]	44 [88.0 (79.0–97.0)]	36 [72.0 (59.6–84.5)]	40 [88.9 (79.7–99.4)]	34 [75.6 (63.0–88.1)]
Anaprazole 20 mg				
[No.] [(%) (95% CI)] . .	40 [85.1 (74.9–95.3)]	33 [70.2 (57.1–83.3)]	37 [86.0 (75.7–96.4)]	31 [(72.1 (58. 7–85.5)]
Anaprazole 40 mg				
[No.] [(%) (95% CI)] .	42 [87.5 (78.1–96.9)]	37 [(77.1 (65.2–89.0)]	40 [90.9 (82.4–99.4)]	35 [(79.5 (67.6–91.5)]
Difference in healing rate between groups				
Anaprazole 20 mg- Rabeprazole 10 mg [% (95% CI)]	-2.9 (-16.5–10.7)	-1.8 (-19.8–16.3)	-2.8 (-16.7–11.0)	-3.5 (-21.8–14.9)
Anaprazole 40 mg- Rabeprazole 10 mg [% (95% CI)]	-0.5 (-13.5–12.5)	5.1 (-12.2–22.3)	2.0 (-10.5–14.5)	4.0 (-13.4–21.3)
Anaprazole 20 mg- Anaprazole 40 mg [% (95% CI)]	2.4 (-11.4–16.2)	6.9 (-10.8–24.6)	4.9 (-8.5–18.3)	7.5 (-10.5–25.4)

FAS, full analysis set; PPS, per protocol set; CI, confidence interval.

Farrington-Manning analysis was used to assess the differences in healing rates between groups with the 95% confidence interval (95% CI).

Safety Data. A total of 81 adverse events were recorded among 47 of 145 (32.4%) patients, with 17 of 50 (34.0%) patients in the 10 mg rabeprazole group, 16 of 47 (34.0%) patients in the 20 mg KBP-3571 group and 14 of 48 (29.2%) patients in the 40 mg KBP-3571 group. The incidences of adverse events were similar among the three groups. Only one patient withdrew from the study due to treatment-emergent serious adverse events (TESAEs) (not treatment-related) in the 10 mg rabeprazole group, while no patient withdrew from the study in the other two treatment arms. The safety data from this clinical trial are summarized in the table below.

	Rabeprazole		Anaprazole			
	10mg (n=50)		20mg (n=47)		40mg (n=48)	
	Patients (%)	Events	Patients (%)	Events	Patients (%)	Events
Any TEAE	17 (34.0)	39	16 (34.0)	22	14 (29.2)	20
Mild	17 (34.0)	35	14 (29.8)	20	14 (29.2)	18
Moderate	4 (8.0)	4	2 (4.3)	2	1 (2.1)	2
Severe	0	0	0	0	0	0

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	Rabeprazole		Anaprazole			
	10mg (n=50)		20mg (n=47)		40mg (n=48)	
	Patients (%)	Events	Patients (%)	Events	Patients (%)	Events
Treatment-related AEs .	9 (18.0)	16	9 (19.1)	9	6 (12.5)	7
Treatment-related SAEs	0	0	0	0	0	0
TESAEs (not treatment-related) leading to drug discontinuation and withdrawal	1 (2.0)	1	0	0	0	0
TEAE leading to death	0	0	0	0	0	0

Phase 2 Clinical Trial for the Treatment of RE in Adults

Trial Design. This phase 2 clinical trial was designed to evaluate the efficacy and safety of KBP-3571 in Chinese patients with RE. This multi-center, randomized, double-blind, positive-controlled, parallel-group study compared two dose levels of KBP-3571 (40 mg and 60 mg) against rabeprazole 20 mg. This study planned to enroll approximately 156 subjects with RE who met the inclusion criteria and did not meet any of the exclusion criteria. Eligible subjects were randomly assigned to one of the three groups (KBP-3571 40 mg, KBP-3571 60 mg, or rabeprazole 20 mg) in a 1:1:1 ratio according to a pre-determined randomization table. All patients received their assigned study medication once daily before breakfast for a duration of four weeks. At week 4, patients underwent an assessment visit. Patients who had achieved healing discontinued treatment and entered a safety follow-up period. Patients who had not achieved healing continued treatment for an additional four weeks (total of eight weeks). All patients completed a safety follow-up assessment after their final treatment dose.

Trial Objectives and Endpoints. The primary objective of this trial was to assess the efficacy of KBP-3571 in RE patients. Secondary objectives included evaluating symptom control, quality of life improvement, safety, and population pharmacokinetics, as well as exploratory analysis of the relationship between genetic polymorphisms and drug exposure or efficacy. The primary endpoint of this study was the endoscopic healing rate of RE at eight weeks evaluated by the BICR. Secondary endpoints included the endoscopic healing rate of RE at eight weeks evaluated by the investigators, the endoscopic healing rate at four weeks and the improvement in individual symptom scores (daytime regurgitation, daytime heartburn, nighttime regurgitation, and nighttime heartburn) at eight weeks. Safety assessments in this study included monitoring of vital signs, physical examinations, AEs, laboratory parameters (hematology, urinalysis, blood chemistry, and coagulation), and electrocardiograms.

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Trial Progress. The clinical trial was completed in May 2023. A total of 156 subjects were enrolled in this clinical trial, with 153 patients in the FAS, 144 patients in PPS and 151 in SS.

Efficacy Data. Based on the FAS, the endoscopic healing rates of RE were assessed by BICR after eight weeks of treatment. Healing was observed in 43 patients (86.0%) in the KBP-3571 40 mg group, 45 patients (86.5%) in the KBP-3571 60 mg group, and 44 patients (86.3%) in the rabeprazole 20 mg group. Similar results were obtained by investigator assessment, with endoscopic healing observed in 44 patients (88.0%) in KBP-3571 40 mg group, 47 patients (90.4%) in the KBP-3571 60 mg group, and 44 patients (86.3%) in the rabeprazole 20 mg group.

Safety Data. Based on the SS, the incidence of TEAEs was 57.1%, 48.1%, and 60.0% in the KBP-3571 40 mg, KBP-3571 60 mg, and rabeprazole 20 mg groups, respectively. The incidence of treatment-related adverse events (TRAEs) was 18.4%, 25.0%, and 24.0% in the respective groups. The safety data from this clinical trial are summarized in the table below.

	KBP-3571 40mg	KBP-3571 60mg	Rabeprazol 20mg	Total	Statistical Test	p-value
	N=49	N=52	N=50	N=151		
	n(%) E	n(%) E	n(%) E	n(%) E		
TEAE	28 (57.1) 63	25 (48.1) 60	30 (60.0) 55	83 (55.0) 178	1.60	0.4487
TRAE	9 (18.4) 22	13 (25.0) 28	12 (24.0) 26	34 (22.5) 76	0.73	0.6941
Grade 1	6 (12.2) 19	10 (19.2) 24	11 (22.0) 25	27 (17.9) 68		
Grade 2	3 (6.1) 3	3 (5.8) 4	1 (2.0) 1	7 (4.6) 8		
Grade 3 or above	0	0	0	0		
TRSAE	0	0	0	0		
TEAE of Special Interest (abnormal liver function and QTcF prolongation)	0	0	0	0		

Phase 1 Clinical Trials in Healthy Subjects

As of the Latest Practicable Date, we had completed six different phase 1 clinical trials in healthy subjects to evaluate the safety, tolerability, pharmacokinetics/pharmacodynamics (PK/PD), food effect, mass balance and DDI of KBP-3571.

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Phase 1a Clinical Trial to Evaluate the Safety, Tolerability and PK/PD of a Single Dose of KBP-3571

This was a single-center, randomized, double-blind, placebo-controlled phase 1a clinical trial to evaluate the safety, tolerability, and PK/PD of a single oral dose of KBP-3571 in healthy subjects. 66 subjects were enrolled in the study (54 receiving KBP-3571 and 12 receiving placebo) and completed seven dose groups, receiving 2.5 mg, 5 mg, 10 mg, 20 mg, 40 mg, 80 mg, and 120 mg of KBP-3571, respectively. The study followed a sequential dose escalation design, with the next higher dose group initiated only after the safety evaluation of the preceding lower dose group was completed.

The clinical trial showed that all AEs were mild in severity except for one case of moderate rash in the 5 mg group and one case of moderate fever and upper respiratory tract infection in the 40 mg group. TRAEs occurred in one subject (50%) with one event in the 2.5 mg group, one subject (16.67%) with two events in the 5 mg group, one subject (10%) with one event in the 10 mg group, two subjects (20%) with two events in the 40 mg group, and one subject (16.67%) with three events in the 120 mg group. TRAEs included increased thyroid stimulating hormone (two events), electrocardiogram QT prolongation (one event), nasal congestion (one event), limb pain (one event), lower abdominal pain (one event), decreased appetite (one event), rash (one event), and headache (one event). With the exception of rash, which was moderate, all TRAEs were mild and resolved without treatment. No SAEs or AEs leading to discontinuation were reported.

Phase 1b Clinical Trial to Evaluate the Effect of a High-fat Meal on the PK of KBP-3571

This was a single-center, randomized, open-label, two-period crossover clinical study to evaluate the impact of a high-fat meal on the PK of KBP-3571 in healthy subjects. The study results demonstrated that administration of KBP-3571 after a meal significantly reduces its bioavailability compared to fasting conditions.

Phase 1c Clinical Trial to Evaluate the Tolerability and PK/PD of Multiple Doses of KBP-3571

This was a single-center, randomized, double-blind, placebo-controlled clinical trial to evaluate the safety, tolerability, and PK/PD of multiple doses of KBP-3571 in healthy subjects. Following a once-daily dose of 20 mg or 40 mg for seven days, steady-state was achieved, with median peak times (T_{max}) of 3.75 and 3.50 hours, and mean elimination half-lives of 1.60 and 2.02 hours, respectively. Accumulation was low, with ratios slightly above 1. A twice-daily regimen of 20 mg for eight days also reached steady-state, showing similar results. Exposure (C_{max} and AUC) increased proportionally with dose, though slightly less than doubled with the 40 mg dose compared to 20 mg.

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Phase 1d Clinical Trial to Evaluate the Tolerability and PK/PD of Multiple Doses of KBP-3571

This is a single-center, randomized, double-blind clinical trial, utilizing both placebo and positive control groups, to assess the safety, tolerability and PK/PD of multiple doses of KBP-3571 in healthy subjects. Following once-daily administration for seven days, steady-state drug levels were achieved across doses of 60 mg, 80 mg, and 100 mg. The drug exhibited a linear PK profile within this dose range, indicating that drug exposure increased proportionally with dose. At steady stage, the T_{max} of KBP-3571 in the three groups were 4.75, 4.00, and 4.00 hours, and the mean elimination half-lives were 1.73, 1.37, and 1.60 hours, respectively. While some mild drug accumulation was observed, it was considered manageable. These findings suggest favorable PK characteristics of KBP-3571.

Phase 1e Clinical Trial to Study the Absorption, Metabolism and Excretion of KBP-3571

This was a single-center, open-label, single-dose mass balance clinical trial investigating the absorption, metabolism, and excretion of a 20 mg/100 µCi dose of [¹⁴C]KBP-3571 in healthy male Chinese subjects. Following a single oral administration of 20 mg/100 µCi [¹⁴C]KBP-3571, drug-related substances were rapidly eliminated, reaching a cumulative excretion rate of 91.60% within 96 hours. Over a period of 0 to 192 hours, the average cumulative excretion rate of total radioactivity was 93.20%, with urine accounting for 53.34% and feces accounting for 39.86% of the administered dose.

Phase 1f Clinical Trial to Evaluate the DDIs of KBP-3571 with Amoxicillin, Clarithromycin and Bismuth Potassium Citrate

This was a single-center, randomized, open-label, crossover clinical trial evaluating the DDIs of KBP-3571 with amoxicillin, clarithromycin, and bismuth potassium citrate in healthy Chinese subjects.

This study comprised two cohorts. Cohort 1 enrolled 24 subjects randomized 1:1:1:1 to four treatment sequences to receive KBP-3571 20mg, amoxicillin 1g, clarithromycin 500mg, and a triple therapy combining all three drugs, respectively. Cohort 2 enrolled eight subjects randomized 1:1 to a 2x2 crossover design with two treatment sequences. Each sequence included two treatment cycles: the aforementioned triple therapy and a quadruple therapy adding bismuth potassium citrate 0.6g to the triple combination. The study demonstrated that, co-administration of KBP-3571 20 mg, amoxicillin 1 g, and clarithromycin 500 mg resulted in a modest increase of KBP-3571 exposure without any dose adjustment required, while the exposure of amoxicillin and clarithromycin remained unchanged compared to monotherapy. Similarly, the addition of potassium bismuth citrate 0.6 g to triple therapy did not significantly alter the exposure of KBP-3571, amoxicillin or clarithromycin.

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Material Communications and Next Steps

We consulted with the CDE and received their approval in 2019 for commencing the phase 3 trial for the treatment of DU. We initiated pre-NDA consultation with the NMPA in July 2021 regarding the NDA submission of KBP-3571 for the treatment of DU. In October 2021, we received feedback from the CDE’s chemistry division and clinical division agreeing for us to submit an NDA and submitted an NDA to the NMPA. We obtained NDA for KBP-3571 from the NMPA for the treatment of DU in June 2023. KBP-3571 was successfully included in the NRDL since the beginning of 2024, which we believe will increase its accessibility at scale.

Pending consultation with the CDE, we expect to complete the phase 3 clinical trial for adult RE by the end of 2026, and subsequently file NDA with the NMPA.

As of the Latest Practicable Date, we had received no major concerns or objections from the CDE to our clinical development plan for KBP-3571.

KBP-3571 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

ONCOLOGY DRUGS

XZP-3287, a Near-commercial Potential Best-in-class CDK4/6 Inhibitor for HR+/HER2-BC, a Core Product

Overview

XZP-3287 is a CDK4/6 inhibitor we developed with complete intellectual property rights for the treatment of HR+/HER2- BC. BC is the second most prevalent cancer in the world with approximately 2.4 million new cases in 2023, of which HR+/HER2- patients account for approximately 75%. CDK4/6 inhibitors in combination with endocrine therapy are the standard treatment for HR+/HER2- advanced BC. CDK4/6 inhibitors have a market size of RMB2.2 billion in 2023 in China for the treatment of BC, which is expected to increase to RMB13.0 billion by 2032.

We are exploring the use of XZP-3287 across a broad spectrum of patients with advanced HR+/HER2- BC, through both first- and second-line combination therapies and late-line monotherapies. In addition, we will seek to extend the coverage of XZP-3287 as an adjuvant therapy for early-stage HR+/HER2- BC patients. According to CIC, early-stage HR+/HER2- BC patients eligible for CDK4/6 inhibitors in adjuvant therapy in China amounted to approximately 178.5 thousand in 2023, and are expected to reach 243.8 thousand in 2032 at a CAGR of 3.5% from 2023. According to the same source, there were only two CDK4/6 inhibitor candidates under clinical development for treating HR+/HER2- BC as an adjuvant therapy as of the Latest Practicable Date. As of the Latest Practicable Date, we had submitted the NDA for XZP-3287 in combination with fulvestrant for second-line endocrine treatment of advanced HR+/HER2- BC, as well as for XZP-3287 monotherapy for late-line treatment of locally advanced or metastatic HR+/HER2- BC. Concurrently, we are conducting a phase 3 trial of XZP-3287 in combination with AI for advanced HR+/HER2- BC.

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Mechanism of Action

CDK4/6 are frequently overexpressed in many cancers, including BC, resulting in uncontrolled cell proliferation. CDK4/6 inhibitors are designed to selectively target these kinases, restoring normal cell cycle regulation and halting tumor cell DNA synthesis and growth. Beyond this direct inhibition, CDK4/6 inhibitors also suppress upstream estrogen receptor signaling pathways, creating a synergistic effect when used with endocrine therapies. This synergy not only enhances treatment efficacy but also helps delay and potentially reverse endocrine resistance, offering a powerful strategy in the fight against BC.

CDK4/6 inhibitors suppress the phosphorylation of tumor suppressor protein, retinoblastoma (Rb), stop G1 to S phase transition in the cell cycle development of tumor cells, and disrupt cancer cell growth and slow tumor progression. CDK4/6 inhibitors can be designed with varying degrees of inhibition of CDK4 and CDK6, which can significantly affect the efficacy and safety of the drug. Strong inhibitory effects on both CDK4 and CDK6 can result in significant efficacy, but overly strong inhibition of the CDK6 target can lead to neutropenia and other serious side effects.

Based on our analysis of the crystal structures of CDK4 and CDK6 proteins, we designed a novel molecule, XZP-3287, that has higher selectivity for CDK4 and moderate inhibitory effects on CDK6 which could reduce the risk of neutropenia associated with strong CDK6 inhibition. Additionally, XZP-3287 also shows certain enzymatic inhibitory effects on CDK2, so it can also exert partial efficacy by inhibiting CDK2, which contributes to its outstanding therapeutic effects when used as a monotherapy.

Market Opportunity and Competition

The CDK4/6 pathway plays a critical role in regulating cell growth, making it a prime target for cancer therapies, particularly in BC where dysregulation of this pathway often fuels uncontrolled proliferation. This therapeutic potential has driven significant growth in the CDK4/6 inhibitor market in China, surging from RMB0.1 billion in 2018 to RMB2.2 billion in 2023. This robust growth is projected to continue, reaching RMB13.0 billion by 2032. This expanding market signifies a substantial opportunity for effective and well-tolerated CDK4/6 inhibitors.

As of the Latest Practicable Date, there were four innovative CDK4/6 inhibitors approved for the treatment of BC and seven CDK4/6 inhibitor candidates in phase 3 or beyond in China. Despite the progress in CDK4/6 inhibitor development, a significant unmet need persists due to limitations in efficacy, ability to treat cancer metastases and safety concerns. Our XZP-3287 demonstrates therapeutic versatility across the treatment paradigm of BC, from its validated efficacy as a monotherapy and combination therapy in late-stage BC, to its potential to treating early-stage BC. This differentiated feature, coupled with the large and underserved patient population seeking alternative treatment options, presents a compelling market opportunity for XZP-3287 to address a critical unmet need and potentially capture a significant market share.

For more details regarding the addressable market size and competitive landscape of CDK4/6 inhibitors, see “Industry Overview — China’s Breast Cancer Drug Market — CDK4/6 Inhibitor.”

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Competitive Advantages

Potentially the First and Only CDK4/6-targeted Monotherapy in China. Our XZP-3287 has demonstrated strong efficacy in clinical trials, giving it the potential to be a monotherapy, while currently approved CDK4/6 inhibitors are only available as combination therapies. In its phase 2 clinical trial, XZP-3287 monotherapy demonstrated good efficacy as of the data cut-off date (July 31, 2023) (objective response rate (ORR): 30.0%; median progression-free survival (mPFS): 9.17 months) in HR+/HER2- locally advanced or metastatic BC patients who have progressed after endocrine therapy and chemotherapy. Abemaciclib, which is the only CDK4/6 inhibitor monotherapy approved in the world for locally advanced or metastatic HR+/HER2-BC, was reported to have an ORR of 17.4% and mPFS of 5.9 months in its non-head-to-head phase 2 trial, according to CIC. In the pre-treated HR+/HER2-low advanced BC population, XZP-3287 monotherapy demonstrated comparable efficacy to DS-8201, according to reported data from non-head-to-head trials. In patients with a median of 3 prior lines of treatment, XZP-3287 achieved mPFS of 11.01 months and median overall survival (OS) of 24.28 months. In a similar patient population, DS-8201 achieved mPFS of 10.0 months and a median OS of 23.9 months. Furthermore, XZP-3287 demonstrated promising activity in patients with even more advanced disease, with a mPFS of 9.17 months and mOS of 29.01 months observed in those with a median of 4 prior lines of treatment.

Broad Patient Coverage with Combination Therapy with Differentiated Efficacy Profile. XZP-3287 stands out as a comprehensive solution for advanced HR+/HER2- BC across all treatment lines, including first-line, second-line, and beyond. In addition to monotherapy, we are also exploring XZP-3287 in combination with fulvestrant for second-line endocrine treatment and with AI for first-line endocrine treatment. As a combination therapy with fulvestrant, XZP-3287 can significantly reduce tumor volume and demonstrated an ORR of 45.6% and 50.3% in ITT population and in patients with measurable disease, respectively. Notably, XZP-3287 plus fulvestrant has shown efficacy in patients with prior chemotherapy, whereas abemaciclib and certain other CDK4/6 inhibitors have excluded such patients from clinical trials.

In similar patient populations without previous chemotherapy for metastatic disease, mPFS was 17.28 months for XZP-3287 plus fulvestrant, compared to 16.4 months or 11.5 months reported for abemaciclib plus fulvestrant in MONARCH 2 and MONARCH Plus studies, respectively. Subgroup analyses further highlighted XZP-3287's efficacy, showing improved PFS across all subgroups with hazard ratios below 1. Notably, in patients with primary resistance to endocrine therapy, liver metastases, and bone-only metastases, the hazard ratios were 0.337 (95% CI, 0.191-0.595), 0.427 (95% CI, 0.271-0.674), and 0.184 (95% CI, 0.063-0.541), respectively, which mark the lowest hazard ratios among all CDK4/6 inhibitors, according to CIC.

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Differentiated Safety Profile. XZP-3287 has exhibited a tolerable and manageable safety profile both as a monotherapy and in combination with fulvestrant. The primary AEs associated with XZP-3287 were gastrointestinal toxicities, such as diarrhea, and hematological toxicities, such as neutropenia. The incidence of grade 3 or 4 neutropenia with XZP-3287 was lower than those observed with other CDK4/6 inhibitors, such as palbociclib, ribociclib, dalpiciclib, and lerociclib. Diarrhea typically occurred within the first treatment cycle, with most cases being grade 1 or 2, and could be effectively alleviated or resolved with supportive care. Most TRAEs were improved or resolved with appropriate clinical management. In non-head-to-head trials, the percentage of patients that discontinued treatment due to AEs was lowest among all approved CDK4/6 inhibitors, underscoring XZP-3287's favorable safety and tolerability profile.

Capable of Treating Cancer Metastases. In the phase 3 clinical trial of XZP-3287 plus fulvestrant, for patients with liver metastases and with bone-only metastases, the hazard ratios were 0.427 (95% CI, 0.271-0.674) and 0.184 (95% CI, 0.063-0.541) respectively, suggesting that XZP-3287 plus fulvestrant significantly reduced the risk of disease progression in patients with both liver metastases and bone-only metastases compared to the control group. Findings in the clinical trials and preclinical studies suggest that XZP-3287 may offer promising intracranial activity and potentially reduce the risk of new brain metastases. According to preclinical efficacy studies, XZP-3287 demonstrated significant antitumor activity in a human glioblastoma orthotopic xenograft brain tumor model. These preliminary data highlights XZP-3287's potential to address the unmet needs of patients with BC brain metastases, particularly when compared to existing therapies such as abemaciclib. Phase 2 clinical trial data for abemaciclib showed that among the seven patients with brain metastases enrolled, only two had SD in intracranial lesions, and just one patient experienced SD for over six months. Early results from the phase 1 dose escalation and expansion study of XZP-3287 have shown promising activity in patients with brain metastases. In the high-dose cohort, all three enrolled patients with brain metastases exhibited clinical benefit, achieving either stable disease (SD) or a partial response (PR) within their intracranial lesions. The incidence of new brain metastases was only 2.1%, significantly lower than the typical 10% to 16% incidence rate for BC brain metastases.

Clinical Development Plan

As of the Latest Practicable Date, we had completed five clinical trials of XZP-3287 in China. These include: one phase 1/2 clinical trial in patients with advanced solid tumors, primarily HR+/HER2- advanced BC; three phase 1 clinical pharmacology studies in healthy subjects; and one phase 3 clinical trial of XZP-3287 plus fulvestrant in the treatment of advanced HR+/HER2- BC.

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We have filed an NDA application for XZP-3287 in combination with fulvestrant for second-line endocrine treatment in August 2023 and as monotherapy for late-line treatment of locally advanced or metastatic HR+/HER2- BC in October 2023. We expect to obtain NDA approval in the first half of 2025. We are conducting extension studies of XZP-3287, both as monotherapy and in combination with fulvestrant, to further evaluate OS data. These studies are estimated to be completed by the first half of 2026.

We are currently conducting a pivotal phase 3 clinical trial of XZP-3287 in combination with letrozole or anastrozole in advanced HR+/HER2- BC. We plan to submit an application to the NMPA for NDA in the first half of 2025. We are also exploring the clinical development plan for XZP-3287 plus endocrine therapy as an adjuvant therapy for HR+/HER2- early BC and plan to submit IND application in the first half of 2025.

Summary of Clinical Trial Data

Phase 3 Clinical Trial of XZP-3287 in combination with Letrozole or Anastrozole in Advanced HR+/HER2- BC

This is a multicenter, randomized, double-blind, placebo-controlled clinical study to compare the efficacy of XZP-3287 plus letrozole/anastrozole versus placebo plus letrozole/anastrozole for patients with advanced HR+/HER2- BC.

Trial Design. 372 subjects with advanced HR+/HER2- BC were recruited and randomly assigned in a 2:1 ratio to the experimental group (248 subjects) and the control group (124 subjects). The experimental group received XZP-3287 at a dose of 360 mg every 12 hours orally and 2.5 mg letrozole or 1 mg anastrozole once daily orally, with each cycle lasting 28 days. The control group received an oral placebo at a dose of 360 mg every 12 hours and 2.5 mg letrozole or 1 mg anastrozole once daily orally, with each cycle lasting 28 days.

Trial Objectives. This clinical trial's primary endpoint is investigator-assessed PFS. Key secondary endpoints include PFS assessed by BICR, ORR, duration of response (DoR), disease control rate (DCR), and clinical benefit rate (CBR) assessed by both investigator and BICR, OS and overall survival rate (OSR) (at 1, 2, 3, 4 and 5 years). Safety would be evaluated throughout the trial, encompassing the incidence and severity of AEs and SAEs, physical examinations and vital signs monitoring, laboratory testing, and 12-lead electrocardiograms. Additionally, the trial aims to evaluate the PK of XZP-3287 in this patient population.

Trial Progress. As of the Latest Practicable Date, this trial had enrolled the required number of subjects.

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Phase 3 Clinical Trial of XZP-3287 plus Fulvestrant for the Treatment of Advanced HR+/HER2- BC

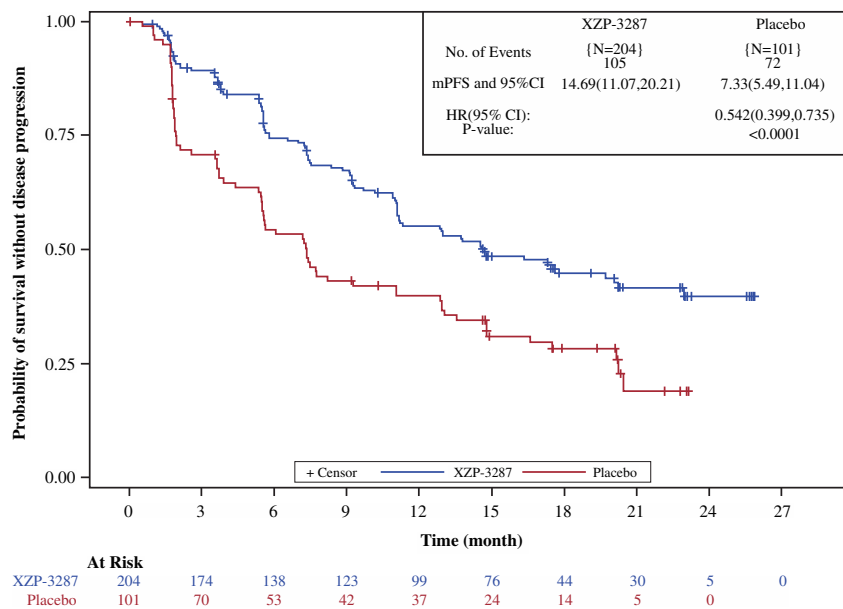
This was a multi-center, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of XZP-3287 in combination with fulvestrant versus placebo combined with fulvestrant in patients with HR+/HER2- advanced BC who have progressed after prior endocrine therapy.

Trial Design. This phase 3 study enrolled 305 patients, with 204 in the test group and 101 in the control group. All subjects were female patients with HR+/HER2- advanced BC who had progressed after prior endocrine therapy. The treatment group received oral XZP-3287 360 mg twice daily along with fulvestrant 500 mg administered via intramuscular injection on the first day and fifteenth day of the first cycle, and then on the first day of each subsequent cycle. The control group received a placebo in place of XZP-3287, with the same fulvestrant dosing schedule.

Trial Objectives. The primary endpoint of the study is PFS as assessed by the investigator. Secondary endpoints include PFS as assessed by BICR, ORR, DoR, DCR and CBR assessed by both investigator and BICR, OS, OSR (at 1, 2, 3, 4 and 5 years) and safety.

Trial Progress. The phase 3 clinical trial was completed in May 2024.

Efficacy Data. As of the data cut-off date (February 22, 2024), based on the FAS and according to investigator’s assessment, the mPFS in the treatment group was 14.69 months (95% CI: 11.070-20.210), and the mPFS in the control group was 7.33 months (95% CI: 5.490-11.040). The PFS data from this clinical trial are summarized in the PFS Kaplan-Meier plot below.



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Based on the FAS according to the investigator’s assessment, the ORRs of the treatment group and the control group were 45.6% (95% CI: 38.62%-52.69%) and 14.9% (95% CI: 8.56%-23.31%), respectively. In addition, for patients with liver metastases and with bone-only metastases, the hazard ratios were 0.427 (95% CI, 0.271-0.674) and 0.184 (95% CI, 0.063-0.541) respectively.

Safety Data. As of the data cut-off date (February 22, 2024), the SS analysis of all TEAEs revealed that 204 subjects (100%) in the treatment group and 95 subjects (94.1%) in the control group experienced TEAEs. Safety data from this clinical trial are summarized in the table below.

	XZP-3287+ Fulvestrant	Placebo+Fulvestrant
	N=204	N=101
	n(%)	n(%)
TEAE	204 (100)	95 (94.1)
TRAE	204 (100)	86 (85.1)
TESAE	50 (24.5)	13 (12.9)
TRSAE	32 (15.7)	2 (2.0)
Grade 3 or above TEAE	152 (74.5)	20 (19.8)
Grade 3 or above TRAE	139 (68.1)	13 (12.9)
TEAE leading to study treatment discontinuation	4 (2.0)	0
TEAE leading to discontinuation of XZP-3287/placebo	9 (4.4)	0
TEAE leading to the interruption of study treatment	82 (40.2)	21 (20.8)
TEAE leading to the interruption of XZP-3287/placebo	150 (73.5)	37 (36.6)
TEAE leading to dose reduction of XZP-3287/placebo	86 (42.2)	1 (1.0)
TEAE leading to death	7 (3.4)	3 (3.0)

Conclusion. Data from this clinical trial demonstrated that for patients with HR+/HER2-advanced BC who have progressed following prior endocrine therapy, PFS assessed by investigators was significantly better in the XZP-3287 plus fulvestrant group compared to the placebo plus fulvestrant group. This indicates a substantial reduction in the risk of disease progression or death. Secondary endpoints consistently supported the primary finding, reinforcing the efficacy of the treatment. Additionally, the safety and tolerability of XZP-3287 combined with fulvestrant were favorable, with TEAEs primarily being hematologic and gastrointestinal toxicities. Importantly, no new safety signals were identified compared to similar products. These results affirm the potential of XZP-3287 as an effective and safe treatment option for this patient population.

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Phase 1/2 Clinical Trial of XZP-3287

This clinical trial comprised three arms to evaluate the safety and efficacy of XZP-3287: (i) a phase 1 dose escalation and expansion study, (ii) a phase 1 combination therapy study, including a study of XZP-3287 in combination with letrozole or anastrozole and a study of XZP-3287 in combination with fulvestrant, and (iii) a phase 2 monotherapy clinical trial.

Phase 1 Dose Escalation and Expansion Study

The dose escalation and expansion study for XZP-3287 was designed to evaluate its safety, tolerability, PK, and preliminary efficacy in patients with locally advanced, recurrent or metastatic solid tumors.

Trial Design. A total of 141 subjects were enrolled in this research. This trial employed a hybrid dose-escalation design, combining an accelerated titration method with the standard 3+3 approach, to determine the maximum tolerated dose (MTD) of XZP-3287. The initial dose level was 20 mg administered once daily. The trial commenced with an accelerated titration phase, where a single patient will be enrolled at each dose level, with a 100% dose escalation increment. Upon observing either: (i) a second occurrence of the same grade 2 or above AE assessed as related to the study drug, or (ii) a dose-limiting toxicity (DLT) event, the trial would transition from the accelerated titration method to the standard 3+3 design at the current and subsequent dose levels. If the accelerated titration phase reached 160 mg once daily without observing a DLT or a second occurrence of the same grade 2 or above AE related to the study drug, the trial would then transition to the 3+3 design for all subsequent dose levels. Following the transition to the 3+3 design, dose escalation would proceed at increments of 50%, 33%, 33%, and so forth, until the maximum planned dose of 560 mg was reached.

Following the completion of DLT evaluation for the 560 mg dose group, the study transitioned to a twice daily dosing schedule using a "3+3" dose escalation design. Starting at 240 mg, subsequent cohorts escalated to 360 mg, 480 mg, 600 mg, 720 mg, and so on. This escalation was guided by safety, tolerability, and PK data. Alternative doses twice daily or dosing intervals would also be explored based on these parameters. Enrollment at the current dose level and higher would be paused if two or more DLTs were reported at the same dose.

Trial Objectives. The primary objectives were to determine the MTD, define the DLTs associated with XZP-3287, and identify the RP2D-S for subsequent clinical evaluation. The primary endpoint of the study was safety and tolerability, which would be assessed through several measures. These include the monitoring and evaluation of TEAEs, regular physical examinations and vital sign measurements, comprehensive laboratory testing (including blood counts, blood chemistry, coagulation profile, and urinalysis), and cardiac monitoring through electrocardiograms and echocardiograms. Secondary endpoints focused on efficacy and PK. The key secondary endpoint was the ORR. Additional efficacy measures include DCR, CBR, DoR, PFS, and OS. PK assessments involved blood sample collection to characterize the single-dose and steady-state PK profiles of both XZP-3287 and its major metabolites.

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Trial Progress. The phase 1 dose escalation and expansion study was completed in June 2022.

Efficacy Data. As of the data cutoff date, June 30, 2022, in the FAS of 141 patients, ORR was 11.3% (95% CI, 6.63-17.77), with 16 patients (11.3%) achieving a PR. Efficacy data from this clinical trial are summarized in the table below.

	20mgQD N=1	40mgQD N=1	80mgQD N=2	160mgQD N=3	240mgQD N=6	320mgQD N=4	420mgQD N=10	560mgQD N=43	240mgBID N=12	360mgBID N=19	480mgBID N=40	Total N=141
Best ORR, n(%)												
CR	0	0	0	0	0	0	0	0	0	0	0	0
PR	0	0	1 (50.0)	0	0	0	0	6 (14.0)	1 (8.3)	1 (5.3)	7 (17.5)	16 (11.3)
SD	0	0	1 (50.0)	0	3 (50.0)	3 (75.0)	8 (80.0)	20 (46.5)	5 (41.7)	13 (68.4)	19 (47.5)	72 (51.1)
PD	1 (100)	1 (100)	0	1 (33.3)	2 (33.3)	1 (25.0)	1 (10.0)	9 (20.9)	6 (50.0)	4 (21.1)	5 (12.5)	31 (22.0)
NE	0	0	0	2 (66.7)	1 (16.7)	0	1 (10.0)	8 (18.6)	0	1 (5.3)	9 (22.5)	22 (15.6)
ORR and 95%	0	0	50.0	0	0	0	0	14.0	8.3	5.3	17.5	11.3
CI	(0.00,97.50)	(0.00,97.50)	(1.26,98.74)	(0.00,70.76)	(0.00,45.93)	(0.00,60.24)	(0.00,30.85)	(5.30,27.93)	(0.21,38.48)	(0.13,26.03)	(7.34,32.78)	(6.63,17.77)
DCR and 95%	0	0	100	0	50.0	75.0	80.0	60.5	50.0	73.7	65.0	62.4
CI	(0.00,97.50)	(0.00,97.50)	(15.81,100.00)	(0.00,70.76)	(11.81,88.19)	(19.41,99.37)	(44.39,97.48)	(44.41,75.02)	(21.09,78.91)	(48.80,90.85)	(48.32,79.37)	(53.87,70.42)
CBR and 95%	0	0	50.0	0	33.3	25.0	40.0	37.2	16.7	31.6	30.0	31.2
CI	(0.00,97.50)	(0.00,97.50)	(1.26,98.74)	(0.00,70.76)	(4.33,77.72)	(0.63,80.59)	(12.16,73.76)	(22.98,53.27)	(2.09,48.41)	(12.58,56.55)	(16.56,46.53)	(23.67,39.55)

Four patients with brain metastases were enrolled, all of whom showed SD in intracranial lesions. Among these, three patients in the high-dose group experienced SD for over six months or PR. The incidence of new brain metastases was only 2.1%, significantly lower than the typical 10% to 16% incidence rate for BC brain metastases. Furthermore, a trend towards improved ORR was observed with increasing dose levels, supporting further evaluation of XZP-3287 in the treatment of advanced solid tumors.

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Safety Data. Safety data revealed that all 141 patients in the SS experienced at least one TEAE. Safety data from this clinical trial are summarized in the table below.

	20mgQD N=1 n(%)	40mgQD N=1 n(%)	80mgQD N=2 n(%)	160mgQD N=3 n(%)	240mgQD N=6 n(%)	320mgQD N=4 n(%)	420mgQD N=10 n(%)	560mgQD N=43 n(%)	240mgBID N=12 n(%)	360mgBID N=19 n(%)	480mgBID N=40 n(%)	Total N=141 n(%)
TEAE	1 (100)	1 (100)	2 (100)	3 (100)	6 (100)	4 (100)	10 (100)	43 (100)	12 (100)	19 (100)	40 (100)	141 (100)
TRAE	0	0	2 (100)	3 (100)	6 (100)	4 (100)	10 (100)	43 (100)	12 (100)	19 (100)	40 (100)	139 (98.6)
TESAE	0	1 (100)	0	1 (33.3)	1 (16.7)	1 (25.0)	2 (20.0)	6 (14.0)	0	3 (15.8)	9 (22.5)	24 (17.0)
TRSAE	0	0	0	0	0	0	0	2 (4.7)	0	1 (5.3)	7 (17.5)	10 (7.1)
TEAE leading to discontinuation of XZP-3287 .	0	0	1 (50.0)	1 (33.3)	0	1 (25.0)	0	4 (9.3)	0	2 (10.5)	7 (17.5)	16 (11.3)
TRAE leading to discontinuation of XZP-3287 .	0	0	1 (50.0)	0	0	0	0	3 (7.0)	0	0	5 (12.5)	9 (6.4)
TEAE leading to dose reduction of XZP-3287 .	0	0	1 (50.0)	0	1 (16.7)	0	0	4 (9.3)	0	1 (5.3)	9 (22.5)	16 (11.3)
TRAE leading to dose reduction of XZP-3287 .	0	0	1 (50.0)	0	1 (16.7)	0	0	4 (9.3)	0	1 (5.3)	9 (22.5)	16 (11.3)
TEAE leading to the interruption of XZP-3287 .	0	1 (100)	1 (50.0)	0	2 (33.3)	0	4 (40.0)	17 (39.5)	3 (25.0)	3 (15.8)	24 (60.0)	55 (39.0)

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	20mgQD N=1 n(%)	40mgQD N=1 n(%)	80mgQD N=2 n(%)	160mgQD N=3 n(%)	240mgQD N=6 n(%)	320mgQD N=4 n(%)	420mgQD N=10 n(%)	560mgQD N=43 n(%)	240mgBID N=12 n(%)	360mgBID N=19 n(%)	480mgBID N=40 n(%)	Total N=141 n(%)
TRAE leading to the interruption of XZP-3287 . . .	0	0	1 (50.0)	0	2 (33.3)	0	3 (30.0)	13 (30.2)	3 (25.0)	3 (15.8)	24 (60.0)	49 (34.8)
TEAE leading to study treatment discontinuation.	0	0	0	1 (33.3)	0	0	0	4 (9.3)	0	0	2 (5.0)	7 (5.0)
TRAE leading to study treatment discontinuation.	0	0	0	0	0	0	0	1 (2.3)	0	0	1 (2.5)	2 (1.4)
TEAE leading to death.	0	0	0	1 (33.3)	0	0	0	3 (7.0)	0	0	1 (2.5)	5 (3.5)

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Phase 1 Clinical Trial of XZP-3287 in Combination Therapies

Trial Design. The phase 1 combination therapy arm enrolled a total of 130 patients with HR+/HER2- advanced BC. Patients were distributed across three distinct cohorts designed to evaluate the safety and efficacy of XZP-3287 in combination with standard endocrine therapies: (i) 35 patients received XZP-3287 plus letrozole or anastrozole as first-line endocrine therapy, (ii) 28 patients received XZP-3287 plus fulvestrant as first-line endocrine therapy, and (iii) 67 patients received XZP-3287 plus fulvestrant as second-line endocrine therapy. In this phase 1 combination therapy study, patients received XZP-3287 orally at 360 mg, twice daily. Treatment continued in 28-day cycles until disease progression, unacceptable toxicity, physician decision, or patient withdrawal. Letrozole tablets were administered orally at a dose of 2.5 mg once daily, concurrently with the first daily dose of XZP-3287. Anastrozole tablets were administered orally at a dose of 1 mg once daily, concurrently with the first daily dose of XZP-3287. Fulvestrant injections were administered intramuscularly at a dose of 500 mg on day one and day 15 of cycle one, followed by administration on day one of each subsequent cycle.

Trial Objectives. This study’s primary endpoint was to evaluate the safety and tolerability of XZP-3287 in combination with endocrine therapy through monitoring of adverse events, physical examinations, vital signs, laboratory parameters (including hematology, blood chemistry, coagulation, and urinalysis), and cardiac assessments using electrocardiograms and echocardiograms. Secondary endpoints included ORR, DCR, CBR, DoR, PFS, and OS, as well as characterizing the PK profile of XZP-3287.

Trial Progress. The phase 1 combination therapy arm was completed in September 2022.

Efficacy Data. As of the data cut-off date, September 30, 2022, efficacy analyses based on the FAS demonstrated promising clinical activity across all three combination therapy cohorts. Efficacy data from this clinical trial are summarized in the table below.

	XZP-3287 plus letrozole or anastrozole as first-line endocrine therapy	XZP-3287 plus fulvestrant as first-line endocrine therapy	XZP-3287 plus fulvestrant as second-line endocrine therapy	Total
	N=35	N=28	N=67	N=130
Best overall response rate, n(%)				
Complete response . . .	1 (2.9)	0	2 (3.0)	3 (2.3)
Partial response	18 (51.4)	15 (53.6)	29 (43.3)	62 (47.7)
Stable disease	13 (37.1)	10 (35.7)	29 (43.3)	52 (40.0)
Progressive disease . .	0	3 (10.7)	7 (10.4)	10 (7.7)
Not evaluable.	3 (8.6)	0	0	3 (2.3)

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	XZP-3287 plus letrozole or anastrozole as first-line endocrine therapy	XZP-3287 plus fulvestrant as first-line endocrine therapy	XZP-3287 plus fulvestrant as second-line endocrine therapy	Total
	N=35	N=28	N=67	N=130
	54.3	53.6	46.3	50.0
ORR and 95% CI. . . .	(36.65,71.17)	(33.87,72.49)	(34.00,58.88)	(41.11,58.89)
	91.4	89.3	89.6	90.0
DCR and 95% CI. . . .	(76.94,98.20)	(71.77,97.73)	(79.65,95.70)	(83.51,94.57)
	71.4	78.6	71.6	73.1
CBR and 95% CI. . . .	(53.70,85.36)	(59.05,91.70)	(59.31,81.99)	(64.60,80.48)

Safety Data. The MTD of XZP-3287 in combination therapy was determined to be 360 mg twice daily based on the analysis of 12 patients. While no DLTs were observed in the six patients receiving XZP-3287 plus fulvestrant, one case of grade 3 elevated liver enzymes, classified as a DLT, occurred in the group receiving XZP-3287 plus letrozole or anastrozole. Safety data from this clinical trial are summarized in the table below.

	XZP-3287 plus letrozole or anastrozole as first-line endocrine therapy	XZP-3287 plus fulvestrant as first-line endocrine therapy	XZP-3287 plus fulvestrant as second-line endocrine therapy	Total
	N=35	N=28	N=67	N=130
	n(%)	n(%)	n(%)	n(%)
TEAE	35 (100)	28 (100)	67 (100)	130 (100)
TRAE	35 (100)	28 (100)	67 (100)	130 (100)
TESAE	10 (28.6)	1 (3.6)	10 (14.9)	21 (16.2)
TRSAE	10 (28.6)	0	8 (11.9)	18 (13.8)
TEAE leading to discontinuation of XZP-3287	4 (11.4)	1 (3.6)	1 (1.5)	6 (4.6)
TRAE leading to discontinuation of XZP-3287	4 (11.4)	1 (3.6)	1 (1.5)	6 (4.6)
TEAE leading to dose reduction of XZP-3287	6 (17.1)	10 (35.7)	17 (25.4)	33 (25.4)
TRAE leading to dose reduction of XZP-3287	6 (17.1)	10 (35.7)	17 (25.4)	33 (25.4)

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	XZP-3287 plus letrozole or anastrozole as first-line endocrine therapy	XZP-3287 plus fulvestrant as first-line endocrine therapy	XZP-3287 plus fulvestrant as second-line endocrine therapy	Total
	N=35	N=28	N=67	N=130
	n (%)	n (%)	n (%)	n (%)
TEAE leading to the interruption of XZP-3287	17 (48.6)	17 (60.7)	34 (50.7)	68 (52.3)
TRAE leading to the interruption of XZP-3287	16 (45.7)	17 (60.7)	33 (49.3)	66 (50.8)
TEAE leading to study treatment discontinuation	1 (2.9)	0	1 (1.5)	2 (1.5)
TRAE leading to study treatment discontinuation	1 (2.9)	0	1 (1.5)	2 (1.5)
TEAE leading to death .	1 (2.9)	0	1 (1.5)	2 (1.5)

Phase 2 Clinical Trial of XZP-3287 Monotherapy

This was a single-arm phase 2 study of XZP-3287 monotherapy for HR+/HER2- advanced BC patients who had progressed after endocrine therapy and chemotherapy.

Trial Design. A total of 131 patients were enrolled in this clinical trial. Patients must have received at least two prior chemotherapy regimens for BC treatment, with at least one of those regimens given for metastatic disease. Additionally, one of the prior chemotherapy regimens must have included a taxane drug, either given in the adjuvant setting or for metastatic disease. Patients must have experienced disease progression on or after prior endocrine therapy for metastatic BC and must have also progressed on or after their most recent anti-cancer treatment. 480 mg XZP-3287 was administered orally on a continuous schedule twice daily in 28-day cycles.

Trial Objectives. The primary endpoint was ORR assessed by an independent review committee (IRC). Secondary endpoints of the study included ORR, DCR, CBR, DoR, PFS, OS, and safety and tolerability.

Trial Progress. The phase 2 clinical trial of XZP-3287 monotherapy was completed in July 2023.

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Efficacy Data. Tumor assessment was performed by investigators and IRC, approximately every eight weeks. The following table sets forth the IRC-assessed and Investigator-assessed tumor response as of the cut-off date of July 31, 2023. 100 subjects with disease progression after receiving two or more prior endocrine therapies and one or more chemotherapies in the metastatic setting were analyzed as of the cut-off date.

	IRC-assessed N=100	Investigator-assessed N=100
BOR, n(%)		
Complete response (CR)	0	1 (1.0)
Partial response (PR)	30 (30.0)	21 (21.0)
Stable disease (SD)	42 (42.0)	42 (42.0)
Progressive disease (PD)	12 (12.0)	21 (21.0)
Not evaluable (NE)	16 (16.0)	15 (15.0)
ORR (%) (95% CI)	30.0 (21.2, 40.0)	22.0 (14.3, 31.4)
DCR (%) (95% CI)	72.0 (62.1, 80.5)	64.0 (53.8, 73.4)
CBR (%) (95% CI)	40.0 (30.3, 50.3)	37.0 (27.6, 47.2)
Survival estimates		
Media DOR (months)	14.78 (7.688, -)	13.08 (7.556, 14.784)
Media PFS (months)	9.17 (7.162, 12.912)	7.29 (5.388, 9.133)
Media OS (months)	29.01 (24.279, -)	

Safety Data. In this study, 100 patients (100%) had at least 1 TEAE. The most common TEAEs were diarrhea (93.0%), neutropenia (85.0%) and leukocytopenia (85.0%). Most of TEAEs were grade 1 or grade 2. Most of them were alleviated or cured by supportive treatments. Most common grade 3 or above TEAE were neutropenia (42.0%) and leukocytopenia (31.0%). Dose reductions due to TEAEs occurred in 49 patients (49.0%). Dose interrupted by TEAE occurred in 69 patients (69.0%). Discontinuations due to TEAEs were infrequent (14.0%), 12 of them had treatment-related AEs. 1 (1.0%) patient had possibly treatment-unrelated TEAE leading to death.

Phase 1 Clinical Trials of XZP-3287 in Healthy Subjects

We conducted three phase 1 clinical trials of XZP-3287 in healthy subjects including: (i) a phase 1b clinical trial to evaluate the effect of a high-fat meal and a standard meal on the PK of XZP-3287 in healthy adult subjects, (ii) a single-center, open-label, DDI study of XZP-3287 in healthy subjects, and (iii) a study on the mass balance and biotransformation of XZP-3287 in healthy male Chinese subjects.

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Phase 1b clinical trial to evaluate the effect of a high-fat meal and a standard meal on the PK of XZP-3287 in healthy adult subjects

This was a three-period, crossover food effect study designed to evaluate the influence of a high-fat meal and a standard meal on the PK of XZP-3287 following oral administration in healthy adult subjects. The study demonstrated that administration of a single 360 mg dose of XZP-3287 with either a high-fat meal or a standard meal resulted in increased XZP-3287 exposure compared to administration under fasting conditions. This suggested that food intake, particularly a high-fat meal, may enhance the solubility and absorption of XZP-3287, leading to higher drug levels in the body.

A single-center, open-label, DDI study of XZP-3287 in healthy subjects

This DDI study aimed to evaluate the impact of clarithromycin, a strong CYP3A4 inhibitor, and rifampin, a strong CYP3A4 inducer, on the PK of XZP-3287. The results demonstrated that XZP-3287 exhibits significant DDIs when co-administered with both clarithromycin and rifampin.

A study on the biotransformation of XZP-3287 in healthy male Chinese subjects

This study was conducted to determine the primary metabolic pathways of XZP-3287 in humans, providing essential data for future clinical trials and clinical practice. The results indicated that following a single oral dose administered with food, fecal excretion represents the primary route of elimination for XZP-3287 in healthy subjects, while urinary excretion constitutes a minor elimination pathway.

Material Communications and Next Steps

We obtained IND approval in June 2017 and subsequently initiated first-in-human phase 1 clinical trials. With the preliminary clinical data from our phase 1 clinical trial and the pivotal phase 3 clinical study design of XZP-3287 in combination with fulvestrant, we conducted communication and exchanges with the CDE. In July 2021, the CDE provided written feedback agreeing to the initiation of the phase 3 clinical trial. We completed the final analysis of this pivotal phase 3 clinical trial in May 2024. We have filed the NDA applications of XZP-3287's combination therapy with fulvestrant and monotherapy for the treatment of advanced HR+/HER2- BC with the NMPA in August and October 2023, respectively, and expect to receive NDA from the NMPA by the first half of 2025 for both applications.

Prior to the initiation of the pivotal phase 3 registrational clinical study of XZP-3287 in combination with letrozole or anastrozole, we engaged in communication and exchanges with the CDE based on preliminary clinical study data and the phase 3 clinical study design. In 2021, the CDE provided written feedback agreeing to the initiation of this phase 3 clinical trial. We finished the patient recruitment in September 2023. As of the Latest Practicable Date, the study was in the follow-up stage. We plan to submit an NDA to the NMPA in the first half of 2025.

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We are also exploring the clinical development plan for XZP-3287 plus endocrine therapy as an adjuvant therapy in the treatment of HR+/HER2- early BC and plan to submit IND application in the first half of 2025.

As of the Latest Practicable Date, we had received no major concerns or objections from the CDE to our clinical development plan for XZP-3287.

XZP-3287 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

XZP-3621, a Differentiated ALK Inhibitor for NSCLC Treatment, a Core Product

XZP-3621 is an in-house developed oral ALK inhibitor specifically designed for the treatment of ALK-rearranged advanced NSCLC. 22% of all cancer incidences in China in 2022 were lung cancer cases, of which NSCLC was the most common subtype representing approximately 85% of all lung cancer cases. Approximately 64% of patients with NSCLC have stage IV disease at diagnosis. In China, NSCLC cases increased from 764.4 thousand cases in 2018 to 937.6 thousand cases in 2023, and is projected to reach 1,236.4 thousand cases by 2032.

ALK is a crucial oncogenic driver in NSCLC, where its alterations are detected in approximately 5-6% of NSCLC cases. ALK alterations, primarily through gene fusions like the echinoderm microtubule-associated protein-like 4-ALK (EML4-ALK) fusion gene, play a significant role. Other genes such as TFG and KIF5B also fuse with ALK. ALK-positive patients are typically younger and exhibit a higher risk of central nervous system involvement, with around 30% presenting with CNS metastases at diagnosis. Treatments are specifically developed to treat this subtype of NSCLC more effectively.

We developed XZP-3621 to target a wide range of ALK mutations, providing a potential solution for resistance that arises from the use of marketed ALK inhibitors. We have completed the interim analysis of phase 3 clinical trial for XZP-3621 and filed NDA with the NMPA for treatment of ALK-rearranged advanced NSCLC. We are exploring the indication expansion of XZP-3621 in post-operative adjuvant therapy for ALK-positive early NSCLC. According to CIC, patients with early NSCLC eligible for ALK inhibitors in adjuvant therapy amounted to 15.8 thousand in 2023, which are expected to reach 26.2 thousand in 2032 at a CAGR of 5.8% from 2023. We submitted the IND application for such indication expansion of XZP-3621 and received the acceptance notice to the IND application from the NMPA in November 2024. According to CIC, there was only one ALK inhibitor candidate under clinical development for treating NSCLC in adjuvant therapy as of the Latest Practicable Date.

Mechanism of Action

The ALK gene, a member of the receptor tyrosine kinase (RTK) family, plays a critical role in regulating cell proliferation and tumor growth. This gene encodes a transmembrane tyrosine kinase receptor and most mutations are in the form of a translocation with another partner gene leading to a fusion oncogene. This fusion gene then becomes overly expressed in cancers, which can activate downstream signaling pathways, driving uncontrolled cell proliferation and ultimately tumor development. There are three primary types of ALK gene mutations: rearrangement, amplification, and point mutation. ALK-rearrangements are particularly significant as they are driving mutations in NSCLC.

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While ALK inhibitors have shown promise in targeting these mutations, drug resistance remains a challenge. This resistance often arises from mutations within the ALK kinase domain, disrupting its function and hindering the inhibitor’s effectiveness. Additionally, amplification of the ALK fusion gene can overwhelm the inhibitor, allowing downstream signaling to persist.

XZP-3621 is a differentiated ALK tyrosine kinase inhibitor designed to overcome these challenges. It binds to the ATP-binding site within the ALK kinase domain, effectively inhibiting ALK protein autophosphorylation and blocking the phosphorylation of downstream targets. This targeted inhibition disrupts the signaling cascade crucial for tumor cell proliferation, growth, and survival.

Market Opportunity and Competition

The competitive landscape of ALK inhibitors in China has evolved significantly since the introduction of crizotinib in 2013. A wave of newer ALK inhibitors, offering improved efficacy and safety profiles, has entered the market, fueling remarkable growth. Driven by this influx of new therapies and their inclusion in the NRDL, the ALK inhibitor market in China has expanded rapidly, surging from RMB0.4 billion in 2018 to RMB4.2 billion in 2023. This strong momentum is projected to continue, with the market expected to reach RMB8.7 billion by 2032.

As of the Latest Practicable Date, there were eight innovative ALK inhibitors approved for marketing in China. The unmet needs for new ALK inhibitors remain high given the development of resistance to ALK inhibitors over time and side effects of certain ALK inhibitors. As of the same date, there were five ALK inhibitor candidates in phase 3 or beyond in China. Within this competitive landscape, our XZP-3621 stands out as the only ALK inhibitor candidate currently under NDA review in China. XZP-3621 is uniquely positioned to address the ongoing demand for effective therapies and potentially capture a significant share of this growing market.

For more details regarding the addressable market size and competitive landscape of ALK inhibitors, see “Industry Overview — China’s Lung Cancer Drug Market — ALK Inhibitor.”

Competitive Advantages

Promising Anti-tumor Effects. XZP-3621 demonstrates significant anti-tumor efficacy in treatment-naïve ALK-positive advanced NSCLC patients (who had received no prior ALK TKI or up to one prior chemotherapy regimen). In phase 3 clinical trial, XZP-3621 had an ORR of 86.9% compared to crizotinib with an ORR of 81.2%. Furthermore, in the phase 3 clinical trial, XZP-3621 demonstrated a statistically significant improvement in PFS in comparison to crizotinib. Based on the investigator assessment, mPFS in the XZP-3621 group was not reached as of the data cut-off date, while the mPFS in the crizotinib group was 12.94 months. Importantly, XZP-3621 treatment was associated with a 57.8% reduction in the risk of disease progression or death (hazard ratio 0.422, 95% CI: 0.279-0.638).

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Notable Efficacy Observed in Patients with Brain Metastases. Clinical studies indicate notable efficacy for XZP-3621 in patients with brain metastases. In a phase 3 clinical trial, XZP-3621 demonstrated a significantly higher intracranial objective response rate (IC-ORR) compared to crizotinib in patients with measurable intracranial lesions at baseline. Investigator assessments showed an impressive 92.3% IC-ORR for XZP-3621, while crizotinib achieved only 11.1%. Furthermore, the median intracranial duration of response (IC-DoR) was not reached for XZP-3621, indicating durable responses, while crizotinib showed a median IC-DoR of only 3.55 months. In the phase 3 clinical trial, XZP-3621 also demonstrated promising efficacy in patients with baseline brain metastases. XZP-3621 achieved a mPFS that was not reached at the time of data cutoff, while crizotinib demonstrated a mPFS of 9.23 months. This translated to a HR of 0.317 (95% CI: 0.143-0.704), indicating that XZP-3621 significantly reduced the risk of disease progression compared to crizotinib in this patient population.

Potentially Effective in Overcoming Resistance to Existing ALK Inhibitors. As a differentiated ALK inhibitor, XZP-3621 demonstrates robust inhibitory activity against various resistance mutations. *In vitro* PD studies show that XZP-3621 effectively targets crizotinib-resistant mutations such as L1196M, G1269A, and I1151Tins. It also inhibits alectinib-resistant mutations, including V1180L, I1171T/N/S, G1202R, and G1202del. These findings have been corroborated in clinical trials involving patients who failed previous ALK inhibitor treatments. In the phase 2 clinical trial, XZP-3621 demonstrated an ORR of 18.4% and a DCR of 65.3% for patients who had progressed on or were intolerant to prior ALK inhibitor therapies, which is comparable to other inhibitors.

Good Safety Profile and Patient Compliance. XZP-3621 exhibits a good safety profile, suitable for long-term use. As of the Latest Practicable Date, based on the clinical trials that have been conducted so far, XZP-3621 demonstrated a manageable safety profile, with AEs primarily involving gastrointestinal disease and liver enzyme elevations. Common side effects in the 500 mg dose (being the clinically recommended dose of XZP-3621) group included diarrhea, vomiting, and nausea. Grade 3 or above AEs were infrequent, with diarrhea being the most common. Most AEs were manageable with symptomatic treatment or dose adjustment. The discontinuation rate due to AEs was low at 1.5%, indicating good tolerability for long-term use.

Clinical Development Plan

As of the Latest Practicable Date, we had completed five clinical trials of XZP-3621 in China. These include: (i) one phase 2 clinical trial in patients with ALK-positive advanced NSCLC, (ii) one phase 1 clinical trial in patients with ALK-positive or ROS1-positive advanced NSCLC, and (iii) three phase 1 clinical pharmacology studies in healthy subjects. As of the same date, we had also completed the interim analysis for one phase 3 clinical trial of XZP-3621 in the first line treatment of patients with ALK-positive advanced NSCLC. With the interim data from the phase 3 clinical trial of XZP-3621, we have filed the NDA application of XZP-3621 in the first-line treatment of patients with ALK-positive advanced NSCLC in April 2024. We are also exploring the indication expansion of XZP-3621 in post-operative adjuvant therapy for ALK-positive early NSCLC. We submitted the IND application for such indication expansion of XZP-3621 and received the acceptance notice to the IND application from the NMPA in November 2024.

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Summary of Clinical Trial Data

Phase 3 Clinical Trial of XZP-3621 in the First-line Treatment of Patients with ALK-positive Advanced NSCLC

The phase 3 clinical trial for XZP-3621 tablets was a randomized, controlled, open-label superiority study, with crizotinib capsules serving as the comparator. This study targeted patients with ALK-positive stage IV NSCLC who have not previously received ALK inhibitor treatment, as well as those with locally advanced, recurrent, or metastatic disease unsuitable for curative surgery or radiotherapy.

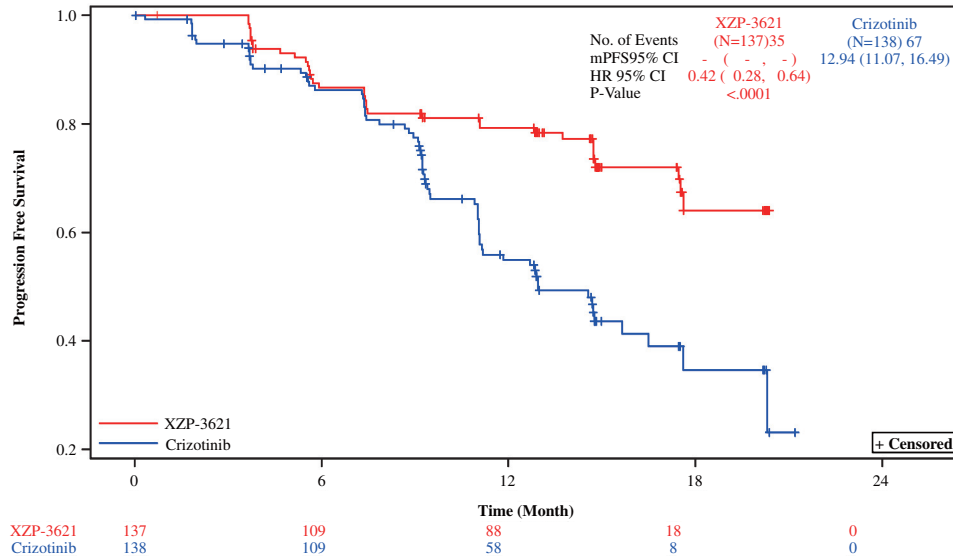
Trial Design. Patients were either treatment-naïve or had received only one prior chemotherapy regimen. Participants were randomly assigned in a 1:1 ratio to receive either XZP-3621 or crizotinib. Patients in the XZP-3621 arm received 500 mg once daily. Patients in the crizotinib arm received 250 mg twice daily. Both treatments were administered continuously in 28-day cycles. Treatment continued until patients experienced disease progression, unacceptable toxicity, withdrew consent, died, or the investigator determined it was no longer in the patient’s best interest to continue, whichever occurred first.

Trial Objectives. The trial’s primary endpoint was PFS as assessed by investigators. Secondary endpoints include PFS assessed by BICR, ORR, DoR, DCR, IC-ORR, and IC-DoR as assessed by both BICR and investigators. Additionally, the study aimed to determine OS and OSR, compare the safety and tolerability of XZP-3621 versus crizotinib, and evaluate the population pharmacokinetic (PopPK) characteristics of XZP-3621 in ALK-positive advanced NSCLC patients. Exploratory endpoints include comparing disease/symptom-related patient-reported outcomes (PRO) and health-related quality of life (HRQoL) scores, as well as assessing health status post-treatment with XZP-3621 versus crizotinib.

Trial Progress. The final analysis of this clinical trial will be completed in the first half of 2025. As of the data cut-off date (January 8, 2024), the study had enrolled 275 patients randomized to receive either XZP-3621 (n=137) or crizotinib (n=138). Study treatment discontinuation was reported in 125 patients (45.5%): 48 patients (35.0%) in the XZP-3621 group and 77 patients (55.8%) in the crizotinib group.

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Efficacy Data. As of the data cut-off date (January 8, 2024), the mPFS for the XZP-3621 group was not reached (95% CI: NE-NE), while it was 12.94 months for the crizotinib group (95% CI: 11.070-16.490). The PFS data from this clinical trial, as assessed by the investigators, are summarized in the PFS Kaplan-Meier plots below.



Per investigator assessment using RANO-BM criteria, IC-ORR was 92.3% in the XZP-3621 group versus 11.1% in the crizotinib group. Median IC-DoR was not reached for XZP-3621 compared to 3.55 months for crizotinib. BICR assessments showed similar trends, with an IC-ORR of 100% for XZP-3621 and 0% for crizotinib. Efficacy data for patients with measurable intracranial lesions at baseline are summarized below.

		XZP-3621	Crizotinib
		n (%)	n (%)
Patients with measurable intracranial lesions at baseline	n	13	9
Best overall response	CR	1 (7.7)	0
	PR	11 (84.6)	1 (11.1)
	SD	0	4 (44.4)
	PD	1 (7.7)	2 (22.2)
	NE	0	2 (22.2)
ORR (CR + PR)	n(%)	12 (92.3)	1 (11.1)
	95% CI ^(a)	63.970, 99.805	0.281, 48.250
	P-value ^(b)	0.6382	
	P-value ^(c)	0.0004	
	Odds ratio	87.000 (5.105,	
	(95% CI) ^(c)	1482.692)	

(a) 95% confidence intervals (CIs) for response rates were calculated using the Pearson-Clopper exact method.

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- (b) The Breslow-Day test was employed to assess the homogeneity of odds ratios (ORs) across strata.
- (c) Provided the ORs were consistent across strata, a stratified Cochran-Mantel-Haenszel (CMH) test was performed to evaluate the treatment effect, accounting for the stratification factors of brain metastasis (yes/no) and prior chemotherapy (yes/no). If the homogeneity assumption was not met, logistic regression was used to compare treatment efficacy, with stratification factors included as covariates.

Safety Data. As of the data cut-off date (January 8, 2024), the median exposure times for the XZP-3621 and crizotinib groups were 447 days and 341 days, respectively, with median relative dose intensities of 99.5% and 98.3%, respectively. Safety data from this clinical trial are summarized in the table below.

	XZP-3621 (N=137)	Crizotinib (N=138)
	n(%)	n(%)
Median exposure duration (day)	447	341
Median relative dose intensity (%)	99.5	98.3
TEAE	137 (100.0)	138 (100.0)
TESAE	24 (17.5)	31 (22.5)
Grade 3 or above AEs	74 (54.0)	91 (65.9)
TEAE leading to dose interruption	52 (38.0)	73 (52.9)
TEAE leading to dose reduction	27 (19.7)	39 (28.3)
TEAE leading to study treatment discontinuation	1 (0.7)	9 (6.5)
TEAE leading to death	1 (0.7)	5 (3.6)

Conclusion. In conclusion, based on the clinical trial data, XZP-3621 tablets significantly reduced the risk of disease progression or death in patients with ALK-positive advanced NSCLC compared to crizotinib capsules. XZP-3621 also exhibited prolonged efficacy, particularly in reducing intracranial lesions in patients with brain metastases. Additionally, XZP-3621 demonstrated better safety and tolerability compared to crizotinib.

Phase 2 Clinical Trial of XZP-3621 for the Treatment of ALK-positive Advanced NSCLC

This multi-center, open-label phase 2 clinical trial evaluated the efficacy and safety of XZP-3621 in patients with ALK-positive advanced NSCLC.

Trial Design. The trial was designed with three cohorts: (i) cohort A included patients who had not previously received any ALK inhibitor treatment, (ii) cohort B consisted of patients who had either progressed or become intolerant after crizotinib treatment, and (iii) cohort C comprised patients who had progressed or become intolerant after treatment with other ALK inhibitors, including those who may or may not have previously used crizotinib. The dosing regimen for XZP-3621 is 500 mg, taken once daily, administered continuously in 4-week treatment cycles. Treatment continued until disease progression, intolerable toxicity, withdrawal of consent, death, or if the investigator deemed the patient’s condition unsuitable for continued treatment.

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Trial Objectives. The primary endpoint was ORR. Secondary endpoints included PFS, DCR, DoR, IC-ORR, and OS. Additionally, the study aimed to assess the safety and tolerability of XZP-3621 tablets and to evaluate their population pharmacokinetic characteristics in these patients. Exploratory objectives involve exploring the correlation between the antitumor efficacy of XZP-3621 and ALK gene mutations, as well as investigating potential resistance mechanisms post-treatment in patients with ALK-positive advanced NSCLC.

Trial Progress. This clinical trial was completed in February 2024. As of the data cut-off date (August 4, 2023), all 113 enrolled patients received at least one dose of XZP-3621. Study treatment discontinuation occurred in 58 patients (51.3%), while 11 patients (9.7%) completed the study.

Efficacy Data. In cohort A (31 patients, ALK inhibitors-naïve), the ORR was 71.0%, DCR was 83.9%, mDoR was 5.88 months, mPFS was 7.66 months, and the 9-month OS rate was 95.83%. In cohort B (33 patients, prior crizotinib treatment only), the ORR was 30.3%, DCR was 87.9%, mDoR and mPFS were not reached, and the 9-month OS rate was 64.52%. In cohort C (49 patients, prior other ALK inhibitors treatment, including those who may or may not have previously used crizotinib), the ORR was 18.4%, DCR was 65.3%, mDoR was 7.39 months, mPFS was 3.75 months, and the 9-month OS rate was 80.43%. XZP-3621 exhibited promising data for the treatment of brain metastases, with IC-ORR reached 75.0%, 70.0% and 37.5% in cohort A, B and C, respectively.

Safety Data. During the study, all 113 participants (100.0%) experienced TEAEs and TRAEs. Safety data from this clinical trial are summarized in the table below.

	Cohort A	Cohort B	Cohort C	Total
	N=31	N=33	N=49	N=113
	n(%)	n(%)	n(%)	n(%)
TEAE.	31 (100)	33 (100)	49 (100)	113 (100)
TRAE	31 (100)	33 (100)	49 (100)	113 (100)
TESAE.	4 (12.9)	4 (12.1)	4 (8.2)	12 (10.6)
TRSAE	3 (9.7)	3 (9.1)	1 (2.0)	7 (6.2)
TEAE leading to dose reduction. .	3 (9.7)	3 (9.1)	12 (24.5)	18 (15.9)
TRAE leading to dose reduction .	3 (9.7)	3 (9.1)	12 (24.5)	18 (15.9)
TEAE leading to the interruption of study treatment.	13 (41.9)	12 (36.4)	21 (42.9)	46 (40.7)
TRAE leading to the interruption of study treatment.	9 (29.0)	11 (33.3)	12 (24.5)	32 (28.3)
TEAE leading to study treatment discontinuation	0	1 (3.0)	1 (2.0)	2 (1.8)
TRAE leading to study treatment discontinuation	0	1 (3.0)	1 (2.0)	2 (1.8)
TEAE leading to death.	0	0	0	0

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Phase 1 Clinical Trial of XZP-3621

This multi-center, open-label, first-in-human clinical trial focused on patients with advanced NSCLC harboring ALK or ROS1 rearrangements. The subject included NSCLC patients who had not been treated with ALK inhibitors, those who had failed crizotinib treatment, and those who had failed other approved ALK inhibitor treatment. Additionally, patients who had previously undergone anti-tumor treatment were eligible for inclusion.

Trial Design. The study was divided into two parts: dose escalation and dose expansion. During the dose escalation phase, the primary goal was to determine the MTD and recommended phase 2 dose (RP2D). Patients with ALK or ROS1-rearranged advanced NSCLC were enrolled for single and multiple dose assessments over a 4-week cycle, starting at 50 mg and increasing based on a “3+3” design.

The dose expansion phase was designed as follows: once a dose level was deemed safe and showed preliminary efficacy (partial or complete response in at least two of three patients), approximately 15 additional patients were enrolled from this dose level to the MTD dose to further evaluate safety, PK, and efficacy. Patients received XZP-3621 in continuous 28-day cycles, with efficacy assessed every two cycles.

Trial Objectives. The primary endpoints included determining the MTD and DLT to guide the selection of the RP2D. Secondary endpoints included assessments of the efficacy of XZP-3621, using measures such as ORR, DCR, DoR and PFS. Additionally, the study evaluated the PK profile following single and multiple doses.

Trial Progress. The phase 1 clinical trial was completed in July 2023.

Efficacy Data. Among the 101 ALK-rearranged NSCLC patients, the best overall response included 47 PR (46.5%) across various doses, 14 cases of SD (13.9%), and 4 cases of non-CR/non-PD (4.0%), resulting in an ORR of 46.5% (95% CI: 36.55%-56.73%) and a DCR of 64.4% (95% CI: 54.21%-73.64%). The table below sets forth the efficacy data from this clinical trial.

	<u>Total N=101</u>
Best Overall Response, n (%)	
CR.	0
PR.	47 (46.5%)
SD.	14 (13.9%)
Neither CR nor PD	4 (4.0%)
PD.	24 (23.8%)
Not evaluable	12 (11.9%)
ORR and 95% CI	46.5% (36.55%, 56.73%)
DCR and 95% CI	64.4% (54.21%, 73.64%)
Median DoR and 95% CI	17.938 (11.828, 31.737)
Median PFS and 95% CI	11.105 (6.472, 14.292)

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Total N=101

Six-month PFS Rate and 95% CI	0.61 (0.50, 0.70)
12-month PFS Rate and 95% CI	0.47 (0.36, 0.57)
18-month PFS Rate and 95% CI	0.39 (0.28, 0.49)
24-month PFS Rate and 95% CI	0.32 (0.22, 0.43)

Safety Data. No DLT events occurred in any dose group; however, the 600 mg dose group experienced a higher dropout rate due to AEs, designating it as the MTD. All patients (100%) experienced at least one TEAE, with 112 patients (98.2%) experiencing TRAEs. Safety data from this clinical trial are summarized in the table below.

	50mg N=2 n(%)	100mg N=4 n(%)	200mg N=3 n(%)	300mg N=8 n(%)	400mg N=14 n(%)	500mg N=75 n(%)	600mg N=8 n(%)	Total N=114 n(%)
TEAE	2 (100.0%)	4 (100.0%)	3 (100.0%)	8 (100.0%)	14 (100.0%)	75 (100.0%)	8 (100.0%)	114 (100.0%)
TRAE	1 (50.0%)	3 (75.0%)	3 (100.0%)	8 (100.0%)	14 (100.0%)	75 (100.0%)	8 (100.0%)	112 (98.2%)
DLT	0	0	0	0	0	0	0	0
TESAE	1 (50.0%)	3 (75.0%)	1 (33.3%)	0	5 (35.7%)	15 (20.0%)	2 (25.0%)	27 (23.7%)
TRSAE	0	0	0	0	0	4 (5.3%)	0	4 (3.5%)
Grade 3 or above								
TEAE	1 (50.0%)	3 (75.0%)	2 (66.7%)	3 (37.5%)	9 (64.3%)	34 (45.3%)	3 (37.5%)	55 (48.2%)
Grade 3 or above								
TRAE	0	0	2 (66.7%)	3 (37.5%)	2 (14.3%)	23 (30.7%)	2 (25.0%)	32 (28.1%)
TEAE leading to study treatment discontinuation	1 (50.0%)	0	0	0	0	4 (5.3%)	2 (25.0%)	7 (6.1%)
TRAE leading to study treatment discontinuation	0	0	0	0	0	2 (2.7%)	2 (25.0%)	4 (3.5%)
TEAE leading to dose reduction	0	0	0	0	1 (7.1%)	7 (9.3%)	2 (25.0%)	10 (8.8%)
TRAE leading to dose reduction	0	0	0	0	1 (7.1%)	7 (9.3%)	2 (25.0%)	10 (8.8%)
TEAE leading to the interruption of study treatment	0	1 (25.0%)	1 (33.3%)	1 (12.5%)	7 (50.0%)	20 (26.7%)	2 (25.0%)	32 (28.1%)
TRAE leading to the interruption of study treatment	0	0	1 (33.3%)	0	2 (14.3%)	12 (16.0%)	1 (12.5%)	16 (14.0%)
TEAE leading to death	0	0	0	0	1 (7.1%)	4 (5.3%)	0	5 (4.4%)

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Material Communications and Next Steps

We received IND approval from the NMPA in March 2018 for initiating XZP-3621’s phase 1 clinical trial on treatment of advanced NSCLC with ALK or ROS1 rearrangements. We completed the phase 1 clinical trial in July 2023. We consulted with the CDE and received their approval in October 2021 for commencing the phase 3 trial of XZP-3621 in the first-line treatment of patients with ALK-positive advanced NSCLC. With the interim data from the phase 3 clinical trial of XZP-3621, we have filed the NDA application of XZP-3621 in the first-line treatment of patients with ALK-positive advanced NSCLC in April 2024. We also plan to initiate an extension study to continue monitoring OS data, with an estimated study completion by the end of 2027. We are exploring the indication expansion of XZP-3621 in post-operative adjuvant therapy for ALK-positive early NSCLC. We submitted the IND application for such indication expansion of XZP-3621 and received the acceptance notice to the IND application from the NMPA in November 2024.

As of the Latest Practicable Date, we had received no major concerns or objections from the CDE to our clinical development plan for XZP-3621.

XZP-3621 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

KM602, the First and Only CD80-Fc Fusion Protein in Clinical Trial in China

Overview

KM602 is a new generation drug of cancer immunotherapy, and is a fusion protein composed of the engineered human CD80 extracellular domain and the Fc domain of human IgG1. It largely maintains the structure of natural CD80 and has low immunogenicity. In addition, KM602 has immune memory function with sustained anti-tumor activity. KM602 is the only clinical-stage anti-tumor CD80-Fc fusion protein drug in China, with the potential for first-in-class.

Mechanism of Action

As a novel immunomodulatory drug, KM602 utilizes the pleiotropic characteristics of CD80-Fc fusion protein to engage in T lymphocyte activation by stimulating the CD28 co-stimulatory signaling pathway. Additionally, it inhibits the suppressive signal mediated by PD-L1/PD-1 and B7-CTLA-4. These pathways may contribute to enhancing and sustaining their role in tumor immunity. Despite the use of ICIs such as PD-1/PD-L1 drugs, many patients still face low efficacy and drug resistance, which may be due to the lack of sufficient T-cell co-stimulation in the tumor microenvironment. KM602 is designed to enhance T cell activation and has the potential to fill a gap in this market.

Market Opportunity and Competition

Given the broad applicability of CD80-Fc fusion proteins in cancer immunotherapy across multiple malignancies, the addressable market for CD80-Fc fusion proteins can potentially extend to the entire cancer immunotherapy market according to CIC. The global cancer immunotherapy market increased from US\$18.6 billion in 2018 to US\$59.3 billion in 2023 at a CAGR of 26.1%, and is expected to reach US\$185.6 billion in 2032 at a CAGR of 14.6% from 2023. The cancer immunotherapy market in China grew from RMB0.8 billion in 2018 to RMB22.0 billion in 2023 at a CAGR of 94.5% and is forecasted to reach RMB155.9 billion in 2032 at a CAGR of 24.3% from 2023. As of the Latest Practicable Date, there were no CD80-Fc fusion protein drugs approved for marketing globally and in China. As of the same date, our Company’s KM602, was the only CD80-Fc fusion protein drug candidate under clinical development in China. For more details, see “Industry Overview — Other Select Oncology Drug Markets in China — CD80-Fc Fusion Protein.”

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Competitive Advantages

Preclinical studies have demonstrated the robust anti-tumor effect of KM602. *In vitro*, KM602 enhances T cell proliferation and activation by providing CD28 co-stimulatory signals in conjunction with TCR engagement, effectively counteracting the inhibitory effects of the CTLA-4 pathway. *In vivo*, KM602 exhibits dose-dependent tumor growth inhibition in both immune-infiltrated and immune-excluded tumor models, demonstrating superior efficacy compared to benchmarks such as anti PD-L1 drugs, anti-mCTLA-4 immune checkpoint drugs, and FPT155. Notably, KM602 treatment induces durable immune memory responses, providing long-term protection against tumor recurrence. Immune profiling reveals that KM602 favorably modulates the tumor microenvironment, increasing the infiltration of effector immune cells while reducing immunosuppressive regulatory T cells specifically within the tumor, further elucidating its mechanism of action. Importantly, this immunomodulatory effect appears localized to the tumor, with no such alterations observed in systemic immune compartments like the spleen or peripheral blood, suggesting a favorable safety profile. This localized activation of tumor-antigen specific T cells, without broadly activating naive T cells, points to a reduced risk of systemic cytokine release syndrome while maintaining potent anti-tumor activity. Furthermore, KM602 exhibits favorable PK characteristics, and a long half-life supporting a convenient once-weekly or less frequent dosing regimen in the clinic.

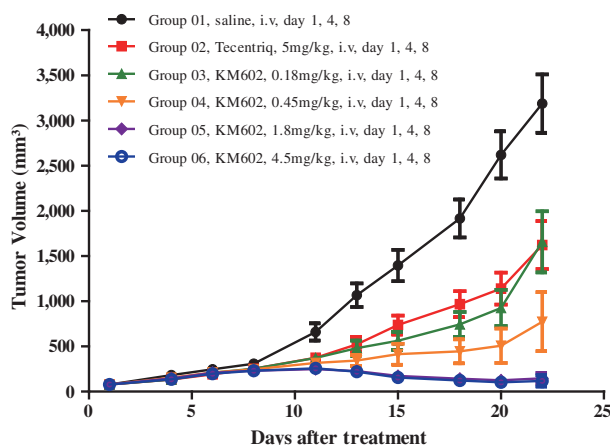
Clinical Development Plan

The IND application for KM602 was approved by the NMPA and FDA in February and September 2023, respectively. We are conducting an open-label, first-in-human, multicenter phase 1 study in China to evaluate the safety, tolerability, PK, and activity of KM602 as monotherapy in patients with advanced solid tumors. We plan to complete patient enrollment for this clinical trial in the second half of 2025 with the trial expected to conclude in 2026. In the second half of 2026, we plan to initiate a dose escalation study for combination therapy with a PD-1 antibody.

Preclinical Data

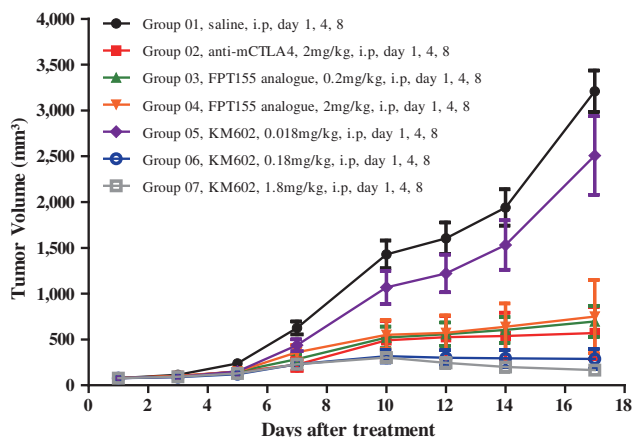
Preclinical study showed that KM602 has better anti-tumor efficacy than anti-PD-L1 drugs, anti-CTLA4 immune checkpoint drugs and the similar product, FPT155, and has better safety, showing the potential to be first-in-class.

In vivo, the therapeutic efficacy of KM602 in the subcutaneous allograft MC38 colon cancer model was evaluated in female C57BL/6 mice. Compared with the saline group, all treatment groups showed significant anti-tumor effects. The anti-tumor activity of KM602 at 0.45mg/kg, 1.8mg/kg or 4.5mg/kg was significantly better than that of Tecentriq (Atezolizumab, anti-PD-L1 drug) at 5 mg/kg ($p=0.0217$, $p<0.001$ and $p<0.001$, respectively).



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In vivo, the therapeutic efficacy of KM602 in the subcutaneous allograft CT26 colon cancer model was evaluated in female BALB/c mice. Compared with the saline group, all treatment groups showed significant anti-tumor effects, except KM602 at 0.018 mg/kg group. Compared to the FPT155 analogues with doses of 0.2 mg/kg and 2 mg/kg, although there was no statistically significant difference, the anti-tumor activity of KM602 with doses of 0.18 mg/kg and 1.8 mg/kg also showed a certain advantage.



KM602 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

KM501, a Potential First-in-class HER2/HER2 Bispecific ADC in China

Overview

KM501 is a potential first-in-class HER2/HER2 bispecific ADC in China. It is intended for the treatment in solid tumors with HER2-low expressing, including breast, gastric, and lung cancers.

Mechanism of Action

HER2 is a transmembrane receptor tyrosine kinase belonging to the ErbB family. HER2 forms heterodimers with other family members to activate signaling pathways that regulate cell proliferation and survival. Overexpression of HER2 is implicated in various cancers, including breast, gastric, lung, and ovarian cancers. Tumor classification based on HER2 expression levels is categorized as high, low, or negative, determined through immunohistochemistry (IHC) and fluorescence *in situ* hybridization (FISH). HER2 low expression is characterized by an IHC score of 1+ or IHC 2+ with either FISH-equivocal or -negative results.

KM501 is a bispecific antibody ADC product targeting HER2 extracellular domains II and IV. It specifically binds to HER2 protein and enters the cell through internalization. It not only inhibits the heterodimerization of HER2 protein with other members of HER family (such as HER1\HER3\HER4), thereby preventing the effective transmission of HER2 downstream signaling pathways (such as PI3K-AKT-mTOR and RAS-Raf-MAPK, etc.), but also can release the toxin molecule monomethyl auristatin E (MMAE) after entering cells. This effectively

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hinders the cell mitosis, thereby inhibiting tumor cells proliferation or inducing their apoptosis. Additionally, the KM501 bispecific-antibody ADC can also kill tumor cells by enhancing the ADCC effect and bystander effect.

Market Opportunity and Competition

As of the Latest Practicable Date, there were no HER2/HER2 bispecific ADCs approved for marketing in China. As of the same date, there were three HER2/HER2 bispecific ADC candidates under clinical development in China and DS-8201 is the only ADC approved for HER2 low expressing BC globally. The addressable market for HER2/HER2 bispecific ADCs primarily includes patients with HER2+ and HER2-low cancers. According to CIC, the incidence of major cancers where HER2 is frequently expressed, such as BC, gastric cancer, biliary cancer, and NSCLC, in China grew from 808.9 thousand in 2018 to 895.5 thousand in 2023 at a CAGR of 2.1%, and is expected to reach 1,057.1 thousand in 2032 at a CAGR of 1.9% from 2023. For more details, see “Industry Overview — Other Select Oncology Drug Markets in China — HER2/HER2 Bispecific ADC.”

Competitive Advantages

KM501 is designed with patented technology of knocking out fucose and with the ability to target both trastuzumab (anti-HER2 domain IV) and pertuzumab (anti-HER2 domain II) epitopes at the same time, potentially translating to better endocytosis of the ADC. This may contribute to KM501’s strong anti-tumor activity in HER2 low expression tumors.

Preclinical data demonstrate the potent anti-tumor activity of KM501. *In vitro*, KM501 exhibits superior internalization efficiency and effectively inhibits the proliferation of HER2-positive cancer cells. The released payload, MMAE, demonstrates a bystander effect, impacting neighboring tumor cells. The use of 100% afucosylation technology significantly enhances KM501’s ADCC activity, which was 10-20 times that of DS-8201 and approximately 6 times that of RC48. *In vivo*, KM501 demonstrates remarkable anti-tumor efficacy across various HER2-expressing tumor models at a dose of approximately 1 mg/kg. In both cell line-derived xenograft and patient-derived xenograft models with varying HER2 expression levels, KM501 exhibits comparable or superior efficacy to DS-8201 and RC48. PK studies in cynomolgus monkeys reveal favorable characteristics of KM501, including stable MMAE levels and consistently low payload exposure. No significant accumulation of KM501, total antibody, or MMAE is observed following repeated administration, supporting a clinically convenient dosing regimen of once every two weeks.

Clinical Development Plan

The IND application for KM501 was approved by the NMPA in February 2023. We are conducting a single-arm, open, multicenter phase 1 study to evaluate the safety, tolerability, pharmacokinetic profile, and efficacy of the KM501 in subjects with advanced solid tumors that express, amplify, or mutate HER2. We plan to complete patient enrollment for this clinical trial in the second half of 2025 with the trial expected to conclude in 2026. In the second half of 2026, we plan to initiate a dose escalation study for combination therapy with a PD-1 antibody.

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Preclinical Data

In vivo, eight mouse models bearing human tumor cell lines and human tumor tissues with varying levels of HER2 expression were selected to interact with KM501 or positive controls. The results demonstrated that for a series of tumor models exhibiting high or medium HER2 expression, KM501 exhibited significant dose-dependent anti-tumor effects. Moreover, at the same dosage, the tumor inhibition rate of KM501 was slightly higher than or comparable to that of DS-8201. For sensitive tumor models displaying medium and low HER2 expression, KM501 displayed notable antitumor activity, with the tumor inhibition rate being similar or slightly higher than that of DS-8201 at equivalent dosages.

KM501 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

XZP-7797, a Next-generation PARP1 Inhibitor with High Selectivity, Low Hematologic Toxicity, and the Ability to Reach the Brain Lesions

Overview

XZP-7797 is a next-generation PARP1 inhibitor characterized by high selectivity, low hematologic toxicity, and the ability to reach the brain lesions. Since the introduction of PARP1/2 inhibitors, these drugs have been approved for treating a wide range of solid tumors with maximal activity against tumors harboring BRCA1/2 mutation or homologous recombination deficiency. Their commercial success is evident, with global sales reaching US\$3.4 billion in 2023, according to CIC.

We strategically developed XZP-7797 to address two significant limitations of first-generation PARP1/2 inhibitors: hematologic toxicity and the inability to reach the brain lesions. In clinical applications, the high incidence of severe (grade 3 or above) hematologic adverse reactions with these inhibitors have often led to dose reductions, treatment interruption or discontinuation, compromising their efficacy and safety. This is largely attributed to the inhibition of PARP2, which contributes to severe hematologic toxicity. Conversely, data suggest that synthetic lethality in the context of BRCA mutations is primarily driven by PARP1 inhibition. Therefore, creating highly selective next-generation PARP1 inhibitors is essential to reduce this toxicity.

Furthermore, about 20% of advanced cancer patients develop brain metastases, with statistical analysis showing that approximately 44.7% of recurrent metastatic BC patients with BRCA1 mutations are diagnosed with brain metastases. However, most first-generation PARP inhibitors cannot reach the brain lesions and therefore limits effectiveness of these drugs.

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Mechanism of Action

XZP-7797 is a nicotinamide adenine dinucleotide (NAD⁺) analog. Its mechanism of action involves competitively binding to the catalytic active site of the PARP enzyme, thereby inhibiting PARP enzyme activity. The inhibitory effects of XZP-7797 are primarily exerted through two mechanisms: direct inhibition of the PARP1 enzyme and capturing and trapping PARP1 at sites of DNA damage. By targeting these two key aspects, XZP-7797 effectively disrupts the PARP1 pathway, offering a potent therapeutic approach for treating cancers with high unmet clinical needs.

XZP-7797 prevents PARP1 from repairing single-strand DNA breaks, which subsequently leads to double-strand DNA breaks. Normally, BRCA proteins repair these double-strand breaks through homologous recombination, allowing the cell to survive. However, mutated BRCA proteins lose this repair capability, resulting in cell death. Additionally, XZP-7797 binds to the catalytic active site of PARP1, inducing a conformational change that enhances the binding strength between PARP1 and damaged DNA. This “traps” PARP1 at the site of DNA damage, preventing it from disassociating and being recycled, thereby exacerbating the DNA damage and further inhibiting DNA repair.

Market Opportunity and Competition

Following the approval of the first PARP1/2 inhibitor in 2018, PARP1 inhibitor market in China surged from RMB19.9 million in 2018 to RMB2.9 billion in 2023, at a CAGR of 171.1%. It is forecasted to reach RMB5.0 billion in 2032, at a CAGR of 6.3% from 2023. As of the Latest Practicable Date, five PARP1/2 inhibitors had received approval for marketing in China. As of the same date, there were nine PARP inhibitor candidates under clinical development in China, three of which were selective PARP1 inhibitor candidates and six were PARP1/2 inhibitor candidates. Two of the three selective PARP1 inhibitor candidates have only recently initiated clinical development. For more details, see “Industry Overview — Other Select Oncology Drug Markets in China — PARP1 Inhibitor.”

Competitive Advantages

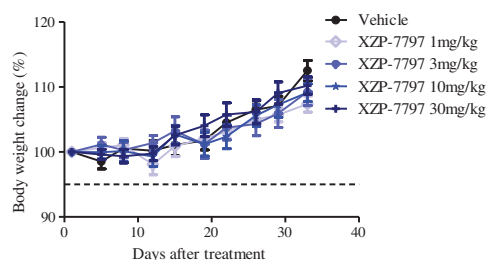
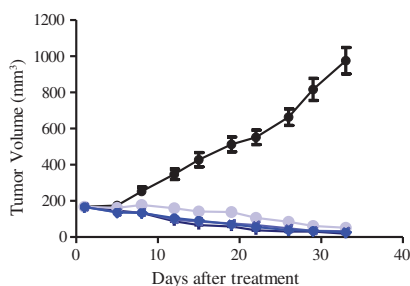
XZP-7797 offers several competitive advantages. *In vitro* efficacy studies show that XZP-7797 exhibits strong inhibitory activity against PARP1 and high selectivity for PARP1 over other kinases in the PARP family. Its efficacy has been demonstrated in various tumor models. In the MDA-MB-436 BC xenograft model, XZP-7797 significantly inhibits tumor growth and induces rapid tumor regression. In the Capan-1 pancreatic cancer xenograft model, XZP-7797 markedly suppresses tumor growth. In an intracranial tumor model in mice, XZP-7797 significantly inhibits intracranial tumor growth, achieving a tumor inhibition rate of 96.6%. Moreover, XZP-7797 demonstrates excellent pharmacokinetic properties both *in vitro* and *in vivo*, with high bioavailability and the ability to reach the brain lesions, indicating strong druggability.

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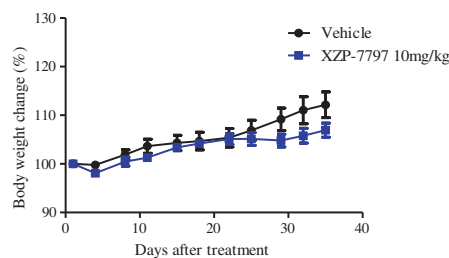
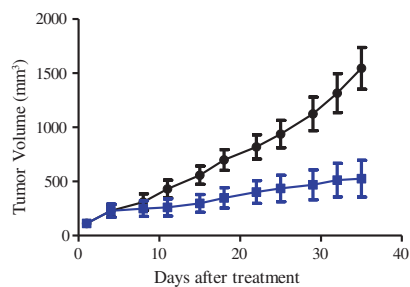
XZP-7797 also exhibits a good tolerability and safety profile. In a 14-day repeated-dose toxicity study in rats, it was well-tolerated, showing no hematologic adverse reactions within a 10-fold safety margin. Furthermore, XZP-7797 has gained recognition at the American Association for Cancer Research (AACR) 2024, where we presented a poster titled "Discovery of a Potent, Selective, and Brain-Penetrating PARP1 Inhibitor, XZP-7797", highlighting its promising potential.

XZP-7797 demonstrates potent and highly selective inhibition of PARP1. Preclinical studies confirm a greater than 1000-fold selectivity for PARP1 over PARP2 and other PARP family kinases. XZP-7797 exhibits strong PARP trapping activity and demonstrates nanomolar potency in inhibiting the growth of BC (MDA-MB-436) and prostate cancer (LNCaP) cell lines, with IC₅₀ values of 2.7 nM and 15.8 nM, respectively.

In vivo efficacy studies using a human BC MDA-MB-436 xenograft model demonstrated that XZP-7797 exhibits potent anti-tumor activity at a well-tolerated dose of 1 mg/kg. Treatment with XZP-7797 resulted in significant tumor regression.

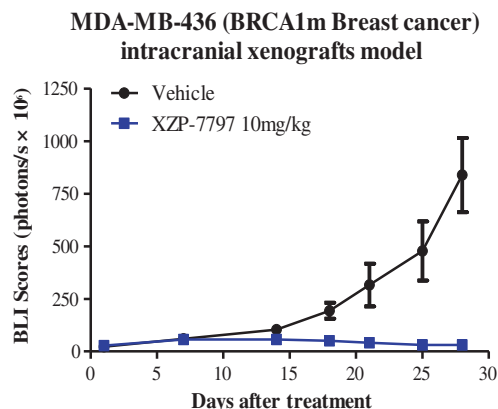


In vivo efficacy studies utilizing a human pancreatic cancer Capan-1 xenograft model demonstrated that XZP-7797 exhibits potent anti-tumor activity at a well-tolerated dose of 10 mg/kg.



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In an intracranial human BC MDA-MB-436 xenograft model, XZP-7797 demonstrated significant suppression of tumor growth. At a well-tolerated dose of 10 mg/kg, XZP-7797 achieved a tumor growth inhibition (TGI) of 96.6%.



XZP-7797 also exhibits favorable PK profile *in vivo*. In a 14-day toxicology study in Sprague-Dawley rats, XZP-7797 was well-tolerated at doses up to 10 times the no observed adverse effect level, with no significant hematological findings.

Next Steps

XZP-7797 is currently in comprehensive preclinical development. We anticipate submitting an IND application by the end of 2024. We plan to initiate a phase 1 dose-escalation study in the second half of 2025, followed by a phase 1 expansion study in 2026.

XZP-7797 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

XZP-6924, a Potent and Highly Selective USP1 Inhibitor

Overview

XZP-6924 is a potent and highly selective USP1 inhibitor. USP1 inhibitors, which have the potential to overcome some of the resistance mechanisms associated with PARP inhibitors, is an emerging research target globally. Research shows that inhibiting USP1 can boost the effectiveness of existing PARP1/2 inhibitors, address resistance issues, and prolong patient survival, highlighting a significant market opportunity.

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Mechanism of Action

Research shows that inhibition of the DNA damage response (DDR) pathway can affect cancer cell replication and survival. Drugs targeting the DDR pathway are effective in the treatment of many types of cancers, such as PARP inhibitors, which, while demonstrating good clinical performance, is not effective in all patients and can be limited by treatment-related drug resistance. USP1 is involved in DNA damage repair processes, and in combination with PARP inhibitors, can synergistically target BRCA1/2 mutant cancers.

In the DDR pathway, USP1 forms a heterodimer with UAF1, deubiquitinating substrate proteins such as FANCD2/FANCI and PCNA. This process is integral to DNA damage repair pathways, distinct from but complementary to those of PARP, such as trans-lesion synthesis and inter-strand crosslinks. Inhibiting USP1 can increase genomic instability and replication stress in tumor cells, ultimately leading to tumor cell death.

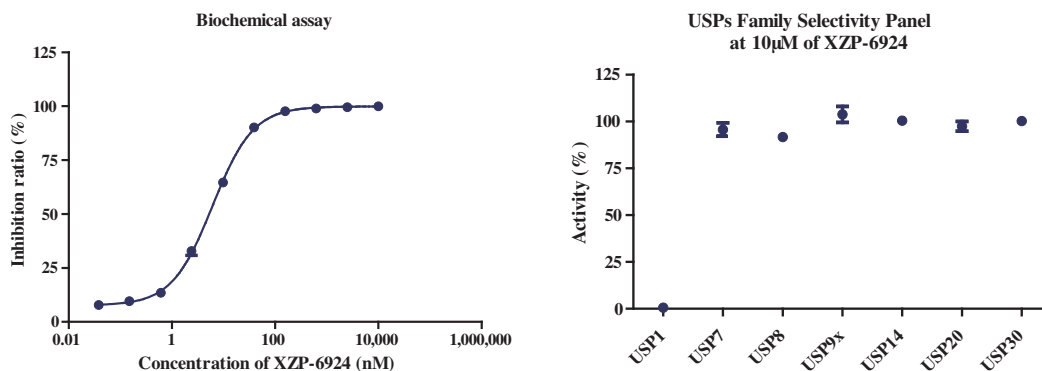
Market Opportunity and Competition

As of the Latest Practicable Date, there were no USP1 inhibitors approved for marketing in China. As of the same date, there were three USP1 inhibitor candidates under clinical development in China. Eligible patients for USP1 inhibitors primarily include patients with BRCA mutations. It is estimated that the number of patients eligible for USP1 inhibitors will reach 398.2 thousand in 2032. For more details, see “Industry Overview — Other Select Oncology Drug Markets in China — USP1 Inhibitor.”

Competitive Advantages

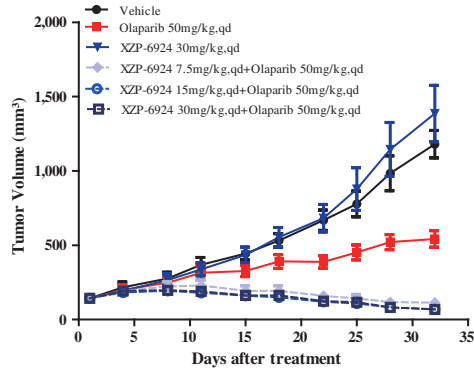
Based on currently available preclinical data, XZP-6924 significantly enhances the activity of PARP inhibitor olaparib-resistant HAD+ tumor cells, showing over a 10-fold increase in activity across multiple cell lines. In several CDX and PDX tumor models, the combination of XZP-6924 and olaparib has demonstrated sustained tumor regression, significantly delaying tumor recurrence and extending the survival period of animals. This suggests potential for developing combination therapies with currently marketed PARP inhibitors or XZP-7797, our next-generation PARP inhibitor.

XZP-6924 exhibits good PK characteristics in preclinical animal studies, indicating high druggability. It also shows good tolerability and a wide safety margin in animal models.

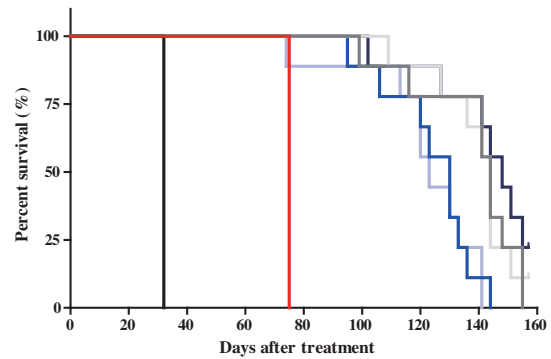
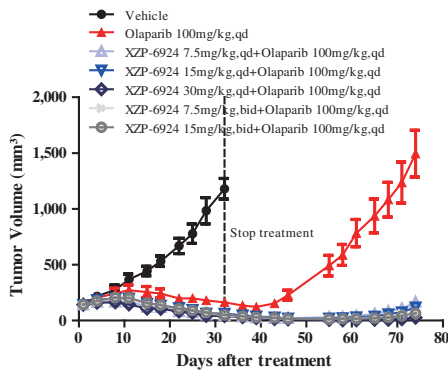


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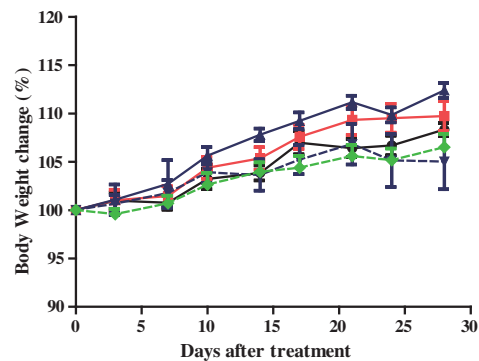
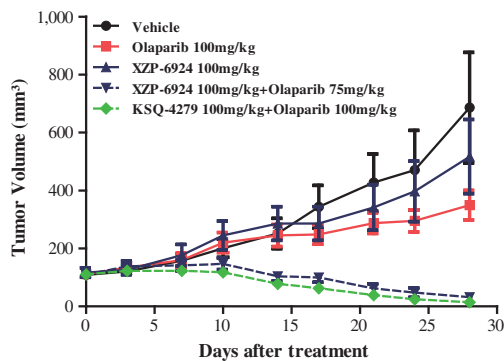
XZP-6924 demonstrates strong inhibition of USP1 with an IC₅₀ of 11 nM and over 100-fold selectivity for USP1 compared to other proteins in the USP family.



In the MDA-MB-436 CDX animal model, XZP-6924 shows a significant synergistic effect with olaparib, resulting in more effective tumor growth inhibition when used in combination.



In the TNBC CDX animal model, the combination of XZP-6924 and olaparib significantly inhibits tumor growth, markedly delays tumor recurrence, and notably extends the survival period of the animals, demonstrating excellent synergistic efficacy.



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In the TNBC PDX animal model, the combination of XZP-6924 and Olaparib resulted in tumor regression, showing a good synergistic effect and was well tolerated by the animals.

Clinical Development Plan

We submitted the IND application to the NMPA, which was accepted in September 2024. In November 2024, we received the IND approval from the NMPA. We plan to initiate a phase 1 dose-escalation study in the first half of 2026, followed by a phase 1 expansion study in 2027.

XZP-6924 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

XZB-0004, a Highly Selective and Well-tolerated Oral Small Molecule AXL Inhibitor

XZB-0004 is a potent and selective oral small molecule AXL inhibitor. AXL, a transmembrane cell surface receptor overexpressed in numerous hematological and solid cancers, is a putative driver of diverse cellular processes that are critical for the development, growth, survival and spread of tumors. AXL overexpression is known to be associated with poor clinical prognosis in many tumor types and inhibiting AXL activity has been shown to interfere with cancer cell survival, migration, invasion, proliferation and ultimately inhibiting tumor cell growth and metastasis. In September 2021, we entered into a license and cooperation agreement (as amended in November 2021) with SignalChem Lifesciences Corporation (“SignalChem”), to in-license certain patents and know-how owned by SignalChem relating to XZB-0004. For details, see “— Our License and Asset Acquisition Arrangements — Our In-licensing and Asset Acquisition Agreements — Agreement with SignalChem to In-license XZB-0004” below.

AXL activation can be either ligand-dependent or ligand-independent. Gas6 has been identified as the main ligand that binds the extracellular domain of AXL, leading to dimerization of the Gas6/AXL complex resulting in autophosphorylation of tyrosine residues on the intracellular tyrosine kinase domain of AXL. Preclinical *in vitro* and *in vivo* data demonstrate that XZB-0004 exhibits promising efficacy and a favorable safety profile across various tumor models. XZB-0004 demonstrated antiproliferative activity *in vitro* against a broad range of tumor cell lines, achieved biomarker suppression, tumor growth inhibition *in vivo* in multiple tumor xenograft models including lung, colon, acute myeloid leukemia (AML) and chronic myeloid leukemia (CML) cancer models, and has shown to have a favorable safety profile in human.

We are conducting an open-label, multicenter, phase 1, dose escalation study to evaluate the safety, PK/PD and efficacy of XZB-0004 administered orally (once or twice daily) in 21-day cycles in patients with advanced solid tumors. The primary endpoints of this study are safety assessments MTD and RP2D. Secondary endpoints include evaluating the PK properties and efficacy.

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XZB-0004 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

XZP-6877, Potentially the First DNA Dependent Protein Kinase (DNA-PK) Inhibitor in China

XZP-6877 is a selective DNA-PK inhibitor which can block the main channels for repairing DNA double-strand breaks caused by radiotherapy or chemotherapy drugs, and improve the sensitivity of tumor cells to radiotherapy and chemotherapy. At the same time, it destroys the stability of telomere DNA structure to inhibit the proliferation and growth of tumor cells. The combination of the two mechanisms can enhance the anti-tumor efficacy and more effectively control tumors.

XZP-6877 has good PK properties, good oral absorption, high bioavailability, and good safety. It has shown enhanced treatment effect of radiotherapy and chemotherapy on multiple PD models, such as triple negative BC model, small cell lung cancer model, and head and neck cancer model, and has broad spectrum anti-cancer potential. Animal PD models also show that XZP-6877 can prolong survival time, providing a new exploration direction for improving patient survival.

XZP-6877 is potentially the first DNA-PK inhibitor in China, with leading research and development progress and technical advantages. Preclinical data indicate that it has good druggability, and is expected to address the domestic market gap in this field.

XZP-6877 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

NASH DRUGS

XZP-5610, a Novel, Potential First-in-class, Non-steroidal Farnesoid X Receptor (FXR) Agonist

XZP-5610 is a novel, potential first-in-class, non-steroidal FXR agonist for the treatment of NASH. The NASH treatment landscape in China currently lacks approved therapies, presenting a significant unmet medical need. While numerous drug candidates are under clinical investigation, FXR agonists have emerged as a promising therapeutic class. By inhibiting bile acid synthesis and absorption in the liver, while simultaneously promoting bile acid excretion, FXR agonists effectively reduce bile acid levels, thereby alleviating NASH symptoms associated with bile acid accumulation.

We have completed the database lock of a phase 1 clinical trial to evaluate the safety, tolerability and PK of XZP-5610 following single- and multiple-ascending doses in healthy subjects in November 2023.

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XZP-5610 exhibits potent FXR agonistic activity in preclinical studies. XZP-5610 effectively modulates downstream gene expression, reduces serum levels of the biomarker C4, and improves key NASH histopathological features in animal models, including steatosis, inflammation, ballooning, and fibrosis. Furthermore, XZP-5610 demonstrates favorable pharmacokinetic properties, such as rapid absorption, high bioavailability in animals, and a long predicted human half-life. Toxicological assessments in rats and dogs revealed a favorable safety profile for XZP-5610, with minimal adverse effects and no genotoxicity observed. Importantly, XZP-5610 did not exhibit any detrimental effects on the central nervous system, peripheral nervous system, or cardiovascular system.

We are preparing the clinical study protocol for the phase 2 trial of XZP-5610.

XZP-5610 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

XZP-6019, a Novel, Potential First-in-class Ketohexokinase (KHK) Inhibitor

XZP-6019, a novel, potential first-in-class ketohexokinase (KHK, also called fructokinase) inhibitor, is being developed for the treatment of NASH. KHK is the principal rate-limiting enzyme of fructose metabolism. By selectively inhibiting KHK activity, KHK inhibitors could decrease hepatic lipogenesis and, directly or indirectly, increase insulin sensitivity. These combined effects result in improvements in liver steatosis, ballooning, inflammation, and fibrosis.

Preclinical studies have demonstrated that XZP-6019 exhibits potent KHK inhibitory activity and significantly improves NASH symptoms in animal models. Furthermore, XZP-6019 displays favorable pharmacokinetic properties, including rapid absorption, high bioavailability, and a long-predicted half-life supporting once-daily dosing. Toxicology studies in rats and dogs have established a wide safety margin for XZP-6019, with no genotoxicity observed within the clinically relevant dose range. Additionally, XZP-6019 demonstrated no adverse effects on the central nervous system, peripheral nervous system, or cardiovascular system. As a frontrunner in KHK inhibitor research with best-in-class potential, XZP-6019 is poised to address the unmet medical need for effective NASH therapies in China and globally.

We are finalizing the clinical study protocol for the phase 1 trial of XZP-6019.

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XZP-6019 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

OUR TECHNOLOGY PLATFORMS

Our commitment to addressing critical medical needs is powered by three core technology platforms, namely the small molecule drug R&D platform, the biological drug R&D platform and the clinical development platform. These proprietary platforms, built on our deep expertise in small molecule drug and biologics development, serve as the foundation for our discovery and development of innovative medicines. Designed to cover the entire R&D process across various drug modalities, these platforms work in concert, enabling valuable cross-functional synergies at key stages of drug development.

Small Molecule Drug R&D Platform

Our small molecule drug R&D platform is designed to efficiently advance promising drug candidates from initial discovery to clinical trials. This streamlined process, encompassing drug discovery and preclinical development, leverages cutting-edge technologies and a data-driven approach to accelerate timelines and increase the likelihood of success. Since its inception in 2008, our small molecule drug R&D platform has been instrumental in advancing innovative small molecule drug candidates, including clinical-stage assets such as KBP-3571, XZP-3287 and XZP-3621, among others.

Our small molecule drug discovery phase centers on identifying and validating high-value therapeutic targets. We then harness the power of CADD and SBDD to accelerate the discovery process. By analyzing the interactions between compound molecules and protein structures, we can design and optimize novel molecular scaffolds with enhanced target specificity and efficacy. This approach allows us to synthesize and screen a diverse library of compounds, significantly increasing the probability of identifying lead candidates with promising drug-like properties. We have leveraged our innovative CADD and SBDD technologies to design and develop a portfolio of small-molecule drug candidates, including our Core Products. This approach has enabled the creation of novel structural designs, potentially leading to enhanced efficacy and safety profiles.

This computational approach is further enhanced by our expertise in structure-activity relationship (SAR) analysis. By meticulously evaluating the relationship between a compound's structure and its biological activity, we can further refine and optimize lead candidates, designing molecules with superior potency, selectivity, and pharmacological profiles. This iterative process of design, synthesis, and evaluation allows us to develop drug candidates with a higher likelihood of achieving clinical success.

Our comprehensive preclinical program ensures that our lead candidates are well-prepared for clinical trials. This phase encompasses a multi-faceted approach, including pharmaceutical development to optimize the drug's synthesis, formulation, and manufacturing process for scalability and cost-effectiveness. We prioritize analytical development,

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establishing robust methods to ensure drug quality and consistency throughout the development process. Finally, our preclinical program includes in-depth pharmacology and toxicology studies in animal models to evaluate the drug's safety, efficacy, and pharmacokinetic/pharmacodynamic profile. This rigorous preclinical evaluation generates a comprehensive data package that supports regulatory submissions and informs the design of safe and effective clinical trials.

The core capabilities of our small molecule drug R&D platform are also illustrated below:

- Fully equipped in-house preclinical evaluation capabilities. This strategic integration eliminates reliance on external providers, ensuring rapid turnaround times, cost-effectiveness, and complete control over data quality. Our preclinical infrastructure includes:
 - o A versatile pharmacology center. Our dedicated pharmacology center boasts a diverse collection of *in vitro* and *in vivo* models for robust efficacy evaluation. We have established platforms for evaluating oncology compounds, including subcutaneous and intracranial xenograft models, as well as syngeneic mouse models. Additionally, we have developed models for NASH, digestive system diseases, and pain and neurodegenerative disorders. This center is equipped with advanced instrumentation, including a multi-mode plate reader, real-time PCR system, and a multi-spectral imaging system, enabling high-throughput screening, sophisticated imaging, and in-depth molecular and cellular analyses. This allows for efficient target validation, mechanistic studies, and comprehensive efficacy assessments.
 - o A dedicated ADME evaluation center. Our absorption, distribution, metabolism, and excretion (ADME) center is equipped with comprehensive *in vitro* and *in vivo* systems to support early drug discovery and lead optimization. We conduct *in vitro* metabolism, protein binding, and DDI studies, as well as *in vivo* pharmacokinetic profiling and metabolite identification in various animal models. By establishing *in vitro-in vivo* correlations, we can optimize dosage regimens, predict human PK, and proactively identify potential safety concerns early in the development process.
 - o A thorough safety evaluation center. Our non-clinical safety evaluation center houses dedicated histopathology and clinical pathology laboratories. The histopathology lab, staffed by experienced pathologists, is equipped to perform detailed tissue analysis and evaluation. Our clinical pathology lab utilizes automated analyzers for comprehensive blood and urine analysis. This setup allows us to independently conduct single and repeat-dose toxicity studies, as well as safety pharmacology studies, in rodents and dogs, generating critical data to support informed decisions about advancing candidates to clinical development.

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- Advanced Formulation Development. Beyond preclinical evaluation, our platform features a sophisticated formulation development capability to optimize drug delivery and enhance bioavailability. This includes platforms for:
 - o Oral solid dosage forms. We develop conventional oral dosage forms such as tablets, capsules, granules, and modified-release dosage forms including delayed release (KBP-3571), controlled release formulation to achieve a desired therapeutic objective or better patient compliance.
 - o Sterile injectable products. Our expertise extends to developing freeze-dried and sterile powder injection formulations, ensuring stability and ease of administration. We are currently utilizing these technologies to enhance our pipeline, including KBP-5081. These proprietary technologies empower us to develop innovative dosage forms tailored to the specific physicochemical properties of each API, enabling us to address unmet clinical needs and expand into new therapeutic indications.
 - o Novel drug delivery systems. A significant majority of APIs in development exhibit poor solubility, potentially limiting their therapeutic effectiveness. We have invested in developing proprietary formulation technologies to address this issue, including micronization (jet milling) and amorphous solid dispersions (ASDs) utilizing spray drying and solvent co-precipitation methods. These technologies are designed to enhance solubility and dissolution rates, ultimately aiming to improve bioavailability. Preclinical studies of our ASD technology have demonstrated significantly enhanced drug absorption profiles compared to conventional formulation approaches, suggesting the potential for improved bioavailability.

By adhering to the principles of Quality by Design, we proactively engineer quality into our formulations from the outset. This integrated, quality-driven drug development platform positions us to efficiently translate promising discoveries into safe and effective therapies for patients in need.

Biological Drug R&D Platform

Our biological drug R&D platform is designed to accelerate the transition of promising antibody candidates from discovery to clinical development. By seamlessly integrating lead candidate selection and optimization with comprehensive preclinical evaluation, the platform shortens development timelines without compromising scientific rigor. This adaptable platform accommodates a range of antibody formats, from traditional monoclonal antibodies to antibody-drug conjugates and bispecific antibodies. Our stringent, data-driven selection process, coupled with a commitment to analytical validation, ensures the identification of high-quality candidates with a greater likelihood of clinical success.

BUSINESS

We utilize a rigorous process to identify and refine high-impact therapeutic antibodies. This begins with validating the drug target and generating the corresponding antigen. Next, we immunize carefully selected animal models and screen the resulting antibodies for desirable characteristics. Promising candidates undergo comprehensive analysis, including assessments of their safety, efficacy, and drug-like properties. This culminates in the selection of a lead candidate with an optimized molecular structure for therapeutic development.

Once a lead candidate is chosen, we initiate a comprehensive preclinical development phase. This includes generating stable cell lines for antibody production and optimizing the manufacturing process. We prioritize the development and validation of robust analytical methods to ensure data quality and reliability. Our preclinical program generates a comprehensive data package, including stability profiles, structural characterization, toxicology assessments, and PK/PD studies.

The core capabilities of our biological drug R&D platform are highlighted by our Mebs-Ig and Mab-Edit technologies. These technologies allow us to engineer antibodies with enhanced therapeutic properties, offering new treatment options for patients with complex diseases.

- The Mebs-Ig technology. Our Mebs-Ig technology is designed for the development of highly potent bispecific antibodies. These innovative molecules can simultaneously bind to two distinct targets or engage different areas on the same target. This offers several advantages over traditional monoclonal antibodies, including broader targeting of complex disease mechanisms, enhanced efficacy through synergistic effects, and improved outcomes for patients who haven't responded well to single-target therapies. By leveraging our deep understanding of antibody structure and function, we can precisely engineer bispecific antibodies with optimized efficacy using techniques like glycoengineering, molecular linking, and toxin conjugation.
- The Mab-Edit technology. Our Mab-Edit technology focuses on enhancing the natural ability of antibodies to eliminate diseased cells. This technology allows us to modify the glycosylation patterns of antibodies produced in Chinese Hamster Ovary (CHO) cells, a standard production system for therapeutic antibodies. Specifically, our technology enables the complete and precise knockout of the FUT8 gene in CHO cells, leading to the production of antibodies with significantly reduced fucosylation. This modification strengthens the binding affinity of antibodies to natural killer (NK) cells, resulting in potent antibody-dependent cell-mediated cytotoxicity (ADCC) and increased tumor cell killing. The Mab-Edit technology offers several key advantages. It achieves near-complete FUT8 knockout, resulting in highly consistent production of afucosylated antibodies. Engineered cell lines demonstrate stable expression levels, exceeding 5g/L, representing a significant advancement in the field. Furthermore, this technology can be applied to develop various antibody therapies, including monoclonal, bispecific, and multispecific antibodies, for treating a range of diseases, including autoimmune diseases, hematological malignancies, and solid tumors. Our patented Mab-Edit technology is the only one of its kind approved in China, solidifying our leadership in this innovative field.

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Clinical Development Platform

We have built a robust and experienced clinical development team, with expertise encompassing a wide range of disciplines crucial for successful drug development. Our team comprises specialists in medical science, translational medicine, pharmacology, biostatistics and statistical programming, clinical operation, and pharmacovigilance. As of June 30, 2024, our clinical research team consisting of over 50 members has managed and advanced over 30 clinical trials over the past five years. Our clinical development team, led by our deputy general manager, Dr. Wang Li, ensures meticulous and efficient medical oversight for our clinical development programs. Their expertise also contributes to efficient and well-designed clinical trials. Moreover, their deep understanding of regulatory affairs and drug registration processes ensures efficient navigation of the complex regulatory landscape.

Our robust clinical development capabilities empower us to maintain stringent control over the R&D process, fostering efficiency and reliability. This control affords us greater flexibility in designing and adapting development strategies to align with evolving scientific insights and regulatory requirements. This agility enables us to advance clinical development with speed and excellence, ultimately accelerating the delivery of innovative therapies to patients in need. For example, by leveraging quantitative pharmacology to support our dose selection for phase 3 study of XZP-5695, we were able to implement a streamlined development pathway that enabled us to advance directly from phase 1 to phase 3 clinical trials. This strategic decision resulted in significant time and resource savings, underscoring our commitment to efficient and cost-effective drug development.

RESEARCH AND DEVELOPMENT

We recognize research and development as essential to our continued growth and ability to compete effectively in the global biopharmaceutical market. Our established in-house R&D capabilities, structured around three technology platforms, allow us greater control and oversight of our research process. This approach also reduces our dependence on external CROs, contributing to increased quality control and efficiency within our drug development programs. For details regarding our R&D platforms, please see “— Our Technology Platforms” above.

We conduct our research and development activities primarily through an in-house R&D team, and engage CROs from time to time to support our preclinical research and clinical trials. During the Track Record Period, we incurred research and development expenditure (including research and development expenses and capitalized research and development costs recorded as intangible assets) of RMB567.5 million, RMB383.9 million, RMB220.6 million, and RMB125.4 million in 2022, 2023 and the six months ended June 30, 2023 and 2024, respectively. In 2022, 2023 and the six months ended June 30, 2024, our research and development expenditure incurred for Core Products were RMB304.8 million, RMB253.4 million, and RMB89.6 million, representing 53.7%, 66.0%, and 71.4% of our total research and development expenditure, respectively. We expect that our expenditure in relation to R&D activities will continue to be significant in line with the future growth of our business.

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In-house R&D

Our R&D team comprises experienced scientists and researchers with a background in drug development. Many team members have previously held positions at established biopharmaceutical companies, bringing valuable knowledge across various stages of the drug development process. As of June 30, 2024, our R&D team, led by Dr. Li Jia Kui and Dr. Wang Li, comprised over 110 highly qualified professionals, with approximately 50% holding a master’s degree or higher, including 12 doctorates, reflecting the team’s strong academic foundation in medical science, pharmacology, biology, and chemistry.

We maintain a systematic and well-structured approach to R&D activities. Our R&D strategy and direction are guided by our experienced management team, ensuring alignment with our overall goals and objectives. To ensure effective leadership and project management, we invest in training and development opportunities for our personnel. We also foster a collaborative and expertise-driven environment by providing ongoing technical guidance and support within our Group. This structured approach, combined with our focus on developing expertise and fostering collaboration, enables us to efficiently manage our R&D initiatives and drive innovation from inside.

Our streamlined and integrated approach to drug development ensures rapid translation of promising drug candidates from preclinical research to clinical trials and accelerates overall program timelines. This is exemplified by our ability to launch clinical development activities within approximately three to six months of IND submission, initiate site activation within approximately one month of IND approval, and achieve first-patient-in for phase 3 trials within approximately two months of study approval. Furthermore, our efficient processes enable us to submit NDA documentation within approximately two months of obtaining positive topline results, underscoring our commitment to delivering novel therapies to patients with urgency.

R&D Facilities

As of the Latest Practicable Date, our R&D activities were primarily conducted in Jinan and Beijing in China. Our Jinan facilities is home to our small molecule drug R&D platforms and research laboratories, which are equipped with state-of-the-art equipment and workspace to support our small molecule drug discovery, preclinical and clinical needs. In addition, we have established our Beijing Clinical Center, where we conduct the R&D of biologics. With the collective efforts of our Jinan and Beijing team, we are able to efficiently manage our drug development plan, clinical protocol design, regulatory affairs and clinical operation across China.

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Collaboration with CROs

In addition to our in-house R&D activities, we also collaborate with reputable CROs to manage, conduct, and support our preclinical research and clinical trials. The services they provide under our supervision include site management, patient recruitment, and pharmacovigilance for our clinical trials, as well as preclinical and clinical laboratory testing and other specialized tasks aligned with our needs.

We select CROs based on various factors, such as professional qualifications, research experience in the related fields, service quality and efficiency, industry reputation, and pricing competitiveness. Depending on the specific services required, we enter into project-based service agreements with our CROs that outline the detailed scope of work, sample size, procedures, deliverables, timelines, and payment terms. We closely supervise our CROs to ensure their performance in a manner that complies with our protocols and applicable laws, which in turn protects the integrity and authenticity of the data from our trials and studies.

Key terms of our agreements that we typically enter into with our CROs are set forth below.

- *Scope of Services.* Each agreement sets out the specific services to be provided by the CRO, such as clinical research coordination, clinical trial data management and statistical analysis, or other agreed-upon activities.
- *Terms.* We establish timelines and deliverables within the agreement to ensure timely completion of services. The CRO is obligated to adhere to these agreed-upon schedules.
- *Payment.* Payment schedules are mutually agreed upon and outlined in the agreement, specifying payment milestones and ensuring timely compensation for services rendered.
- *Confidentiality.* We prioritize the protection of confidential information. This is achieved through robust confidentiality clauses integrated into our master agreements or through separate, stand-alone confidentiality agreements.
- *Intellectual Property.* We retain full ownership of all intellectual property rights arising from the services provided.

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OUR LICENSE AND ASSET ACQUISITION ARRANGEMENTS

Our In-licensing and Asset Acquisition Agreements

Technology Transfer Agreement with Beijing Xuanyi for KM602

In January 2022, we entered into a technology transfer agreement with Beijing Xuanyi PharmaSciences Co., Ltd. (“Beijing Xuanyi”). Pursuant to this agreement, Beijing Xuanyi agreed to transfer us its intellectual property and know-how in relation to KM602, a CD80 fusion protein candidate then in the drug discovery stage. Beijing Xuanyi shall provide us (i) all technology materials pertaining to preclinical studies and, if applicable, for the purpose of an IND application; and (ii) necessary assistance in transferring the underlying patents and patent applications. In consideration of this agreement, we agreed to pay a total of RMB39.0 million, all of which had been fully paid as of the Latest Practicable Date. Pursuant to this agreement, all the inventions and other intellectual property conceived, generated or developed in the subsequent development process of KM602, shall solely owned by us.

Agreement with SignalChem to In-license XZB-0004

In September 2021, we entered into a license and cooperation agreement with SignalChem Lifesciences Corporation (“SignalChem”), to in-license certain patents and know-how owned by SignalChem relating to XZB-0004. SignalChem, an Independent Third Party, is a Canada-based clinical-stage biotechnology company that is developing a pipeline of small-molecule drugs to overcome therapeutic refractoriness and resistance in modern cancer medicines.

Pursuant to the terms of this agreement, we have been granted a license by SignalChem for the utilization of its current and future-created intellectual property and know-how pertaining to a specific AXL inhibitor (the “Licensed IP”). This license confers upon us the exclusive right to develop, manufacture, and commercialize products containing the AXL inhibitor (the “Licensed Product(s)”) within the territory of Greater China. Furthermore, we retain the right to sub-license these rights to third parties. SignalChem retains the right to manufacture products containing the AXL inhibitor within the territory of Greater China, but solely for our benefit and in accordance with the provisions stipulated within this agreement or a separate supply agreement. As of the Latest Practicable Date, XZB-0004 was the only Licensed Product under this agreement.

We shall bear all the development, manufacturing, and commercialization-related expenses for the Licensed Products and are responsible for the preparation and submission of the requisite regulatory filings, to the extent such activities are within the scope of the license. SignalChem shall use commercially reasonable efforts to provide necessary assistance in the process. We and SignalChem have established a joint steering committee to support and oversee the overall coordination and oversight of the activities under this agreement. The joint steering committee shall endeavor to make decisions by consensus. If consensus is not reached by the joint steering committee, senior executives from both parties shall engage in

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consultation and decision-making. If the senior executives are unable to reach a consensus, we shall have the final decision-making authority regarding whether to initiate and/or conduct a clinical trial in Greater China, and SignalChem shall have the sole authority to make the final decision with respect to any aspects of manufacturing by itself for the development of the Licensed Products in Greater China.

In partial consideration of this agreement, we have paid a one-time and non-refundable upfront fee of US\$13.0 million (tax-inclusive). SignalChem may receive from us, for each Licensed Product, (i) up to US\$38.0 million, payable by installments upon the achievement of specified development and regulatory milestones for the first indication, (ii) up to US\$15.0 million, payable by installments upon the achievement of specified development and regulatory milestones for each additional indication, and (iii) tiered one-time and non-refundable payments upon the achievement of cumulative net sales milestones which occurs within the valid claim term of the Licensed Product. Upon commercialization, SignalChem is eligible to receive tiered royalties at a percentage not exceeding mid-teens on the annual cumulative net sales of the Licensed Product(s) in Greater China, subject to certain adjustments under specific circumstances. As of the Latest Practicable Date, we had paid a total of US\$13.0 million.

Except that the intellectual property rights and know-how assigned by CROs in the case of employing certain CROs in our development process, shall be deemed our intellectual property rights and know-how, all the other intellectual property rights and know-how conceived, made or acquired, either by SignalChem or by or on behalf of us, in the performance of this agreement, shall be owned by SignalChem.

Unless terminated earlier pursuant to its terms, the agreement will remain in effect until the later of (i) the expiration of the license term or (ii) the tenth anniversary of the first commercial sale of the latest in time Licensed Product in Greater China, with a possibility of extension of two years. SignalChem is entitled to early termination upon a written notice in the event that we fail to make the first commercial sale of the Licensed Product for any indication in Greater China within ten years from the effective date of this agreement. We are able to terminate this agreement without any cause, by a 60 days' prior written notice to SignalChem. Either party may terminate this agreement in the event of (i) the other party's uncured material breach of this agreement, or (ii) the other party's liquidation, dissolution, bankruptcy, winding-up or similar insolvency proceedings.

Any dispute arising from or in connection with this agreement shall be first settled through friendly negotiation between the parties. If the dispute cannot be resolved, the dispute shall be submitted to the Singapore International Arbitration Centre for final resolution.

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Our Asset Transfer and Out-licensing Agreements

Technology Transfer Agreement with Beijing Huizhiheng for XZP-5695

In August 2020, we entered into a technology transfer agreement (as amended and supplemented in July 2021) with Beijing Huizhiheng Biotechnology Co., Ltd. (“Beijing Huizhiheng”), one of our related parties. Under this agreement, we transferred our intellectual property and know-how in relation to XZP-5695, a janagliflozin candidate then in phase 3 clinical stage, to Beijing Huizhiheng. Our responsibilities include providing (i) all technology and regulatory materials related to preclinical studies and clinical trials; and (ii) necessary assistance in transferring the underlying intellectual property, including patents, patent applications and trademarks. Beijing Huizhiheng is responsible for the subsequent phase 3 clinical development, NDA submission, manufacturing and commercialization of XZP-5695. All inventions and intellectual property conceived, generated or developed in the subsequent development process, shall solely owned by Beijing Huizhiheng. In the event of a breach of contract, the breaching party is subject to liquidated damages as specified in this agreement. Disputes will be settled through friendly negotiation, and if unresolved, will be submitted to the Beijing Arbitration Commission for final resolution.

The agreement stipulates that we shall not amend existing agreements with certain CRO service providers. We are responsible for fee payment on behalf of Beijing Huizhiheng, but Beijing Huizhiheng assumes all responsibilities under these agreements. Beijing Huizhiheng and we shall enter into supplementary agreements with other third-party service providers to transition contractual rights and obligations from us to Beijing Huizhiheng (the “Transitional Arrangement”).

In consideration of this technology transfer, Beijing Huizhiheng agreed to pay a lump-sum of RMB212.4 million (tax-inclusive), including advanced payments for the Transitional Arrangement which were subject to adjustment based on actual conditions. As of the Latest Practicable Date, we had received a total of RMB229.0 million. In addition, we are eligible to receive tiered royalties on the annual net sales of XZP-5695, until the expiration of key patents.

Transfer of Interests and Collaboration Agreement with SL Pharm for KM118

In August 2016, Beijing Combio Pharmaceutical Inc. (“Combio”) entered into a transfer of interests and collaboration agreement (the “2016 Agreement”) with Beijing SL Pharmaceutical Co., Ltd. (“SL Pharm”), for the manufacturing and commercialization of KM118, a pertuzumab biosimilar candidate. In April 2021, we, together with our wholly-owned subsidiary, Beijing Xuanzhu Combio Biotechnology Co., Ltd. (“Xuanzhu Combio”), signed an asset acquisition agreement with Combio and Combio’s controlling shareholder, to acquire Combio’s biologics business, including relevant assets, liabilities and labor relationships (the “2021 Asset Acquisition”). As part of this transaction, an amendment to the 2016 Agreement (collectively with the 2016 Agreement, the “Pertuzumab Agreement”) was signed by Combio, SL Pharm, and Xuanzhu Combio in April 2021. This amendment transferred all of Combio’s rights and obligations under the 2016 Agreement to us.

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Pursuant to the Pertuzumab Agreement, we are responsible for conducting preclinical studies and preparing IND documentation. SL Pharm is then responsible for submitting the IND application, obtaining IND approval, conducting clinical trials, submitting the NDA and obtaining NDA approval, as well as manufacturing and commercialization of KM118.

The Pertuzumab Agreement remains in effect until all obligations are fulfilled. SL Pharm can terminate the agreement if NDA is not obtained due to our technical defects. Disputes will be settled amicably; otherwise, litigation will occur in the PRC court where the plaintiff is situated.

Following the 2021 Asset Acquisition, we are eligible to receive future milestone payments up to an aggregate amount of RMB1.5 million. As of the Latest Practicable Date, we had not received any milestone payments. Upon commercialization, we will receive single-digit royalties on annual cumulative sales for five years. If KM118 is among the first three approved pertuzumab biosimilars in mainland China, we will be able to receive a one-time incentive fee of RMB2.0 million.

Out-licensing and Collaboration Agreements with SPH New Asia for KBP-5081 and XZP-P803

In June 2022, we entered into two out-licensing and collaboration agreements with Shanghai SPH New Asia Pharmaceutical Co., Ltd. (“SPH New Asia”), to out-license certain patents and know-how owned by us relating to (i) KBP-5081, a Class 1 innovative benapenem candidate that had then completed the phase 2 trial (the “Benapenem Agreement”), and (ii) XZP-P803, a plazomicin candidate of which underlying patents and know-how were transferred from a Controlling Shareholder to us in 2021 and held by us without development until our subsequent out-licensing (the “Plazomicin Agreement”).

Under these agreements, we granted SPH New Asia an exclusive, perpetual, irrevocable, royalty-bearing and sublicensable license to develop, manufacture, commercialize or exploit KBP-5081 and XZP-P803 (including APIs and injections) and related products (the “Benapenem Products” and the “Plazomicin Products,” collectively, the “Licensed Products”) in Greater China (the “Licensed IP”). We will provide SPH New Asia with technical supports for its subsequent development and manufacturing activities. SPH New Asia will bear all development, manufacturing and commercialization expenses. However, we agreed to voluntarily contribute 25% of third-party R&D expenses for the phase 3 trial of the KBP-5081, up to RMB15.0 million. Joint steering committees will oversee activities under these agreements. SPH New Asia owns all intellectual property and know-how arising from the research, development and commercialization of the Licensed Products. We retain ownership of the Licensed IP but grant SPH New Asia an exclusive license to use it for developing, manufacturing and commercializing the Licensed Products. These agreements will remain in effect until the expiration of relevant royalty terms. Either party is entitled to early termination in the event of (i) the other party’s uncured material breach of these agreements, or (ii) the other party’s bankruptcy. Disputes will be solved through amicable negotiation. If the dispute cannot be resolved amicably within 60 days, either party may initiate legal proceedings, the result of which shall be final and binding upon both parties.

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Pursuant to the Benapenem Agreement, we are entitled to receive upfront fees totalling RMB14.0 million, which consist of (i) RMB4.0 million upon signing the Benapenem Agreement, and (ii) RMB10.0 million upon reaching a written consensus with the CDE regarding the phase 3 trial protocol. We may receive milestone payments up to RMB30.0 million based on development and regulatory milestones and up to RMB222.0 million based on sales milestones. As of the Latest Practicable Date, we had received upfront fees of RMB4.0 million under the Benapenem Agreement. SPH New Asia also agrees to pay us tiered royalties ranging from mid-single-digit to low-double-digit percentages on annual net sales, subject to adjustments, until the earlier of (i) three or more generic drugs approvals in Greater China; or (ii) ten years from the effective date of the Benapenem Agreement.

As partial consideration of the Plazomicin Agreement, we had received upfront fees of RMB7.0 million. We are eligible to receive milestone payments up to RMB19.0 million based on development and regulatory milestones and up to RMB148.0 million based on future sales milestones. As of the Latest Practicable Date, we had not received any milestone payments under the Plazomicin Agreement. SPH New Asia also agrees to pay us tiered royalties ranging from mid-single-digit to low-double-digit percentages on annual net sales, subject to adjustments, until the earlier of (i) three or more generic drugs approvals in Greater China; or (ii) ten years from the effective date of the Plazomicin Agreement.

Out-licensing and Technology Transfer Agreement with Livzon for XZP-5849

In June 2024, we entered into an out-licensing and technology transfer agreement with Livzon Group Livzon Pharmaceutical Factory (“Livzon”) to grant certain patents, know-how and interests related to XZP-5849, a PDE5 inhibitor candidate to Livzon. Livzon, an Independent Third Party, is the core production base of Livzon Pharmaceutical Group Inc. for producing chemical and biochemical preparations.

Pursuant to this agreement, we granted Livzon an exclusive, royalty-bearing, and sublicensable license to use our patents covering XZP-5849 (the “Licensed IP”) in Greater China and other targeted territories specified in the agreement (the “Licensed Territories”). We also agreed to transfer all rights and interests related to XZP-5849 in the Licensed Territories (other than the Licensed IP) to Livzon. This includes, but is not limited to, relevant know-how and rights to develop, manufacture, commercialize, or exploit XZP-5849 or related products (collectively, the “PDE5 Product(s)"). We will provide Livzon with all technology and regulatory materials related to preclinical studies and clinical trials, and necessary assistance for the transfer. Livzon is responsible for subsequent development, manufacturing, and commercialization activities at its own cost. Intellectual property and know-how jointly generated, developed, or conceived by both parties during this agreement are co-owned by Livzon and us.

This agreement will remain in effect until the later of: (i) the expiration of the royalty term; or (ii) the expiration of the Licensed IP. If any identified druggability issues—arising from causes other than the failure of subsequent clinical trials—cannot be solved through negotiation and verification, Livzon may terminate this agreement. Any milestone payments we received will be returned to Livzon. Livzon may also terminate this agreement without cause

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by providing three months' prior written notice. We may terminate this agreement with three months' prior written notice if Livzon fails to initiate any PDE5 Product development within two years from the effective date of this agreement. Either party may terminate this agreement if: (i) the other party materially breaches this agreement and fails to cure the breach; or (ii) the other party undergoes liquidation, dissolution, bankruptcy, winding-up, or similar insolvency proceedings. Any dispute arising from or related to this agreement will first be settled through friendly negotiation between the parties. If the dispute cannot be resolved through negotiation, it will be submitted for litigation in the PRC court where the plaintiff is situated.

Livzon paid us upfront fees of RMB7.0 million. We are eligible to receive future milestone payments up to RMB43.5 million based on development and regulatory milestones, subject to certain adjustments. As of the Latest Practicable Date, we had received RMB7.0 million in milestone payments. Livzon will also pay us tiered royalties of single-digit percentages on the annual net sales of PDE5 Products, subject to certain reduction arrangements, until the earlier of: (i) the tenth anniversary of the first commercial sale of the PDE5 Products in Greater China and other targeted territories; or (ii) the latest expiration date of patents covering the chemical structure of PDE5 Products in Greater China.

COMMERCIALIZATION

Our commercial strategy is built on a flexible, tailored approach designed to maximize the strengths of each product and target market. This involves strategically leveraging external partnerships while simultaneously building a high-performing internal sales force. We believe in adapting our approach to the unique dynamics of each therapeutic area.

As of the Latest Practicable Date, we had one commercialized product, KBP-3571. In addition, our XZP-3287, as a monotherapy and in combination therapy with fulvestrant, is anticipated to obtain NDA approval from the NMPA in the first half of 2025.

With the successful commercialization of KBP-3571, and in anticipation of the approval of other late-stage assets, we have established a solid foundation for a commercialization system tailored to our key therapeutic areas that will have synergistic benefits for future products:

- ***Digestive Disease Drugs.*** Recognizing the importance of broad market coverage for chronic disease drugs in this relatively mature market, we have prioritized building a wide distribution network to mobilize the resources of experienced distributors and rapidly ramp up sales coverage. By leveraging our distributors' channels, we are able to effectively capture market share while maintaining cost efficiency. Since the approval of KBP-3571 in June 2023, our lean in-house sales team consisting of over 30 members has built a 70+ distributor network to cover over 600 hospitals nationwide in China as of the Latest Practicable Date, with further growth expected as we ramp up sales. Moreover, with the specialized experience of our in-house commercialization team in digestive disease, we have been able to successfully include KBP-3571 in the NRDL since the beginning of 2024, substantially increasing its accessibility at scale.

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- ***Oncology Drugs.*** For our rich oncology drug pipeline, we are adopting a dual-pronged “market + medical” strategy, focused on academic promotion to highlight the distinguishing features of our drugs and drug candidates that address unmet clinical needs. We are actively participating in academic conferences and publishing our findings and data in scientific journals, as well as conducting market education for our drugs candidates. In anticipation of commercialization of XZP-3287 in 2025, we are building and optimizing our commercialization team with a focus on market, medical science, distribution management and retail sales experience. We have also established detailed and tailored sales and marketing strategies for XZP-3287, including the selection of distributors across major hospitals. We are actively seeking and enhancing our cooperation with distributors nationwide, which we believe will actively drive our distribution network build-up nationwide going forward.

MANUFACTURING

We currently outsource the production of our approved drug to industry recognized CDMOs in China, and we intend to continue doing so in the near future. We believe it is cost-effective and efficient to engage CDMOs for manufacturing activities as it reduces the capital expenditure required for setting up and maintaining the necessary production lines, and allows us to focus on the clinical development of our pipeline drugs.

We select CDMOs by taking into account a number of factors, such as their manufacturing capacity and qualifications, geographic proximity and track record, as well as applicable regulations and guidelines. We maintain rigorous quality control throughout our manufacturing process to ensure the production of safe and effective therapies. This is achieved through comprehensive quality agreements with our CDMOs, regular on-site audits and inspections, batch-by-batch monitoring of drug product manufacturing and testing, thorough review of all manufacturing and testing documentation, and independent sample testing of finished products.

Following a rigorous consultation and bidding process, we enter into formal agreements with the selected CDMOs. Key terms of our agreements that we typically enter into with our CDMOs are set forth below.

- ***Services.*** The CDMO provides us with manufacturing services according to the types of deliverables, location, unit price, volume and requested delivery date specified by us.
- ***Payments.*** We are required to make payments to the CDMOs in accordance with the payments schedule set forth in the agreement, which is typically linked to the stages of the manufacturing process and the deliverables we receive.
- ***Intellectual property rights.*** We own all intellectual property rights arising from the outsourced manufacturing processes.
- ***Remedies for non-conforming products.*** We are entitled to remedies for products that fail to conform to our specifications. The CDMOs are required to replace the non-conforming products.

For risks relating to CDMOs, see “Risk Factors — Risks Relating to Dependence on Third Parties — We currently rely on third parties to manufacture our drug products for clinical development and commercial sales. Our business could be harmed if these third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality or price levels.”

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QUALITY CONTROL

We place the utmost importance on patient safety and product quality. As of June 30, 2024, our quality management team comprised 14 members, including six overseeing the manufacturing process of our drugs and eight overseeing our preclinical studies and clinical trials. They oversee the quality systems covering all key stages of our drug development process, from R&D, manufacturing to commercialization, including discovery, preclinical research and discovery, clinical trials, procurement, supply chain, process development, production, warehousing, delivery and recalls.

We demonstrate our commitment on product quality through a robust Quality Management System (QMS) that governs every stage of our operations. This system adheres to Good Manufacturing Practices (GMP) and is meticulously documented through comprehensive Standard Operating Procedures (SOPs).

As the product quality begins with supplier selection, we maintain a rigorous supplier qualification program. This program includes thorough audits of potential suppliers, formal quality agreements outlining specific requirements, and ongoing performance monitoring to ensure consistent adherence to our standards.

We carefully select CDMOs to ensure that our manufacturing processes take place in controlled environments specifically designed to minimize risks and maintain product integrity. We utilize validated manufacturing processes, conduct rigorous in-process controls, and perform comprehensive finished product testing to ensure every batch meets our stringent quality standards.

We are dedicated to continuous improvement and regularly evaluate our processes to identify opportunities for enhancement. This includes analyzing data for trends, conducting thorough investigations of deviations, implementing corrective and preventive actions, and managing change through a formal system to prevent quality compromises.

Through these measures, we strive to deliver products that consistently meet the needs of our patients and exceed industry expectations.

SALES NETWORK

To ensure our products reach patients efficiently, we are dedicated to building a robust sales network, which includes selectively partnering with distributors and building an in-house sales team. In selecting distribution partners, we primarily focus on companies that have a proven track record in our target markets, strong regional presence, and dedicated sales teams. Our distribution network is managed by our in-house sales team, which is also responsible for developing and executing our market strategy, including product positioning, market access initiatives, and promotional activities.

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Distributor Network

We primarily operate a seller-buyer model with our distributors, who then distribute our drugs to hospitals and pharmacies. As of June 30, 2024, we had over 70 distributors, covering a network of over 600 hospitals nationwide in China. During the Track Record Period, we have maintained good business relationships with our key distributors. We believe our distributorship model is in line with the industry form. The following table sets forth the total number of distributors to whom we directly sold our products and their movement during the Track Record Period:

	Year ended December 31,		Six Months ended
	2022	2023	June 30, 2024
Number of distributors at the beginning of the period	–	–	3
Number of new distributors during the period	–	3	71
Number of discontinued distributors during the period	–	–	–
Number of increased (decreased) distributors during the period	–	3	71
Number of distributors at the end of the period	–	3	74

Management of Distributors

We consider several factors in our distributor selection process, including the scale and geographical coverage of their existing distribution networks, their reputation and industry track record, their compliance history, the types of pharmaceutical products they already sell, their delivery capabilities, the number and geographic coverage of their distribution centers and warehouses, and their financial conditions and creditworthiness.

To ensure our sales to distributors reflect genuine market demand and an orderly sales and distribution market for our products, we primarily rely on our distribution agreements, policies, and monitoring measures to manage our distribution network. If we discover any potential non-compliance issues with a distributor, we address them directly with the distributor in question. We investigate the issue and request the distributor to cease the problematic activities within a specified period. Any non-compliance would entitle us to terminate the corresponding distribution agreement and to claim compensation for any losses caused by the breach. We did not have to terminate any distributors during the Track Record Period due to breaches of their distribution agreements or other non-compliance incidents.

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During the Track Record Period, to the best of our Directors' knowledge, all of our distributors were Independent Third Parties, and none of them was wholly-owned or majority controlled by our former employees. None of our Directors or their respective associates or any shareholder of our Company who, to the knowledge of our Directors, owns more than 5% of the issued share capital of our Company, have any interest in any of these distributors, and none of our Directors or their respective associates and our Controlling Shareholders have any present or past relationship (other than their relationship through our Group) with any of these distributors. In addition, to our best knowledge, there was no past or present relationship or arrangement, including family, business, financing, guarantee or otherwise, between us and our distributors during the Track Record Period.

Inventory Management

We actively manage inventory levels across our distribution network to maintain optimal product availability while minimizing excess stock. Our comprehensive inventory management system includes monitoring of distributor stock levels and the requirement for distributors to report sales amount. We also intend to establish target inventory ranges based on historical demand patterns and forecasted hospital needs. We conduct reviews with our distributors to assess their inventory positions and work closely with them to optimize order quantities and delivery schedules. Through our distributor management policies, we maintain visibility of inventory movement and implement measures to prevent overstocking, ensuring efficient distribution channel operations while maintaining product quality and stability.

Prevention of Cannibalization

We maintain strict control over our distribution network to prevent unauthorized sales or cannibalization. Our distributor agreements clearly define authorized sales territories and strictly prohibit cross-region sales. We outline a clear schedule of penalties for violations, up to and including termination of the distributorship. Any suspected instances of unauthorized cross-region sales would be promptly investigated in a timely manner, and appropriate action would be taken to uphold the integrity of our distribution network.

Reinforcing this commitment to controlled distribution, we have implemented a robust track-and-trace system for all products. Before leaving our facilities, each package is scanned, creating a traceable record of its intended destination. We require our distributors to maintain this chain of custody through scanning upon receipt and distribution, providing us with regular updates on product flow. Our sales team conducts periodic audits to verify the accuracy of this data and ensure compliance. During the Track Record Period and as of the Latest Practicable Date, we were not aware of any material cannibalization or competition among our distributors within the same geographical area. We believe that the above measures are sufficient to address potential cannibalization and competition among distributors.

Summary of Key Terms of Distribution Agreements

We engage our distributors through distribution agreements that vary in terms depending on the type of distributor. Most of our distributors, who maintain their own sales channels, are usually granted the right to distribute KBP-3571 under long-term agreements. Each order they place is governed by a standard sales contract that outlines the purchase quantity, pricing, and payment terms. On the other hand, we also partner certain distributors that primarily focus on the distribution of our products while we cultivate and maintain relationships with hospitals. With these distributors, we typically enter into shorter-term agreements tailored to streamline the distribution process. Our standard practice for processing and shipping orders is upon receipt of both the purchase order and full payment.

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Key terms of our standard distribution agreement include:

- *Duration.* Our standard distribution agreement typically has a term of five years.
- *Lump-sum fee.* Our distributors are required to make an upfront, lump-sum payment upon execution of the distribution agreement. The lump-sum fee is generally non-refundable, except in cases where the distributor is unable to continue sales due to factors attributable to us or if the agreement is terminated prematurely.
- *Minimum purchase amounts.* Distribution agreements mandate a mutually agreed upon minimum purchase volume for the first year. We monitor distributor performance and reserve the right to assist with marketing activities should a distributor fall short of its target. Annual purchase targets are renegotiated during the final month of each contract year.
- *Prices.* While the NRDL establishes a ceiling price for included drugs like KBP-3571, we determine the specific selling price to distributors through mutual agreement. These prices are consistent nationwide and are set forth in each of the sales contracts.
- *Reporting of complaints and adverse events.* Distributors are responsible for promptly reporting to us upon their awareness of any adverse events or other safety-related issues which may be related to our products.
- *Product return.* Generally, our distributors are permitted to return products to us only if there are quality defects.
- *Termination.* These agreements typically have customary termination provisions, such as for breaches that are not remedied after notice. These agreements are typically not automatically renewable.

Pricing

During the Track Record Period and up to the Latest Practicable Date, we had only one commercialized drug, KBP-3571. While the end-market price of KBP-3571 was set by the price guidance after its inclusion in NRDL, we sell KBP-3571 to our distributors at a mutually agreed upon price. When determining the price of KBP-3571 sold to distributors, we take into account factors such as our products’ advantages, our costs, prices of competing products, and differences in features between our products and competing products. In addition, we expect the end-market price of XZP-3287, which is anticipated to launch in 2025, to also be set by the price guidance as we will strive for its inclusion in the NRDL.

We have not formulated any definitive pricing policy for our other drug candidates yet. When our drug candidates progress to commercialization in the future, we will determine their prices based on various factors, such as current medical needs, our drugs’ pharmacoeconomic evaluation, our production costs, prices of prior line treatment options, competitive landscape and prices of competing drugs (if any), and differences in features between our drugs and competing drugs. We will conduct extensive market research before pricing our drugs.

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CUSTOMERS

During the Track Record Period, our customers were mainly distributors. See “— Sales Network” above.

Revenue generated from our five largest customers for the year ended December 31, 2023 and the six months ended June 30, 2024 amounted to RMB28.6 thousand and RMB6.7 million, representing approximately 100.0% and 42.1% of our total revenue for the respective year/period, respectively. We did not generate revenue for the year ended December 31, 2022. Revenue generated from our largest customer for the year ended December 31, 2023 and the six months ended June 30, 2024 amounted to RMB12.7 thousand and RMB2.6 million, representing approximately 44.5% and 16.2% of our total revenue for the respective year/period, respectively.

The following table sets forth details of our five largest customers during the Track Record Period:

Customer	Background	Product Sold	Commencement of Business Relationship	Credit Terms	Revenue Contribution <i>(RMB'000)</i>	Percentage of Total Revenue
<i>For the six months ended June 30, 2024</i>						
Customer A	A China-based company primarily engaged in wholesale distribution of pharmaceuticals and medical devices	Anaprazole	2023	0-45 days	2,600.8	16.2%
Customer B	A China-based company primarily engaged in wholesale distribution of pharmaceuticals and medical devices	Anaprazole	2023	Advance payment before delivery	1,518.6	9.5%
Customer C	A large pharmaceutical and healthcare group based in China, mainly engaged in pharmaceutical development, manufacturing and distribution, as well as healthcare services	Anaprazole	2023	0-7 days	942.0	5.9%
Customer D	A China-based company primarily engaged in wholesale distribution of pharmaceuticals and medical devices	Anaprazole	2023	Advance payment before delivery	844.8	5.3%
Customer E	A China-based company primarily engaged in wholesale distribution of pharmaceuticals and medical devices	Anaprazole	2023	Advance payment before delivery	834.4	5.2%
Total					<u>6,740.6</u>	<u>42.1%</u>

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Customer	Background	Product Sold	Commencement of Business Relationship	Credit Terms	Revenue Contribution <i>(RMB'000)</i>	Percentage of Total Revenue
<i>For the year ended December 31, 2023</i>						
Jiangxi Hui Ren Pharmaceutical Trade Co., Ltd. (江西匯仁醫藥貿易有限公司)	A China-based company primarily engaged in wholesale distribution of pharmaceuticals and medical devices	Anaprazole	2023	Advance payment before delivery	12.7	44.5%
Fuzhou Pientzhuang Honest Medicine Co., Ltd. (福州片仔癀宏仁醫藥有限公司)	A China-based company primarily engaged in wholesale distribution of pharmaceuticals and medical devices	Anaprazole	2023	Advance payment before delivery	11.2	39.2%
Customer F	A China-based company primarily engaged in wholesale distribution of pharmaceuticals and medical devices	Anaprazole	2023	Advance payment before delivery	4.7	16.3%
Total					<u>28.6</u>	<u>100.0%</u>

None of our Directors, their associates or any Shareholders who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, had any interest in any of our five largest customers during the Track Record Period.

INTELLECTUAL PROPERTY

Intellectual property rights are important to the success of our business. Our future commercial success depends, in part, on our ability to obtain and maintain patent and other intellectual property and proprietary protection 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.

BUSINESS

We have a global portfolio of patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we (i) owned 84 issued patents in China, and 79 issued patents in the U.S. and other jurisdictions, and (ii) filed 46 published patent applications in China, and 53 published patent applications in the U.S. and other jurisdictions relating to certain of our drug assets and platform technologies, which we consider material to our business operations. The patents granted to, or under application by, our Company cover all material aspects of our Core Products.

As of the Latest Practicable Date, with respect to our three Core Products, KBP-3571, XZP-3287 and XZP -3621, we owned 15 issued patents in China, five issued patents in the U.S. and 22 issued patents in other jurisdictions, as well as 21 patent applications, including 12 in China, two in the U.S. and seven in other jurisdictions. The following table summarizes the details of the material granted patents and patent applications in connection with our Core Products. For details, please see “Appendix VI — Statutory and General Information — Further Information about Our Business — Intellectual Property Rights — Patents.”

Scope of Patent Protection	Category	Patent/Application Number	Jurisdiction	Patent Holder/ Applicant	Expiration Year
KBP-3571					
An enteric-coated tablet of an andazole sodium and a method of preparing thereof	Invention	ZL202210159337.1	PRC	Beijing Xuanzhu	2042
A method of preparing anandazole	Invention	ZL202110746758.X	PRC	Beijing Xuanzhu	2041
Benzimidazole derivatives and pharmaceutical compositions and uses thereof	Invention	EP2532665	Europe	Shandong Xuanzhu	2031
		HK1177933	Hong Kong	Shandong Xuanzhu	2031
		JP5948252	Japan	Shandong Xuanzhu	2031
		US9315513B2	the United States	Shandong Xuanzhu	2032
An enteric-coated tablet of anaprazole sodium and a preparation method thereof	Invention	ZL201180006795.1 TW112106544	PRC Taiwan	Beijing Xuanzhu Beijing Xuanzhu	2031 N/A*
XZP-3287					
A pharmaceutical composition for the prevention and/or treatment of cancer	Invention	ZL202110021418.0	PRC	Our Company and Shandong Xuanzhu	2041
		ZL202110021508.X	PRC	Our Company and Shandong Xuanzhu	2041
Benzimidazole derivatives and pharmaceutical compositions and uses thereof	Invention	RU2670762C2	Russia	Our Company	2034
Crystallization of inhibitors targeting serine/threonine kinases.	Invention	ZL201910470296.6	PRC	Our Company	2039

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Scope of Patent Protection	Category	Patent/Application Number	Jurisdiction	Patent Holder/ Applicant	Expiration Year
Crystal form targeting CDK4/6 kinase inhibitor	Invention	AU2018404690	Australia	Our Company	2038
		CA3089243C	Canada	Our Company	2038
		EA042455B1	Russia	Our Company	2038
		EP3747880	Europe	Our Company	2038
		HK40033772	Hong Kong	Our Company	2038
		JP6972390	Japan	Our Company	2038
		KR102531772	Korea	Our Company	2038
		US11299474B2	the United States	Our Company	2038
		ZL201910077459.4	PRC	Our Company	2039
		ZL201880087850.6	PRC	Our Company	2038
Kinase inhibitor and uses thereof.	Invention	AU2014375500	Australia	Our Company	2034
		CA2935103C	Canada	Shandong Xuanzhu	2034
		EP3091008	Europe	Our Company	2034
		HK1223089	Hong Kong	Our Company	2034
		JP6263269	Japan	Our Company	2034
		KR101787680	Korea	Shandong Xuanzhu	2034
		US9796701B2	the United States	Our Company	2034
		US9949976B2	the United States	Our Company	2034
		ZL201480065837.2	PRC	Our Company	2034
		ZL201910893109.5	PRC	Shandong Xuanzhu and our Company	2039
Novel uses of kinase inhibitors.	Invention	ZL202080033803.0	PRC	Shandong Xuanzhu and our Company	2040
Uses of kinase inhibitors	Invention	CN202210773530.4	PRC	Our Company	N/A*
A novel use for a kinase inhibitor	Invention	CN202180085717.9	PRC	Our Company and Shandong Xuanzhu	N/A*
A pharmaceutical composition for the treatment of cancer	Invention	CN202280068953.4	PRC	Our Company	N/A*
		US18/270,495	the United States	Our Company and Shandong Xuanzhu	N/A*
A pharmaceutical composition for the treatment of prostate cancer	Invention	CN202410509102.X	PRC	Our Company	N/A*
CDK kinase selective inhibitors	Invention	CN202410509103.4	PRC	Our Company	N/A*
Pharmaceutical compositions of CDKs inhibitors and methods of preparing the same	Invention	CN202311534116.9	PRC	Our Company	N/A*
		PCT/CN2023/132177	PCT	Our Company	N/A*
		TW112144492	Taiwan	Our Company	N/A*
Preparation of benzimidazole-based CDK4/6 kinase inhibitor compounds.	Invention	CN202410372949.8	PRC	Our Company	N/A*
Preparation of CDK4/6 kinase inhibitor compounds	Invention	CN202211323710.9	PRC	Our Company	N/A*

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Scope of Patent Protection	Category	Patent/Application Number	Jurisdiction	Patent Holder/ Applicant	Expiration Year
XZP-3621					
Crystal form of a polycyclic inhibitor of anaplastic lymphoma kinase. . .	Invention	JP7494435	Japan	Our Company	2041
Crystalline forms of polycyclic mesenchymal lymphoma kinase inhibitors.	Invention	ZL202110052053.8	PRC	Our Company	2041
Polycyclic anaplastic lymphoma kinase inhibitor	Invention	EP3202765	Europe	Our Company	2035
		HK1235786	Hong Kong	Our Company	2035
		JP6554538	Japan	Our Company	2035
		KR101909404	Korea	Shandong Xuanzhu	2035
		US10011592B2	the United States	Our Company	2035
		ZL201580052631.0	PRC	Our Company	2035
Pyrimidine derivatives of mesenchymal lymphoma kinase inhibitors.	Invention	ZL201810442695.7	PRC	Our Company	2034
Crystalline form of polycyclic anaplastic lymphoma kinase inhibitor	Invention	EP21741695.7	Europe	Our Company	N/A*
		HK62023068386.9	Hong Kong	Shandong Xuanzhu and our Company	N/A*
		KR1020227028083	Korea	Shandong Xuanzhu and our Company	N/A*
		RU2022122281	Russia	Shandong Xuanzhu and our Company	N/A*
		US17/793,275	the United States	Shandong Xuanzhu and our Company	N/A*
Pharmaceutical compositions of kinase inhibitors for mesenchymal lymphoma and methods of preparation thereof	Invention	CN202311832278.0	PRC	Our Company	N/A*
Polycyclic mesenchymal lymphoma kinase inhibitors.	Invention	CN202311841260.7	PRC	Our Company	N/A*
Salts and crystal forms of polycyclic mesenchymal lymphoma kinase inhibitors.	Invention	CN202410344023.8	PRC	Our Company	N/A*
Salts and crystal forms of polycyclic mesenchymal lymphoma kinase inhibitors.	Invention	CN202411444120.0	PRC	Our Company	N/A*

Note:

* Patent application

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The actual protection afforded by a patent varies on a claim-by-claim and jurisdiction-by-jurisdiction basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular jurisdiction and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our issued patents or any such patents that may be issued in the future will be commercially useful in protecting our drug assets and methods of manufacturing the same. See “Risk Factors — Risks Relating to Intellectual Property Rights” for a description of risks related to our intellectual property.

We also own a number of registered trademarks and pending trademark applications. We conduct our business under the brand name of “Xuanzhu” (“軒竹”). As of the Latest Practicable Date, we had 80 registered trademarks in China. We are seeking trademark protection for our Company and our corporate logo in the jurisdictions where available and appropriate. In addition, we are the registered owner of four domain names.

During the Track Record Period and up to the Latest Practicable Date, (i) we were not involved in any legal, arbitral or administrative proceedings in respect of, and we had not received notice of any claims of infringement, misappropriation or other violations of third-party intellectual property; and (ii) we were not involved in any proceedings in respect of any intellectual property rights that may be threatened or pending and that may have an influence on the research and development for any of our drug candidates in which we may be a claimant or a respondent.

SUPPLIERS AND PROCUREMENT

Our suppliers are mainly CROs, CDMOs, and raw materials and equipment providers. For details regarding collaboration with CROs and CDMOs, see “— Research and Development — Collaboration with CROs” and “— Manufacturing” in this section.

In addition, we source raw materials and equipment from reputable manufacturers and suppliers, prioritizing those with proven industry leadership and a strong commitment to quality. Our supplier selection process involves careful evaluation of various factors, including cost-effectiveness, product quality, production capacity, technical capabilities, reliable delivery, supplier reputation, and adherence to regulatory standards. This rigorous approach, guided by our internal supplier selection policy, ensures that we consistently obtain quality materials and equipment to support our drug development and manufacturing processes.

For the years ended December 31, 2022 and 2023 and the six months ended June 30, 2024, our purchases from our five largest suppliers in aggregate amounted to RMB154.9 million, RMB90.6 million and RMB21.8 million, accounting for 34.7%, 34.5% and 32.5% of our total purchases for the respective year/period, respectively, and our purchases from our largest supplier alone amounted to RMB64.8 million, RMB36.7 million and RMB5.7 million, accounting for 14.5%, 14.0% and 8.5% of our total purchases for the respective year/period, respectively.

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The tables below set forth certain information about our five largest suppliers during the Track Record Period:

Supplier	Background	Commencement of Business Relationship	Product or service supplied	Typical Credit terms	Purchase amount	Percentage of total purchases
					<i>(RMB'000)</i>	
<i>For the six months ended June 30, 2024</i>						
Porton Pharma Solutions Ltd. (重慶博騰製藥科技股份有限公司) ⁽¹⁾	A public company listed on the Shenzhen Stock Exchange, which is engaged in provision of CDMO solutions	2018	Pharmaceutical manufacturing services	15-30 days	5,712.5	8.5%
Supplier A	A public company listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange, which is primarily engaged in provision of pharmaceutical R&D services	2016	Preclinical study and clinical support services	10-30 days	5,029.0	7.5%
Supplier B	A Class IIIA specialty hospital in China specializing in tumor prevention, medical care, teaching, scientific research, and rehabilitation	2020	Clinical trial execution	15 days	4,839.0	7.2%
Supplier C	An international company that operates primarily through its subsidiaries in real estate management business	2021	Rental and property management services	5 days	3,252.2	4.9%
Supplier D	A Class IIIA specialty hospital in China specializing in cancer diagnosis, treatment, research, and education	2019	Clinical trial execution	10-30 days	2,965.1	4.4%
Total					<u>21,797.8</u>	<u>32.5%</u>

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Supplier	Background	Commencement of Business Relationship	Product or service supplied	Typical Credit terms	Purchase amount <i>(RMB'000)</i>	Percentage of total purchases
<i>For the year ended December 31, 2023</i>						
Supplier E	A public company listed on the Shenzhen Stock Exchange and the Hong Kong Stock Exchange, mainly engaged in provision of CDMO services	2019	Pharmaceutical development and manufacturing services	15-20 days	36,696.0	14.0%
Porton Pharma Solutions Ltd. (重慶博騰製藥科技股份有限公司) ⁽¹⁾	A public company listed on the Shenzhen Stock Exchange, which is engaged in provision of CDMO solutions	2018	Pharmaceutical manufacturing services	15-30 days	23,123.3	8.8%
Supplier D	A Class IIIA specialty hospital in China specializing in cancer diagnosis, treatment, research, and education	2019	Clinical trial execution	10-30 days	12,692.6	4.8%
Supplier C	An international company that operates primarily through its subsidiaries in real estate management business	2021	Rental and property management services	5 days	9,584.1	3.7%
Supplier F	A China-based pharmacy chain operator	2019	Pharmaceuticals and clinical trial supplies	5-15 days	8,485.5	3.2%
Total					<u>90,581.5</u>	<u>34.5%</u>

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Supplier	Background	Commencement of Business Relationship	Product or service supplied	Typical Credit terms	Purchase amount <i>(RMB'000)</i>	Percentage of total purchases
<i>For the year ended December 31, 2022</i>						
Supplier G	A China-based company primarily engaged in drug development	2021	Asset and technology and know-how of CD80	10-20 days	64,787.0	14.5%
Supplier F	A China-based pharmacy chain operator	2019	Pharmaceuticals and clinical trial supplies	5-15 days	29,934.9	6.7%
Supplier E	A public company listed on the Shenzhen Stock Exchange and the Hong Kong Stock Exchange, mainly engaged in provision of CDMO services	2019	Pharmaceutical development and manufacturing services	5-20 days	25,296.2	5.7%
Supplier H	An international company mainly engaged in CRO services	2015	Preclinical study services	30 days	18,187.7	4.1%
Supplier I	A public company listed on the Shanghai Stock Exchange, mainly engaged in provision of CRO services	2019	Preclinical study services	7-15 days	16,731.8	3.7%
Total					<u>154,937.6</u>	<u>34.7%</u>

Note:

- (1) Suppliers under the ultimate common control have been consolidated and treated as a single supplier group in each period of the Track Record Period.

None of our Directors, their respective associates or any Shareholders who, to the best knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, had any interest in any of our five largest suppliers during the Track Record Period.

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COMPETITION

The pharmaceutical industry is a dynamic and highly competitive landscape, characterized by rapid advancements and evolving market demands. While we are confident that our fully integrated platform, robust pipeline of approved drug and drug candidates, and experienced leadership team provide us with a competitive edge, we also recognize the challenges inherent in this dynamic environment. We face competition from a variety of sources, including established pharmaceutical giants, innovative biotech startups, renowned academic institutions, and government agencies, all endeavoring to develop breakthrough therapies in the same areas we are targeting. Moreover, any drug candidates we successfully bring to market will face competition not only from existing treatments but also from new therapies that may emerge in the future.

EMPLOYEES

As of June 30, 2024, we had 213 full-time employees, substantially all of whom were based in China. The following table sets forth the details of our employees by function:

Function	As of June 30, 2024	
	Number of Employees	% of Total
Research and development.	119	55.9
Sales and marketing	41	19.2
Quality control	14	6.6
Others	39	18.3
Total	213	100.0

We recruit our employees primarily through online platforms, recruiting websites, headhunter referral and job fairs. We conduct induction programs and periodic professional training for all employees. We enter into individual employment contracts with our employees covering matters such as salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clause and grounds for termination. The remuneration package of our employees includes salary and bonus, which are generally determined by their qualifications, performance review, and seniority. We also enter into separate confidentiality agreements, which contain non-competition clauses, with our senior management and certain key members of our R&D team and other employees who have access to trade secrets or confidential information about our business and may be considered possible, directly or indirectly, to compete with us.

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.

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INSURANCE

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. Our existing insurance policies cover clinical trial liability, employee accidental injury and product liability. In line with industry practice in the PRC, we have elected not to maintain certain types of insurances, such as business interruption insurance or key person insurance. We believe our existing insurance coverage is adequate for our present operations and in line with the industry practice in the PRC. See also “Risk Factors — Risks Relating to Our Operations — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.”

SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

We believe our continued growth rests on integrating social values into our business. As our Company grows, we remain dedicated to our mission of addressing significant medical needs in China and globally. We are committed to providing world-class treatments and therapies that improve patient lives and contribute to a healthier world.

Governance on ESG Matters

Our Board is responsible for evaluating and managing material ESG issues. Our Company’s management is responsible for developing the Company’s ESG strategy, policy and reporting, including assessing and managing environmental and climate-related risks, with oversight provided by the Board.

Under the leadership of our Board, we have put in place a cross-department collaboration mechanism, which is intended to muster the expertise and specialty of different departments to address ESG-related matters in our everyday operations. Such mechanism is responsible for managing environmental risks and climate-related risks arising from our business operations, including identifying key environment factors, implementation of ESG policies, monitoring ESG-related performance and targets, adjusting ESG strategies as appropriate and preparing the ESG report after the proposed [REDACTED]. In addition, we have coordinated efforts across departments, including but not limited to our human resources, research and development, and sales departments, led by our management, to report ESG issues to our Board.

Compliance with Regulations

We are subject to evolving and increasingly stringent environmental, occupational, health and safety laws and regulations. We believe that our operations are in substantial compliance with the terms of applicable health, safety and environmental laws and regulations as currently interpreted in all material respects. During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material fines or other penalties due to non-compliance in relation to environmental, health or occupational safety laws and

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regulations and have not been involved in any significant accident or claim for personal or property damage made by our employees which had materially and adversely affected our financial condition or business operations.

We may be subject to more stringent compliance requirements and may incur additional costs in the future if there is any change to the existing laws or regulations. Please refer to the sections headed “Regulatory Overview” and “Risk Factors — Risks Relating to Government Regulations” in this document for more details.

Environmental Protection

Energy Consumption

The main types of energy we consume on a daily basis include electricity and water. The amount of our energy and resource consumption during the Track Record Period is as follows:

Unit	For the year ended December 31		For the six months ended June 30
	2022	2023	2024
Electricity kWh	3,035,286	2,879,066	1,014,706
Water M ³	14,011	13,270	4,868

We intend to continually reduce the level of our energy consumption. In 2025, we target to achieve a 5% decrease in electricity and water consumption compared to the levels in 2023. We will be implementing a number of implementation measures, including but not limited to (i) adopting more energy-efficient equipment and appliances in our offices and laboratories, (ii) maintaining the good condition of equipment to ensure optimal performance, and (iii) continuously educating employees on resource conservation practices.

Waste Management

We have procedures in place for waste management to ensure compliant waste disposal and reduce environmental impact. The waste we produce is divided into hazardous waste (such as chemical waste and liquid) and non-hazardous waste (such as domestic waste from general office operations). The wastewater and solid waste generated in our in-house research and development process are pretreated by us before being processed by qualified third-party medical waste treatment companies. The following table sets forth the amount of hazardous waste generated by us during the Track Record Period.

Unit	For the year ended December 31		For the six months ended June 30
	2022	2023	2024
Hazardous waste Tons	8.14	8.97	4.34

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Greenhouse Gas Emission

Our greenhouse gas emissions consist of Scope 1 and Scope 2 emissions. Scope 1 direct emissions include the greenhouse gas emissions from our facilities and other stationary combustion sources. Scope 2 energy indirect emissions primarily include the greenhouse gas emissions from our usage of purchased electricity. In response to the national target of carbon neutrality, we actively focus on reducing the greenhouse gas emissions generated during our operations.

Social Responsibility

Board and Management Diversity

We have adopted a board diversity policy which sets out the approach to achieve diversity of the Board. Our Company recognizes and embraces the benefits of having a diverse Board and sees increasing diversity at our Board level, including gender diversity, as an essential element in maintaining our Company’s competitive advantage and enhancing our ability to attract, retain and motivate employees from the widest possible pool of available talent. With respect to gender diversity, Ms. Xu Yanjun, Ms. Li Huiying, Ms. Chen Yanling, Ms. Wang Yu, and Dr. Wang Li, having extensive experience in their respective field, contribute to gender diversity of our Board and our senior management. As we recognize that gender diversity of our Company can be improved given that four out of nine of our Directors and one of our senior management members are female upon the [REDACTED], we will continue to take steps to promote gender diversity at the Board of our Company. After the [REDACTED], we will strive to achieve gender balance of the Board through certain measures to be implemented by our Nomination Committee in accordance with our board diversity policy. In particular, we will actively identify female individuals suitably qualified to become our Board members. To further ensure gender diversity in a long run, our Nomination Committee will periodically review our board diversity policy and its implementation to ensure its implementation and monitor its continued effectiveness, and the same will be disclosed in our corporate governance report, including any measurable objectives set for implementing the board diversity policy and the progress on achieving these objectives on an annual basis. When we hire additional personnel in line with our production expansions, we will also take into consideration factors such as gender diversity and gender balance among our workforces.

PROPERTIES

Owned Properties

Our headquarters are located in Beijing, China. As of the Latest Practicable Date, we owned land use rights to two parcels of land in the PRC, with an aggregate site area of approximately 53,000 square meters, and we had three self-owned properties in the PRC with an aggregate gross floor area of approximately 31,000 square meters. We hold the valid title for these parcels of land and properties. For additional details, see “Risk Factors — Risks Relating to Our Operations — Our properties may be subject to non-compliances or challenges that could potentially affect our future use of them.”

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Leased Properties

As of the Latest Practicable Date, we leased seven properties with an aggregate gross floor area of approximately 4,700 square meters in Beijing, China for our daily business operations and office purposes.

Although we have reached out to our lessors for their necessary support with regard to the filing of the lease agreements, as of the Latest Practicable Date, we and our lessors have not filed the leases for our leased properties with the governmental authorities due to various reasons, including, without limitation, the failure or unwillingness of the lessors to provide relevant documents. For details, see “Risk Factors — Risks Relating to Our Operations — Our properties may be subject to non-compliances or challenges that could potentially affect our future use of them.”

AWARDS AND RECOGNITION

The table below sets forth a summary of the major awards and recognition we received during the Track Record Period.

Award/Recognition	Year Granted	Granting Authority
National Intellectual Property Advantage Enterprise (國家知識產權優勢企業)	2022	National Intellectual Property Administration, the PRC
Unicorn Enterprise (獨角獸企業)	2023	Great Wall Enterprise Institute
Hebei Province Science and Technology SME (河北省科技型中小企業)	2023	Hebei Provincial Department of Science and Technology
Hebei Province Innovative SME (河北省創新型中小企業)	2023	Hebei Provincial Department of Industry and Information Technology
Beijing Specialized and Sophisticated SMEs (北京市“專精特新”中小企業)	2022	Beijing Municipal Bureau of Economy and Information Technology
Beijing New Technology and New Product Certification (北京市新技術新產品認定)	2022	Beijing Municipal Science & Technology Commission
High-Tech Enterprise (高新技術企業)	2022	Shandong Provincial Department of Science & Technology, Shandong Provincial Department of Finance, Shandong Provincial Tax Service, State Taxation Administration

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Award/Recognition	Year Granted	Granting Authority
2024 Specialized and Sophisticated SMEs of Shandong Province (2024年度山東省專精特新中小企業)	2024	Shandong Provincial Department of Industry and Information Technology
2023 Beijing Municipal Science and Technology SME (2023北京市科技型中小企業)	2023	Beijing Municipal Science & Technology Commission and Zhongguancun Science Park Administrative Committee

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. As advised by our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from the relevant government authorities that are material for our business operations in the PRC. The table below sets forth the relevant details of the material licenses and approvals (apart from our extensive portfolio of IND approvals and NDA approval) we hold for our operations in China.

License/Permit	Holder	Issuing Authority	Effective Date	Expiration Date
Laboratory Animal Use Permit (實驗動物使用許可證)	Shandong Xuanzhu	Shandong Provincial Department of Science & Technology	July 21, 2020	July 20, 2025
Drug Manufacturing License (藥品生產許可證)	Beijing Xuanzhu	Beijing Municipal Medical Products Administration	September 3, 2021	July 18, 2026
Shandong Province Pathogenic Microorganism Laboratory and Experimental Activity Filing Certificate (山東省病原微生物實驗室及實驗活動備案證明)	Shandong Xuanzhu	Jinan Municipal Health Commission	October 15, 2021	October 14, 2026
Drug Manufacturing License (藥品生產許可證)	Our Company	Hebei Medical Products Administration	November 5, 2021	November 4, 2026

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LEGAL PROCEEDING AND COMPLIANCE

During the Track Record Period and as of the Latest Practicable Date, we had not been a party to any actual or threatened material legal or administrative proceedings, and our Directors had not been involved in any such proceedings. We are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business. During the Track Record Period and up to the Latest Practicable Date, we had complied in all material respects with the applicable laws and regulations relating to our business operations. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business. See “Risk Factors — Risk Relating to Our Operations — We may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business.”

RISK MANAGEMENT AND INTERNAL CONTROL

We have devoted ourselves to establishing and maintaining risk management and internal control systems consisting of policies and procedures that we consider to be appropriate for our business operations, and we are dedicated to continuously improving these systems.

Risk Management

We recognize that risk management is critical to the success of our business operations. Key operational risks faced by us include changes in general market conditions and the regulatory environment of China and other target markets, our ability to develop and commercialize our product candidates, and our ability to compete with other pharmaceutical companies. See “Risk Factors” for a discussion of various risks and uncertainties we face. We also face various market risks. In particular, we are exposed to credit and liquidity risks that arise in the normal course of our business.

We have established an Audit Committee and also adopted a series of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis. The following key principles outline our approach to risk management:

- Our Audit Committee will oversee and manage the overall risks associated with our business operations, including (i) overseeing the external audit; (ii) reviewing financial statements; (iii) overseeing internal control over financial reporting; and (iv) coordinating communication among relevant stakeholders in the financial reporting process.
- We have established an audit compliance department, which is responsible for (i) formulating and updating our risk management policy and targets; (ii) reviewing and approving major risk management issues of our Company; (iii) recommending policy updates or new controls to relevant departments, including the Board of Directors and our finance department; (iv) providing guidance on our risk management approach to the relevant departments in our Company; (v) evaluating the effectiveness of risk management practices across all departments; (vi) supervising the implementation of our risk management measures by the relevant

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departments; (vii) ensuring that the appropriate structure, processes and competencies are in place across our Company; and (viii) reporting to our Audit Committee on our material risks.

- The relevant departments in our Company, including but not limited to the finance department, the legal department and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to standardize risk management across our Company and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) continuously monitor the key risks relating to their operation or function; (iv) implement appropriate risk responses where necessary; and (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. We have engaged an independent internal control consultant, or the Internal Control Consultant, to perform certain agreed-upon procedures, or the Internal Control Review, in connection with the internal control of our Company and our major operating subsidiaries and to report factual findings on our Group’s entity-level controls and internal controls of various processes, including financial reporting and disclosure controls, human resources and payroll management, general controls of IT system, taxation management, contract management, and other procedures of our operations. The Internal Control Consultant performed the Internal Control Review in July 2024 and follow-up reviews in November 2024. As of the Latest Practicable Date, there were no material outstanding issues relating to our Group’s internal control.

During the Track Record Period, we regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operations, such as related party transactions, risk management, protection of intellectual property, environmental protection and occupational health and safety. For more information, see “— Intellectual Property” and “— Social, Health, Work Safety and Environmental Matters” in this section. We provide periodic training about these measures and procedures to our employees as part of our employee training program. Our internal audit department conducts audit field work to monitor the implementation of our internal control policies, reports the weakness identified to our management and Audit Committee, and follows up on the rectification actions.

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- Our Directors (who are responsible for monitoring the corporate governance of our Group) with help from our legal advisors, will also periodically review our compliance status with all relevant laws and regulations after the [REDACTED]. For more details, please refer to the paragraph headed “Relationship with Our Controlling Shareholders — Corporate Governance Measures” in this document.
- We have established an Audit Committee which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and renders advice in respect of financial reporting as well as oversees internal control procedures of our Group.
- We have engaged First Shanghai Capital Limited as our Compliance Advisor to provide advice and guidance to us in respect of compliance with the Listing Rules and applicable laws, rules, codes and guidelines, including but not limited to various requirements relating to Directors’ duties and internal controls. Our Compliance Advisor is expected to ensure our use of funding complies with the section headed “Future Plans and [REDACTED]” in this document after the [REDACTED], as well as to provide support and advice regarding requirements of relevant regulatory authorities in a timely fashion.
- We plan to engage a PRC law firm to advise us on and keep us abreast with PRC laws and regulations after the [REDACTED]. We will continue to arrange various trainings to be provided by external legal advisor from time to time when necessary and/or any appropriate accredited institution to update our Directors, senior management, and relevant employees on the latest PRC laws and regulations.
- We intend to maintain strict anti-corruption policies among our sales personnel and distributors in our future sales and marketing activities. We will also strive to ensure that our sales and marketing personnel comply with applicable promotion and advertising requirements in the future.
- We will conduct periodic review of relevant laws and regulations and amend our internal policies to ensure compliance with the latest applicable laws and regulations.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

OVERVIEW

As of the Latest Practicable Date, (i) Dr. Che Fengsheng, Dr. Guo Weicheng, Mr. Meng Xianhui, and Dr. Zhang Jionglong, acting in concert through their respective wholly-owned entities (Network Victory Limited and Proper Process International Limited for Dr. Che Fengsheng; Successmax Global Holdings Limited for Dr. Guo Weicheng; Victory Faith International Limited for Mr. Meng Xianhui; and Mingyao Capital Limited for Dr. Zhang Jionglong) were deemed to be indirectly interested in approximately 55.02% of the total issued share capital of Sihuan Pharm; (ii) Sihuan Pharm, through its indirectly wholly-owned subsidiaries, Xuanzhu Biopharma and Hainan Sihuan, was interested in approximately 56.47% of the total issued share capital of our Company. Xuanzhu Biopharma was wholly owned by Xuanzhu Cayman, which in turn was indirectly wholly owned by Sihuan Pharm through Sun Moral. Hainan Sihuan was wholly owned by Sun Moral, which in turn was directly wholly owned by Sihuan Pharm.

Immediately following the completion of the [REDACTED], (i) Sihuan Pharm will have an indirect interest (through its interests in its subsidiaries, Sun Moral, Xuanzhu Cayman, Xuanzhu Biopharma and Hainan Sihuan) in approximately [REDACTED]% of the Shares in issue (assuming the [REDACTED] is not exercised), (ii) our Company will remain as an indirect non-wholly owned subsidiary of Sihuan Pharm, and (iii) Dr. Che Fengsheng, Dr. Guo Weicheng, Mr. Meng Xianhui, Dr. Zhang Jionglong, Network Victory Limited, Proper Process International Limited, Successmax Global Holdings Limited, Victory Faith International Limited, Mingyao Capital Limited, Sihuan Pharm, Sun Moral, Xuanzhu Cayman, Xuanzhu Biopharma and Hainan Sihuan will be our Controlling Shareholders. Please refer to “History and Corporate Structure” for the shareholding and corporate structure of our Group.

BACKGROUND OF THE CONTROLLING SHAREHOLDERS

Founded in 2001 and listed on the Main Board of the Stock Exchange in 2010 (Stock Code: 0460), Sihuan Pharm is an international medical aesthetic and pharmaceutical company.

Each of Network Victory Limited, Proper Process International Limited, Successmax Global Holdings Limited, Victory Faith International Limited, Mingyao Capital Limited, Sun Moral, Xuanzhu Cayman and Xuanzhu Biopharma is an investment holding company.

Hainan Sihuan is a company primarily engaged in the marketing and distribution of pharmaceutical products in the PRC.

Dr. Che Fengsheng, Dr. Guo Weicheng, Mr. Meng Xianhui, and Dr. Zhang Jionglong, as the ultimate Controlling Shareholders, have no interests in biopharmaceutical businesses other than through their respective interests in Sihuan Pharm and its subsidiaries.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

DELINEATION OF BUSINESS

There is a clear delineation between the business of the Remaining Sihuan Group (the “**Remaining Business**”) and our business. The table below sets forth the principal businesses of our Group and the Remaining Sihuan Group:

Our Group:	The business of R&D, manufacturing and commercialization of innovative drugs, focusing on a number of therapeutic areas such as digestion, oncology and NASH (the “ Principal Business ”).
Remaining Sihuan Group:	<ul style="list-style-type: none">(i) the medical aesthetics business offering a comprehensive array of medical aesthetics products, including the filling, shaping, supporting, supplementing, optoelectronic device, body sculpturing, skin care and others (the “Medical Aesthetics Business”);(ii) the diabetes pharmaceutical businesses mainly focusing on the R&D, production and sales of drugs for diabetes and its complications (the “Diabetes Pharmaceutical Business”); and(iii) the generic drug business focusing on the R&D, production and sales of generic drugs such as cardiovascular and cerebrovascular, nervous system, digestive system and anti-infectives (the “Generic Drug Business”).

The Remaining Sihuan Group structured its business into various distinct business segments and each of them has a particular business focus, whereby our Principal Business does not overlap with any segment of the Remaining Business as discussed below. The Remaining Business focuses on different types of products and services that are of a different nature and have different applications from those of the Principal Business. The products and services of our Group and those of the Remaining Sihuan Group function independently and are not supplemental to or interchangeable with each other.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Delineation with the Generic Drug Business

While both our Group and the Remaining Sihuan Group are engaged in the R&D and commercialization of drugs, the drugs and drug candidates of our Principal Business and the Remaining Business are clearly delineated in terms of indication and innovative nature:

Difference in treatment of disease

Our Group is committed to the continuous research and development, manufacturing and commercialization of Category 1 Drugs (as defined below) focusing on major disease fields such as digestion, oncology and NASH. The products and product candidates of our Principal Business and the Remaining Business are designed to treat different types of diseases, which can be distinguished from each other in nature. The products and product candidates of our Principal Business and the Remaining Business are not interchangeable nor can they be replaced by each other.

Difference in product category

The Generic Drug Business of the Remaining Sihuan Group mainly focuses on research, development and commercialization of generic drugs. In contrast, our Principal Business mainly focuses on the discovery, R&D, manufacturing and commercialization of innovative drugs. In general, innovative drugs and generic drugs are two different classes of drugs and are generally not in competition with each other.

Innovative drugs usually have independent intellectual property rights and patents, emphasize novel chemical structure or new therapeutic use, and have not been reported in previous research literature or patents. Innovative drugs generally refer to category 1 drugs and products (“**Category 1 Drugs**”):

- Under the Reform Plan for Registration Category of Chemical Medicine (《化學藥品註冊分類改革工作方案》) issued by the NMPA in March 2016, Category 1 drugs refer to new drugs that have not been marketed anywhere in the world, improved new drugs that are not marketed anywhere in the world fall into Category 2, generic drugs that have equivalent quality and efficacy to the originator’s drugs have been marketed abroad but not yet in China fall into Category 3, generic drugs that have equivalent quality and efficacy to the originator’s drugs and have been marketed in China fall into Category 4, and Category 5 drugs are drugs which have already been marketed abroad, but are not yet approved in China.
- Under the Registration Category and Application Documents Requirements of Biological Products (《生物製品註冊分類及申報資料要求》) issued by the NMPA in June 2020, Category 1 innovative therapeutic biological products or novel vaccines refer to those have not been marketed in the PRC or abroad, Category 2 improved therapeutic biological products or vaccines refer to improved ones which compared with the existing products marked in the PRC or abroad could improve the

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

safety, effectiveness and quality controllability, and have obvious advantages, and Category 3 therapeutic biological products or vaccines refer to those have been marketed in the PRC or abroad (including biosimilars). Drugs and therapeutic biological products or vaccines that had been accepted and registered as Category 1 will remain being categorized as Category 1 after their registration by the NMPA.

Generic drugs are pharmaceutical drugs not categorized as Category 1 Drugs which contain the same chemical substances as a drug that was originally protected by chemical patents (i.e., brand-name drug). A generic drug has the same active pharmaceutical ingredients as the brand-name drug and is allowed for sale after the patents of the brand name drug expire. As such, a generic drug is identical to or within an acceptable bioequivalent range of the brand-name drug with respect to pharmacokinetic and pharmacodynamics properties. In the Chinese market, generic drugs and innovative drugs differ significantly in various aspects, including the R&D model and cycle, time to market, R&D costs, treatment costs, clinical needs, physician prescribing behavior, and direct competitors.

Based on the above, the Principal Business is clearly delineated from the Generic Drug Business.

Delineation with the Diabetes Pharmaceutical Business

Huisheng Biopharmaceutical Co., Ltd. (惠升生物製藥股份有限公司) (“**Huisheng**”), a subsidiary of Sihuan Pharm, specializes in the development and commercialization of drugs for the treatment of diabetes and its complications, boasting a robust portfolio of over 40 generic and innovative drugs and drug candidates in this therapeutic area.

In August 2020, we transferred the ownership (including all intellectual property rights) of and rights to Janagliflozin, a self-developed innovative anti-diabetic drug, to Beijing Huizhiheng Biotechnology Co., Ltd. (北京惠之衡生物科技有限公司), a wholly-owned subsidiary of Huisheng. The ownership of Janagliflozin was transferred to the Remaining Sihuan Group to streamline the various business segments of the Sihuan Group, consolidate the diabetes-related businesses of the Sihuan Group into the relevant entities, clarify the scope of our Principal Business which shall exclude all matters relating to the medical indication of diabetes, delineating our Principal Business from the business of the Remaining Sihuan Group clearly, and thereby reducing potential competition between our Group and the Remaining Sihuan Group. Upon completion of such transfer, the diabetes-related drugs business had been and will be operated by the Remaining Sihuan Group independently without any services provided by our Group and our Group has ceased and shall not further engage in any activities related to the medical indication of diabetes. Upon obtaining the marketing approval of Janagliflozin and the commencement of sales, the Remaining Sihuan Group shall pay to our Group a pre-determined royalty. The Remaining Sihuan Group and our Group note that the aggregate fee structure for the transfer of Janagliflozin (being an initial consideration plus royalty) is a common fee structure adopted by the market for innovative drugs-related transfers, primarily for the vendor and purchaser to share the commercial risks in the transfer that arise from the long cycle and substantial capital required for the R&D of innovative drugs.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Upon completion of the Janagliflozin transfer, all key R&D personnel and intellectual properties involved in its development, or the development of any other diabetes-related drugs or drug candidates, no longer remain with our Group.

Although certain drugs of the Diabetes Pharmaceutical Business are or are expected to be categorized as Category 1 Drugs, there is a clear delineation of our Principal Business and the Diabetes Pharmaceutical Business in terms of the indication of the drugs. Considering the aforementioned difference in indication and target patients, we believe that our Principal Business is clearly delineated from the Diabetes Pharmaceutical Business.

Delineation with the Medical Aesthetics Business

The Remaining Sihuan Group offers a comprehensive array of medical aesthetics products, including the filling, shaping, supporting, supplementing, optoelectronic device, body sculpturing, skin care and others, through a dual strategy combining self-research with exclusive distribution for internationally sourced products, while our Group is not involved in the business related to medical aesthetics products. Based on the distinct difference in business nature and the products offerings, our Principal Business is clearly delineated from the Medical Aesthetics Business.

Given there is a clear delineation between the businesses of our Group and the Remaining Sihuan Group, our Directors are of the view that the Remaining Business does not compete and is unlikely to compete, directly or indirectly, with our Group’s business.

INDEPENDENCE FROM CONTROLLING SHAREHOLDERS

Having considered the following factors, our Directors are satisfied that we are capable of carrying out our business independently from our Controlling Shareholders after the [REDACTED].

Operational Independence

We have full rights to make all decisions on, and to carry out, our own business operation independently from our Controlling Shareholders and their respective close associates and will continue to do so after the [REDACTED]. Our Group is able to operate independently without reliance on the Remaining Sihuan Group on the following basis:

R&D

We have our own R&D team covering all key functions from clinical development to new drug registration, which is independent from the R&D team of the Remaining Sihuan Group. As of the Latest Practicable Date, our R&D team comprised 91 members, who were all full-time employees of our Group and was not holding any position in the Remaining Sihuan Group. In addition, as of the Latest Practicable Date, we owned over 163 patents in the PRC and globally for our operations, which are required for the R&D and manufacturing of the

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

products of our Group. Currently, all of our on-going R&D process, including preclinical studies, clinical trials, post-market clinical studies, are conducted independently by our R&D team without reliance on any patented technology or personnel of the Remaining Sihuan Group. Thus, we are capable of independently carrying on the R&D process without reliance on the Remaining Sihuan Group.

Production

We currently engage and will continue to engage independent manufacturers for the production of our drugs. The Remaining Sihuan Group have production facilities located in Beijing, Liaoning Province and Jilin Province owned by and dedicated to serving the production needs of the Remaining Sihuan Group.

Historically, we entrusted the Remaining Sihuan Group to manufacture certain drugs for clinical trials. The majority of such entrusted production arrangements have ceased in 2020 with only minimal transaction amounts incurred in 2021 due to certain ad hoc production needs of our Group. As our Group is engaging independent manufacturers and also taking into consideration the production facilities under construction, it is expected that we can carry out the production of our drugs without reliance on the Remaining Sihuan Group. The historical entrusted manufacturing arrangement between our Group and the Remaining Sihuan Group has already terminated in 2022 and will not continue upon the [REDACTED].

Procurement

We are able to procure raw materials independently and to negotiate and enter into procurement agreements with raw material suppliers separate from the Remaining Sihuan Group. Our Group and the Remaining Sihuan Group have been and will be carrying out their respective selection of suppliers independently in accordance with their respective supplier management system.

Overlapping suppliers between the Remaining Sihuan Group and our Group

Whilst there are certain overlaps between the suppliers of our Group and the Remaining Sihuan Group, our Directors are of the view that procurement from overlapping suppliers does not affect the business delineation between the Remaining Sihuan Group and us, or result in any reliance issue, on the following basis:

- (i) as set out above, our Group and the Remaining Sihuan Group have been and will be carrying out their selection of suppliers independently in accordance with their respective supplier management system. We have established our own supplier list, which is separate from the Remaining Sihuan Group. The respective procurement teams of our Group and the Remaining Sihuan Group may select supplier candidates from their respective supplier list or reach out to supplier candidates which are not within the list according to their specific procurement demand;

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

- (ii) as set out above, the respective procurement teams of our Group and the Remaining Sihuan Group are responsible for the supplier selection process and the procurement process independently, and they negotiate the terms of the procurement agreements with the suppliers directly and independently. The qualification, capability and satisfactory cooperation history of the suppliers are the reasons that our Group procures the relevant products and services from them, instead of their business relationship with the Remaining Sihuan Group, and vice versa;
- (iii) we have full discretion to select our suppliers, and all the terms of the procurement agreements are negotiated between our Group and the suppliers directly and independently without bundling. There are no cross-referrals of suppliers between the Remaining Sihuan Group and our Group. Such arrangements can ensure an independent access and management of suppliers between our Group and the Remaining Sihuan Group;
- (iv) the overlap in suppliers between our Group and the Remaining Sihuan Group can be largely attributed to the strategic selection of top industry suppliers known for their large scale, competitive pricing, and high-quality offerings. These overlapping suppliers, primarily leading companies in their respective fields, ensure that both groups have access to the best resources and services available in the market. Furthermore, utilizing these overlapping suppliers promotes long-term and stable relationships, which are invaluable for ensuring consistent supply, reliability in procurement, and potential for collaborative development of new solutions or improvements, thereby strengthening the overall supply chain resilience for both our Group and the Remaining Sihuan Group; and
- (v) the procurement amount from each overlapping supplier is relatively low. The low supplier concentration minimizes the risk that may be caused by potential change of any single supplier.

Sales and Marketing

KBP-3571 (Anaprozole Sodium), one of our Core Products, received registration approval from the NMPA for the treatment of DU on June 26, 2023, becoming our first commercialized product. In anticipation of the fast progress of the clinical study and registration of the drug candidates, we have built up our independent sales and marketing teams and channels. Members of the marketing team are recruited by our Group independently, and most of them have prior working experience in the biopharmaceutical industry. None of the members of our marketing team will concurrently hold any position with the Remaining Sihuan Group.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

We did not generate any revenue in 2022 and only recorded a total revenue of RMB29,000 in 2023. For the six months ended June 30, 2024, we recorded a total revenue of approximately RMB16.00 million, all of which were generated from the sale of KBP-3571 (Anaprozole Sodium), and a large proportion of such revenue was attributable to sales to overlapping distributors between our Group and the Remaining Sihuan Group. The existence of such overlapping distributors can be attributed to the following reasons:

- (i) The Remaining Sihuan Group has a well-established commercial presence in the PRC’s pharmaceutical market, supported by an extensive distribution network nationwide. As of June 30, 2024, the Remaining Sihuan Group had over 1,600 customers most of whom are distributors, strategically positioned to ensure comprehensive market penetration. Given the strength of this robust network and the fact that most overlapping distributors contribute less than 0.1% of the total revenue of the Remaining Sihuan Group for the six months ended June 30, 2024, it is neither commercially viable nor necessary for our Group to exclude these distributors solely based on their existing relationships with the Remaining Sihuan Group. Excluding these distributors would unnecessarily limit market access and weaken competitive positioning in key regions, which would not serve the interests of our Group or its Shareholders.
- (ii) According to CIC, the number of distributors in the PRC that meet the stringent qualifications necessary for pharmaceutical distribution is limited. A large portion of the overlapping distributors are prominent paratheatrical distributor groups, which command significant market shares in China’s drug distribution sector. CIC confirms that it is a common practice within the pharmaceutical industry, both for biopharmaceutical and traditional pharmaceutical companies, to share distributors when few possess the necessary scale and qualifications.

Notwithstanding the existence of the overlapping distributors and their revenue contribution to our Group, each of the Remaining Sihuan Group and our Group entered into distribution agreements with their distributors independently. The distribution agreements of the Remaining Sihuan Group and our Group are not bundled together, and neither the Remaining Sihuan Group nor our Group will generate any benefits by virtue of the sales of the other to the overlapping distributors. Both the Remaining Sihuan Group and our Group have the autonomy to negotiate sales terms independently with overlapping distributors, without any restrictions or interference from the other party. We have been developing, and will continue to develop our own distribution channel independent of that of the Remaining Sihuan Group upon the [REDACTED].

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Administrative independence

We have an independent R&D center, full-time management team and team of staff to carry out our own administration and operation independent of the Remaining Sihuan Group. Upon the [REDACTED], the support services comprising accounting, administration, corporate secretarial, compliance and human resource management will also continue to be handled by a team of staff employed directly by our Group and are separated from the Remaining Sihuan Group.

Management Independence

Our Board is comprised of nine Directors, including three executive Directors, three non-executive Directors and three independent non-executive Directors. While being a consolidated subsidiary of Sihuan Pharm, Sihuan Pharm has nominated directors to preside on our Board. Our Group and the Remaining Sihuan Group have their respective directors and management teams independent of each other. Ms. Li Huiying (李惠英) (“**Ms. Li**”) currently serves as the director of the Value Management Center (價值管理中心總監) of Sihuan Pharm and Ms. Chen Yanling (陳燕玲) (“**Ms. Chen**”) serves as an executive director, one of the joint company secretaries and the co-chairman of the risk management committee of Sihuan Pharm. As each of Ms. Li and Ms. Chen only holds a directorship of our Company with non-executive nature, they are not involved in day-to-day management of affairs and operations of our Group.

Our Directors are of the view that each of the Remaining Sihuan Group and our Group will be managed and will operate independently of each other in the interests of their respective shareholders as a whole on the following basis:

- (i) none of our executive Directors and senior management members, who are responsible for the day-to-day management of our Group’s business, has any ongoing role with the Remaining Sihuan Group;
- (ii) save for Ms. Li and Ms. Chen who are our non-executive Directors, none of the Directors or senior management members of our Company holds positions within the Remaining Sihuan Group, and vice versa;
- (iii) should there be a conflict of interest or a connected transaction between our Group and members of the Remaining Sihuan Group, the relevant common directors, if any, will abstain from voting on, and will not be counted in the quorum for, the relevant board resolution(s) of our Company and relevant member(s) of the Remaining Sihuan Group; and
- (iv) our Company will adopt corporate governance policies, including but not limited to, rules relating to the procedure for board meetings and decision-making protocols on connected transactions, setting out circumstances that require the relevant common directors to abstain from voting on, and not to be counted in the quorum for, the relevant board resolutions.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Financial Independence

We have established our own finance department with a team of independent financial staff responsible for discharging treasury, accounting, reporting, group credit and internal control functions independently from our Controlling Shareholders and their respective close associates, as well as a sound and independent financial system, and makes independent financial decisions according to our own business needs. Our Company maintains bank accounts independently and does not share any bank account with our Controlling Shareholders. Our Company makes tax registration and pays tax independently with its own funds. As such, our Company's financial functions, such as cash and accounting management, invoices and bills, operate independently of our Controlling Shareholders and their close associates.

As of the Latest Practicable Date, there was no outstanding loan, advance, balance of non-trade nature due to or from, or pledge or guarantee provided by our Controlling Shareholders or their respective close associates. We do not expect to rely on our Controlling Shareholders and their close associates for financing after the [REDACTED] as we expect that our working capital will be funded by cash flows generated from operating activities, equity financing, bank loans as well as the [REDACTED] from the [REDACTED].

Based on the above, our Directors believe that we do not place undue reliance on our Controlling Shareholders and their respective close associates.

CORPORATE GOVERNANCE MEASURES

Upon the [REDACTED], we will comply with the provisions of the Corporate Governance Code set forth in Appendix C1 to the Listing Rules, which sets out the principles of good corporate governance.

Our Directors recognize the importance of good corporate governance in the protection of our Shareholders' interests. We would adopt the following measures to safeguard good corporate governance standards and to avoid potential conflict of interest between our Group and Controlling Shareholders:

- (i) where a Board meeting is held for the matters in which any Directors has a material interest, such Director(s) shall abstain from voting on the relevant resolutions and shall not be counted in the quorum for the voting;
- (ii) where a Shareholders' meeting is to be held for considering proposed transactions in which our Controlling Shareholders or any of their associates has a material interest, the relevant member in our Controlling Shareholders will not vote on the resolutions and shall not be counted in the quorum in the voting;

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

- (iii) our Company has established internal control mechanisms to identify connected transactions. Upon the [REDACTED], if our Company enters into connected transactions with our Controlling Shareholders or any of their associates, our Company will comply with the relevant requirements of Chapter 14A of the Listing Rules, including the announcement, reporting and independent Shareholders’ approval requirements (if applicable) under the Listing Rules;
- (iv) our Board will consist of a balanced composition of executive and non-executive Directors, including not less 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. They are committed to providing experienced and professional advice to protect the interests of our minority Shareholders;
- (v) our independent non-executive Directors will review, on an annual basis, whether there are any conflicts of interests between our Group and any Controlling Shareholder and provide impartial and professional advice to protect the interests of our minority Shareholders;
- (vi) our Controlling Shareholders will provide our independent non-executive Directors with all relevant financial, operational and market and any other necessary information as required by the independent non-executive Directors for the purpose of their annual review;
- (vii) our Company shall disclose the decisions of the independent non-executive Directors either in its annual reports or by way of announcements as required by the Listing Rules;
- (viii) we have established our Audit Committee, Remuneration and Appraisal Committee and Nomination Committee with written terms of reference in compliance with the Listing Rules and the Corporate Governance Code in Appendix C1 to the Listing Rules;
- (ix) where our Directors reasonably request the advice of independent professionals, such as financial advisors, the appointment of such independent professionals will be made at our Company’s expenses; and
- (x) we have appointed First Shanghai Capital Limited as our Compliance Advisor, which will provide advice and guidance to us in respect of compliance with the Listing Rules and applicable laws, rules, codes and guidelines, including but not limited to various requirements relating to Directors’ duties and internal controls.

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 Shareholders to protect minority Shareholders’ rights after the [REDACTED].

CONNECTED TRANSACTION

OVERVIEW

We have entered into a technology transfer agreement with Beijing Huizhiheng Biotechnology Co., Ltd. (北京惠之衡生物科技有限公司) (“**Beijing Huizhiheng**”), a member of the Remaining Sihuan Group, who will become a connected person of our Company upon the [REDACTED], and such transaction will continue following the [REDACTED], thereby constituting a non-exempt continuing connected transaction subject to the reporting, annual review, announcement, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules. The following table sets forth a summary of the details of such non-exempt continuing connected transaction:

Transaction	Applicable Listing Rules	Waivers sought	Proposed annual caps for the year ending December 31,		
			2024	2025	2026
Technology Transfer Agreements . .	14A.34 to 14A.36, 14A.49, 14A.51 to 14A.59 and 14A.71	Waiver from monetary annual cap, announcement requirement, circular, and independent shareholders’ approval requirements	N/A	N/A	N/A

NON-EXEMPT CONTINUING CONNECTED TRANSACTION

Technology Transfer Agreements

Beijing Xuanzhu entered into a technology transfer agreement dated August 3, 2020, and a supplemental agreement dated July 27, 2021 (collectively, the “**Technology Transfer Agreements**”), with Beijing Huizhiheng. Pursuant to the Technology Transfer Agreements, we agreed to transfer to Beijing Huizhiheng the ownership of and rights relating to Janagliflozin, a self-developed innovative anti-diabetic drug, which include, among others, (a) all ownership rights (including the marketing authorization holder of Janagliflozin (the “**MAH**”), an authorization acquired by the holder upon receipt of the drug registration certificate granted by the NMPA) thereto, (b) all intellectual property rights relating thereto, including all know-how, technologies, and processes related to its R&D and registration, (c) all contractual interests and liabilities associated therewith, and (d) any trademarks employed in connection therewith.

CONNECTED TRANSACTION

In consideration, Beijing Huizhiheng agreed to pay us (i) an one-off payment (the “**One-Off Payment**”) of approximately RMB212.4 million¹ within 20 days after the execution of the agreement, which has already been made, and (ii) the pre-determined royalties (the “**Royalty Payments**”) based on the net sales (as defined in Technology Transfer Agreements) generated from the sales of Janagliflozin, details of which are set out in “— Annual Caps” below.

The fees paid and payable under the Technology Transfer Agreements, including the One-Off Payment and the Royalty Payments to be received by us were determined after arms’ length negotiations between our Group and Beijing Huizhiheng with reference to, among others, the valuation of Janagliflozin conducted by a qualified external valuer.

Reasons for and benefits of the transaction

We entered into the Technology Transfer Agreements with Beijing Huizhiheng for the following reasons:

- (a) the Technology Transfer Agreements were entered into by our Group and Beijing Huizhiheng out of independent commercial considerations since Beijing Huizhiheng focuses its resources on the R&D and commercialization of drugs for the treatment of diabetes and its complications, while our Group is committed to R&D, manufacturing and commercialization of innovative drugs, focusing on a number of therapeutic areas such as digestion, oncology and NASH (the “**Principal Business**”). The transfer of Janagliflozin to the Remaining Sihuan Group to streamline the business segments of the Sihuan Group, consolidate the diabetes-related businesses of the Sihuan Group into the relevant entities, clarify the scope of the Principal Business which shall exclude all matters relating to the medical indication of diabetes, delineate the Principal Business from the business of the Remaining Sihuan Group, and thereby reduce potential competition between our Group and the Remaining Sihuan Group. It is natural and commercially beneficial for both our Group and the Remaining Sihuan Group to enter into the Technology Transfer Agreements so that both groups will be able to stick to their respective business plans and development paths; and
- (b) the One-Off Payment and the Royalty Payments under the Technology Transfer Agreements are fair and reasonable as the roles of our Group and the Remaining Sihuan Group under the Technology Transfer Agreements are complementary and beneficial to each other. It allows our Group to mitigate the potential significant capital investment and financial risks associated with late-stage drug development and commercialization by leveraging the Remaining Sihuan Group’s well-established commercial presence and extensive distribution network in the PRC pharmaceutical market. Since Janagliflozin was a near-commercialization drug candidate already in phase 3 clinical trials prior to the execution of the Technology Transfer Agreements, the Royalty Payments ensure that our Group continues to benefit economically from the success of Janagliflozin in the market without incurring additional R&D and commercialization costs.

¹ Inclusive of all costs and expenses incurred by us in connection with the phase 3 clinical trial of Janagliflozin conducted from May 1, 2020, to the date when Beijing Huizhiheng obtained the MAH

CONNECTED TRANSACTION

As confirmed by CIC, the Technology Transfer Agreements, including its term and schedule, and the One-Off Payment and the Royalty Payments contemplated thereunder, are in line with the industry prevailing practice. Taking into consideration of the above, in particular the corporate governance procedures in place as set out below, we believe that the Technology Transfer Agreements is in the interest of our Company and the Shareholders as a whole.

Corporate governance measures

During the ordinary and usual course of business of our Company, we review potential product transfer, acquisition and licensing opportunities from time to time. When potential opportunity arises, we would normally assess the advantages and development prospect of the product, market forecasts for the demand of the product, competitive landscape and regulatory requirements of the product for that market as well as the regulatory and commercial capability of the potential business partner to commercialize the product. Furthermore, our business development team routinely evaluates product transfer, acquisition and licensing arrangements by third parties in respect of drug products with similar mechanism of action for deal benchmarking and for term sheet evaluation purposes.

In addition, the commercial negotiations with potential business partners are led by our senior management, who will independently evaluate the terms taking into account all relevant factors as we consider necessary. A decision on whether to entering into the transaction will be made purely based on the commercial considerations and only if we consider it is in the best interest of our Company and the Shareholders to enter into such arrangement.

Term of the Technology Transfer Agreements

Unless otherwise terminated earlier in accordance with the terms of the Technology Transfer Agreements, the Technology Transfer Agreements shall take effect from the date of the agreement and continue to be in force until the expiration date of the core patents (as defined in Technology Transfer Agreements) of Janagliflozin, being May 27, 2037.

Rule 14A.52 of the Listing Rules provides that the period for the agreement of a continuing connected transaction must not exceed three years except in special circumstances where the nature of the transaction requires a longer period.

Our Directors are of the view that the nature of the Technology Transfer Agreements requires a longer period, on the grounds that: (i) the Technology Transfer Agreements allow our Group and the Remaining Sihuan Group to spread the risks and costs associated with the marketing and sales of Janagliflozin following the market practice and to leverage their respective resources and established capabilities to expeditiously establish an advantageous position in relevant markets, both of which are long term in nature. Imposing a restriction on the term of the Technology Transfer Agreements for a period of three years would deviate from the market prevailing practice and be contrary to the business intention of the parties; (ii) such

CONNECTED TRANSACTION

a long-term agreement is in the interest of our Company and the Shareholders as a whole; and (iii) as confirmed by CIC, the term of the Technology Transfer Agreements, which exceeds three years, is in line with the industry prevailing practice.

Historical transaction amounts

In 2020, Beijing Huizhiheng paid us the One-Off Payment of approximately RMB212.4 million under the Technology Transfer Agreements. As the market approval for Janagliflozin was just obtained in January 2024, there was no historical amount received by our Group from Beijing Huizhiheng in relation to the Royalty Payments during the Track Record Period.

Annual Caps

The amount of the Royalty Payments to be paid by Beijing Huizhiheng to our Group will be determined in accordance with the following formula:

$$\begin{array}{l} \text{Amount of the Royalty} \\ \text{Payments} \end{array} = \begin{array}{l} 8\% \times \text{net sales of Janagliflozin for the first five years} \\ \text{following the commencement of sales} \\ \\ 5\% \times \text{net sales of Janagliflozin thereafter until the} \\ \text{expiration of the core patents of Janagliflozin} \end{array}$$

Note:

1. Net sales shall mean the results of the gross sales of Janagliflozin, net of applicable taxes, less all costs and expenses incurred in the sale of Janagliflozin by Beijing Huizhiheng.

The above formula is fair and reasonable and in the interest of our Company and the Shareholders as a whole because (i) the terms of the Technology Transfer Agreements, including the formula set out above, were determined after arm’s length negotiation between our Group and Beijing Huizhiheng and in the ordinary and usual course of our business; (ii) as advised by CIC, it is a common practice in the pharmaceutical industry that acquirer to share a portion of the profit with the acquiree from the sales of products developed under the transferred asset; and (iii) taking into account the cost of the developing, manufacturing and commercialization of Janagliflozin, the percentage of the net sales of Janagliflozin to be enjoyed by our Group is in line with the industry average for arrangement of similar nature, as advised by CIC.

CONNECTED TRANSACTION

We have applied to the Stock Exchange for a waiver from strict compliance with the requirement under Rule 14A.53 of the Listing Rules so as to allow us to set the annual caps in relation to continuing connected transactions under the License Agreement as the formula in accordance with the terms as set out in the Technology Transfer Agreements for the following reasons:

- there was no sufficient historical amount and data for us to establish a model to estimate the future sales volume and amount for Janagliflozin as it is a newly developed drug without sufficient market data to analyze the extent of acceptance of such product. It is impractical for our Company to accurately estimate the amount of the royalty to be paid by Beijing Huizhiheng to our Group pursuant to the Technology Transfer Agreements as the amount of the net sales of Janagliflozin depends on the actual addressable market of Janagliflozin, which will in turn depend on various factors including the acceptance by the medical community and patient access, drug pricing, reimbursement and the number of affordable patients, all of which are beyond the control of our Group. Even if we are able to set up a projection model to for estimation purpose, such a model will only present hypothetical predictions, which is not based on scientific analysis using historical data, and could be inaccurate, unreliable and even misleading;
- imposing an arbitrary monetary cap on the potential sales volume of Janagliflozin does not demonstrate commercial reasonableness and would be counter-productive as far as the interests of our Group, Beijing Huizhiheng as well as their respective shareholders are concerned. In the absence of a factually and mathematically reliable model to estimate the annual net sales of Janagliflozin, imposing an arbitrary monetary cap may become an arbitrary ceiling on the transaction amount under the Technology Transfer Agreements. In addition, a fixed annual cap is not helpful to incentivize Beijing Huizhiheng to generate more revenue and profit from selling Janagliflozin, which would go against the commercial objective of the Technology Transfer Agreements. Further, if the actual Royalty Payments exceed the cap, Beijing Huizhiheng would be suspended from selling Janagliflozin to the market until relevant shareholder approval is obtained, which will affect not only the business of both parties but also the patients who need Janagliflozin for treatment, and further affect both parties' market recognition among the doctors and hospitals because they are not able to sustain a stable supply of Janagliflozin. As far as the transaction is on normal commercial terms and the profit margin of Janagliflozin is commercially reasonable and in line with market standards, the interests of our Group, Beijing Huizhiheng and their respective shareholders are protected, and there is no reason or benefit for both parties to impose such fixed cap;
- the disclosure of the annual caps in monetary terms would in effect provide Shareholders and investors as well as competitors of our Company with an indication of our Company's estimated revenue. The disclosure of such information is highly sensitive and would therefore put our Company in disadvantageous position in relation to its business operation and competition with other market players; and

CONNECTED TRANSACTION

- instead of setting a fixed annual cap on the Royalty Payments, if there is any material change to the percentage prescribed in the formulas for the calculation of the Royalty Payments, we will re-comply with the applicable rules under Chapter 14A of the Listing Rules, including seeking independent shareholders’ approval where the case may so require, so as to further ensure the interest of the shareholders of both our Company and Beijing Huizhiheng.

Listing Rules implications

Since the highest applicable percentage ratio in respect of the Technology Transfer Agreements as we currently expect is, on an annual basis, no less than 5%, the transactions under the Technology Transfer Agreements will constitute a continuing connected transaction subject to reporting, annual review, announcement, circular and independent Shareholders’ approval requirements under Chapter 14A of the Listing Rules.

WAIVER APPLICATION FOR NON-EXEMPT CONTINUING CONNECTED TRANSACTION

By virtue of Rule 14A.76(2) of the Listing Rules, the transaction contemplated under the Technology Transfer Agreements will constitute a non-exempt continuing connected transaction subject to reporting, annual review, announcement, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

As the above non-exempt continuing connected transaction is expected to continue on a recurring, continuing basis and will extend over a period of time, our Directors consider that compliance with the above announcement, circular and independent shareholders’ approval requirements would be impractical, unduly burdensome and would impose unnecessary administrative costs on our Company. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver to us under Rule 14A.105 of the Listing Rules from strict compliance with the announcement, circular and independent shareholders’ approval requirements in respect of the above non-exempt continuing connected transaction.

We have further applied for, and the Stock Exchange [has granted] us the waiver from strict compliance with the requirements under Rule 14A.52 and Rule 14A.53 of the Listing Rules in respect of the continuing connected transactions under the Technology Transfer Agreements subject to the following conditions:

- (i) our Company will comply with the announcement, circular and independent Shareholder’s approval requirements under Chapter 14A of the Listing Rules if there is any material change to the terms of the Technology Transfer Agreements;
- (ii) our Company will designate a team to execute and ensure that the transactions in relation to the Technology Transfer Agreements are undertaken in accordance with the terms of the Technology Transfer Agreements;

CONNECTED TRANSACTION

- (iii) our senior management will use their best endeavours to supervise the compliance with the terms of the Technology Transfer Agreements and applicable Listing Rules requirements to the extent not waived by the Stock Exchange on a regular basis;
- (iv) the independent non-executive Directors and the auditors of our Company will review the transactions in relation to the License Agreement on an annual basis and confirm in our annual reports the matters set out in Rules 14A.55 and 14A.56 of the Listing Rules, respectively;
- (v) our Company will disclose in this document the background for entering into the Technology Transfer Agreements, the terms of the Technology Transfer Agreements, the grounds for the waiver sought and the Directors' views on the fairness and reasonableness of the transactions under the Technology Transfer Agreements; and
- (vi) in the event of any future amendments to the Listing Rules imposing more stringent requirements than those as of the date of this document on the above continuing connected transactions, our Company will take immediate steps to ensure compliance with such new requirements.

CONFIRMATION FROM THE DIRECTORS

Our Directors, including the independent non-executive Directors, are of the view that: (i) the non-exempt continuing connected transaction as set out above has been and will be entered into in the ordinary and usual course of our business, on normal commercial terms or terms better to us, that are fair and reasonable and in the interest of us and our Shareholders as a whole; and (ii) the proposed annual caps for the non-exempt continuing connected transaction described in this section are fair and reasonable and in the interest of our Company and the Shareholders as a whole.

CONFIRMATION FROM THE SOLE SPONSOR

Having considered the above, the Sole Sponsor is of the view that: (i) the aforesaid non-exempt continuing connected transaction has been entered into in the ordinary and usual course of business of our Group, on normal commercial terms or better, which are fair and reasonable, and in the interests of our Group and the Shareholders as a whole; and (ii) it is normal business practice for agreement of this type to be of such duration.

SHARE CAPITAL

OVERVIEW

Immediately before the [REDACTED]

As of the Latest Practical Date, our registered capital was RMB450,614,290, comprising 450,614,290 Unlisted Shares with a nominal value of RMB1.00 each.

In the course of the [REDACTED], certain Shareholders of our Company [have applied] to the CSRC, the Stock Exchange and other relevant regulatory authorities to convert the Unlisted Shares held by them into H Shares, details of which are set out below:

Name	Number of Unlisted Shares held as of the Latest Practicable Date	Number of Unlisted Shares applied for conversion into H Shares	% of Number of Unlisted Shares applied for conversion into H Shares to number of Shares held by the Shareholder(s) as of the Latest Practicable Date
Xuanzhu Biopharma	215,294,494	–	–
MIIF	70,032,855	–	–
Hainan Sihuan	39,156,920	–	–
Tianjin Zhenxuan	36,049,144	36,049,144	100%
FIIF II	23,344,465	–	–
Beihai Baimei'en	13,039,600	13,039,600	100%
Shijiazhuang Keshuo	11,672,143	3,501,643	30%
Beihai Jixin	8,466,510	8,466,510	100%
Beijing Tonghe	7,353,450	7,353,450	100%
Ms. Xu	4,714,400	4,714,400	100%
Beihai Keya	3,849,190	3,849,190	100%
Dr. Li	3,020,800	3,020,800	100%
Tianjin Hongzekang	2,969,200	2,969,200	100%
Tianjin Xuansheng	2,485,600	2,485,600	100%
Tianjin Hongteng	1,919,600	1,919,600	100%
Beijing SL	1,780,800	534,240	30%
Dr. Shih	1,700,000	1,700,000	100%
Shanghai Yunxin	1,152,319	1,152,319	100%
Tianjin Pusheng	999,200	999,200	100%
Tianjin Guoding	958,000	958,000	100%
Tianjin Huize	655,600	655,600	100%
Total	450,614,290	93,368,496	20.72%

SHARE CAPITAL

Upon the Completion of the [REDACTED]

Immediately following the completion of the [REDACTED] and the Conversion of Unlisted Shares into H Shares, the share capital of our Company will be as follows:

Assuming the [REDACTED] is not exercised:

Description of Shares	Number of Shares	% of the total issued share capital
Unlisted Shares	[REDACTED]	[REDACTED]
H Shares converted from Unlisted Shares ⁽¹⁾	[REDACTED]	[REDACTED]
H Shares to be issued pursuant to the [REDACTED]	[REDACTED]	[REDACTED]
Total	<u>[REDACTED]</u>	<u>100.0%</u>

Assuming the [REDACTED] is exercised in full:

Description of Shares	Number of Shares	% of the total issued share capital
Unlisted Shares	[REDACTED]	[REDACTED]
H Shares converted from Unlisted Shares ⁽¹⁾	[REDACTED]	[REDACTED]
H Shares to be issued pursuant to the [REDACTED]	[REDACTED]	[REDACTED]
Total	<u>[REDACTED]</u>	<u>100.0%</u>

Note:

(1) Following the completion of the [REDACTED], [REDACTED] Unlisted Shares held by our existing Shareholders will be converted into H Shares on a one-for-one basis and listed on the Stock Exchange for trading. Filing of such conversion of Unlisted Shares into H shares [has been completed] with the CSRC on [●], 2025.

SHARES OF OUR COMPANY

Upon completion of the [REDACTED], depending on whether Shares are listed on the Stock Exchange, our Company will consist of Unlisted Shares and H Shares. Unlisted Shares and H Shares are both ordinary Shares in the share capital of our Company and are regarded as the same class of Shares under the Articles of Association. However, the H Shares generally may not be subscribed for by, or traded between, legal or natural persons of the PRC, apart from certain qualified domestic institutional investors in the PRC, the qualified PRC investors under the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect, and other persons who are entitled to hold the H Shares pursuant to relevant PRC laws and regulations or upon approval by any competent authorities.

SHARE CAPITAL

RANKING

Unlisted Shares and the H Shares carry the same rights and will rank *pari passu* with each other in all 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 the H Shares are to be declared in RMB and paid by our Company in Hong Kong dollars or RMB, whereas all dividends for Unlisted Shares will be paid in RMB. Other than cash, dividends could also be paid in the form of Shares or a combination of cash and Shares.

CONVERSION OF UNLISTED SHARES INTO H SHARES

According to the regulations issued by the securities regulatory authorities of the State Council and the Articles of Association, the Unlisted Shares may be converted into H Shares, and such converted Shares may be listed and traded on an overseas stock exchange provided that the conversion, listing and trading of such converted Shares have been filed with the CSRC. Additionally, such conversion, trading and listing shall meet any requirement of internal approval process and in all respects comply with the regulations prescribed by the securities regulatory authorities of the State Council and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange.

Pursuant to the filing notice of the CSRC dated [REDACTED], [REDACTED] Unlisted Shares will be converted to H Shares on a one-for-one basis and be listed for trading on the Stock Exchange upon completion of the [REDACTED].

[REDACTED] Review and Filing with the CSRC

In accordance with the Guidelines for the “Full Circulation Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境内未上市股份申请全流通业务指引》)” announced by the CSRC, H-share listed companies which apply for the conversion of shares into H shares for listing and circulation on the Stock Exchange shall file the application with the CSRC. An unlisted domestic joint stock company may apply for “full circulation” when applying for an overseas listing.

Our Company [has applied] for a “full circulation” filing when applying for an [REDACTED] with the CSRC on [●], 2024, and submitted the application reports, authorization documents of the shareholders of unlisted shares for which an H-share “full-circulation” was applied, undertaking about the compliance of share acquisition and other documents in accordance with the requirements of CSRC. Our Company [has received] the filing notice from the CSRC dated [●], 2025 in relation to the filing of the [REDACTED] and H-share “full circulation.”

SHARE CAPITAL

Where the [REDACTED] cannot be completed within one year upon receipt of the filing notice, and our Company will continue to conduct [REDACTED] after that, it shall update the filing materials, and the CSRC will update the public filing information accordingly.

[REDACTED] by the Stock Exchange

We [have applied] to the [REDACTED] for the granting of [REDACTED], our H Shares to be issued pursuant to the [REDACTED] (including any H Shares which may be issued pursuant to the exercise of the [REDACTED]) and the H Shares to be converted from [REDACTED] Unlisted Shares on the Stock Exchange.

We will perform the following procedures for the Conversion of Unlisted Shares into H Shares after receiving the approval of the Stock Exchange: (i) giving instructions to our [REDACTED] regarding relevant share certificates of the converted H Shares; and (ii) enabling the converted H Shares to be accepted as eligible securities by [REDACTED] for deposit, clearance and settlement in the [REDACTED]. The Full Circulation Participating Shareholders may only [REDACTED] the Shares upon completion of following domestic procedures. Any application for [REDACTED] of the converted Shares on the Stock Exchange after our initial [REDACTED] is subject to prior notification by way of announcement to inform the Shareholders and the public of any proposed conversion.

Domestic Procedures

The Full Circulation Participating Shareholders may only [REDACTED] the Shares upon completion of the below arrangement procedures for the registration, deposit and transaction settlement in relation to the conversion and [REDACTED]:

- (i) we will appoint China Securities Depository and Clearing Corporation Limited (“CSDC”) as the nominal holder to deposit the relevant securities at CSDC (Hong Kong), which will then deposit the securities at [REDACTED] in its own name. CSDC, as the nominal holder of the Full Circulation Participating Shareholders, shall handle all custody, maintenance of detailed records, cross-border settlement and corporate actions, etc. relating to the converted H Shares for the Full Circulation Participating Shareholders;
- (ii) we will engage a domestic securities company (the “**Domestic Securities Company**”) to provide services such as sending orders for trading of the converted H Shares and receipt of transaction returns. The Domestic Securities Company will engage a Hong Kong securities company (the “**Hong Kong Securities Company**”) for settlement of share transactions. We will make an application to CSDC, Shenzhen Branch for the maintenance of a detailed record of the initial holding of the converted H Shares held by our Shareholders. Meanwhile, we will submit applications for a domestic transaction commission code and abbreviation, which shall be confirmed by CSDC, Shenzhen Branch as authorized by Shenzhen Stock Exchange;

SHARE CAPITAL

- (iii) the Shenzhen Stock Exchange shall authorize Shenzhen Securities Communication Co., Ltd. to provide services relating to transmission of trading orders and transaction returns in respect of the converted H Shares between the Domestic Securities Company and the Hong Kong Securities Company, and the real-time market forwarding services of the H Shares;
- (iv) according to the Notice of SAFE on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》), the Full Circulation Participating Shareholders shall complete the overseas shareholding registration with the local foreign exchange administration bureau before the Shares are sold, and after the overseas shareholding registration, open a specified bank account for the holding of overseas shares by domestic investors at a domestic bank with relevant qualifications and open a fund account for the H Share “Full Circulation” at the Domestic Securities Company. The Domestic Securities Company shall open a securities trading account for the H Share “Full Circulation” at the Hong Kong Securities Company; and
- (v) the Full Circulation Participating Shareholders shall submit trading orders of the converted H Shares through the Domestic Securities Company. Trading orders of the Full Circulation Participating Shareholders for the relevant Shares will be submitted to the Stock Exchange through the securities trading account opened by the Domestic Securities Company at the Hong Kong Securities Company. Upon completion of the transaction, settlements between each of the Hong Kong Securities Company and CSDC (Hong Kong), CSDC (Hong Kong) and CSDC, CSDC and the Domestic Securities Company, and the Domestic Securities Company and the Full Circulation Participating Shareholders, will all be conducted separately.

As a result of the conversion, the shareholding of the relevant Full Circulation Participating Shareholders in our Unlisted Shares shall be reduced by the number of the Unlisted Shares converted and the number of H Shares shall be increased by the number of converted H Shares.

RESTRICTION ON TRANSFER OF SHARES ISSUED PRIOR TO THE [REDACTED]

The PRC Company Law provides that in relation to the public share offering of a company, the shares of the company which have been issued prior to the offering shall not be transferred within one year from the date of the listing. Accordingly, Shares issued by our Company prior to the [REDACTED] shall be subject to this statutory restriction and shall not be transferred for a period of one year from the [REDACTED].

Our Company will work with the Domestic Securities Company to be engaged by our Company to restrict the trading of the H Shares converted from Unlisted Shares technically within one year after the [REDACTED].

SHARE CAPITAL

Pursuant to the PRC Company Law, Shares transferred by our Directors, Supervisors and members of the senior management each year during their term of office shall not exceed 25% of their total respective shareholdings in our Company. The Shares that the aforementioned persons held in our Company cannot be transferred within one year from the date on which the H Shares are [REDACTED], nor within half a year after they leave their positions in our Company. The Articles of Association may contain other restrictions on the transfer of our Shares held by our Directors, Supervisors and members of senior management, a summary of which is set out in “Appendix V — Summary of Articles of Association.”

SHAREHOLDER’S GENERAL MEETINGS

For details of circumstances under which our general Shareholders’ meeting required, see “Appendix IV — Summary of Principal Legal and Regulatory Provisions” and “Appendix V — Summary of Articles of Association.”

GENERAL MANDATES TO ISSUE H SHARES

Subject to the completion of the [REDACTED], our Board has been granted a general mandate to allot and issue Shares at any time within a period up to the date of the conclusion of the next annual general meeting of the Shareholders or the date on which our Shareholders pass a special resolution to revoke or change such mandate, whichever is earlier, upon such terms and conditions and for such purposes and to such persons as our Board in their absolute discretion deem fit, and to make necessary amendments to the Articles of Association, provided that, the number of H Shares to be issued shall not exceed 20% of the number of Shares in issue as of the [REDACTED].

For details, see “Appendix VI — Statutory and General Information — Further Information about Our Group — Shareholders’ Resolutions.”

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and the Conversion of Unlisted Shares into H Shares (assuming the [REDACTED] is not exercised), the following persons will have interests and/or short positions in the Shares or underlying Shares of our Company, which would be required to be disclosed to us and the Stock Exchange pursuant to the provisions of Divisions 2 and 3 of Part XV of the SFO, or will be, directly or indirectly, entitled to exercise, or control the exercise of, 10% or more of the voting power at any general meeting of our Company:

LONG POSITIONS IN THE SHARES OF OUR COMPANY

Name	Nature of Interest	Shares held as of the Latest Practicable Date		Shares held immediately following the completion of the [REDACTED] and the Conversion of Unlisted Shares into H Shares (assuming the [REDACTED] is not exercised)		
		Number and description	% of shareholding in the total issued share capital	Number and description	% of shareholding in the Unlisted Shares/H Shares ⁽¹⁾	% of shareholding in the total issued share capital ⁽¹⁾
Sihuan Pharm.	Interest in a controlled corporation ⁽²⁾	254,451,414 Unlisted Shares	56.47% [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
CS Capital Co., Ltd. (國投招商投資管理有限公司) (“CS Capital”).	Interest in a controlled corporation ⁽³⁾	93,377,320 Unlisted Shares	20.72% [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Mr. Che Yuxuan (車雨軒) (“Mr. Che”)	Interest in a controlled corporation ⁽⁴⁾	36,049,144 Unlisted Shares	8.00% [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Mr. Zhu Xiaodong (朱曉東) (“Mr. Zhu”)	Interest in a controlled corporation ⁽⁵⁾	13,039,600 Unlisted Shares	2.89% [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Mr. He Chengming (何成明) (“Mr. He”)	Interest in a controlled corporation ⁽⁶⁾	10,952,110 Unlisted Shares	2.43% [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Notes:

- (1) The calculation is based on the total number of [REDACTED] Unlisted Shares and [REDACTED] H Shares in issue immediately upon completion of the [REDACTED] and the Conversion of Unlisted Shares into H Shares (assuming the [REDACTED] is not exercised). Unlisted Shares and H Shares are both ordinary Shares of our Company.
- (2) Each of Xuanzhu Biopharma and Hainan Sihuan is wholly owned by Sihuan Pharm. Therefore, Sihuan Pharm was deemed to be interested in the aggregate number of Shares held by Xuanzhu Biopharma and Hainan Sihuan under the SFO.

SUBSTANTIAL SHAREHOLDERS

- (3) Each of Metropolitan Industrial Investment Fund (京津冀產業協同發展投資基金(有限合夥)) (“MIIF”) and Future Industry Investment Fund II (先進製造產業投資基金二期(有限合夥)) (“FIIF II”) is a limited partnership established under the laws of the PRC and is managed by its general partner, CS Capital. Therefore, CS Capital was deemed to be interested in the aggregate number of Shares held by MIIF and FIIF II under the SFO.
- (4) Tianjin Zhenxuan is a limited partnership established under the laws of the PRC and managed by its general partner, Mr. Che. Therefore, Mr. Che was deemed to be interested in the Shares held by Tianjin Zhenxuan under the SFO.
- (5) Beihai Baimei'en is a limited partnership established under the laws of the PRC and managed by its general partner, Mr. Zhu. Therefore, Mr. Zhu was deemed to be interested in the Shares held by Beihai Baimei'en under the SFO.
- (6) Each of Beihai Jixin and Tianjin Xuansheng is a limited partnership established under the laws of the PRC and managed by their general partner, Mr. He. Therefore, Mr. He was deemed to be interested in the aggregate number of Shares held by Beihai Jixin and Tianjin Xuansheng under the SFO.

Save as otherwise disclosed herein, our Directors are not aware of any persons who will, immediately following the [REDACTED] and the Conversion of our Unlisted Shares into H Shares (assuming the [REDACTED] is not exercised), have any interests and/or short positions in the Shares or underlying Shares of our Company which would fall to be disclosed to our Company and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or will be, directly or indirectly, entitled to exercise, or control the exercise of, 10% or more of the voting power at any general meeting of our Company.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board consists of nine Directors, comprising three executive Directors, three non-executive Directors and three independent non-executive Directors. Pursuant to the Articles of Association, our Directors are elected and appointed by our Shareholders at a Shareholders’ meeting for a term of three years, which is renewable upon re-election and re-appointment. The following table sets forth the key information about our Directors as of the Latest Practicable Date.

Name	Age	Positions	Date of joining our Group	Date of appointment as a Director	Roles and responsibilities
Ms. Xu Yanjun (徐艷君)	52	Chairperson of the Board and executive Director	May 25, 2020	May 25, 2020	Responsible for leading our Board in its governance and oversight of our Group and guiding our Company on significant matters.
Dr. Li Jia Kui (李嘉逵)	59	Executive Director and the general manager	September 1, 2013	December 12, 2018	Responsible for the daily management and operation of our Group, managing the R&D activities, developing and implementing medium- and long-term strategic plans, and assisting the chairperson with the overall management of our Group.
Dr. Shih Cheng-Kon (史澈空)	69	Executive Director	July 1, 2011	December 1, 2018	Responsible for leading the Scientific Committee of our Company and overseeing the progress of our R&D activities.
Ms. Li Huiying (李惠英)	57	Non-executive Director	August 28, 2020	August 28, 2020	Responsible for overseeing Board affairs and giving strategic advice and guidance on the business operations of our Group.
Mr. Yu Lifeng (尉麗峰)	52	Non-executive Director	November 16, 2021	November 16, 2021	Responsible for overseeing Board affairs and giving strategic advice and guidance on the business operations of our Group.
Ms. Chen Yanling (陳燕玲)	46	Non-executive Director	November 17, 2024	November 17, 2024	Responsible for overseeing Board affairs and giving strategic advice and guidance on the business operations of our Group.
Mr. Liu Shuo (劉碩)	41	Independent non-executive Director	December 1, 2021	December 1, 2021	Responsible for providing independent advice and judgment to our Board.
Ms. Wang Yu (王宇)	43	Independent non-executive Director	December 1, 2021	December 1, 2021	Responsible for providing independent advice and judgment to our Board.
Mr. Fan Chi Chiu (范智超)	39	Independent non-executive Director	November 17, 2024	November 17, 2024	Responsible for providing independent advice and judgment to our Board.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Executive Directors

Ms. Xu Yanjun (徐艷君), aged 52, is the chairperson of our Board and our executive Director. She was appointed as our Director and the chairperson of our Board in May 2020 and was then re-designated as our executive Director in November 2024. Ms. Xu also holds directorships and managerial positions across our subsidiaries. She is primarily responsible for leading our Board in its governance and oversight of our Group and guiding our Company on significant matters.

Ms. Xu brings nearly three decades of experience in the pharmaceutical industry to our Company. She began her career as a manager of the Production Department at Harbin Sequel Biological Engineering Pharmaceutical Co., Ltd. (哈爾濱世亨生物工程藥業股份有限公司) (currently known as Harbin Pacifico Biopharmaceutical Co., Ltd. (哈爾濱派斯菲科生物製藥有限公司)), where she was primarily responsible for manufacturing and R&D of blood products, from August 1995 to March 2003. Ms. Xu later joined Changchun Gaoxin BCHT Pharmaceutical Research Institute Co., Ltd. (長春高新百克藥物研究院有限公司) (currently known as Changchun BCHT Biotechnology Co. (長春百克生物科技股份有限公司)), the shares of which are listed on the Shanghai Stock Exchange STAR Market (stock code: 688276) in April 2003, and left in February 2019 with her last position as the deputy general manager.

Ms. Xu subsequently assumed several managerial and leadership roles within Sihuan Group, including: (i) the chairperson at Jilin Huikang Pharmaceutical Co., Ltd. (吉林匯康製藥有限公司) from January 2019 to June 2020; (ii) the chief project officer and director of the operation management center at Sihuan Pharm from February 2019 to May 2020; and (iii) a director at both Jilin Sihuan Pharmaceutical Co., Ltd. (吉林四環製藥有限公司) and Jilin Zhenao Pharmaceutical Co., Ltd. (吉林振澳製藥有限公司) from November 2019 to August 2020. Since July 2020, Ms. Xu has also served as a director and the general manager of Shijiazhuang Pusheng Pharmaceutical Technology Co., Ltd. (石家莊普晟醫藥科技有限公司).

Ms. Xu graduated from Heilongjiang College of Chinese Medicine (黑龍江中醫學院) (currently known as Heilongjiang University of Chinese Medicine (黑龍江中醫藥大學)) in the PRC, majoring in Chinese medicine resources, in July 1995 and a master’s degree in bioengineering from Jilin University (吉林大學) in the PRC in June 2006.

Dr. Li Jia Kui (李嘉達), aged 59, was appointed as our Director in December 2018 and the general manager of our Company in June 2024. He was then re-designated as our executive Director in November 2024. Dr. Li also holds several managerial positions across our subsidiaries. He is primarily responsible for the daily management and operation of our Group, managing the R&D activities, developing and implementing medium- and long-term strategic plans, and assisting the chairperson with the overall management of our Group.

Dr. Li began his career as a surgeon at Ruijin Hospital affiliated with Shanghai Second Medical University (上海第二醫科大學附屬瑞金醫院) (currently known as Ruijin Hospital-Shanghai Jiao Tong University School of Medicine (上海交通大學醫學院附屬瑞金醫院)) from July 1988 to January 1994. He transitioned to the pharmaceutical industry in 1999 by joining Hoffmann-La Roche Ltd., a listed Swiss pharmaceutical company (SIX: RO), primarily engaged in *in-vitro* diagnostics and innovative solutions for major disease areas. During his

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

tenure at Hoffmann-La Roche Ltd. from October 1999 to March 2013, Dr. Li successively served as the research scientist, senior research scientist, associate principal scientist and principal scientist. He developed extensive hands-on expertise in drug discovery and the development of new chemical entities (“NCEs”), leading and participating in the screening, optimization and later-stage development of numerous NCEs for oncology, metabolic diseases, viral infection and inflammatory diseases. In September 2013, Dr. Li joined our Group as a senior director (高級總監) of Shandong Xuanzhu and then got promoted as the executive director (執行總監), a position he held until June 2020, when he was further promoted to the chairperson and general manager of Shandong Xuanzhu.

Dr. Li obtained a bachelor’s degree of clinical medicine from Shanghai Second Medical University (上海第二醫科大學) (currently known as Shanghai Jiao Tong University School of Medicine (上海交通大學醫學院)) in the PRC in July 1988, followed by a master’s degree in industrial pharmacy in September 1997 and a degree of doctor of philosophy in May 2011, both from Long Island University in the U.S.

Dr. Shih Cheng-Kon (史澂空), aged 69, was appointed as our Director in December 2018 and was then re-designated as our executive Director in November 2024. Dr. Shih currently holds several directorships in our subsidiaries. He is primarily responsible for leading the Scientific Committee of our Company and overseeing the progress of our R&D activities.

Dr. Shih has over 40 years of experience in the pharmaceutical industry, marked by remarkable expertise in R&D. Dr. Shih began his career as a post-doctoral researcher focusing on oncogene research at Memorial Sloan-Kettering Cancer Center, a globally renowned institution in cancer treatment, research, and education, from April 1984 to August 1988. Subsequently, from December 1989 to April 2010, Dr. Shih served as a senior principal scientist and research project director at Boehringer Ingelheim International GmbH where he was primarily responsible for the overall management of innovative drugs and technology platforms.

Dr. Shih has extensive experience across multiple therapeutic areas, including HIV, immunological diseases, and cardio-metabolic disorders. He was instrumental in leading the discovery and development of Viramune, a first-in-class, non-nucleoside reverse transcriptase inhibitor in the cocktail regimen for the successful treatment of AIDS.

Since joining our Group in July 2011, Dr. Shih has demonstrated management capabilities and unwavering commitment to our Company’s growth through a series of strategic leadership roles, including: (i) the vice president of Shandong Xuanzhu from July 2011 to January 2016; (ii) the general manager of Shandong Xuanzhu from January 2016 to October 2020, (iii) the general manager of our Company from December 2018 to June 2024, and (iv) the deputy chairperson of the Board from November 2021 to November 17, 2024.

Dr. Shih obtained a bachelor’s degree in agricultural chemistry from National Taiwan University (台灣國立大學) in June 1977 and a doctoral degree in molecular genetics and oncology from the Rockefeller University in the U.S. in June 1985.

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Non-Executive Directors

Ms. Li Huiying (李惠英), aged 57, is our non-executive Director. Ms. Li was appointed as our Director in August 2020 and re-designated as our non-executive Director in November 2024. She is primarily responsible for overseeing Board affairs and giving strategic advice and guidance on the business operations of our Group.

Ms. Li has almost 30 years’ experience in pharmaceutical production management. She worked at Shijiazhuang Second Pharmaceutical Factory (石家莊市第二製藥廠) from January 1996 to September 2001. From November 2001 to December 2012, she worked at Hebei UNION Pharmaceutical Co., Ltd. (河北聯合製藥有限公司), successively serving as an assistant to general manager, the deputy general manager, and the general manager. Subsequently, she joined Sihuan Group, where she has served as the director of the Value Management Center (價值管理中心總監) and assistant to the chairperson of the board of Sihuan Pharm since December 2012, primarily responsible for investment, financing, and corporate value management for Sihuan Group.

Currently, Ms. Li is also holding directorships and managerial positions at various companies, including:

Period of service	Name of company	Position
Since November 2017	Pharmadax (Foshan) Co., Ltd. (佛山德芮可製藥有限公司)	Deputy chairperson of the board and director
Since September 2017	Jilin Sihuan Haisikaier Technology Co., Ltd. (吉林四 環海斯凱爾科技有限公司)	Director
Since April 2021	Jilin Zesheng Environment Protection Engineering Co., Ltd. (吉林省澤盛環保工程有限 公司)	Deputy chairperson of the board
Since January 2023	Longyu Hongda Investment Management Co., Ltd. (隆裕弘 達投資管理有限公司)	Director

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Ms. Li obtained a bachelor’s degree in industrial analysis from Hebei Light Chemical Institute (河北輕化工學院) (currently known as Hebei University of Science & Technology (河北科技大學)) in the PRC in July 1990.

Mr. Yu Lifeng (尉麗峰), aged 52, is our non-executive Director. He was appointed as our Director in November 2021 and re-designated as our non-executive Director in November 2024. He is primarily responsible for overseeing Board affairs and giving strategic advice and guidance on the business operations of our Group.

From December 2001 to October 2004, he served as a manager of the Finance Department at Hebei Information Industry Investment Group Co., Ltd. (河北信息產業投資集團有限公司). Subsequently, he served as an assistant to the general manager, the deputy general manager, the general manager, the deputy chairperson of the board and deputy secretary of the party committee, successively, at Hebei Information Industry Investment Group Co., Ltd. from October 2004 to July 2016. Mr. Yu then joined Gaokang Capital Investment Management Co., Ltd. (高康資本投資管理有限公司) as the president from July 2016 to June 2018. In addition to assuming the role of a non-executive Director at our Company, Mr. Yu has also been serving as a managing director at CS Capital (Nanjing) Investment Management Co., Ltd. (國投招商(南京)投資管理有限公司), a company engaged in equity investments, since July 2018.

In addition to the above positions, Mr. Yu is also holding positions at various companies, including:

<u>Period of service</u>	<u>Name of company</u>	<u>Position</u>
Since December 2023 . . .	Beijing Jiejie West Technology Co., Ltd. (北京捷傑西科技股份有限公司)	Director
Since March 2023	Xingtai Naknor Technology Co., Ltd. (邢台納科諾爾精軋科技股份有限公司), the shares of which are listed on Beijing Stock Exchange (stock code: 832522)	Director
Since December 2022 . . .	Shanghai Yutian Guanjia Technology Co., Ltd. (上海毓恬冠佳科技股份有限公司)	Director
Since October 2020	Hengong Precision Equipment Co., Ltd. (河北恒工精密裝備股份有限公司), the shares of which are listed on the Shenzhen Stock Exchange (stock code: 301261)	Director

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Period of service	Name of company	Position
Since October 2020	Shougang Zhixin Electromagnetic Materials Co., Ltd. (首鋼智新電磁材料(遷安)股份有限公司)	Director
Since December 2020 . . .	Zhonghang Shangda Superalloys Co., Ltd. (中航上大高溫合金材料股份有限公司), the shares of which are listed on Shenzhen Stock Exchange (stock code: 301522)	Director

Mr. Yu obtained a bachelor’s degree in business management and administration from Hebei University of Science and Technology (河北科技大學) in the PRC in July 2005 and a master’s degree in business management and administration from Beijing Jiaotong University (北京交通大學) in the PRC in January 2008.

Ms. Chen Yanling (陳燕玲), aged 46, is our non-executive Director. She was appointed as our non-executive Director in November 2024. Ms. Chen is primarily responsible for overseeing Board affairs and giving strategic advice and guidance on the business operations of our Group.

Ms. Chen is currently an executive director, one of the joint company secretaries and the co-chairman of the risk management committee of Sihuan Pharm and was appointed to its board on 20 April 2018. Currently, her main responsibilities at Sihuan Group are to manage day-to-day matters of the board, the daily compliance matters relating to the listing, the ESG and risk control and management matters and day-to-day matters on the management of Sihuan Group in Hong Kong, Macau and overseas companies. She joined Sihuan Group in March 2006 and has served in Sihuan Group for 18 years. Since joining Sihuan Group in 2006, she has been working as an assistant to the chairman of Sihuan Group and the board secretariat.

Prior to joining Sihuan Group, she worked as an English translation officer at the information centre of Guangzhou Tourism Bureau in 2001. In 2002, she worked as an assistant to general manager at Yip’s Ink & Chemicals (Zhongshan) Company Ltd. (葉氏油墨(中山)有限公司) and was in charge of the daily management of the general manager’s office as well as planning and promotion. In 2004, she worked as an assistant to the president of Guangzhou Culturecom Company Ltd. (廣州文化傳信有限公司) and was in charge of the daily management of the president’s office, planning and budgeting, media resources integration and development, and maintenance, etc.

Ms. Chen obtained a bachelor’s degree in English from Hunan University (湖南大學) in the PRC in June 2001.

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Independent Non-Executive Directors

Mr. Liu Shuo (劉碩), aged 41, is our independent non-executive Director, primarily responsible for providing independent advice and judgment to our Board.

Mr. Liu has been working at Commerce & Finance Law Offices (通商律師事務所) since May 2006, focusing on the areas of corporate financing, mergers & acquisitions, corporate reorganization, securities and capital market, successively serving as an associate and a partner. He also served as an independent director at Beijing Bashi Media Co., Ltd. (北京巴士傳媒股份有限公司), the shares of which are listed on the Shanghai Stock Exchange (stock code: 600386) from June 2014 to June 2020. Apart from that, Mr. Liu has been serving as an independent director at Thunder Software Technology Co., Ltd. (中科創達軟件股份有限公司), the shares of which are listed on the Shenzhen Stock Exchange (stock code: 300496), since June 2024. He has also become a member of the Legal Committee for the Digital Economy and Artificial Intelligence of Beijing Lawyers Association (北京市律師協會數字經濟與人工智能領域法律專業委員會) since June 2024.

Mr. Liu obtained a bachelor’s degree in law from Fudan University (復旦大學) in the PRC in July 2005. Mr. Liu is licensed to practice law in the PRC.

Ms. Wang Yu (王宇), aged 43, is our independent non-executive Director, primarily responsible for providing independent advice and judgment to our Board.

Ms. Wang has been serving as an executive director and general manager at Qingdao Aimeiruikang International Trade Co., Ltd. (青島艾美睿康國際貿易有限公司) since January 2014 and the chairperson of the board and chief executive officer at Beijing Darwin Cell Biotechnology Co., Ltd. (北京達爾文細胞生物科技股份有限公司) since June 2016, where she was primarily responsible for the tactic planning and overall operation management.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

In addition to the above roles, Ms. Wang is currently holding various positions in several private companies as the follows:

Period of service	Name of company	Position
Since July 2021	Beijing Darwin Beagle Biotechnology Co., Ltd. (北京達爾 文小獵犬生物科技有限公司)	Executive director and manager
Since August 2021	Darwin New Research (Beijing) Biotechnology Co., Ltd. (達爾文新 研(北京)生物科技有限公司)	Executive director
Since January 2014	Qingdao Aimeirui Kang International Trade Co., Ltd. (青島艾美睿康國際 貿易有限公司)	Executive director and general manager
Since March 2016	Qingdao Aida Microcomputer Network Technology Co., Ltd. (青 島艾達微訊網絡科技有限公司)	Executive director and general manager
Since September 2015	Qingdao Yinna Microcomputer Electronic Technology Co., Ltd. (青島銀納微訊電子科技有限公司)	Executive director and general manager
Since November 2022	Darwin Guangxian (Beijing) Biotechnology Co., Ltd. (達爾文光 線(北京)生物技術有限公司)	Executive director and manager
Since October 2022	Darwin Qidian (Beijing) Biopharmaceutical Co., Ltd. (達爾 文起點(北京)生物製藥有限責任公 司)	Executive director and manager
Since October 2022	Darwin Yuandian (Beijing) Biotechnology Co., Ltd. (達爾文圓 點(北京)生物技術有限責任公司)	Executive director and manager

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Ms. Wang obtained her master’s degree in management from North Borneo University College in Malaysia in November 2021.

Mr. Fan Chi Chiu (范智超), aged 39, is our independent non-executive Director, primarily responsible for providing independent advice and judgment to our Board.

Mr. Fan has more than 15 years of experience in accounting and corporate finance. Mr. Fan worked at PricewaterhouseCoopers from October 2007 to June 2011 with his last position as a senior associate. He then served as (i) an analyst at Barclays Capital Asia Limited from July 2011 to February 2014; (ii) a finance director at Vantasia Holdings (H.K.) Limited from April 2014 to March 2015; (iii) the chief financial officer at the ELL Environmental Holdings Limited (強泰環保控股有限公司), the shares of which are listed on the Main Board of the Stock Exchange (stock code: 1395) from April 2015 to September 2021; and (iv) an executive director at Grace Wine Holdings Limited (怡園酒業控股有限公司), the shares of which are listed on the GEM of the Stock Exchange (stock code: 8146), from July 2017 to September 2021.

Mr. Fan has been serving as the chief investment director at AB Builders Group Limited (奧邦建築集團有限公司), the shares of which are listed on the Stock Exchange (stock code: 1615), from November 2021. He has been acting as an independent non-executive director at several companies listed on the Stock Exchange, including (i) Shinelong Automotive Lightweight Application Limited (stock code: 1930), since June 2019; (ii) Hevol Services Group Co. Limited (stock code: 6093), since June 2019; and (iii) Weihai City Commercial Bank Co., Ltd. (威海市商業銀行股份有限公司) (stock code: 9677), since February 2020.

Mr. Fan obtained his bachelor’s degree in professional accountancy from the Chinese University of Hong Kong in December 2007. Mr. Fan is a certified public accountant of the Hong Kong Institute of Certified Public Accountants in January 2011.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

SUPERVISORY COMMITTEE

Our Supervisory Committee comprises three members. Our Supervisors serve a term of three years and may be re-elected for successive reappointments. The following table sets forth the key information about our Supervisors as of the Latest Practicable Date.

Name	Age	Positions	Date of joining our Group	Date of appointment as a Supervisor	Roles and responsibilities
Mr. Lu Benyu (盧本玉)	51	Chairperson of the Supervisory Committee	November 16, 2021	November 16, 2021	Responsible for supervising the performance of duties by Directors and senior management.
Mr. Wang Xiaoping (王曉平)	37	Supervisor	June 28, 2024	June 28, 2024	Responsible for supervising the performance of duties by Directors and senior management.
Ms. Yue Xin (岳鑫)	31	Supervisor	January 1, 2019	November 16, 2021	Responsible for the administrative management of our Group and supervising the performance of duties by Directors and senior management.

Mr. Lu Benyu (盧本玉), aged 51, was appointed as our Supervisor and the chairperson of the Supervisory Committee of our Company in November 2021. He is primarily responsible supervising the performance of duties by Directors and senior management.

Mr. Lu is equipped with affluent experiences in internal control, internal audit, and risk management. He worked at Beijing Aorui Jinguofeng Biological Technology Co., Ltd. (北京奧瑞金國豐生物技術有限公司) from February 2008 to October 2009. He subsequently served as (i) a financial manager at Nofibre Banye (Yangling) Co., Ltd. (諾菲博爾板業(楊凌)有限公司) from October 2009 to March 2012, and (ii) the risk management director at Xi'an Haotian Biotechnology Co., Ltd. (西安皓天生物工程技術有限責任公司) from March 2012 to April

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2013. Mr. Lu then joined Sihuan Group in April 2013 as the director (總監) of audit and supervision center at Sihuan Pharm, primarily responsible for overseeing internal control, audit, supervision, compliance, risk management, and ESG matters. Currently, he also serves as a supervisor at several subsidiaries of Sihuan Group.

Mr. Lu obtained a bachelor’s degree in accounting from Tianjin Business School (天津商學院) (currently known as Tianjin University of Commerce (天津商業大學)) in the PRC in July 1995. He obtained the Certified Internal Auditor (CIA) certification and the Certification in Control Self-Assessment (CCSA), both awarded by the Institute of Internal Auditors (國際內部審計師協會) in November 2009. He was certified as a senior audit by Beijing Municipal Human Resources and Social Security Bureau (北京市人力資源和社會保障局) in October 2020. Mr. Lu has been an executive council member (常務理事) of the Beijing Internal Audit Association (北京市內部審計協會).

Mr. Wang Xiaoping (王曉平), aged 37, was appointed as our Supervisor in June 2024. He is primarily responsible for supervising the performance of duties by Directors and senior management.

Mr. Wang began his career at Sihuan Group in July 2011, initially serving as a project manager at Beijing Sihuan Pharmaceutical Co., Ltd. (北京四環製藥有限公司) until July 2014. He then took on several managerial positions within Sihuan Group, including (i) manager of the Procurement Department from July 2015 to December 2017, (ii) assistant to the executive president from December 2017 to December 2020, and (iii) head of the office of the president and vice president since 2021.

Mr. Wang obtained a bachelor’s degree in applied physics from Guilin University of Technology (桂林理工大學) in the PRC in June 2011, and a master’s degree in business management from Peking University (北京大學) in the PRC in July 2023.

Ms. Yue Xin (岳鑫), aged 31, was appointed as our Supervisor in November 2021. She is primarily responsible for the administrative management of our Group and supervising the performance of duties by Directors and senior management.

Ms. Yue worked at Beijing Asia-East Bio-Pharmaceutical Co., Ltd. (北京亞東生物製藥有限公司) from October 2015 to February 2016. In January 2019, she joined in our Group serving as an administrative assistant and successively got promoted to the positions of administrative specialist and head of administration in January 2020 and January 2022, respectively, primarily responsible for the administrative management affairs.

Ms. Yue graduated from China University of Political Science and Law (中國政法大學) in the PRC, majoring in law, in July 2018.

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SENIOR MANAGEMENT

Our senior management is responsible for the day-to-day management of our business. The following table sets forth the key information about our senior management as of the Latest Practicable Date.

Name	Age	Positions	Date of joining our Group	Date of appointment as a senior management	Roles and responsibilities
Dr. Li Jia Kui (李嘉逵)	59	General manager	September 1, 2013	September 1, 2013	Responsible for the daily management and operation of our Group, managing the R&D activities, developing and implementing medium- and long-term strategic plans, and assisting the chairperson with the overall management of our Group.
Dr. Wang Li (王莉)	52	Deputy general manager	May 25, 2021	May 25, 2021	Responsible for leading clinical development activities, formulating, organizing and implementing clinical development plans, and overseeing the business development initiatives.
Mr. Yu Tao (余濤)	48	Deputy general manager	June 3, 2024	June 3, 2024	Responsible for the overall management and operations of the marketing center and sales department of our Group.
Mr. He Chengming (何成明)	43	Deputy general manager and Board secretary	September 5, 2018	January 1, 2019	Responsible for the overall management and operations of the legal center, securities center and finance center of our Group.

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Dr. Li Jia Kui (李嘉逵), aged 59, is the executive Director and the general manager of our Company. For his biography, see “— Board of Directors — Executive Directors” in this section.

Dr. Wang Li (王莉), aged 52, joined our Group as the vice president of clinical medicine in May 2021 and was later appointed as our deputy general manager in May 2024. She also holds managerial positions at Beijing Xuanzhu. Dr. Wang is primarily responsible for leading clinical development activities, formulating, organizing and implementing clinical development plans, and overseeing the business development initiatives.

Dr. Wang began her career as a physician oncologist at the Chinese PLA General Hospital (中國人民解放軍陸軍總醫院) (currently known as Seventh Medical Center of Chinese People’s Liberation Army General Hospital (中國人民解放軍總醫院第七醫學中心)) from August 2000 to March 2018. She then joined as the associate medical director at Shanghai Kezhou Drug Research and Development Co., Ltd. (上海科州藥物研發有限公司) (currently known as Shanghai Kezhou Drug Co. (上海科州藥物股份有限公司)) where she was primarily responsible for medical monitoring and the design of clinical development programs, from April 2018 to September 2018. From September 2018 to November 2019, she served as the medical director of the solid tumor therapeutic area at Guangzhou Yuheng Biotechnology Co., Ltd. (廣州譽衡生物科技有限公司). From November 2019 to May 2021, Dr. Wang worked at Chuangshi (Beijing) Pharmaceutical Technology Co., Ltd. (創石(北京)醫藥科技有限公司), a wholly-owned subsidiary of CStone Pharmaceuticals as the medical director (醫學總監), a biotech company listed on the Stock Exchange (stock code: 2616), where she was primarily responsible for medical monitoring and the design of clinical development programs.

Dr. Wang obtained her bachelor’s degree in Japanese language medicine from China Medical University (中國醫科大學) in the PRC in July 1997. She then obtained a master’s degree in internal medicine and a doctoral degree in immunology from the Academy of Military Medical Sciences (軍事醫學科學院) in the PRC in July 2000 and July 2007, respectively.

Mr. Yu Tao (余濤), aged 48, joined our Group as a deputy general manager of our Company in June 2024. He is primarily responsible for the overall management and operations of the marketing center and sales department of our Group.

Mr. Yu has extensive experience in market promotion and sales within the pharmaceutical sector. Over the course of his career, Mr. Yu has held several senior positions in prominent pharmaceutical companies. He joined the marketing department (市場部) of Sihuan Pharm in December 2008, serving as the regional product manager and was successively promoted to the positions of market manager and the director of market promotion (市場部推廣總監). From July 2012 to September 2021, he transitioned to the sales and promotion center (營銷中心) of Sihuan Pharm, consecutively serving as the commercial region director (商務大區總監), commercial director (商務總監) and the general manager of sales and promotion. During his

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tenure, he took the primary responsibilities for the overall management of sales and market to make sure the effectiveness and goal achievement of the center. Mr. Yu served as the general manager at Beijing Xuansheng Pharmaceutical Co., Ltd. (北京軒升製藥有限公司) from September 2021 to June 2024.

Mr. Yu graduated from Hebei Medical University (河北醫科大學) in the PRC in July 1998 and from Renmin University of China (中國人民大學) in the PRC in March 2006. He is currently enrolled in the EMBA program at Emlyon Business School in France.

Mr. He Chengming (何成明), aged 43, joined our Group in September 2018 and was appointed as a deputy general manager of our Company in June 2024. Mr. He was also appointed on as our Board secretary in November 2024. He is primarily responsible for the overall management and operations of the legal center, securities center and finance center of our Group.

Mr. He has accumulated extensive legal and managerial experience in the pharmaceutical industry. He joined our Group in September 2018 and held several senior managerial positions, including a Supervisor from September 2018 to November 2021, the legal director from January 2019 to December 2023, and the deputy general manager of legal and investment affairs from December 2023 to July 2024, during which he oversaw our Group’s legal affairs and equity investment divisions. Prior to joining our Group, Mr. He served as the legal director at Sihuan Pharm from June 2011 to December 2017, before transitioning to the strategic investment director from December 2017 to December 2018.

Before his tenure at Sihuan Pharm, Mr. He served as the legal manager at Beijing Beida Pharmaceutical Co., Ltd. (北京北大藥業有限公司), from May 2010 to June 2011, responsible for legal risk control, corporate compliance and restructuring affairs. Prior to that, he served as the legal manager and office head of Union Development Group Co., Ltd. (Cambodia) (優聯發展集團有限公司(柬埔寨)) from February 2009 to April 2010. From July 2005 to December 2008, Mr. He served as the overseas legal manager responsible for overseas legal affairs at Tiens Group Co., Ltd. (天獅集團有限公司).

Mr. He obtained a bachelor’s degree in law from China University of Political Science and Law (中國政法大學) in the PRC in July 2003.

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OTHER INFORMATION IN RELATION TO OUR DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Certain of our Directors and Supervisors held positions in the following entities, each of which had dissolved by deregistration under the relevant laws and regulations:

Name of individual	Name of entity	Place of establishment	Principal business immediately prior to cessation of business	Role(s)	Reason of dissolution
Ms. Xu Yanjun . . .	Jilin Maida Food Co., Ltd. (吉林麥達食品有限公司)	PRC	Food manufacturing	Director	Voluntary dissolution
Ms. Li Huiying . . .	Jilin Kangtong Pharmaceutical Group Co., Ltd. (吉林康通醫藥集團有限公司)	PRC	Health services	Chairperson of the board	Voluntary dissolution
Ms. Wang Yu .	Suzhou Guangxian Biotechnology Co., Ltd. (蘇州光線生物科技有限公司)	PRC	Medical device manufacturing	Executive director and general manager	Voluntary dissolution
	Beijing Huaqing Yinrong Enterprise Management Co. Ltd. (北京華清銀榕企業管理有限公司)	PRC	Enterprise management	Manager	Voluntary dissolution
	Tianxi Chuangxiang (Beijing) Cultural Development Co., Ltd. (天璽創想(北京)文化發展有限公司)	PRC	Consulting	Executive director	Voluntary dissolution
	Shanxi Darwin Cell Biotechnology Co., Ltd. (山西達爾文細胞生物科技有限公司)	PRC	Medical device manufacturing	Supervisor	Voluntary dissolution
	Zhedifan (Beijing) Health Management Co., Ltd. (喆蒂梵(北京)健康管理有限公司)	PRC	Health management	Executive director	Voluntary dissolution
	Qiqihar Ping'an Logistic Co., Ltd. (齊齊哈爾市平安運輸有限責任公司)	PRC	Cargo transportation	Supervisor	Voluntary dissolution
	Hohhot Jushi Alliance Real Estate Consulting Co., Ltd. (呼和浩特市巨石聯盟房地產諮詢有限責任公司)	PRC	Real estate	Executive director and manager	Voluntary dissolution
	Hohhot Jushi Cultural Communication Co., Ltd. (呼和浩特市巨石文化傳播有限責任公司)	PRC	Advertisement	Supervisor	Voluntary dissolution

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Name of individual	Name of entity	Place of establishment	Principal business immediately prior to cessation of business	Role(s)	Reason of dissolution
Mr. Lu Benyu.	Jilin Sihuan Biotechnology Information Consulting Co., Ltd. (吉林四環生物技術信息諮詢有限公司)	PRC	Biotech information consulting	Supervisor	Voluntary dissolution
	Beijing Boaotai Pharmaceutical Technology Co., Ltd. (北京博奧泰藥業科技有限公司)	PRC	Biotech information consulting	Supervisor	Voluntary dissolution
	Shengke cosmetic medical technology (Jilin) Co., Ltd. (仁方醫院投資管理有限公司)	PRC	Hospital management	Supervisor	Voluntary dissolution
	Jilin Diansheng Biopharmaceutical Co., Ltd. (吉林典升生物製藥有限公司)	PRC	Chemical manufacturing	Supervisor	Voluntary dissolution
	Jilin Kangtong Pharmaceutical Group Co., Ltd. (吉林康通醫藥集團有限公司)	PRC	Health services	Supervisor	Voluntary dissolution
	Jilin Maida Foods Co., Ltd. (吉林麥達食品有限公司)	PRC	Food manufacturing	Supervisor	Voluntary dissolution
	Jilin North Four Biotechnology Information Consulting Co., Ltd. (吉林北四生物技術信息諮詢有限公司)	PRC	Biotech information consulting	Supervisor	Voluntary dissolution
	Jilin Kangda Oral Solid Dosage Co., Ltd. (吉林康達口服固體製劑有限公司)	PRC	Chemical manufacturing	Supervisor	Voluntary dissolution
	Beijing Yunxi Network Technology Co., Ltd. (北京雲義網絡科技有限公司)	PRC	Health consulting	Supervisor	Voluntary dissolution

Each of aforementioned Directors and Supervisors has confirmed that (i) each of these entities was solvent at the time of the deregistration; (ii) there was no wrongful act on his/her part leading to the deregistration; (iii) he/she is not aware of any outstanding or potential claim that has been or will be made against him/her as a result of the respective deregistration; and (iv) no misconduct or misfeasance had been involved in the respective deregistration.

Mr. Yu Tao graduated from the School of Online Education of Renmin University of China after completion of the long distance course majoring in business and enterprise management in March 2006.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Save as disclosed above, to the best knowledge, information and belief of the Directors having made all reasonable inquiries, there are no material matters relating to their appointment as a Director or Supervisor that need to be brought to the attention of our Shareholders and there is no other information in relation to his or her appointment which is required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules as of the Latest Practicable Date.

Save as disclosed above, none of the Directors, Supervisors and senior management held any other directorships in any other company listed in Hong Kong or overseas during the three years immediately preceding the date of this document.

None of our Directors, Supervisors and senior management is related to other Directors, Supervisors and senior management.

JOINT COMPANY SECRETARIES

Mr. He Chengming (何成明), aged 43, is our deputy general manager and one of the joint company secretaries with effect from the [REDACTED]. For his biography, see “— Senior Management” in this section.

Mr. Ng Tung Ching Raphael (吳東澄) was appointed as one of the joint company secretaries of our Company with effect from the [REDACTED]. Mr. Ng is a seasoned professional with over 14 years of extensive experience in the legal and company secretarial domains, specializing in corporate governance and compliance. He currently serves as the assistant vice president, Entity Solutions of Computershare Hong Kong Investor Services Limited.

Mr. Ng holds a master’s degree in Chinese business law from The Chinese University of Hong Kong and a master’s degree in professional accounting and corporate governance from The City University of Hong Kong. He earned his bachelor’s degree in law from Manchester Metropolitan University in the United Kingdom. Mr. Ng is an associate member of both The Hong Kong Chartered Governance Institute (the “HKCGI” formerly known as the Hong Kong Institute of Chartered Secretaries) and The Chartered Governance Institute in the United Kingdom. He also possesses the practitioner’s endorsement from HKCGI.

BOARD COMMITTEES

Our Company has established three committees under the Board in accordance with the relevant laws and regulations in mainland China, the Articles of Association and the code of corporate governance practices under the Listing Rules, including the Audit Committee, the Remuneration and Appraisal Committee and the Nomination Committee.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Audit Committee

We have established an Audit Committee in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code set out in Appendix C1 to the Listing Rules. The primary duties of the Audit Committee are to review and supervise the financial reporting process and internal control system of our Group, review and approve connected transactions and to advise the Board. The Audit Committee comprises one non-executive Director and two independent non-executive Directors, namely, Ms. Chen Yanling, Mr. Fan Chi Chiu and Ms. Wang Yu. Mr. Fan Chi Chiu, being the chairperson of the Audit Committee, holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules.

Remuneration and Appraisal Committee

We have established a Remuneration and Appraisal Committee in compliance with Rule 3.25 of the Listing Rules and the Corporate Governance Code set out in Appendix C1 to the Listing Rules. The primary duties of the Remuneration and Appraisal Committee are to review and make recommendations to the Board regarding the terms of remuneration packages, bonuses and other compensation payable to our Directors and senior management. The Remuneration and Appraisal Committee comprises one executive Director and two independent non-executive Directors, namely, Ms. Xu Yanjun, Ms. Wang Yu and Mr. Liu Shuo. Ms. Wang Yu is the chairperson of the Remuneration and Appraisal Committee.

Nomination Committee

We have established a Nomination Committee in compliance with the Corporate Governance Code set out in Appendix C1 to the Listing Rules. The primary duties of the Nomination Committee are to make recommendations to our Board regarding the appointment of Directors and Board succession. The Nomination Committee comprises one executive Director and two independent non-executive Directors, namely, Ms. Xu Yanjun, Ms. Wang Yu and Mr. Liu Shuo. Mr. Liu Shuo is the chairperson of the Nomination Committee.

CORPORATE GOVERNANCE CODE

We recognize the importance of incorporating elements of good corporate governance in our management structure and internal control procedures as to achieve effective accountability. We have adopted the code provisions stated in the Corporate Governance Code.

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We are committed to the view that the Board should include a balanced composition of executive Directors, non-executive Directors, and independent non-executive Directors so that there is a strong independent element on the Board that can effectively exercise independent judgment.

To accomplish the high standards of corporate governance, we will comply with the Corporate Governance Code set out in Appendix C1 to the Listing Rules and the associated Listing Rules after the [REDACTED].

MANAGEMENT PRESENCE IN HONG KONG

According to Rules 8.12 and 19A.15 of the Listing Rules, we must have sufficient management presence in Hong Kong. This normally means that at least two of our executive Directors must be ordinarily resident in Hong Kong. Since the principal business operations of our Group are conducted in mainland China, members of our senior management are, and are expected to continue to be, based in mainland China. Further, as our executive Directors have a vital role in our Group’s operations, it is crucial for them to remain in close proximity to our Group’s central management located in mainland China. Our Company does not and, for the foreseeable future, will not have a sufficient management presence in Hong Kong. We have applied for, and the Stock Exchange [has granted], a waiver from compliance with Rules 8.12 and 19A.15 of the Listing Rules. For further details, see “Waivers and Exemption — Management Presence in Hong Kong.”

BOARD DIVERSITY POLICY

Our Board has adopted a board diversity policy which sets out the approach to achieve diversity on our Board. Our Company recognizes and embraces the benefits of having a diverse Board and sees increasing diversity at the Board level as an essential element in supporting the attainment of our Company’s strategic objectives and sustainable development. Our Company seeks to achieve Board diversity through the consideration of a number of factors, including but not limited to talent, skills, gender, age, cultural and educational background, ethnicity, professional experience, independence, knowledge and length of service. We will select potential Board candidates based on merit and their potential contribution to our Board while taking into consideration our own business model and specific needs from time to time. All Board appointments will be based on meritocracy and candidates will be considered against objective criteria, having due regard to the benefits of diversity on our Board.

Our Board has a balanced mix of knowledge, skills and experience. They completed studies in various majors including but without limitation to pharmaceuticals, bioengineering, finance, business management, accounting and law. We have three independent non-executive Directors who have different industry backgrounds. Furthermore, our Directors are of a wide range of age, from 31 to 69 years old. Taking into account our business model and specific needs as well as the presence of four female Directors out of a total of nine Board members, we consider that the composition of our Board satisfies our board diversity policy.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

We recognize the particular importance of gender diversity on our Board. We have taken, and will continue to take, steps to promote gender diversity at all levels of our Company, including but not limited to our Board and the senior management levels. Our board diversity policy provides that our Board shall take opportunities when selecting and making recommendations on suitable candidates for Board appointments with the aim of increasing the proportion of female members over time after the [REDACTED]. In particular, taking into account the business needs of our Group and changing circumstances that may affect our business plans, we will actively identify and select several female individuals with a diverse range of skills, experience and knowledge in different fields from time to time, and maintain a list of such female individuals who possess qualities to become our Board members, which will be periodically reviewed by our Nomination Committee in order to develop a pipeline of potential successors to our Board and promote gender diversity. Additionally, female representatives of our [REDACTED] are also considered as potential candidates for Board appointments. We will also ensure that there is gender diversity when recruiting staff at the mid- to senior- levels so that we have a pipeline of female senior management and potential successors to our Board going forward. We plan to offer well-rounded trainings to female employees whom we consider have the requisite experience, skills and knowledge of our operation and business, on topics including but not limited to business operation, management, accounting and finance, and legal compliance. We are of the view that such strategies will provide our Board with ample opportunities to identify capable female employees to be nominated as Directors in the future, fulfilling our aim to develop a pipeline of female candidates to achieve greater gender diversity in our Board in the long run. We believe that such a merit-based selection process with reference to our diversity policy and the nature of our business will be in the best interests of our Company and our Shareholders as a whole. It is our objective to maintain an appropriate balance of gender diversity with reference to the stakeholders’ expectations and international and local recommended best practices.

Our Nomination Committee is responsible for ensuring the diversity of our Board members. After the [REDACTED], our Nomination Committee will review our board diversity policy and its implementation annually to monitor its continued effectiveness and we will disclose the implementation of our board diversity policy, including any measurable objectives set for implementing the board diversity policy and the progress on achieving these objectives, in our corporate governance report on an annual basis.

COMPLIANCE ADVISOR

We have appointed First Shanghai Capital Limited as our Compliance Advisor pursuant to Rule 3A.19 of the Listing Rules. The Compliance Advisor will provide us with guidance and advice as to compliance with the Listing Rules and applicable Hong Kong laws. Pursuant to Rule 3A.23 of the Listing Rules, our Compliance Advisor will advise our Company in certain circumstances including:

- (a) before the publication of any regulatory announcement, circular, or financial report;

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- (b) where a transaction, which might be a notifiable or connected transaction, is contemplated, including share issues and share repurchases;
- (c) where we propose to [REDACTED] of the [REDACTED] in a manner different from that detailed in this document or where the business activities, development or results of our Group deviate from any forecast, estimate or other information in this document; and
- (d) where the Stock Exchange makes an inquiry to our Company regarding unusual movements in the [REDACTED] 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 Advisor 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 Advisor 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 applicable requirements under the Listing Rules and laws and regulations.

The term of appointment of our Compliance Advisor shall commence on the [REDACTED] and is expected to end on the date on which we comply with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED].

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into employment contracts, including confidentiality terms and non-competition terms with key employees. Below sets forth the key terms of these contracts we enter into with our senior management and other key personnel.

Non-conflict

During to term of the employment contract, unless expressly agreed by us, the employee shall not, among others, directly or indirectly, engage in any business activities which create a conflict of interest with our Group. If the employee breaches this provision, we may choose to terminate the employment contract and hold the employee accountable for all of the loss incurred by us as a result of the breach.

Non-competition

Within a period from the date of the employee's departure and during the course of employment by our Group, they shall not, among others, directly or indirectly engage in any business that competes with us. In addition, the employee shall not have any business connection with any our customer during the employment with us. Depending on the seriousness of the case, we may, according to the internal rules and regulations, impose disciplinary actions on the employee until the termination of this contract.

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Confidentiality

The employee shall keep in confidence and shall not disclose our trade secrets, including but not limited to our technical information, operational information and computer system information in confidence of our Group as well as other information assumed the obligation of confidentiality by our Group during the term of their employment and thereafter.

Service Invention

The intellectual property rights in any invention, work or non-patent technical result that is (i) resulted from performing employee duties or (ii) developed mainly using our material, technologies and information shall belong to us.

REMUNERATION OF DIRECTORS, SUPERVISORS AND FIVE HIGHEST PAID INDIVIDUALS

The Directors, Supervisors and senior management members who receive remuneration from our Company are paid in forms of fees, wages, salaries, bonuses, pension scheme contributions, and other benefits in kind. When reviewing and determining the specific remuneration packages for our Directors, Supervisors and members of the senior management of our Company, the Shareholders’ meetings and the Board of Directors take into account factors such as salaries paid by comparable companies, time commitment, level of responsibilities, employment elsewhere in our Group and desirability of performance-based remuneration. As required by the relevant PRC laws and regulations, our Company also participates in various defined contribution plans organized by relevant provincial and municipal government authorities and welfare schemes for employees of our Company, including medical insurance, injury insurance, unemployment insurance, pension insurance, maternity insurance and housing provident fund.

Under the arrangement currently in force, we estimate the total compensation before taxation to be accrued to our Directors for the year ending December 31, 2025 to be RMB5.4 million.

For the years ended December 31, 2022 and 2023 and the six months ended June 30, 2024, the total amount of remuneration (including fees, wages, salaries, bonuses and pension scheme contributions) and other benefits in kind (if applicable) paid to our Directors were RMB35.4 million, RMB35.8 million and RMB10.1 million, respectively. For details on the remuneration of each Director during the Track Record Period, please refer to Note 8 to the Accountants’ Report in Appendix I to this document.

For the years ended December 31, 2022 and 2023 and six months ended June 30, 2024, the total emoluments paid to the five highest paid individuals (excluding three, three and two Directors) by us amounted to RMB15.5 million, RMB15.3 million and RMB17.2 million, respectively. For details on the remuneration of the five highest-paid employees during the Track Record Period, please refer to Note 9 to the Accountants’ Report in Appendix I to this document.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

During the Track Record Period, no remuneration was paid by our Company to, or receivable by, our Directors, Supervisors or the five highest paid individuals as an inducement to join or upon joining our Company or as compensation for loss of office in connection with the management positions of our Company or any of our subsidiaries.

During the Track Record Period, none of our Directors or Supervisors waived any remuneration. Save as disclosed above, during the Track Record Period, no other amounts shall be paid or payable by us or any of our subsidiaries to our Directors, Supervisors or the five highest paid individuals.

CONFIRMATIONS FROM OUR DIRECTORS

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 November 8, 2024, and (ii) understands his or her obligations as a director of a listed issuer under the Listing Rules.

Rule 3.13 of the Listing Rules

Each of the independent non-executive Directors has confirmed (i) that 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 have no past or present financial or other interest in the business of our Company or its subsidiaries or any connection with any core connected person of our 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/her appointments.

Rule 8.10 of the Listing Rules

From time to time our non-executive Directors 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 non-executive Directors and independent non-executive Directors are not members of our executive management team, we do not believe that their interests in such companies as directors would render us incapable of carrying on our business independently from the other companies in which these non-executive Directors and independent non-executive Directors may hold directorships from time to time.

Save as disclosed herein and in the section headed “Relationship with Our Controlling Shareholders,” 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 business and requires disclosure under Rule 8.10 of the Listing Rules.

SHARE INCENTIVE SCHEME

We adopted the Share Incentive Scheme and established the Incentive Platforms. See “Appendix VI — Statutory and General Information — Further Information about Our Directors, Supervisors, Chief Executive and Substantial Shareholders — Share Incentive Scheme” for further details.

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You should read the following discussion and analysis in conjunction with our historical financial information, together with the accompanying notes, included in the Accountants’ Report set out in Appendix I to this document. Our consolidated financial information has been prepared in accordance with IFRS, which may differ in material aspects from generally accepted accounting principles in other jurisdictions. You should read the entire Accountants’ Report and not rely solely on the information contained in this section.

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance. These statements are based on assumptions and analyses made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors that we believe are appropriate under the circumstances. However, our actual performance may differ materially from those anticipated in these forward-looking statements, as a result of various risks and uncertainties over which we do not have full control. For details, see “Forward-looking Statements” and “Risk Factors.”

OVERVIEW

We are an innovation-driven biopharmaceutical company in China with a global vision, leveraging our deep understanding of China’s pharmaceutical industry and profound insights of its unique clinical needs to better patient health and life. Since our inception in 2008, we have built a comprehensive in-house R&D platform that has supported our development of a highly competitive and balanced pipeline. As of the Latest Practicable Date, we had over ten drug assets under active development covering digestive diseases, oncology and NASH, including one NDA approved asset, two drug programs with four indications in pivotal trial or NDA registration-stage, four drug programs in phase 1 clinical trial and four at IND-enabling stage or IND-approved. Our track record also includes the successful development of four drug candidates that were subsequently transferred and/or out-licensed to leading pharmaceutical companies.

While we have begun to generate revenue from product sales, we were loss-making during the Track Record Period. In 2022, 2023 and the six months ended June 30, 2023 and 2024, we had net losses of RMB512.3 million, RMB300.6 million, RMB187.2 million, and RMB111.0 million, respectively, primarily attributable to the research and development expenses and administrative expenses incurred by us during the Track Record Period. We expect to incur significant expenses for at least the next several years as we continue to advance our preclinical research, implement clinical development plans, and commercialize our drug and drug candidates.

BASIS OF PRESENTATION

Our historical financial information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which comprise all standards and interpretations approved by the International Accounting Standards Board (the “IASB”). All IFRSs effective for the accounting period commencing from January 1, 2024, together with the relevant transitional provisions, have been early adopted by our Group in the preparation of the historical financial information throughout the Track Record Period. The historical financial information has been prepared under the historical cost convention, except for financial assets at fair value which have been measured at fair value at the end of each of the Track Record Period.

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KEY FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations have been, and are expected to continue to be, affected by a number of factors, many of which may be beyond our control. A discussion of the key factors is set out below.

Our Ability to Successfully Develop and Commercialize Our Drug Candidates

Our ability to successfully develop and commercialize our drug candidates is essential for driving revenue growth and enhancing profitability. By navigating the complex stages of drug development, regulatory approval, and market launch, we can establish recurring revenue streams from product sales, which bolsters our top-line performance and improves our profit margins. Moreover, successful drug commercialization also enhances our brand equity and market position within the biopharmaceutical industry. Each approved innovative drug strengthens our reputation as a leading biotech company and increases our industry influence. A strong brand presence provides us with a robust platform for ongoing R&D and future commercial endeavors, laying the groundwork for our sustained long-term growth.

The commercialization of KBP-3571 since its NDA approval in June 2023 has begun to bring us revenue, demonstrating the effectiveness of our integrated development and commercialization strategy. We successfully negotiated the inclusion of KBP-3571 in the NRDL since 2024, which enabled us to increase revenue to RMB16.0 million for the six months ended June 30, 2024. In addition to KBP-3571, we had two drug programs with four indications in pivotal trial or NDA registration-stage as of the Latest Practicable Date, which are expected to gradually launch in the market in the next few years. As more of our drug candidates are commercialized, our business and results of operations will be driven by the market acceptance and supply of these current and future commercialized drugs.

Our Cost Structure

Our results of operations are significantly affected by our costs and expenses, particularly research and development expenses, as well as administrative expenses.

We, as an innovation-driven biopharmaceutical company, have devoted a significant portion of our efforts and resources to R&D activities. During the Track Record Period, we incurred research and development expenditure (including research and development expenses and capitalized research and development costs recorded as intangible assets) of RMB567.5 million, RMB383.9 million, RMB220.6 million, and RMB125.4 million in 2022, 2023 and the six months ended June 30, 2023 and 2024, respectively. We incurred higher research and development expenditure in 2022 compared to 2023, because we had several phase 2 or phase 3 clinical trials in 2022 that were completed or close to completion in 2023. We also strategically managed the cadence of other drug development programs considering our financial resources. Similarly, since the end of 2023, we filed NDA for three indications of two drug programs, and were still in the preparatory stages of initiating indication expansion studies, leading to lower research and development expenditure in the six months ended June 30, 2024 compared to the same period in 2023. Going forward, our research and development expenditure will continue to fluctuate based on the cadence of our drug development programs.

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In addition to research and development expenses, administrative expenses also constitute a significant component of our cost and expense structure. Our administrative expenses primarily consist of share-based compensation, employee compensation and benefits, professional service fees, depreciation and amortization expenses, office expenses, and taxes and surcharges. In 2022, 2023 and the six months ended June 30, 2023 and 2024, our administrative expenses amounted to RMB96.4 million, RMB87.8 million, RMB52.2 million, and RMB36.5 million, respectively.

We expect our cost structure to evolve as we continue to develop and expand our business. As the preclinical studies and clinical trials of our drug candidates continue to progress and as we gradually bring more drugs to commercialization, we expect to incur additional costs in relation to regulatory affairs, staff costs and sales and marketing efforts, among other things. Moreover, we anticipate increasing legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company in Hong Kong.

Funding for Our Operations

During the Track Record Period, we funded our operations primarily through equity financing. We expect to fund our future operations primarily with existing cash and cash equivalents and [REDACTED] from the [REDACTED]. In addition, we also expect to fund our operations in part with revenue generated from sales of KBP-3571 and any other future commercialized drug products. Changes in our ability to fund our operations may affect our cash flow and results of operations. See also “Risk Factors — Risks Relating to Our Financial Position and Need for Additional Capital — We may need to obtain substantial additional financing to fund our operations and expansion, and if we fail to do so, we may be unable to complete the development and commercialization of our drugs and drug candidates” in this document.

Our Existing and Future Collaboration and Licensing Arrangements

Our results of operations may be affected by our existing and future collaboration and licensing arrangements with business partners. In recent years, we have engaged in both out-licensing and in-licensing arrangements as part of our strategic approach to boost the growth of our business operations. Through out-licensing agreements, we leverage the expertise of our partners to improve the value of specific assets. Meanwhile, through in-licensing and asset acquisition agreements, we can further enhance our pipeline and capabilities. In the future, we may engage in more collaboration and licensing arrangements, which are likely to facilitate our access to new technologies and expand our market reach.

SIGNIFICANT ACCOUNTING POLICIES AND CRITICAL JUDGMENTS AND ESTIMATES

The preparation of financial statements in conformity with IFRSs requires our management to make judgments, estimates and assumptions that affect the application of policies and reported amounts of assets, liabilities, income and expenses. Such judgments, estimates and assumptions are continually evaluated and are based on historical experience and various other factors, including expectations of future events, that are believed to be reasonable under the circumstances, from which our actual results may differ.

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Set out below is a summary of the significant accounting policies, judgements and estimates which we believe are most important for understanding our results of operations and financial condition. See note 2.3 and note 3 to the Accountants’ Report set out in Appendix I to this document for a detailed description of our significant accounting policies, judgments and estimates.

Significant Accounting Policies

Research and Development Costs

All research costs are charged to profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalized and deferred only when our Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Deferred development costs are stated at cost less any impairment losses and are amortized using the straight-line basis over the commercial lives of the underlying products not exceeding ten years, commencing from the date when the products are put into commercial production.

Leases

Our Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Our Group as a lessee

Our Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. Our Group recognizes lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

Right-of-use assets are recognized at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Leasehold land	50 years
Buildings	2.04-5.58 years

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If ownership of the leased asset transfers to our Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

(b) Lease liabilities

Lease liabilities are recognized at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by our Group and payments of penalties for termination of a lease, if the lease term reflects our Group exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognized as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, our Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

(c) Short-term leases and leases of low-value assets

Our Group applies the short-term lease recognition exemption to its short-term leases of buildings (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the recognition exemption for leases of low-value assets to leases of office equipment and laptop computers that are considered to be of low value.

Lease payments on short-term leases and leases of low-value assets are recognized as an expense on a straight-line basis over the lease term.

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Investments and other financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortized cost and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and our Group’s business model for managing them. With the exception of trade and bills receivables that do not contain a significant financing component or for which our Group has applied the practical expedient of not adjusting the effect of a significant financing component, our Group initially measures a financial asset at its fair value plus in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade and bills receivables that do not contain a significant financing component or for which our Group has applied the practical expedient are measured at the transaction price determined under IFRS 15 in accordance with the policies set out for “— Revenue recognition” below.

In order for a financial asset to be classified and measured at amortized cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest (“SPPI”) on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

Our Group’s business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortized cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

Purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace are recognized on the trade date, that is, the date that our Group commits to purchase or sell the asset.

Subsequent measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial assets at amortized cost (debt instruments)

Financial assets at amortized cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognized in profit or loss when the asset is derecognized, modified or impaired.

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Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognized in the profit or loss.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as payables, as appropriate.

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

Our Group’s financial liabilities include trade and other payables.

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at amortized cost (trade payables, other payables and accruals)

After initial recognition, trade payables, other payables are subsequently measured at amortized cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognized in profit or loss when the liabilities are derecognized as well as through the effective interest rate amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortization is included in finance costs in profit or loss.

Fair Value Measurement

Our Group measures certain financial instruments at fair value at the end of each of the Track Record Period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or

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liability. The principal or the most advantageous market must be accessible by our Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

Our Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1	based on quoted prices (unadjusted) in active markets for identical assets or liabilities
Level 2	based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly
Level 3	based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognized in the financial statements on a recurring basis, our Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the Track Record Period.

Revenue recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount that reflects the consideration to which our Group expects to be entitled in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which our Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

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When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between our Group and the customer at contract inception. When the contract contains a financing component which provides our Group with a significant financial benefit for more than one year, revenue recognized under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

(a) Sales of pharmaceutical products

Revenue from the sale of pharmaceutical products is recognized at the point in time when control of the asset is transferred to the customer, generally on receipt of the pharmaceutical products.

Other income

Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Critical Judgments and Estimates

The preparation of our Group’s financial statements requires our management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

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Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of each of the Track Record Period, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Provision for expected credit losses on trade and bills receivables

Our Group uses a provision matrix to calculate ECLs for trade and bills receivables. The provision rates are based on days past due for groupings of various customer segments that have similar loss patterns (i.e., by customer type).

The provision matrix is initially based on our Group’s historical observed default rates. Our Group will calibrate the matrix to adjust the historical credit loss experience with forward-looking information. For instance, if forecast economic conditions (i.e., gross domestic product) are expected to deteriorate over the next year which can lead to an increased number of defaults in the manufacturing sector, the historical default rates are adjusted. At each reporting date, the historical observed default rates are updated and changes in the forward-looking estimates are analyzed.

The assessment of the correlation among historical observed default rates, forecast economic conditions and ECLs is a significant estimate. The amount of ECLs is sensitive to changes in circumstances and forecast economic conditions. Our Group’s historical credit loss experience and forecast of economic conditions may also not be representative of a customer’s actual default in the future. The information about the ECLs on our Group’s trade and bills receivables is disclosed in note 17 to the Accountants’ Report set out in Appendix I to this document.

Leases — Estimating the incremental borrowing rate

Our Group cannot readily determine the interest rate implicit in a lease, and therefore, it uses an incremental borrowing rate (“IBR”) to measure lease liabilities. The IBR is the rate of interest that our Group would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The IBR therefore reflects what our Group “would have to pay”, which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when it needs to be adjusted to reflect the terms and conditions of the lease (for example, when leases are not in the subsidiary’s functional currency). Our Group estimates the IBR using observable inputs (such as market interest rates) when available and is required to make certain entity-specific estimates (such as the subsidiary’s stand-alone credit rating).

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Impairment of non-financial assets (other than goodwill)

Our Group assesses whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of each of the Track Record Period. Intangible assets with indefinite useful lives and intangible assets not yet available for use are tested for impairment annually and at other times when such an indicator exists. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm’s length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

DESCRIPTION OF SELECTED COMPONENTS OF THE CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

The following table sets forth a summary of our consolidated statements of profit or loss and other comprehensive income for the periods indicated. Our historical results presented below are not necessarily indicative of the results that may be expected for any future period.

	For the year ended December 31,		For the six months ended June 30,	
	2022	2023	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
			<i>(unaudited)</i>	
Revenue	–	29	–	16,030
Cost of sales	–	(9)	–	(8,811)
Gross profit	–	20	–	7,219
Other income and gains	40,531	40,800	17,405	7,492
Selling and distribution expenses	–	(10,235)	(2,319)	(6,161)
Research and development expenses	(400,983)	(239,061)	(149,540)	(74,426)
Administrative expenses	(96,401)	(87,845)	(52,208)	(36,486)
Other expenses	(53,670)	(3,267)	(9)	(8,198)
Impairment/(reversal of impairment) on financial assets, net	(220)	199	108	(129)
Finance costs	(1,517)	(1,167)	(621)	(282)
Loss before tax	(512,260)	(300,556)	(187,184)	(110,971)

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	For the year ended December 31,		For the six months ended June 30,	
	2022	2023	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i> <i>(unaudited)</i>	<i>(RMB'000)</i>
Income tax expense	(5)	(6)	(6)	(6)
Loss and total comprehensive loss for the year/period	(512,265)	(300,562)	(187,190)	(110,977)

Revenue

During the Track Record Period, all of the revenue we generated was from the sales of our commercialized drug product — KBP-3571. In June 2023, KBP-3571 received NDA approval from the NMPA. For more information about KBP-3571, see “Business — Digestive Disease Drugs — KBP-3571, a Commercialized PPI for Duodenum Ulcers with Phase 2 Completed Second Indication in Reflux Esophagitis, a Core Product” in this document. In 2022, 2023 and the six months ended June 30, 2023 and 2024, our revenue amounted to nil, RMB29 thousand, nil and RMB16.0 million, respectively.

Cost of Sales

During the Track Record Period, our cost of sales primarily consisted of payments to CDMOs for the manufacturing of KBP-3571 and amortization of intangible assets. For more details about our arrangements with industry-recognized CDMOs for outsourced production, see “Business — Manufacturing” in this document. In 2022, 2023 and the six months ended June 30, 2023 and 2024, our cost of sales was nil, RMB9 thousand, nil and RMB8.8 million, respectively.

Gross Profit and Gross Profit Margin

In 2022, 2023 and the six months ended June 30, 2023 and 2024, our gross profit was nil, RMB20 thousand, nil and RMB7.2 million, respectively. For the same periods, our gross profit margin was nil, 69.0%, nil and 45.0%, respectively.

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Other Income and Gains

During the Track Record Period, we recorded other income and gains. Our other income primarily included (i) government grants, (ii) bank interest income, and (iii) other miscellaneous income. Our gains primarily included (i) investment income on wealth management products, (ii) gain on fair value changes of financial assets at FVTPL, representing the increase in the market value of our financial assets at FVTPL, and (iii) gain on disposal of items of right-of-use assets. The following table sets forth a breakdown of our other income and gains in absolute amounts and as percentages of the total other income and gains for the periods indicated:

	For the year ended December 31,				For the six months ended June 30,			
	2022		2023		2023		2024	
	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%
	<i>(unaudited)</i>							
Other income:								
Government grants . . .	11,222	27.7	23,487	57.6	7,951	45.7	1,766	23.6
Bank interest income . .	1,737	4.3	372	0.9	190	1.1	158	2.1
Others	469	1.1	178	0.4	53	0.3	131	1.7
Subtotal	<u>13,428</u>	<u>33.1</u>	<u>24,037</u>	<u>58.9</u>	<u>8,194</u>	<u>47.1</u>	<u>2,055</u>	<u>27.4</u>
Gains:								
Gain on disposal of items of right-of-use assets	19	0.1	1,035	2.6	-	-	-	-
Gain on fair value changes of financial assets at FVTPL . . .	5,070	12.5	1,682	4.1	2,767	15.9	3,656	48.8
Investment income on financial assets at FVTPL	22,014	54.3	14,046	34.4	6,444	37.0	1,781	23.8
Subtotal	<u>27,103</u>	<u>66.9</u>	<u>16,763</u>	<u>41.1</u>	<u>9,211</u>	<u>52.9</u>	<u>5,437</u>	<u>72.6</u>
Total	<u>40,531</u>	<u>100.0</u>	<u>40,800</u>	<u>100.0</u>	<u>17,405</u>	<u>100.0</u>	<u>7,492</u>	<u>100.0</u>

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During the Track Record Period, the government grants we received were from PRC local government authorities, which were aimed at supporting our operating and R&D activities. These grants are one-off in nature, and their availability is subject to fluctuations due to a wide array of factors, many of which are beyond our control. There are no unfulfilled conditions relating to these government grants.

Selling and Distribution Expenses

We began to record selling and distribution expenses in 2023 upon the NDA approval of our first drug product, KBP-3571. Our selling and distribution expenses primarily consisted of employee compensation and benefits for sales and marketing staff, travel expenses, labor costs for non-employee personnel, consulting service fees, and others. The following table sets forth a breakdown of our selling and distribution expenses in absolute amounts and as percentages of the total selling and distribution expenses for the periods indicated:

	For the year ended December 31,				For the six months ended June 30,			
	2022		2023		2023		2024	
	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%
Employee compensation and benefits	–	–	8,121	79.3	2,100	90.6	5,141	83.5
Travel expenses	–	–	856	8.4	126	5.4	354	5.7
Labor costs	–	–	401	3.9	70	3.0	178	2.9
Consulting service fees	–	–	171	1.7	–	–	–	–
Others	–	–	686	6.7	23	1.0	488	7.9
Total	–	–	<u>10,235</u>	<u>100.0</u>	<u>2,319</u>	<u>100.0</u>	<u>6,161</u>	<u>100.0</u>

Research and Development Expenses

During the Track Record Period, our research and development expenses primarily consisted of (i) expenses for clinical trial services, representing costs associated with conducting clinical trials to test the safety, efficacy and overall performance of our drug assets, (ii) employee compensation and benefits for R&D personnel, including salaries, social security, housing provident fund and benefits, (iii) share-based compensation for R&D personnel, (iv) raw materials and processing fees, representing costs associated with acquiring and processing necessary components to develop and test our drug candidates, (v) depreciation and amortization expenses, representing such expenses for right-of-use assets, property and equipment used for R&D purposes, (vi) technology transfer consideration, representing the one-off payments made to acquire rights associated with technological projects, (vii) daily operating expenses, representing expenses used to support our daily R&D activities, and (viii) others, representing various expenses related to R&D activities, such as rent, database usage

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and retrieval fees, consulting service fees, registration and patent fees, testing and analysis fees, and travel expenses. The following table sets forth a breakdown of our research and development expenses in absolute amounts and as percentages of the total research and development expenses for the periods indicated:

	For the year ended December 31,				For the six months ended June 30,			
	2022		2023		2023		2024	
	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%
	<i>(unaudited)</i>							
Expenses for clinical trial services	167,286	41.7	67,237	28.1	45,183	30.2	19,751	26.5
Employee compensation and benefits	88,621	22.1	76,588	32.0	47,320	31.6	17,792	23.9
Share-based compensation	39,646	9.9	34,826	14.6	25,658	17.2	19,014	25.5
Raw materials and processing fees	22,402	5.6	18,166	7.6	10,716	7.2	3,462	4.7
Depreciation and amortization expenses	18,366	4.6	22,423	9.4	11,233	7.5	10,413	14.0
Technology transfer consideration	42,480	10.6	-	-	-	-	-	-
Daily operating expenses	7,199	1.8	8,420	3.5	3,165	2.1	1,348	1.8
Others	14,983	3.7	11,401	4.8	6,265	4.2	2,646	3.6
Total	<u>400,983</u>	<u>100.0</u>	<u>239,061</u>	<u>100.0</u>	<u>149,540</u>	<u>100.0</u>	<u>74,426</u>	<u>100.0</u>

During the Track Record Period, a certain portion of our expenditure incurred for R&D activities was capitalized upon meeting the criteria set out in “— Significant Accounting Policies and Critical Judgments and Estimates — Significant Accounting Policies — Research and Development Costs.” Our research and development costs, representing capitalized expenditure incurred for projects to develop late-stage products, amounted to RMB166.5 million, RMB144.8 million, and RMB51.0 million in 2022, 2023 and the six months ended June 30, 2024, respectively. For details on our research and development costs, see “— Description of Selected Items from the Consolidated Balance Sheets — Other Intangible Assets.” In 2022, 2023, and the six months ended June 30, 2023 and 2024, our total research and development expenditure amounted to RMB567.5 million, RMB383.9 million, RMB220.6 million, and RMB125.4 million, respectively.

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In 2022, 2023 and the six months ended June 30, 2023 and 2024, our research and development expenditure incurred for Core Products were RMB304.8 million, RMB253.4 million, RMB141.7 million, and RMB89.6 million, representing 53.7%, 66.0%, 64.2%, and 71.4% of our total research and development expenditure, respectively; and our research and development expenditure incurred for other drug products were RMB262.7 million, RMB130.5 million, RMB78.9 million, and RMB35.8 million, representing 46.3%, 34.0%, 35.8%, and 28.6% of our total research and development expenditure, respectively.

Administrative Expenses

During the Track Record Period, our administrative expenses primarily consisted of (i) share-based compensation for management and administrative staff, (ii) employee compensation and benefits, (iii) professional service fees, representing payments we made to external professionals, such as legal professionals, finance experts and financing consultants, (iv) depreciation and amortization expenses, (v) office expenses, and (vi) taxes and surcharges. The following table sets forth a breakdown of our administrative expenses in absolute amounts and as percentages of the total administrative expenses for the periods indicated:

	For the year ended December 31,				For the six months ended June 30,			
	2022		2023		2023		2024	
	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%
	<i>(unaudited)</i>							
Share-based								
compensation	30,483	31.6	37,441	42.6	23,447	44.9	11,081	30.4
Employee								
compensation and								
benefits	28,013	29.1	27,678	31.5	14,163	27.1	13,502	37.0
Professional service								
fees	17,585	18.2	4,527	5.1	2,620	5.0	4,897	13.5
Depreciation and								
amortization								
expenses	7,555	7.8	8,580	9.8	3,783	7.2	3,463	9.5
Office expenses	3,334	3.5	2,861	3.3	1,232	2.4	815	2.2
Taxes and surcharges .	2,484	2.6	2,395	2.7	1,127	2.2	1,218	3.3
Others	6,947	7.2	4,363	5.0	5,836	11.2	1,510	4.1
Total	<u>96,401</u>	<u>100.0</u>	<u>87,845</u>	<u>100.0</u>	<u>52,208</u>	<u>100.0</u>	<u>36,486</u>	<u>100.0</u>

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Other Expenses

During the Track Record Period, we incurred other expenses, primarily including (i) loss on disposal of items of other intangible assets, representing the difference between the research and development costs related to such intangible assets and the payment we received or are entitled to receive for such intangible assets at the time of disposal, (ii) loss on disposal of items of property, plant and equipment, (iii) loss on disposal items of right-of-use assets, (iv) loss on obsolescence of inventories, (v) foreign exchange losses/(gains), net and (vi) others. The following table sets forth a breakdown of our other expenses in absolute amounts and as percentages of the total other expenses for the periods indicated:

	For the year ended December 31,				For the six months ended June 30,			
	2022		2023		2023		2024	
	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%	<i>(RMB'000)</i>	%
	<i>(unaudited)</i>							
Asset impairment losses	1,367	2.5	-	-	-	-	449	5.5
Loss on disposal of items of other intangible assets . . .	52,251	97.4	-	-	-	-	7,424	90.6
Loss on disposal of items of property, plant and equipment	-	-	11	0.3	3	33.3	5	0.1
Loss on disposal items of right-of-use assets	-	-	-	-	-	-	211	2.6
Loss on obsolescence of inventories	-	-	2,185	66.9	-	-	-	-
Foreign exchange losses/(gains), net . .	(19)	-	98	3.0	6	66.7	109	1.3
Others	71	0.1	973	29.8	-	-	-	-
Total	<u>53,670</u>	<u>100.0</u>	<u>3,267</u>	<u>100.0</u>	<u>9</u>	<u>100.0</u>	<u>8,198</u>	<u>100.0</u>

Finance Costs

During the Track Record Period, our finance costs represented interest on lease liabilities. Our interest on lease liabilities refers to interests charged to profit or loss over the lease period for the lease of offices for which we made fixed or minimum rental payments. The difference between the actual amount of fixed rental payments we made and amount of principal portion of fixed rental payments is recorded as interest on lease liabilities under finance costs. In 2022, 2023 and the six months ended June 30, 2023 and 2024, our finance costs amounted to RMB1.5 million, RMB1.2 million, RMB0.6 million and RMB0.3 million, respectively.

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Income Tax Expense

Our income tax expenses amounted to RMB5 thousand, RMB6 thousand, RMB6 thousand and RMB6 thousand in 2022, 2023 and the six months ended June 30, 2023 and 2024, respectively. Our principal applicable taxes and tax rates are set out below:

United States of America

Pursuant to Tax Cuts and Jobs Act (“TCJA”) enacted on December 22, 2017, the US federal statutory income tax rate for the subsidiary is 21%. Our subsidiary in the US was incorporated in the state of California and State income tax rate is 8.84%. Taxes on profits assessable elsewhere have been calculated at the rates of tax prevailing in the countries (or jurisdictions) in which our Group operates.

Hong Kong

Our subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the statutory rate of 16.5% on any estimated assessable profits arising in Hong Kong during each of the Track Record Period.

Mainland China

Pursuant to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》), as amended, supplemented or otherwise modified from time to time, our subsidiaries which operate in mainland China are subject to EIT at a rate of 25% on the taxable income during each of the Track Record Period.

One of our PRC subsidiaries, Shandong Xuanzhu was accredited as a “High and New Technology Enterprise” under the relevant tax rules and regulations in November 2019 and December 2022, respectively, and accordingly, was entitled to a reduced preferential EIT rate of 15% during the Track Record Period. This qualification is subject to review by the relevant tax authority in the PRC for every three years.

Loss for the Year/Period

As a result of the foregoing, we incurred losses of RMB512.3 million, RMB300.6 million, RMB187.2 million and RMB111.0 million for the years ended December 31, 2022 and 2023 and the six months ended June 30, 2023 and 2024, respectively.

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PERIOD-TO-PERIOD COMPARISON OF RESULTS OF OPERATIONS

Six Months Ended June 30, 2024 Compared to Six Months Ended June 30, 2023

Revenue

In the six months ended June 30, 2023 and 2024, our revenue was nil and RMB16.0 million, respectively. Such difference was primarily because we brought a drug candidate, KBP-3571, to commercialization after its NDA approval in June 2023 and started to generate revenue from drug sales in late 2023.

Cost of Sales

In the six months ended June 30, 2023 and 2024, our cost of sales was nil and RMB8.8 million, respectively, primarily reflecting an increase in payments to CDMOs and amortization of intangible assets as we commercialized KBP-3571.

Gross Profit and Gross Profit Margin

In the six months ended June 30, 2023 and 2024, our gross profit was nil and RMB7.2 million, respectively, reflecting the commercialization of KBP-3571. In the six months ended June 30, 2024, our overall gross profit margin was 45.0%. As we are in early stages of commercializing KBP-3571, our historical margins may not be representative and may be subject to fluctuations.

Other Income and Gains

Our other income and gains decreased by 57.0% from RMB17.4 million in the six months ended June 30, 2023 to RMB7.5 million in the six months ended June 30, 2024, primarily due to (i) a decrease in government grants we received from local government authorities as these grants are one-off in nature, and (ii) a reduced amount of wealth management products purchased.

Selling and Distribution Expenses

Our selling and distribution expenses increased by 165.7% from RMB2.3 million in the six months ended June 30, 2023 to RMB6.2 million in the six months ended June 30, 2024, primarily driven by an increase in employee compensation and benefits for sales and marketing personnel as our internal sales team gradually expanded in line with our commercialization efforts.

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Research and Development Expenses

Our research and development expenses decreased by 50.2% from RMB149.5 million in the six months ended June 30, 2023 to RMB74.4 million in the six months ended June 30, 2024, primarily due to (i) a decrease in expenses for clinical trial services, mainly because of the completion of phase 1/2 trials in late 2023 and early 2024, (ii) a decrease in compensation and benefits and share-based compensation for R&D personnel, mainly attributable to staff structure optimization, and (iii) a decrease in raw material and processing fees, also primarily due to the pace of our clinical trials.

Administrative Expenses

Our administrative expenses decreased by 30.1% from RMB52.2 million in the six months ended June 30, 2023 to RMB36.5 million in the six months ended June 30, 2024, primarily due to (i) a decrease in share-based compensation for administrative staff, mainly attributable to the reduced amortization in the six months ended June 30, 2024, following the expiration of a batch of granted share options in August 2023, and the departure of certain administrative staff who had been granted share options, (ii) a decrease in employee compensation and benefits, mainly attributable to staff structure optimization, (iii) a decrease in professional service fees, mainly attributable to the termination and/or completion of certain transactions, (iv) a decrease in office expenses, mainly attributable to our initiative to increase cost efficiencies, and (v) a decrease in other administrative expenses, mainly attributable to a decrease in travel expenses and business entertainment expenses, following the staff structure optimization.

Other Expenses

Our other expenses increased significantly from RMB9.0 thousand in the six months ended June 30, 2023 to RMB8.2 million in the six months ended June 30, 2024, primarily because we recorded RMB7.4 million in loss on disposal of items of other intangible assets as we out-licensed certain rights related to XZP-5849 to Livzon in June 2024. For further details, see “Business — Our License and Asset Acquisition Arrangements — Our Asset Transfer and Out-licensing Agreements — Out-Licensing and Technology Transfer Agreement with Livzon for XZP-5849” in this document.

Finance Costs

Our finance costs decreased by 54.6% from RMB0.6 million in the six months ended June 30, 2023 to RMB0.3 million in the six months ended June 30, 2024, primarily due to the termination of the lease for certain office areas in 2023.

Income Tax Expense

In the six months ended June 30, 2023 and 2024, our income tax expense remained stable at RMB6 thousand.

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Loss for the Period

For the reasons discussed above, our loss for the period decreased by 40.7% from RMB187.2 million in the six months ended June 30, 2023 to RMB111.0 million in the six months ended June 30, 2024.

Year Ended December 31, 2023 Compared to Year Ended December 31, 2022

Revenue

In 2022 and 2023, our revenue was nil and RMB29 thousand, respectively. Such difference was primarily because we brought a drug candidate, KBP-3571, to commercialization after its NDA approval in June 2023 and started to generate revenue from drug sales in late 2023.

Cost of Sales

In 2022 and 2023, our cost of sales was nil and RMB9 thousand, respectively, reflecting an increase in payments to CDMOs and amortization of intangible assets as we commercialized KBP-3571.

Gross Profit and Gross Profit Margin

In 2022 and 2023, our gross profit was nil and RMB20 thousand, respectively, reflecting the commercialization of KBP-3571. In 2023, our overall gross profit margin was 69.0%. As we are in early stages of commercializing KBP-3571, our historical margins may not be representative and may be subject to fluctuations.

Other Income and Gains

Our other income and gains remained stable at RMB40.5 million in 2022 and RMB40.8 million in 2023.

Selling and Distribution Expenses

In 2022 and 2023, our selling and distribution expenses were nil and RMB10.2 million, respectively, the difference of which was primarily driven by an increase in employee compensation and benefits for sales and marketing personnel as our internal sales team gradually expanded in line with our commercialization efforts.

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Research and Development Expenses

Our research and development expenses decreased by 40.4% from RMB401.0 million in 2022 to RMB239.1 million in 2023, primarily due to (i) a decrease in expenses for clinical trial services, primarily because we had several active phase 2 clinical trials in 2022 that were completed or close to completion in 2023, (ii) a decrease in technology transfer consideration as we acquired the technology and patent rights of the CD80 fusion protein project from Beijing Xuanyi in 2022, and (iii) a decrease in employee compensation and benefits and share-based compensation for R&D personnel, mainly attributable to staff structure optimization.

Administrative Expenses

Our administrative expenses decreased by 8.9% from RMB96.4 million in 2022 to RMB87.8 million in 2023, primarily due to a decrease in professional service fees as we completed or terminated certain transactions, partially offset by an increase in share-based compensation for management and administrative staff, mainly attributable to the grant of additional share options to our management and administrative staff.

Other Expenses

We incurred other expenses of RMB53.7 million in 2022, compared to RMB3.3 million in 2023, because we incurred loss on disposal of items of other intangible assets in 2022 primarily related to our out-licensing of KBP-5081. For further details, see “Business — Our License and Asset Acquisition Arrangements — Our Asset Transfer and Out-licensing Agreements — Out-licensing and Collaboration Agreements with SPH New Asia for KBP-5081 and XZP-P803” in this document.

Finance Costs

Our finance costs decreased by 23.1% from RMB1.5 million in 2022 to RMB1.2 million in 2023, primarily due to the termination of the lease for certain office areas in 2023.

Income Tax Expense

In 2022 and 2023, our income tax expense remained stable, with the amount standing at RMB5 thousand and RMB6 thousand, respectively.

Loss for the Year

For the reasons discussed above, our loss for the year decreased by 41.3% from RMB512.3 million in 2022 to RMB300.6 million in 2023.

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DESCRIPTION OF SELECTED ITEMS FROM THE CONSOLIDATED BALANCE SHEETS

The following table sets forth a summary of our consolidated balance sheets as of the dates indicated:

	As of December 31,		As of June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Non-current assets			
Property, plant and equipment	148,366	128,477	128,176
Right-of-use assets	81,066	68,950	55,907
Other intangible assets	391,752	533,803	567,002
Prepayments, other receivables and other assets-non current	32,231	47,344	39,566
Total non-current assets	653,415	778,574	790,651
Current assets			
Inventories	49,447	62,317	51,249
Trade and bill receivables	–	–	3,155
Prepayments, other receivables and other assets-current	45,843	30,396	36,026
Financial assets at fair value through profit or loss	482,180	306,832	332,376
Cash and cash equivalents	224,112	142,891	25,339
Total current assets	801,582	542,436	448,145
Total assets	1,454,997	1,321,010	1,238,796
Current liabilities			
Trade payables	39,736	69,212	73,431
Other payables and accruals	47,486	68,767	78,487
Lease liabilities	6,519	5,148	2,375
Total current liabilities	93,741	143,127	154,293
Net current assets	707,841	399,309	293,852
Total assets less current liabilities	1,361,256	1,177,883	1,084,503
Non-current liabilities			
Other payables and accruals	–	55,719	55,138
Lease liabilities	22,713	11,917	–
Total non-current liabilities	22,713	67,636	55,138
Total liabilities	116,454	210,763	209,431
Net assets	1,338,543	1,110,247	1,029,365

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Property, Plant and Equipment

During the Track Record Period, our property, plant and equipment primarily consisted of leasehold improvements, buildings, laboratory equipment, office equipment, and electronic equipment. Our property, plant and equipment decreased by 13.4% from RMB148.4 million as of December 31, 2022 to RMB128.5 million as of December 31, 2023, primarily due to the provision for depreciation of our fixed assets. Our property, plant and equipment amounted to RMB128.2 million as of June 30, 2024, which remained largely stable as compared to the amount as of December 31, 2023.

Right-of-Use-Assets

During the Track Record Period, our right-of-use assets represented leases of offices. Our right-of-use assets decreased by 14.9% from RMB81.1 million as of December 31, 2022 to RMB69.0 million as of December 31, 2023, and further to RMB55.9 million as of June 30, 2024, primarily due to (i) the termination of the lease for certain office areas in December 2023 and (ii) amortization of right of use assets.

Other Intangible Assets

During the Track Record Period, our other intangible assets primarily consisted of research and development costs, patents and licenses, and software. We are eligible to capitalize research and development expenditure only when we can demonstrate (i) the technical feasibility of completing the intangible asset so that it will be available for use or sale, (ii) our intention to complete and our ability to use or sell the asset, (iii) how the asset will generate future economic benefits, (iv) the availability of resources to complete the project, and (v) the ability to measure reliably the expenditure during the development. Historically, we capitalized research and development expenditure of a drug asset upon meeting the criteria set out in “— Significant Accounting Policies and Critical Judgments and Estimates — Significant Accounting Policies — Research and Development Costs.”

In addition to research and development costs, we also recorded research and development expenses, representing our expensed expenditure on R&D activities, during the Track Record Period. In 2022, 2023 and the six months ended June 30, 2024, our research and development expenses amounted to RMB401.0 million, RMB239.1 million and RMB74.4 million, respectively. For details on our research and development expenses, see “— Description of Selected Components of the Consolidated Statements of Profit or Loss and Other Comprehensive Income — Research and Development Expenses.”

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The following table sets forth the details of our intangible assets as of the dates indicated:

	As of December 31,		As of June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Research and development costs	382,783	459,482	496,528
Patents and licenses	6,462	72,345	69,023
Software	2,507	1,976	1,451
Total	<u>391,752</u>	<u>533,803</u>	<u>567,002</u>

Our other intangible assets increased by 36.3% from RMB391.8 million as of December 31, 2022 to RMB533.8 million as of December 31, 2023, primarily driven by an increase in research and development costs as we capitalized certain expenditures for the phase 3 clinical trials of XZP-3287 and XZP-3621. Our other intangible assets further increased by 6.2% to RMB567.0 million as of June 30, 2024, primarily driven by an increase of research and development costs over the period as we continued to invest in R&D activities to optimize our highly competitive and balanced pipeline of drug assets.

Prepayments, Other Receivables and Other Assets

During the Track Record Period, our non-current portion of prepayments, other receivables and other assets primarily consisted of (i) prepayment for property, plant and equipment, representing our advance payments for construction costs, (ii) deductible value-added tax, representing our input value-added tax, and (iii) rental deposits, representing the deposits placed for our leases. Over the same period, our current portion of prepayments, other receivables and other assets primarily consisted of (i) prepayments, representing advance payments for clinical trial and technical service fees, processing fees associated with drugs used for R&D purposes, and equipment purchase fees, (ii) other receivables, representing our receivables under out-licensing arrangements with business partners, and (iii) deferred [REDACTED]. The following tables sets forth the details of our prepayments, other receivables and other assets as of the dates indicated:

	As of December 31,		As of June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Non-current:			
Prepayments for property, plant and equipment	10,414	10,044	–
Deductible value-added tax	19,573	36,238	39,566
Rental deposits	2,244	1,062	–
Total	<u>32,231</u>	<u>47,344</u>	<u>39,566</u>

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	As of December 31,		As of June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Current:			
Prepayments	28,118	12,847	15,241
Deposits	649	73	226
Other receivables	13,012	13,556	20,588
Deductible value-added tax	736	–	105
Deferred [REDACTED]	3,554	3,947	–
Impairment allowance	(226)	(27)	(134)
Total	45,843	30,396	36,026

Our non-current portion of prepayments, other receivables and other assets increased by 46.9% from RMB32.2 million as of December 31, 2022 to RMB47.3 million as of December 31, 2023, primarily driven by an increase in deductible value-added tax as we recorded an increasing amount of input value-added tax with the procurement of materials and services. Our non-current portion of prepayments, other receivables and other assets decreased by 16.4% from RMB47.3 million as of December 31, 2023 to RMB39.6 million as of June 30, 2024, primarily due to a decrease of prepayments of property, plant and equipment with the completion and acceptance of a construction project.

Our current portion of prepayments, other receivables and other assets decreased by 33.7% from RMB45.8 million as of December 31, 2022 to RMB30.4 million as of December 31, 2023, primarily due to a decrease in prepayments as we settled expenses to suppliers. Our current portion of prepayments, other receivables and other assets increased by 18.5% from RMB30.4 million as of December 31, 2023 to RMB36.0 million as of June 30, 2024, primarily due to (i) an increase in other receivables as we out-licensed certain rights related to XZP-5849 to Livzon in June 2024, which we subsequently received as of the Latest Practicable Date, and (ii) an increase in prepayments as we incurred extra advance payments under a technology service contract entered into in June 2024.

As of September 30, 2024, RMB10.2 million, or 28.2%, of our current portion of prepayments, other receivables and other assets as of June 30, 2024 had been subsequently settled.

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Inventories

During the Track Record Period, our inventories primarily consisted of (i) raw materials, (ii) work in progress, and (iii) finished goods. The following tables sets forth the details of our inventories as of the dates indicated:

	As of December 31,		As of June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Raw materials	41,608	54,533	44,088
Work in progress	7,738	5,485	5,068
Finished goods	–	2,053	1,838
Others	101	246	255
Total	49,447	62,317	51,249

Our inventories increased by 26.0% from RMB49.4 million as of December 31, 2022 to RMB62.3 million as of December 31, 2023, primarily driven by (i) an increase in raw materials to support our drug research and development and (ii) an increase in finished goods, resulting from the commercialization of KBP-3571. Our inventories decreased by 17.8% from RMB62.3 million as of December 31, 2023 to RMB51.2 million as of June 30, 2024, primarily due to a decrease in raw materials, which was in line with the schedule of our research and development and commercial activities.

As of September 30, 2024, RMB17.2 million, or 33.5% of our inventories as of June 30, 2024, had been consumed.

Trade and Bill Receivables

During the Track Record Period, our trade receivables represented amounts owed to us by customers in connection with the sales of KBP-3571 and our bill receivables represented an acceptance bill transferred to us in connection with the sales of KBP-3571. The following table sets forth the details of our trade and bill receivables as of the dates indicated:

	As of December 31,		As of June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Bill receivables	–	–	2,350
Trade receivables	–	–	827
Impairment allowance	–	–	(22)
Total	–	–	3,155

Our trade and bill receivables were nil and nil as of December 31, 2022 and 2023. Our trade and bill receivables increased from nil as of December 31, 2023 to RMB3.2 million as of June 30, 2024, primarily because we started to achieve sales following the commercialization of KBP-3571.

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Our trading terms with customers are mainly payment in advance, except for certain customers who make small-volume purchases on an urgent basis. The payment term generally ranges from 30 to 180 days. We seek to maintain strict control over our outstanding receivables. Overdue balances are reviewed regularly by our senior management. We do not hold any collateral or other credit enhancements over our trade receivable balances. Our trade receivables are non-interest-bearing.

The following table sets forth an aging analysis of our trade receivables, based on the transaction dates and net of loss allowance, as of the dates indicated:

	As of December 31,		As of June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Within three months	—	—	3,155
Total	—	—	3,155

An impairment analysis is performed at the end of each of the Track Record Period, using a provision matrix to measure expected credit losses. We use the simplified method to calculate the credit impairment losses on trade receivables. Our management’s estimate of the expected loss rate is based on the expected loss rate calculated by establishing the default rate of the corporate bonds in the recent three years and combining with forward-looking factors.

As of September 30, 2024, RMB3.1 million, or 99.7%, of our trade and bill receivables as of June 30, 2024 had been subsequently settled.

Financial Assets at Fair Value through Profit or Loss

During the Track Record Period, our financial assets at fair value through profit or loss represented wealth management products that we purchased from creditworthy commercial banks in mainland China. These wealth management products, which are low-risk and redeemable on demand, offer relatively strong liquidity. For more details, please refer to note 19 to the Accountants’ Report set out in Appendix I to this document.

Our financial assets at fair value through profit or loss decreased by 36.4% from RMB482.2 million as of December 31, 2022 to RMB306.8 million as of December 31, 2023, primarily due to the maturity and redemption of some of our wealth management products. Our financial assets at fair value through profit or loss increased by 8.3% from RMB306.8 million as of December 31, 2023 to RMB332.4 million as of June 30, 2024, primarily because we redeemed certain wealth management products in late 2023 and had a higher balance of wealth management products as of June 30, 2024.

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Cash and Cash Equivalents

During the Track Record Period, our cash and cash equivalents primarily consisted of (i) cash and bank balances and (ii) time deposits. The following table sets forth the details of our cash and cash equivalents as of the dates indicated:

	As of December 31,		As of June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Cash and bank balances	219,312	140,637	19,954
Time deposits	4,800	2,254	5,385
Total	224,112	142,891	25,339

Our cash and cash equivalents decreased by 36.2% from RMB224.1 million as of December 31, 2022 to RMB142.9 million as of December 31, 2023, and further decreased to RMB25.3 million as of June 30, 2024, primarily due to the expenditure for our daily operations.

Trade Payables

During the Track Record Period, our trade payables primarily consisted of our payments for clinical trial and technical services. Our trade payables increased by 74.2% from RMB39.7 million as of December 31, 2022 to RMB69.2 million as of December 31, 2023, and further increased by 6.1% to RMB73.4 million as of June 30, 2024. The continuous increase of our trade payables was primarily due to (i) our efforts to push forward the development of our drug assets, particularly KBP-3571 and XZP-3621, and (ii) our enhanced ability to control the payment schedule to our trading partners.

The following table sets forth an aging analysis of our trade payables presented based on the invoice date as of the dates indicated:

	As of December 31,		As of June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Within one year	38,914	68,634	72,003
Over one year	822	578	1,428
Total	39,736	69,212	73,431

As of September 30, 2024, RMB56.0 million, or 76.2%, of our trade payables as of June 30, 2024 had been subsequently settled.

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Our Directors confirm that there has not been any material default on our part in the payment of trade payables during the Track Record Period and up to the date of this document.

Other Payables and Accruals

During the Track Record Period, our non-current portion of other payables and accruals represented advances we received for sales of pharmaceutical products and consideration we received in advance from distributors for granting them exclusive distribution rights. As of December 31, 2022 and 2023 and June 30, 2024, our non-current portion of other payables and accruals amounted to nil, RMB55.7 million and RMB55.1 million, respectively.

Our non-current portion of other payables and accruals increased from nil as of December 31, 2022 to RMB55.7 million as of December 31, 2023, primarily because we started to receive advances for sales of pharmaceutical products and grant distribution rights following the commercialization of KBP-3571. Our non-current portion of other payables and accruals as of December 31, 2023 and June 30, 2024 remained at similar levels, with the amount standing at RMB55.7 million and RMB55.1 million, respectively.

Our current portion of other payables and accruals primarily consisted of (i) other payables, mainly including deposits we received from pharmaceutical distributors, following the commercialization of KBP-3571, (ii) contract liabilities, mainly including advances received for sales of pharmaceutical products and consideration we received in advance from distributors for granting them exclusive distribution rights, (iii) payroll payables, representing payables related to salaries, bonuses, social security and labor union funding, (iv) other tax payables, and (v) amounts due to related parties. For details on amounts due to related parties, see “— Material Related Party Transactions — Outstanding Balances with Related Parties.”

Our current portion of other payables and accruals increased by 44.8% from RMB47.5 million as of December 31, 2022 to RMB68.8 million as of December 31, 2023, primarily due to (i) an increase in other payables and (ii) an increase in contract liabilities, both resulting from the commercialization of KBP-3571 as we started to charge distributors both deposits and fees for granting them distribution rights and to receive advances for sales of KBP-3571. Our current portion of other payables and accruals increased by 14.1% from RMB68.8 million as of December 31, 2023 to RMB78.5 million as of June 30, 2024, primarily due to an increase in contract liabilities as we continued to increase the sales of KBP-3571.

The following table sets forth the details of our other payables and accruals as of the dates indicated:

	As of December 31,		As of June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Non-current:			
Contract liabilities	—	55,719	55,138
Total	—	55,719	55,138
	=	=	=

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	As of December 31,		As of June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Current:			
Other payables	18,934	39,612	38,602
Contract liabilities	–	7,253	22,683
Payroll payables	27,229	18,595	8,820
Other tax payables	1,323	1,647	5,997
Amounts due to related parties	–	1,660	2,385
Total	<u>47,486</u>	<u>68,767</u>	<u>78,487</u>

As of September 30, 2024, RMB36.6 million, or 46.6%, of our current portion of other payables and accruals as of June 30, 2024 had been subsequently settled.

Our Directors confirm that there has not been any material default on our part in the payment of other payables during the Track Record Period and up to the date of this document.

Lease Liabilities

Our lease liabilities represent the present value of the lease payments that we are contractually obligated to make over the remaining lease term. The following table sets forth the details of our lease liabilities as of the dates indicated:

	As of December 31,		As of June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Current lease liabilities	6,519	5,148	2,375
Non-current lease liabilities	22,713	11,917	–
Total	<u>29,232</u>	<u>17,065</u>	<u>2,375</u>

Our lease liabilities decreased by 41.6% from RMB29.2 million as of December 31, 2022 to RMB17.1 million as of December 31, 2023, and further decreased by 86.1% to RMB2.4 million as of June 30, 2024, primarily due to (i) the termination of the lease for a portion of office areas in December 2023, and (ii) amortization.

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LIQUIDITY AND CAPITAL RESOURCES

During the Track Record Period, our primary uses of cash were to fund the preclinical and clinical development of our drug candidates, administrative expenses and other operating expenses. During the Track Record Period and up to the Latest Practicable Date, we have primarily funded our working capital requirements through proceeds from equity financing. Our management closely monitors uses of cash and cash balances and strives to maintain a healthy liquidity for our operations.

Going forward, we believe our liquidity requirements will be satisfied by a combination of existing cash and cash equivalents, sales from commercialized drug products, and [REDACTED] from the [REDACTED]. With the continuing expansion of our business, we may require further funding through equity offerings, debt financing, license and collaboration arrangements, and other sources. As of September 30, 2024, our cash resources amounted to RMB308.5 million, including cash and cash equivalents of RMB20.7 million and financial assets at FVTPL of RMB287.8 million.

Except as discussed under the paragraphs headed “— Indebtedness” in this section, we did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities as of September 30, 2024.

Current Assets and Liabilities

	<u>As of December 31,</u>		<u>As of June 30,</u>	<u>As of</u> <u>September 30,</u>
	<u>2022</u>	<u>2023</u>	<u>2024</u>	<u>2024</u>
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i> <i>(Unaudited)</i>
Current assets				
Inventories	49,447	62,317	51,249	62,396
Trade and bill receivables	—	—	3,155	2,686
Prepayments, other receivables and other assets	45,843	30,396	36,026	35,744
Financial assets at FVTPL	482,180	306,832	332,376	287,842
Cash and cash equivalents	224,112	142,891	25,339	20,693
Total current assets	<u>801,582</u>	<u>542,436</u>	<u>448,145</u>	<u>409,361</u>

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	As of December 31,		As of June 30,	As of September 30,
	2022	2023	2024	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i> <i>(Unaudited)</i>
Current liabilities				
Bills payables	–	–	–	9,237
Trade payables	39,736	69,212	73,431	59,481
Other payables and accruals	47,486	68,767	78,487	84,470
Lease liabilities	6,519	5,148	2,375	956
Total current liabilities	93,741	143,127	154,293	154,144
Net current assets	707,841	399,309	293,852	255,217

Our net current assets decreased by 43.6% from RMB707.8 million as of December 31, 2022 to RMB399.3 million as of December 31, 2023, primarily due to (i) a decrease in financial assets at FVTPL, as a result of the maturity and redemption of some of our wealth management products, (ii) a decrease in our cash and cash equivalents, resulting from the expenditure for our daily operations, (iii) an increase in trade payables as we pushed forward the development of our drug assets, particularly KBP-3571 and XZP-3621, and (iv) an increase in current portion of other payables and accruals, primarily driven by the commercialization of KBP-3571, partially offset by (i) an increase in inventories, primarily driven by an increase in raw materials and finished goods, and (ii) a decrease in lease liabilities, due to the termination of the lease for certain office areas in 2023 and amortization.

Our net current assets decreased by 26.4% from RMB399.3 million as of December 31, 2023 to RMB293.9 million as of June 30, 2024, primarily due to (i) a decrease in cash and cash equivalents, mainly attributable to the expenditure for our daily operations, (ii) a decrease in inventories, which was in line with the schedule of our research and development and commercial activities, (iii) an increase in trade payables, as a result of our efforts to further push forward the development of our drug assets, particularly KBP-3571 and XZP-3621, and (iv) an increase in the current portion of other payables and accruals, as we continued to increase the sales of KBP-3571, partially offset by an increase in financial assets at fair value through profit or loss as we redeemed certain wealth management products in late 2023 and had a higher balance of wealth management products as of June 30, 2024.

Our net current assets decreased by 13.1% from RMB293.9 million as of June 30, 2024 to RMB255.2 million as of September 30, 2024, primarily due to (i) a decrease in financial assets at FVTPL, as a result of the maturity and redemption of some of our wealth management products, (ii) the addition of bills payables, as we have since the third quarter of 2024 started paying suppliers through bank acceptance bills to better manage our liquidity, and (iii) a decrease in cash and cash equivalents, mainly attributable to the expenditure for our daily operations, partially offset by (i) a decrease in trade payables, as a result of our payment arrangements in everyday operations and use of bank acceptance bills, and (ii) an increase in inventories, primarily driven by an increase in raw materials and finished goods.

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Cash Flows

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

	For the year ended December 31,		Six months ended June 30,	
	2022	2023	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
			<i>(unaudited)</i>	
Operating cash flows before				
movement in working capital	(389,697)	(212,183)	(131,769)	(60,659)
Changes in working capital	1,728	95,865	(3,025)	7,609
Interest received	1,737	372	190	158
Income tax paid	<u>(5)</u>	<u>(6)</u>	<u>(6)</u>	<u>(6)</u>
Net cash used in operating				
activities	(386,237)	(115,952)	(134,610)	(52,898)
Net cash (used in)/from investing				
activities	(498,024)	44,732	156,684	(61,674)
Net cash used in financing				
activities	<u>(12,156)</u>	<u>(9,903)</u>	<u>(4,342)</u>	<u>(2,871)</u>
Net increase/(decrease) in cash and				
cash equivalents	(896,417)	(81,123)	17,732	(117,443)
Cash and cash equivalents at				
beginning of year/period	1,120,510	224,112	224,112	142,891
Effect of foreign exchange rate				
changes, net	<u>19</u>	<u>(98)</u>	<u>(6)</u>	<u>(109)</u>
Cash and cash equivalents at the				
end of year/period	<u>224,112</u>	<u>142,891</u>	<u>241,838</u>	<u>25,339</u>

Net Cash Flows Used in Operating Activities

In the six months ended June 30, 2024, we had net cash used in operating activities of RMB52.9 million, which was primarily attributable to our loss before tax of RMB111.0 million adjusted by certain non-cash and working capital items, including (i) positive adjustments, which primarily included share-based payment expenses of RMB30.1 million, depreciation of property, plant and equipment of RMB10.7 million, a decrease in inventories of RMB10.6 million, an increase in other payables and accruals of RMB9.1 million, an increase in trade payables of RMB4.2 million, depreciation of right-of-use assets of RMB2.9 million, and amortization of other intangible assets of RMB3.6 million, and (ii) negative adjustments, which primarily included an increase in prepayments, other receivables and other assets of RMB13.2 million, gain on fair value changes of financial assets at FVTPL of RMB3.7 million, and an increase in trade receivables of RMB3.2 million.

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In 2023, we had net cash used in operating activities of RMB116.0 million, which was primarily attributable to our loss before tax of RMB300.6 million adjusted by certain non-cash and working capital items, including (i) positive adjustments, which primarily included an increase in other payables and accruals of RMB77.0 million, share-based payment expenses of RMB72.3 million, an increase in trade payables of RMB29.5 million, depreciation of property, plant and equipment of RMB21.8 million, depreciation of right-of-use assets of RMB7.4 million, amortization of other intangible assets of RMB2.9 million, a decrease in prepayments, other receivables and other assets of RMB2.2 million and finance costs of RMB1.2 million, and (ii) negative adjustments, which primarily included investment income on financial assets at FVTPL of RMB14.0 million, an increase in inventories of RMB12.9 million, gain on fair value changes of financial assets at FVTPL of RMB1.7 million, and gain on disposal of items of rights-of-use assets of RMB1.0 million.

In 2022, we had net cash used in operating activities of RMB386.2 million, which was primarily attributable to our loss before tax of RMB512.3 million adjusted by certain non-cash and working capital items, including (i) positive adjustments, which primarily included share-based payment expenses of RMB70.1 million, loss on disposal of items of other intangible assets of RMB52.3 million, an increase in trade payables of RMB22.5 million, depreciation of property, plant and equipment of RMB17.9 million, depreciation of right-of-use assets of RMB7.5 million, finance costs of RMB1.5 million, and provision of inventories of RMB1.4 million, and (ii) negative adjustments, which primarily included investment income on financial assets at FVTPL of RMB22.0 million, an increase in prepayments, other receivables and other assets of RMB12.5 million, a decrease in other payables and accruals of RMB8.3 million, gain on fair value changes of financial assets at FVTPL of RMB5.1 million, and interest income of RMB1.7 million.

Net Cash Flows from Investing Activities

In the six months ended June 30, 2024, we had net cash used in investing activities of RMB61.7 million, primarily attributable to (i) purchases of financial assets at FVTPL of RMB275.7 million and (ii) purchases of items of other intangible assets of RMB41.2 million, partially offset by proceeds from disposal of financial assets at FVTPL of RMB255.5 million.

In 2023, we had net cash from investing activities of RMB44.7 million, primarily attributable to proceeds from disposal of financial assets at FVTPL of RMB1,408.5 million, partially offset by (i) purchases of financial assets at FVTPL of RMB1,217.4 million, (ii) purchases of items of other intangible assets of RMB144.6 million, and (iii) purchases of items of property, plant and equipment of RMB1.7 million.

In 2022, we had net cash used in investing activities of RMB498.0 million, primarily attributable to (i) purchases of financial assets at FVTPL of RMB2,504.1 million, (ii) purchases of items of other intangible assets of RMB122.5 million, and (iii) purchases of items of property, plant and equipment of RMB44.7 million, partially offset by (i) proceeds from disposal of financial assets at FVTPL of RMB2,161.8 million, and (ii) proceeds from disposal of items of intangible assets of RMB11.0 million.

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Net Cash Flows Used in Financing Activities

In the six months ended June 30, 2024, we had net cash used in financing activities of RMB2.9 million, representing lease payments of RMB2.9 million.

In 2023, we had net cash used in financing activities of RMB9.9 million, representing (i) lease payments of RMB7.6 million and (ii) payment of [REDACTED] of RMB2.3 million.

In 2022, we had net cash used in financing activities of RMB12.2 million, representing the (i) lease payments of RMB5.0 million and (ii) payment of [REDACTED] of RMB7.2 million.

CASH OPERATING COSTS

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

	For the year ended December 31,		For the six months ended June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Costs relating to research and development of our Core Products			
Staff cost	62,129	64,637	20,539
Trial and testing expenses	181,568	124,741	31,822
Raw materials and others	42,759	22,879	4,541
<i>Subtotal</i>	<u>286,455</u>	<u>212,257</u>	<u>56,902</u>
Costs relating to research and development of our other drug candidates			
Staff cost	57,712	47,994	14,128
Trial and testing expenses	129,691	15,841	14,395
Raw materials and others	32,693	26,491	6,668
<i>Subtotal</i>	<u>220,097</u>	<u>90,326</u>	<u>35,191</u>
Total	<u>506,552</u>	<u>302,583</u>	<u>92,093</u>
Workforce employment costs ⁽¹⁾	27,239	36,416	20,053
Direct production costs ⁽²⁾	–	2,062	8,596
Others	23,423	14,955	10,660
Total cash operating cost	<u>557,214</u>	<u>356,016</u>	<u>131,402</u>

Notes:

- (1) Workforce employment costs represent total non-research and development personnel costs mainly including salaries and benefits.
- (2) Direct production costs represent the payments we make to the CDMOs that we collaborate with and the movement in the balances of our inventory.

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WORKING CAPITAL CONFIRMATION

Our Directors are of the opinion that, taking into account of the financial resources available to us, including cash and cash equivalents, revenue generated from the sales of our commercialized product, the estimated [REDACTED] from the [REDACTED], and our cash burn rate, we have sufficient working capital to cover at least 125% of our costs, including research and development costs, business development and marketing expenses, and administrative and operating costs for at least the next 12 months from the date of this document.

Our cash burn rate refers to the average monthly amount of net cash used in operating activities, capital expenditures, capitalized research and development expenditure, and other scheduled cash payment. We estimate that we will receive [REDACTED] of approximately HK\$[REDACTED] million, after deducting [REDACTED], fees and estimated expenses payable by us in connection with the [REDACTED], and assuming an [REDACTED] of HK\$[REDACTED] per H Share and the [REDACTED] is not exercised, being the [REDACTED] of the indicative [REDACTED] range stated in this document. Assuming an average cash burn rate going forward of 1.0 times the level in 2023, we estimate that our cash and cash equivalents and financial assets at FVTPL as of September 30, 2024 will be able to maintain our financial viability for [REDACTED] months from September 30, 2024, without taking into account the estimated [REDACTED] from the [REDACTED]; or, we estimate we will be able to maintain our financial viability for [REDACTED] months from September 30, 2024, if we take into account the estimated [REDACTED] from the [REDACTED]. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.

INDEBTEDNESS

As of December 31, 2022 and 2023, June 30, 2024, and September 30, 2024, being the most recent practicable date for determining our indebtedness, except as disclosed in the table below, we did not have any material indebtedness:

	As of December 31,	As of June 30,	As of September 30,	
	2022	2023	2024	2024
	(RMB'000)	(RMB'000)	(RMB'000)	(RMB'000)
				(Unaudited)
Current lease liabilities	6,519	5,148	2,375	956
Non-current lease liabilities	22,713	11,917	—	—
Total	29,232	17,065	2,375	956

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 our Group 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. There had not been any material change in our indebtedness since the Latest Practicable Date up to the date of this document.

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CAPITAL EXPENDITURE

Our capital expenditures during the Track Record Period were related to our purchases of property, plant, and equipment. In 2022, 2023 and the six months ended June 30, 2024, we incurred capital expenditures of RMB44.7 million, RMB1.7 million and RMB0.4 million, respectively. These purchases were primarily for our R&D and business operations.

We funded our capital expenditure requirements during the Track Record Period mainly from private equity financing. We plan to finance our future capital expenditures primarily with our existing cash as well as [REDACTED] from the [REDACTED]. We may reallocate the funds to be utilized on capital expenditures based on our ongoing business needs.

CAPITAL COMMITMENTS

As of December 31, 2022 and 2023 and June 30, 2024, we had capital commitments contracted for but not yet provided of RMB2.3 million, RMB1.1 million and nil, in connection with contracts entered into for the acquisition of property, plant and equipment. The following table sets forth our contractual commitments as of the dates indicated:

	As of December 31,		As of June 30,
	2022	2023	2024
	(RMB'000)	(RMB'000)	(RMB'000)
Contracted, but not provided for:			
Acquisition of property, plant and equipment	2,345	1,059	–
Total	2,345	1,059	–

CONTINGENT LIABILITIES

As of December 31, 2022 and 2023 and June 30, 2024, we did not have any contingent liabilities. Our Directors confirm that there has been no material change in our contingent liabilities since June 30, 2024 to the date of this document.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

We did not have, during the years or periods presented, and we do not currently have, any off-balance sheet arrangements such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

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KEY FINANCIAL RATIO

The following table set forth our key financial ratio as of the dates indicated:

	As of December 31,		As of June 30,
	2022	2023	2024
Current ratio ⁽¹⁾	8.6	3.8	2.9

Note:

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

Our current ratio decreased from 8.6 as of December 31, 2022 to 3.8 as of December 31, 2023, primarily because of (i) a decrease in financial assets at FVTPL, as a result of the maturity and redemption of some of our wealth management products, (ii) a decrease in cash and cash equivalents, mainly attributable to the expenditure for our daily operations, (iii) an increase in trade payables, mainly attributable to our efforts to push forward the development of our drug assets, particularly KBP-3571 and XZP-3621, and (iv) an increase in the current portion of other payables and accruals, mainly driven by the commercialization of KBP-3571.

Our current ratio further decreased from 3.8 as of December 31, 2023 to 2.9 as of June 30, 2024, primarily because of (i) a decrease in cash and cash equivalents, mainly attributable to the expenditure for our daily operations, (ii) an increase in trade payables, mainly because we further pushed forward the development of our drug assets, particularly KBP-3571 and XZP-3621, and (iii) an increase in other payables and accruals, mainly driven by our efforts to increase the sales of KBP-3571.

MATERIAL RELATED PARTY TRANSACTIONS

Transactions with Related Parties

During the Track Record Period, we had the following material transactions with related parties:

	For the year ended December 31,		For the six months ended June 30,
	2022	2023	2024
	<i>(RMB'000)</i>	<i>(RMB'000)</i>	<i>(RMB'000)</i>
Purchases of products and services from Beijing Sihuan	268	702	–
Lease from Beijing Sihuan	1,476	898	767
Total	<u>1,744</u>	<u>1,600</u>	<u>767</u>

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Purchases of products and services

During the Track Record Period, we purchased various products and services from Beijing Sihuan, including domestic utilities like water, electricity, and heating, as well as packing services for clinical trials and processing services for XZP-3621 preparation. Our expenditures for these purchases were RMB0.3 million in 2022, RMB0.7 million in 2023, and nil in the six months ended June 30, 2024.

Lease

During the Track Record Period, we rented a building from Beijing Sihuan for office use. In 2022, 2023 and the six months ended June 30, 2024, we paid RMB1.5 million, RMB0.9 million and RMB0.8 million to Beijing Sihuan for such lease.

Outstanding Balances with Related Parties

We had an outstanding balance due from an entity under common control of the ultimate holding company of RMB0.5 million, RMB23 thousand and RMB17 thousand as of December 31, 2022 and 2023 and June 30, 2024, respectively. Such outstanding balance during the Track Record Period was related to the deposits we paid to such entity in connection with the leases we entered into. This balance is unsecured, interest-free and has no fixed terms of repayment.

We had an outstanding balance due to the same entity mentioned in the immediately preceding paragraph of nil, RMB1.7 million and RMB2.4 million as of December 31, 2022 and 2023 and June 30, 2024, respectively. Such outstanding balance during the Track Record Period was related to the leases we entered into with the entity and the accompanying utility usage. This balance is unsecured, interest-free and has no fixed terms of repayment.

It is the view of our Directors that our related party transactions during the Track Record Period (i) were conducted in the ordinary and usual course of business and on normal commercial terms between the relevant parties, and (ii) do not distort our Track Record Period results or make our historical results not reflective of future performance. See note 28 to the Accountants' Report as set out in Appendix I for a detailed information of our transactions with related parties.

FINANCIAL INFORMATION

QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISKS

Our principal financial instruments comprise cash and cash equivalents, trade and bills receivables, and financial assets included in prepayments, other receivables and other assets. The main purpose of these financial instruments is to raise finance for our operations. The main risks arising from our financial instruments are credit risk and liquidity risk. Our Directors review and agree policies for managing each of these risks and they are summarized below. For more details, please refer to note 31 to the Accountants' Report set out in Appendix I to this document.

Credit Risk

We trade only with recognized and creditworthy third parties. Our policy requires that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and our exposure to bad debts is not significant.

The credit risk of our financial assets, which comprise cash and cash equivalents, trade receivables, bills receivables and financial assets included in prepayments, other receivables and other assets, arises from default of the counterparty, with a maximum exposure equal to the carrying amount of these instruments.

Since we trade only with recognized and creditworthy third parties, there is no requirement for collateral. Concentrations of credit risk are managed by customer/counterparty, by geographical region and by industry sector. There is no significant concentration of credit risk.

Further quantitative data in respect of our credit quality and maximum exposure to credit risk arising from financial assets are disclosed in note 31 to the Accountants' Report set out in Appendix I to this document.

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.

The primary objectives of our capital management are to safeguard our ability to continue as a going concern and to maintain healthy capital ratios in order to support our business and maximize shareholders' value.

We manage our capital structure and make adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, we may adjust the dividend payment to Shareholders, return capital to Shareholders or issue new Shares. We are not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the Track Record Period.

FINANCIAL INFORMATION

Further quantitative data in respect of the maturity profile of our financial liabilities and lease liabilities are disclosed in note 31 to the Accountants’ Report set out in Appendix I to this document.

DIVIDENDS

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

DISTRIBUTABLE RESERVES

As of June 30, 2024, we did not have any reserves available for distribution to our Shareholders.

[REDACTED]

[REDACTED] to be borne by us are estimated to be approximately HK\$[REDACTED] million (assuming an [REDACTED] of HK\$[REDACTED] per H Share, being the [REDACTED] of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per H Share), representing approximately [REDACTED]% of the estimate [REDACTED] from the [REDACTED] assuming no Shares are issued pursuant to the [REDACTED]. The [REDACTED] consist of (i) [REDACTED], including [REDACTED], of approximately HK\$[REDACTED] million, and (ii) [REDACTED] of approximately HK\$[REDACTED] million, comprising (a) fees and expenses of our legal advisors and reporting accountants of approximately HK\$[REDACTED] million, and (b) other fees and expenses of approximately HK\$[REDACTED] million. During the Track Record Period, we did not incur [REDACTED] in connection with this proposed [REDACTED]. After the Track Record Period, approximately HK\$[REDACTED] million is expected to be charged to our consolidated statements of profit or loss, and approximately HK\$[REDACTED] million is expected to be accounted for as a deduction from equity upon

FINANCIAL INFORMATION

the [REDACTED]. We do not believe any of the above fees or expenses are material or are unusually high to our Group. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

UNAUDITED [REDACTED] ADJUSTED NET TANGIBLE ASSETS

The following unaudited [REDACTED] statement of our adjusted net tangible assets prepared in accordance with Rule 4.29 of the Listing Rules is to illustrate the effect of the [REDACTED] on our consolidated net tangible assets attributable to the owners of our Company as of June 30, 2024 as if the [REDACTED] had taken place on that date.

The unaudited [REDACTED] statement of adjusted consolidated net tangible assets of our Group attributable to the owners of our Company has been prepared for illustrative purpose only and, because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of our Group attributable to the owners of our Company as of June 30, 2024 or at any further dates following the [REDACTED].

[REDACTED]

FINANCIAL INFORMATION

[REDACTED]

NO MATERIAL ADVERSE CHANGE

After performing sufficient due diligence work which our Directors consider appropriate and after due and careful consideration, our Directors confirm that there has been no material adverse change in our business, financial condition and results of operations since June 30, 2024, being the latest balance sheet date of our consolidated financial statements in the Accountants’ Report set out in Appendix I to this document, and up to the date of this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors confirm that, as of the Latest Practicable Date, they were not aware of any circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

FUTURE PLANS AND [REDACTED]

FUTURE PLANS AND PROSPECTS

See “Business — Our Development Strategies” for a detailed description of our future plans.

[REDACTED]

We estimate that we will receive [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED] million, after deducting [REDACTED], fees and estimated expenses payable by us in connection with the [REDACTED], and assuming an [REDACTED] of HK\$[REDACTED] per Share and that the [REDACTED] is not exercised, being the [REDACTED] of the indicative [REDACTED] range stated in this document.

We currently intend to apply these [REDACTED] for the following purposes:

- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for the research, development and commercialization of our Core Products, namely, KBP-3571, XZP-3287 and XZP-3621:
 - approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for KBP-3571, of which:
 - (i) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund planned clinical trials of KBP-3571 for the treatment of RE. We plan to commence the phase 3 clinical trial in the second half of 2025;
 - (ii) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund the preparation for NDA submission of KBP-3571 for the treatment of RE. Pending regulatory and marketing approvals, we expect to launch KBP-3571 for RE in China by the end of 2027; and
 - (iii) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund post-marketing clinical studies to support indication expansion of KBP-3571, including the exploratory studies investigating the potential of KBP-3571 for stress ulcer prevention and *Helicobacter pylori* eradication.

For details of KBP-3571’s clinical development plan, see “Business — Digestive Disease Drugs — KBP-3571, a Commercialized PPI for Duodenum Ulcers with Phase 2 Completed Second Indication in Reflux Esophagitis, a Core Product — Clinical Development Plan.”

FUTURE PLANS AND [REDACTED]

- approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for XZP-3287, of which:
 - (i) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund the NDA submission and extension study of XZP-3287 in combination therapy with fulvestrant. We filed an NDA application for XZP-3287 in combination with fulvestrant for second-line treatment of HR+/HER2- advanced BC in 2023, and expect to receive NDA approval in the first half of 2025. We are conducting an extension study to further evaluate overall survival (OS) data, with an estimated study completion by the first half of 2026;
 - (ii) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund the NDA submission and extension study of XZP-3287 in combination therapy with letrozole or anastrozole. We are currently conducting a pivotal phase 3 clinical trial of XZP-3287 in combination with letrozole or anastrozole in advanced HR+/HER2- BC. Pending positive results in an interim analysis, we anticipate submitting the NDA to the NMPA in the first half of 2025;
 - (iii) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund the NDA submission of XZP-3287 monotherapy and its extension study. We have filed an NDA application for XZP-3287 as monotherapy for late-line treatment of locally advanced or metastatic HR+/HER2- BC in October 2023, and expect to receive NDA approval in the first half of 2025. We are conducting an extension study to further evaluate OS data, with an anticipated study completion by the first half of 2026; and
 - (iv) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund planned clinical trials of XZP-3287 in combination with endocrine therapy as an adjuvant therapy for the treatment of HR+/HER2- early BC. We plan to submit IND application in the first half of 2025.

For details of XZP-3287’s clinical development plan, see “Business — Oncology Drugs — XZP-3287, a Near-commercial Potential Best-in-class CDK4/6 Inhibitor for HR+/HER2- BC, a Core Product — Clinical Development Plan.”

- approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for XZP-3621, of which:
 - (i) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund the planned clinical trials of XZP-3621 in post-operative adjuvant therapy for ALK-positive advanced NSCLC, including a planned phase 3 clinical trial. We submitted the IND application for such indication expansion of XZP-3621 and received the acceptance notice to the IND application from the NMPA in November 2024; and

FUTURE PLANS AND [REDACTED]

(ii) [REDACTED]%, or HK\$[REDACTED] million, is expected to be used to fund the NDA submission and extension study of XZP-3621 in the first-line treatment of patients with ALK-positive advanced NSCLC. With the interim data from the phase 3 clinical trial, we have filed the NDA application of XZP-3621 in the first-line treatment of patients with ALK-positive advanced NSCLC in April 2024. We also plan to initiate an extension study to continue monitoring OS data, with an estimated study completion by the end of 2027.

For details of XZP-3621’s clinical development plan, see “Business — Oncology Drugs — XZP-3621, a Differentiated ALK Inhibitor for NSCLC Treatment, a Core Product — Clinical Development Plan.”

- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for the research and development of our key products, namely, KM602, KM501, XZP-7797 and XZP-6924:
 - approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund ongoing and planned clinical trials of KM602 for the treatment of solid tumors, including our ongoing phase 1 study for KM602 as monotherapy in patients with advanced solid tumors, as well as our planned dose escalation study for combination therapy with a PD-1 antibody in the second half of 2026;
 - approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund ongoing and planned clinical trials of KM501 for the treatment of HER2+ solid tumors. We are conducting a single-arm, open, multicenter phase 1 study to evaluate the safety, tolerability, pharmacokinetic profile, and efficacy of the KM501 in subjects with advanced solid tumors that express, amplify, or mutate HER2. In the second half of 2026, we plan to initiate a dose escalation study for combination therapy with a PD-1 antibody;
 - approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund planned clinical trials of XZP-7797 for the treatment of solid tumors. We plan to initiate a phase 1 dose-escalation study in the second half of 2025, followed by a phase 1 expansion study in 2026; and
 - approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund planned clinical trials of XZP-6924 for the treatment of solid tumors. We plan to initiate a phase 1 dose-escalation study in the first half of 2026, followed by a phase 1 expansion study in 2027.
- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to fund the research and development of other drug candidates, including XZB-0004, XZP-5610, XZP-6019 and XZP-6877.

FUTURE PLANS AND [REDACTED]

- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be allocated to strengthening our commercialization and marketing capabilities, particularly through the expansion of our sales and marketing teams to approximately 70 members by the end of 2025. In addition, we will conduct significant sales and marketing activities in the initial sales ramp-up of KBP-3571 and XZP-3287, once approved, over the next few years.
- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for working capital and other general corporate purposes.

The above allocation of the [REDACTED] from the [REDACTED] will be adjusted on a pro rata basis in the event that the [REDACTED] is fixed at a higher or lower level compared to the [REDACTED] of the indicative [REDACTED] range stated in this document. If the [REDACTED] is set at HK\$[REDACTED] per Share, being the high end of the indicative [REDACTED] range, the [REDACTED] from the [REDACTED] will increase by approximately HK\$[REDACTED] million. If the [REDACTED] is set at HK\$[REDACTED] per Share, being the low end of the indicative [REDACTED] range, the [REDACTED] from the [REDACTED] will decrease by approximately HK\$[REDACTED] million.

If the [REDACTED] is exercised in full, the [REDACTED] that we will receive will be approximately HK\$[REDACTED] million, assuming an [REDACTED] of HK\$[REDACTED] per Share (being the [REDACTED] of the indicative [REDACTED] range). In the event that the [REDACTED] is exercised in full, we intend to apply the additional [REDACTED] to the above purposes in the proportions stated above.

To the extent that the [REDACTED] from the [REDACTED] are not immediately used for the purposes described above and to the extent permitted by the relevant laws and regulations, they will be [REDACTED] in demand deposits with authorized and licensed commercial banks or financial institutions (as defined under the Securities and Futures Ordinance).

We will issue an appropriate announcement if there is any material change to the above proposed [REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED] AND [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED] AND [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED] AND [REDACTED]

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HOW TO APPLY FOR [REDACTED] AND [REDACTED]

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HOW TO APPLY FOR [REDACTED] AND [REDACTED]

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HOW TO APPLY FOR [REDACTED] AND [REDACTED]

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HOW TO APPLY FOR [REDACTED] AND [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED] AND [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED] AND [REDACTED]

[REDACTED]

APPENDIX I

ACCOUNTANTS’ REPORT

[To insert the firm’s letterhead]

ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF XUANZHU BIOPHARMACEUTICAL CO., LTD. AND CHINA INTERNATIONAL CAPITAL CORPORATION HONG KONG SECURITIES LIMITED

Introduction

We report on the historical financial information of Xuanzhu Biopharmaceutical Co., Ltd. (the “Company”) and its subsidiaries (together, the “Group”) set out on pages I-4 to I-59, which comprises the consolidated statements of profit or loss and other comprehensive income, statements of changes in equity and statements of cash flows of the Group for each of the years ended 31 December 2022 and 2023, and the six months ended 30 June 2024 (the “Relevant Periods”), and the consolidated statements of financial position of the Group and the statement of financial position of the Company as at 31 December 2022 and 2023 and 30 June 2024 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-59 forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [Date] (the “Document”) in connection with the initial [REDACTED] of the shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

Directors’ responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information, and for such internal control as the directors determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountants’ responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 *Accountants’ Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s

APPENDIX I

ACCOUNTANTS’ REPORT

preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information, in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountants’ report, a true and fair view of the financial position of the Group and the Company as at 31 December 2022 and 2023 and 30 June 2024 and of the financial performance and cash flows of the Group for each of the Relevant Periods in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information.

Review of interim comparative financial information

We have reviewed the interim comparative financial information of the Group which comprises the consolidated statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the six months ended 30 June 2023 and other explanatory information (the “**Interim Comparative Financial Information**”). The directors of the Company are responsible for the preparation and presentation of the Interim Comparative Financial Information in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information. Our responsibility is to express a conclusion on the Interim Comparative Financial Information based on our review. We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the HKICPA. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has come to our attention that causes us to believe that the Interim Comparative Financial Information, for the purposes of the accountants’ report, is not prepared, in all material respects, in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information.

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ACCOUNTANTS' REPORT

Report on matters under the Rules Governing the Listing of Securities on the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-4 have been made.

Dividends

We refer to note 11 to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

No historical financial statements for the Company

As at the date of this report, no statutory financial statements have been prepared for the Company since its date of incorporation.

[●]

Certified Public Accountants

Hong Kong

[Date]

I. HISTORICAL FINANCIAL INFORMATION

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The financial statements of the Group for the Relevant Periods, on which the Historical Financial Information is based, were audited by Ernst & Young in accordance with Hong Kong Standards on Auditing issued by the Hong Kong Institute of Certified Public Accountants (the “Underlying Financial Statements”).

The Historical Financial Information is presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	<i>Notes</i>	<u>Year ended 31 December</u>		<u>Six months ended 30 June</u>	
		<u>2022</u>	<u>2023</u>	<u>2023</u>	<u>2024</u>
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
				<i>(Unaudited)</i>	
Revenue	5	–	29	–	16,030
Cost of sales		–	(9)	–	(8,811)
Gross profit		–	20	–	7,219
Other income and gains	5	40,531	40,800	17,405	7,492
Selling and distribution expenses		–	(10,235)	(2,319)	(6,161)
Research and development expenses		(400,983)	(239,061)	(149,540)	(74,426)
Administrative expenses		(96,401)	(87,845)	(52,208)	(36,486)
Other expenses	5	(53,670)	(3,267)	(9)	(8,198)
Impairment/(reversal of impairment) on financial assets, net		(220)	199	108	(129)
Finance costs	7	(1,517)	(1,167)	(621)	(282)
LOSS BEFORE TAX	6	(512,260)	(300,556)	(187,184)	(110,971)
Income tax expense	10	(5)	(6)	(6)	(6)
LOSS AND TOTAL COMPREHENSIVE LOSS FOR THE YEAR/PERIOD .		<u>(512,265)</u>	<u>(300,562)</u>	<u>(187,190)</u>	<u>(110,977)</u>
Attributable to:					
Owners of the parent		<u>(512,265)</u>	<u>(300,562)</u>	<u>(187,190)</u>	<u>(110,977)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT					
Basic and diluted (RMB)		<u>(1.14)</u>	<u>(0.67)</u>	<u>(0.42)</u>	<u>(0.25)</u>

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Notes	As at 31 December		As at
		2022	2023	30 June
		RMB’000	RMB’000	2024
				RMB’000
NON-CURRENT ASSETS				
Property, plant and equipment	13	148,366	128,477	128,176
Right-of-use assets	14	81,066	68,950	55,907
Other intangible assets	15	391,752	533,803	567,002
Prepayments, other receivables and other assets – non current	18	32,231	47,344	39,566
Total non-current assets		653,415	778,574	790,651
CURRENT ASSETS				
Inventories	16	49,447	62,317	51,249
Trade and bills receivables	17	–	–	3,155
Prepayments, other receivables and other assets – current	18	45,843	30,396	36,026
Financial assets at fair value through profit or loss	19	482,180	306,832	332,376
Cash and cash equivalents	20	224,112	142,891	25,339
Total current assets		801,582	542,436	448,145
CURRENT LIABILITIES				
Trade payables	21	39,736	69,212	73,431
Other payables and accruals	22	47,486	68,767	78,487
Lease liabilities	14	6,519	5,148	2,375
Total current liabilities		93,741	143,127	154,293
NET CURRENT ASSETS		707,841	399,309	293,852
TOTAL ASSETS LESS CURRENT LIABILITIES		1,361,256	1,177,883	1,084,503
NON-CURRENT LIABILITIES				
Other payables and accruals	22	–	55,719	55,138
Lease liabilities	14	22,713	11,917	–
Total non-current liabilities		22,713	67,636	55,138
Net assets		1,338,543	1,110,247	1,029,365
EQUITY				
Equity attributable to owners of the parent				
Share capital	23	450,614	450,614	450,614
Reserves	24	887,929	659,633	578,751
Total equity		1,338,543	1,110,247	1,029,365

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

Year ended 31 December 2022

	Share capital	Share premium*	RSU reserve*	Other reserve*	Surplus reserve*	Accumulated losses*	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 1 January 2022	450,614	1,890,073	39,304	111,987	72	(711,371)	1,780,679
Loss and total comprehensive loss for the year	-	-	-	-	-	(512,265)	(512,265)
Recognition of share-based payment expenses (note 25)	-	-	70,129	-	-	-	70,129
At 31 December 2022	<u>450,614</u>	<u>1,890,073</u>	<u>109,433</u>	<u>111,987</u>	<u>72</u>	<u>(1,223,636)</u>	<u>1,338,543</u>

Year ended 31 December 2023

	Share capital	Share premium*	RSU reserve*	Other reserve*	Surplus reserve*	Accumulated losses*	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 1 January 2023	450,614	1,890,073	109,433	111,987	72	(1,223,636)	1,338,543
Loss and total comprehensive loss for the year	-	-	-	-	-	(300,562)	(300,562)
Recognition of share-based payment expenses (note 25)	-	-	72,266	-	-	-	72,266
At 31 December 2023	<u>450,614</u>	<u>1,890,073</u>	<u>181,699</u>	<u>111,987</u>	<u>72</u>	<u>(1,524,198)</u>	<u>1,110,247</u>

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Six months ended 30 June 2024

	Share capital	Share premium*	RSU reserve*	Other reserve*	Surplus reserve*	Accumulated losses*	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 1 January 2024 . .	450,614	1,890,073	181,699	111,987	72	(1,524,198)	1,110,247
Loss and total comprehensive loss for the period	-	-	-	-	-	(110,977)	(110,977)
Recognition of share-based payment expenses (note 25)	-	-	30,095	-	-	-	30,095
At 30 June 2024 . . .	<u>450,614</u>	<u>1,890,073</u>	<u>211,794</u>	<u>111,987</u>	<u>72</u>	<u>(1,635,175)</u>	<u>1,029,365</u>

Six months ended 30 June 2023

	Share capital	Share premium	RSU reserve	Other reserve	Surplus reserve	Accumulated losses	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 1 January 2023 . .	450,614	1,890,073	109,433	111,987	72	(1,223,636)	1,338,543
Loss and total comprehensive loss for the period (unaudited)	-	-	-	-	-	(187,190)	(187,190)
Recognition of share-based payment expenses (note 25) (unaudited)	-	-	49,105	-	-	-	49,105
At 30 June 2023 (unaudited)	<u>450,614</u>	<u>1,890,073</u>	<u>158,538</u>	<u>111,987</u>	<u>72</u>	<u>(1,410,826)</u>	<u>1,200,458</u>

* The reserve accounts comprised RMB887,929,000, RMB659,633,000 and RMB578,751,000 in the consolidated statements of financial position as at 31 December 2022 and 2023 and 30 June 2024, respectively. RSU represents Restricted Share Unit scheme.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

	<i>Notes</i>	Year ended 31 December		Six months ended 30 June	
		2022	2023	2023	2024
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
				<i>(Unaudited)</i>	
CASH FLOWS FROM					
OPERATING ACTIVITIES					
Loss before tax:					
From continuing					
operations		(512,260)	(300,556)	(187,184)	(110,971)
Adjustments for:					
Finance costs	7	1,517	1,167	621	282
Interest income	5	(1,737)	(372)	(190)	(158)
Foreign exchange					
losses/(gains), net	5	(19)	98	6	109
Loss on disposal of items					
of property, plant and					
equipment	5	–	11	3	5
(Gain)/Loss on disposal					
of items of right-of-use					
assets	5	(19)	(1,035)	–	211
Loss on disposal of items					
of other intangible					
assets	5	52,251	–	–	7,424
Fair value gains, net:					
Investment income on					
financial assets at					
FVTPL	5	(22,014)	(14,046)	(6,444)	(1,781)
Gain on fair value changes					
of financial assets at					
FVTPL	5	(5,070)	(1,682)	(2,767)	(3,656)
Depreciation of property,					
plant and equipment	13	17,924	21,839	11,025	10,681
Depreciation of					
right-of-use assets	14	7,479	7,393	3,697	2,910
Amortisation of other					
intangible assets	15	535	2,933	467	3,612
Provision for inventories					
		1,367	–	–	449
Impairment/(reversal					
of impairment) on					
financial assets, net		220	(199)	(108)	129
Share-based payment					
expenses	25	70,129	72,266	49,105	30,095

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	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Decrease/(increase) in				
inventories	124	(12,870)	(8,701)	10,618
Increase in trade and bills				
receivables	–	–	–	(3,155)
(Increase)/decrease in				
prepayments, other				
receivables and other				
assets	(12,547)	2,235	(6,029)	(13,214)
Increase in trade payables . . .	22,484	29,477	14,597	4,219
(Decrease)/increase in other				
payables and accruals	(8,333)	77,023	(2,892)	9,141
Cash used in operations	(387,969)	(116,318)	(134,794)	(53,050)
Interest received	1,737	372	190	158
Income tax paid	(5)	(6)	(6)	(6)
Net cash flows used in				
operating activities	(386,237)	(115,952)	(134,610)	(52,898)
CASH FLOWS FROM				
INVESTING ACTIVITIES				
Purchases of items of				
property, plant and				
equipment	(44,717)	(1,739)	(1,148)	(354)
Proceeds from disposal of				
items of property, plant				
and equipment	502	8	3	–
Purchases of items of other				
intangible assets	(122,494)	(144,613)	(71,145)	(41,218)
Proceeds from disposal of				
items of other intangible				
assets	10,975	–	–	5
Purchases of financial assets				
at fair value through profit				
or loss	(2,504,130)	(1,217,380)	(645,250)	(275,650)
Proceeds from disposal of				
financial assets at fair				
value through profit				
or loss	2,161,840	1,408,456	874,224	255,543
Net cash flows from/(used in)				
investing activities	(498,024)	44,732	156,684	(61,674)

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<i>Notes</i>	<u>Year ended 31 December</u>		<u>Six months ended 30 June</u>	
	<u>2022</u>	<u>2023</u>	<u>2023</u>	<u>2024</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
CASH FLOWS FROM				
FINANCING				
ACTIVITIES				
Lease payments	(4,957)	(7,576)	(3,733)	(2,871)
Payment of [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Net cash flows used in				
financing activities	<u>(12,156)</u>	<u>(9,903)</u>	<u>(4,342)</u>	<u>(2,871)</u>
NET INCREASE/				
(DECREASE) IN CASH				
AND CASH				
EQUIVALENTS				
Cash and cash equivalents at	(896,417)	(81,123)	17,732	(117,443)
beginning of year/period . .	1,120,510	224,112	224,112	142,891
Effect of foreign exchange				
rate changes, net	<u>19</u>	<u>(98)</u>	<u>(6)</u>	<u>(109)</u>
CASH AND CASH				
EQUIVALENTS AT END				
OF YEAR/PERIOD				
	<u>224,112</u>	<u>142,891</u>	<u>241,838</u>	<u>25,339</u>

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ACCOUNTANTS’ REPORT

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

	<i>Notes</i>	As at 31 December		As at
				30 June
		2022	2023	2024
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
NON-CURRENT ASSETS				
Property, plant and equipment	13	3,941	3,396	2,607
Right-of-use assets	14	62,581	51,537	40,195
Other intangible assets	15	152,704	356,810	396,493
Investments in subsidiaries		647,146	663,213	604,275
Prepayments, other receivables and other assets – non current	18	7,263	24,752	25,944
Total non-current assets		873,635	1,099,708	1,069,514
CURRENT ASSETS				
Inventories	16	27,511	45,021	34,373
Prepayments, other receivables and other assets – current	18	554,099	544,934	395,911
Financial assets at fair value through profit or loss	19	334,900	124,404	293,641
Cash and cash equivalents	20	191,414	136,152	10,159
Total current assets		1,107,924	850,511	734,084
CURRENT LIABILITIES				
Trade payables	21	25,115	95,326	71,425
Other payables and accruals	22	141,806	171,098	186,296
Lease liabilities	14	5,956	4,558	2,101
Total current liabilities		172,877	270,982	259,822
NET CURRENT ASSETS		935,047	579,529	474,262
TOTAL ASSETS LESS CURRENT LIABILITIES				
		1,808,682	1,679,237	1,543,776
NON-CURRENT LIABILITIES				
Lease liabilities	14	20,748	10,543	–
Total non-current liabilities		20,748	10,543	–
Net assets		1,787,934	1,668,694	1,543,776
EQUITY				
Share capital	23	450,614	450,614	450,614
Reserves	24	1,337,320	1,218,080	1,093,162
Total equity		1,787,934	1,668,694	1,543,776

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II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE INFORMATION

Xuanzhu Biopharmaceutical Co., Ltd. (the “Company”) was a limited liability company established in Shijiazhuang City, Hebei Province, the PRC on September 5, 2018, and converted into a joint stock company with limited liability on November 22, 2021.

The Group is principally engaged in the research and development of new molecular entity drugs, and its business scope is: research, development, transfer, technical services and sales of new pharmaceutical and chemical technologies and new pharmaceutical products in the People’s Republic of China (the “PRC”).

As at the date of this report, the Company had direct and indirect interests in its subsidiaries, all of which are private limited liability companies (or, if incorporated outside Hong Kong, have substantially similar characteristics to a private company incorporated in Hong Kong), the particulars of which are as follows:

Name	Note	Place and date of incorporation/ registration and place of operations	Nominal value of issued ordinary/ registered share capital	Percentage of equity attributable to the Company		Principal activities
				Direct	Indirect	
山東軒竹醫藥科技有限公 司 Shandong Xuanzhu Pharma Co., Ltd. (“Shandong Xuanzhu”) .	a	Jinan 23 April 2002	RMB100,000,000	100%	–	R&D, clinical development and registration of innovative drugs
軒竹(北京)醫藥科技有限公 司 Xuanzhu (Beijing) Biopharmaceutical Co., Ltd. (“Beijing Xuanzhu”)	a	Beijing 10 December 2018	RMB560,000,000	100%	–	R&D, clinical development and registration of innovative drugs
北京軒竹康明生物科技有 限公司 Beijing Xuanzhu Combio Co., Ltd. (“Xuanzhu Combio”) . . .	a	Beijing 24 March 2021	RMB30,000,000	100%	–	R&D, clinical development and registration of innovative drugs
海南慧軒醫藥科技有限公 司 Hainan Huixuan Pharmaceutical Technology Co., Ltd. (“Hainan Huixuan”) . . .	a	Haikou 10 August 2020	RMB8,000,000	–	100%	No substantial business operations
軒竹(香港)生物科技有限公 司 Xuanzhu (HK) Biotechnology Limited (“Xuanzhu HK”)	a	Hong Kong 3 June 2021	RMB13,000,000	–	100%	Investment holding
XZenith Biotechnology Inc. (“Xuanzhu US”) . . .	a	USA 18 June 2021	USD100,000	–	100%	Overseas business development

Notes:

a. No audited statutory financial statements have been prepared for these subsidiaries for the years ended 31 December 2022 and 2023 and the six months ended 30 June 2024, as they are either newly incorporated or not subject to any statutory audit requirements under the relevant rules and regulations in their jurisdictions of incorporation.

* The English names of the Chinese Mainland companies and statutory auditors referred to above in this note represent management’s best effort in translating the Chinese names of those companies as no English names have been registered or are available.

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2.1 BASIS OF PREPARATION

The Historical Financial Information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which comprise all standards and interpretations approved by the International Accounting Standards Board (the “IASB”). All IFRSs effective for the accounting period commencing from 1 January 2024, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the Historical Financial Information throughout the Relevant Periods.

The Historical Financial Information has been prepared under the historical cost convention, except for financial assets at fair value. These financial statements are presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand except when otherwise indicated.

Basis of consolidation

The Historical Financial Information includes the financial statements of the Company and its subsidiaries for the Relevant Periods. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

Generally, there is a presumption that a majority of voting rights results in control. When the Company has less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- (a) the contractual arrangement with the other vote holders of the investee;
- (b) rights arising from other contractual arrangements; and
- (c) the Group’s voting rights and potential voting rights.

The financial statements of the subsidiaries are prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognises the related assets (including goodwill), liabilities, any non-controlling interest and the exchange fluctuation reserve; and recognises the fair value of any investment retained and any resulting surplus or deficit in profit or loss. The Group’s share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

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2.2 ISSUED BUT NOT YET EFFECTIVE IFRSs

The Group has not applied the following new and revised IFRSs, that have been issued but are not yet effective, in the Historical Financial Information. The Group intends to apply these new and revised IFRSs, if applicable, when they become effective.

Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture²</i>
Amendments to IAS 21	<i>Lack of Exchangeability¹</i>
IFRS 18	<i>Presentation and Disclosure in Financial Statements³</i>
IFRS 19	<i>Subsidiaries without Public Accountability: Disclosures³</i>
Amendments to IFRS 9 and IFRS 7	<i>Amendments to the Classification and Measurement of Financial Instruments⁴</i>
Annual Improvements to IFRS Accounting Standards – Volume 11	<i>Amendments to: IFRS 1, IFRS 7, IFRS 9, IFRS 10 and IAS 7⁴</i>

¹ Effective for annual periods beginning on or after 1 January 2025

² No mandatory effective date yet determined but available for adoption

³ Effective for annual periods beginning on or after 1 January 2027

⁴ Effective for annual periods beginning on or after 1 January 2026

The application of IFRS 18 will have no impact on the consolidated statements of financial position of the Group, but will have impact on the presentation of the consolidated statements of profit or loss and other comprehensive income. Except for IFRS 18, the directors of the Company anticipate that the application of these amendments to IFRSs will have no material impact on the Group’s financial performance and financial position in the foreseeable future.

Further information about those IFRSs that are expected to be applicable to the Group is described below.

2.3 MATERIAL ACCOUNTING POLICIES

Fair value measurement

The Group measures certain financial instruments at fair value at the end of each of the Relevant Periods. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

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All assets and liabilities for which fair value is measured or disclosed in the Historical Financial Information are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly
- Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognised in the Historical Financial Information on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the Relevant Periods.

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than inventories, deferred tax assets and financial assets), the asset’s recoverable amount is estimated. An asset’s recoverable amount is the higher of the asset’s or cash-generating unit’s value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

An impairment loss is recognised only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each of the Relevant Periods as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to profit or loss in the period in which it arises.

Related parties

A party is considered to be related to the Group if:

- (a) the party is a person or a close member of that person’s family and that person
 - (i) has control or joint control over the Group;
 - (ii) has significant influence over the Group; or
 - (iii) is a member of the key management personnel of the Group or of a parent of the Group;
- or
- (b) the party is an entity where any of the following conditions applies:
 - (i) the entity and the Group are members of the same group;
 - (ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);

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- (iii) the entity and the Group are joint ventures of the same third party;
- (iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;
- (v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group;
- (vi) the entity is controlled or jointly controlled by a person identified in (a);
- (vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and
- (viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

Property, plant and equipment and depreciation

Property, plant and equipment, other than construction in progress, are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalised in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognises such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal annual rates used for this purpose are as follows:

Category	Principal annual rate
Leasehold improvements	Over the shorter of the lease terms and 33.33%
Buildings	3.17%-4.75%
Laboratory equipment	19.00%
Office equipment	19.00%
Electronic equipment	31.67%
Motor vehicles	23.75%

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at the end of each of the Relevant Periods.

An item of property, plant and equipment including any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in profit or loss in the year the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress is stated at cost less any impairment losses, and is not depreciated. It is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

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Intangible assets (other than goodwill)

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortised over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at the end of each of the Relevant Periods.

Intangible assets with indefinite useful lives and intangible assets not yet available for use are tested for impairment annually either individually or at the cash-generating unit level. Such intangible assets are not amortised. The useful life of an intangible asset with an indefinite life is reviewed annually to determine whether the indefinite life assessment continues to be supportable. If not, the change in the useful life assessment from indefinite to finite is accounted for on a prospective basis.

Software

Purchased software is stated at cost less any impairment losses and is amortised on the straight-line basis over its estimated useful lives of three years.

Patents and licences

Purchased patents and licences are stated at cost less any impairment losses and are amortised on the straight-line basis over their estimated useful lives of five years.

Research and development costs

All research costs are charged to profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Deferred development costs are stated at cost less any impairment losses and are amortised using the straight-line basis over the commercial lives of the underlying products not exceeding ten years, commencing from the date when the products are put into commercial production.

Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

Right-of-use assets are recognised at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Leasehold land	50 years
Buildings	2.04-5.58 years

If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

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(b) Lease liabilities

Lease liabilities are recognised at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for termination of a lease, if the lease term reflects the Group exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognised as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

(c) Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of buildings (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the recognition exemption for leases of low-value assets to leases of office equipment and laptop computers that are considered to be of low value.

Lease payments on short-term leases and leases of low-value assets are recognised as an expense on a straight-line basis over the lease term.

Investments and other financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and the Group’s business model for managing them. With the exception of trade and bills receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially measures a financial asset at its fair value plus in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade and bills receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15 in accordance with the policies set out for “Revenue recognition” below.

In order for a financial asset to be classified and measured at amortised cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest (“SPPI”) on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group’s business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortised cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

Purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace are recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset.

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Subsequent measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial assets at amortised cost (debt instruments)

Financial assets at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognised in profit or loss when the asset is derecognised, modified or impaired.

Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognised in profit or loss.

Derecognition of financial assets

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group’s consolidated statements of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a “pass-through” arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of the Group’s continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

The Group recognises an allowance for expected credit losses (“ECLs”) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

General approach

ECLs are recognised in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At each reporting date, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information. The Group considers that there has been a significant increase in credit risk when contractual payments are more than 30 days past due.

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The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group.

A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Financial assets at amortised cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade and bills receivables which apply the simplified approach as detailed below.

- Stage 1 – Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs
- Stage 2 – Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs
- Stage 3 – Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs

Simplified approach

For trade and bills receivables that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date during the Relevant Periods. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as payables, as appropriate.

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group’s financial liabilities include trade and other payables.

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at amortised cost (trade payables, other payables and accruals)

After initial recognition, trade payables, other payables are subsequently measured at amortised cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognised in profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in profit or loss.

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Derecognition of financial liabilities

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in profit or loss.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the weighted average cost basis. Net realisable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

Cash and cash equivalents

Cash and cash equivalents in the statements of financial position comprise cash on hand and at banks, and short-term highly liquid deposits with a maturity of generally within three months that are readily convertible into known amounts of cash, subject to an insignificant risk of changes in value and held for the purpose of meeting short-term cash commitments.

For the purpose of the consolidated statements of cash flows, cash and cash equivalents comprise cash on hand and at banks, and short-term deposits as defined above, less bank overdrafts which are repayable on demand and form an integral part of the Group's cash management.

Provisions

A provision is recognised when a present obligation (legal or constructive) has arisen as a result of a past event and it is probable that a future outflow of resources will be required to settle the obligation, provided that a reliable estimate can be made of the amount of the obligation.

When the effect of discounting is material, the amount recognised for a provision is the present value at the end of the reporting period of the future expenditures expected to be required to settle the obligation. The increase in the discounted present value amount arising from the passage of time is included in finance costs in profit or loss.

Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognised outside profit or loss is recognised outside profit or loss, either in other comprehensive income or directly in equity.

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the Relevant Periods, taking into consideration interpretations and practices prevailing in the countries in which the Group operates.

Deferred tax is provided, using the liability method, on all temporary differences at the end of each of the Relevant Periods between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences; and
- in respect of taxable temporary differences associated with investments in subsidiaries, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

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Deferred tax assets are recognised for all deductible temporary differences, and the carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carryforward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences; and
- in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at the end of each of the Relevant Periods and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at the end of each of the Relevant Periods and are recognised to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the Relevant Periods.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Government grants

Government grants are recognised at their fair value where there is reasonable assurance that the grant will be received, and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed.

Revenue recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognised when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which the Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognised will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between the Group and the customer at contract inception. When the contract contains a financing component which provides the Group with a significant financial benefit for more than one year, revenue recognised under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

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Sale of pharmaceutical products

Revenue from the sale of pharmaceutical products is recognised at the point in time when control of the asset is transferred to the customer, generally on receipt of the pharmaceutical products.

Other income

Interest income is recognised on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Contract liabilities

A contract liability is recognised when a payment is received or a payment is due (whichever is earlier) from a customer before the Group transfers the related services. Contract liabilities are recognised as revenue when the Group performs under the contract (i.e., transfers control of the related services to the customer).

Share-based payments

The Company operates a Restricted Share Unit (“RSU”) scheme. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services in exchange for equity instruments (“equity-settled transactions”). The cost of equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using the market-value model, further details of which are given in note 25 to the Historical Financial Information.

The cost of equity-settled transactions is recognised in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognised for equity-settled transactions at the end of each of the Relevant Periods until the vesting date reflects the extent to which the vesting period has expired and the Group’s best estimate of the number of equity instruments that will ultimately vest. The charge or credit to profit or loss for a period represents the movement in the cumulative expense recognised as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group’s best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognised. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification. Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately.

This includes any award where non-vesting conditions within the control of either the Group or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

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Other employee benefits

Pension scheme

The employees of the Group which operates in Chinese Mainland are required to participate in a central pension scheme operated by the local municipal government. The subsidiaries operating in Chinese Mainland are required to contribute a certain percentage of their payroll costs to the central pension scheme. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension scheme.

Foreign currencies

The Historical Financial Information is presented in RMB, which is the Company’s functional currency. Each entity in the Group uses RMB as its functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of each of the Relevant Periods. Differences arising on settlement or translation of monetary items are recognised in profit or loss.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognised in other comprehensive income or profit or loss is also recognised in other comprehensive income or profit or loss, respectively).

In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of initial transaction is the date on which the Group initially recognises the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of the advance consideration.

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group’s Historical Financial Information requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of each of the Relevant Periods, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Provision for expected credit losses on trade and bills receivables

The Group uses a provision matrix to calculate ECLs for trade and bills receivables. The provision rates are based on days past due for groupings of various customer segments that have similar loss patterns (i.e., by customer type).

The provision matrix is initially based on the Group’s historical observed default rates. The Group will calibrate the matrix to adjust the historical credit loss experience with forward-looking information. For instance, if forecast economic conditions (i.e., gross domestic product) are expected to deteriorate over the next year which can lead to an increased number of defaults in the manufacturing sector, the historical default rates are adjusted. At each reporting date, the historical observed default rates are updated and changes in the forward-looking estimates are analysed.

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The assessment of the correlation among historical observed default rates, forecast economic conditions and ECLs is a significant estimate. The amount of ECLs is sensitive to changes in circumstances and forecast economic conditions. The Group’s historical credit loss experience and forecast of economic conditions may also not be representative of a customer’s actual default in the future. The information about the ECLs on the Group’s trade and bills receivables is disclosed in note 17 to the Historical Financial Information.

Leases — Estimating the incremental borrowing rate

The Group cannot readily determine the interest rate implicit in a lease, and therefore, it uses an incremental borrowing rate (“IBR”) to measure lease liabilities. The IBR is the rate of interest that the Group would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The IBR therefore reflects what the Group “would have to pay”, which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when it needs to be adjusted to reflect the terms and conditions of the lease (for example, when leases are not in the subsidiary’s functional currency). The Group estimates the IBR using observable inputs (such as market interest rates) when available and is required to make certain entity-specific estimates (such as the subsidiary’s stand-alone credit rating).

Impairment of non-financial assets (other than goodwill)

The Group assesses whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of each reporting period. Intangible assets with indefinite useful lives and intangible assets not yet available for use are tested for impairment annually and at other times when such an indicator exists. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm’s length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

Recognition of income taxes and deferred tax assets

Determining income tax provision involves judgement on the future tax treatment of certain transactions and when certain matters relating to the income taxes have not been confirmed by the local tax bureau. Management evaluates tax implications of transactions and tax provisions are set up accordingly. The tax treatments of such transactions are reconsidered periodically to take into account all changes in tax legislation. Deferred tax assets are recognised in respect of deductible temporary differences and unused tax losses. As those deferred tax assets can only be recognised to the extent that it is probable that future taxable profits will be available against which the deductible temporary differences and the losses can be utilised, management’s judgement is required to assess the probability of future taxable profits. Management’s assessment is revised as necessary and additional deferred tax assets are recognised if it becomes probable that future taxable profits will allow the deferred tax asset to be recovered.

Fair value of share-based payment transactions

The Group has granted RSUs to the Group’s employees during the Relevant Periods. The fair values of the RSUs were determined through the application of the market-value model at the grant dates. Significant estimates on assumptions, including the future cash flows and discount rate, were made by the board of directors of the Company. Further details are included in note 25 to the Historical Financial Information.

4. OPERATING SEGMENT INFORMATION

For management purposes, the Group has only one reportable operating segment, which is the sale of pharmaceutical products. Since this is the only reportable operating segment of the Group, no further operating segment analysis thereof is presented.

Geographical information

During the Relevant Periods, all of the Group’s revenue was derived from customers located in the PRC and nearly all of the Group’s non-current assets were located in the PRC, and therefore no geographical segment information is presented in accordance with IFRS 8 *Operating Segments*.

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Information about major customers

Revenue from continuing operations of approximately RMB2,600,000 was derived from sales to a single customer during the six months ended 30 June 2024, including sales to a group of entities which are known to be under common control with that customer.

5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
			(Unaudited)	
<i>Revenue from contracts with customers</i>	–	29	–	16,030
	=	=	=	=

Revenue from contracts with customers

(a) Disaggregated revenue information

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
			(Unaudited)	
Types of goods or services				
Sales of medicines	–	29	–	16,030
	=	=	=	=
Geographical market				
Chinese Mainland	–	29	–	16,030
	=	=	=	=
Timing of revenue recognition				
Goods transferred at a point in time	–	29	–	16,030
	=	=	=	=

All the revenue from contracts with customers is derived from external customers.

The following table shows the amounts of revenue recognised during the Relevant Periods and the six months ended 30 June 2023 that were included in the contract liabilities at the beginning of each of the Relevant Periods and the six months ended 30 June 2023:

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
			(Unaudited)	
<i>Revenue recognised that was included in contract liabilities at the beginning of the year/period</i>				
Sales of medicines	–	–	–	3,906
	=	=	=	=

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(b) Performance obligations

Information about the Group’s performance obligations is summarised below:

Sale of pharmaceutical products

The performance obligation is satisfied upon delivery of the pharmaceutical products and payment in advance is normally required.

Under the practical expedient allowed by IFRS 15, the Group does not disclose the value of unsatisfied performance obligation.

Other income and gains

An analysis of other income is as follows:

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
			(Unaudited)	
Other income				
Government grants*	11,222	23,487	7,951	1,766
Bank interest income	1,737	372	190	158
Others	469	178	53	131
Total other income	13,428	24,037	8,194	2,055
Gains				
Gain on disposal of items of right-of-use assets	19	1,035	–	–
Gain on fair value changes of financial assets at FVTPL	5,070	1,682	2,767	3,656
Investment income on financial assets at FVTPL	22,014	14,046	6,444	1,781
Total gains	27,103	16,763	9,211	5,437
Total	40,531	40,800	17,405	7,492
Other expenses				
Asset impairment losses	1,367	–	–	449
Loss on disposal of items of other intangible assets	52,251	–	–	7,424
Loss on disposal of items of property, plant and equipment . . .	–	11	3	5
Loss on disposal of items of right-of-use assets	–	–	–	211
Loss on obsolescence of inventories .	–	2,185	–	–
Foreign exchange losses/(gains), net	(19)	98	6	109
Others	71	973	–	–
Total other expenses	53,670	3,267	9	8,198

* The government grants have been received from the PRC local government authorities to support certain subsidiaries’ operating activities. There are no unfulfilled conditions relating to these government grants.

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6. LOSS BEFORE TAX

The Group’s loss before tax is arrived at after charging/(crediting):

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000	RMB’000
			(Unaudited)	
Cost of sales	–	9	–	8,811
Depreciation of property, plant and equipment	13	17,924	21,839	11,025
Depreciation of right-of-use assets	14	7,479	7,393	3,697
Amortisation of other intangible assets	15	535	2,933	467
Research and development costs:				
Current year expenditure		400,983	239,061	149,540
Total		400,983	239,061	149,540
Impairment of financial assets		220	(199)	(108)
Government grants		(11,222)	(23,487)	(7,951)
Lease payments not included in the measurement of lease liabilities		2,862	2,466	1,519
Employee benefit expense (excluding directors’ and chief executive’s remuneration (note 9)):				
Wages and salaries		97,200	97,264	53,892
Equity-settled share option expense		42,509	43,385	37,426
Pension scheme contributions (defined contribution scheme)		11,642	7,978	6,243
Total		151,351	148,627	97,561
Foreign exchange differences, net	5	(19)	98	6
Fair value (gains)/losses, net:				
Financial assets at fair value through profit or loss				
Investment income on financial assets at FVTPL	5	(22,014)	(14,046)	(6,444)
Gain on fair value changes of financial assets at FVTPL	5	(5,070)	(1,682)	(2,767)
Bank interest income	5	(1,737)	(372)	(190)
Loss on obsolescence of inventories	5	–	2,185	–
Loss on disposal of items of property, plant and equipment	5	–	11	3
(Gain)/losses on disposal of items of right-of-use assets	5	(19)	(1,035)	–
Loss on disposal of items of other intangible assets	5	52,251	–	–
				7,424

Cost of inventories sold and research and development costs include expenses relating to depreciation of property, plant and equipment, depreciation of right-of-use assets, amortisation of other intangible assets and employee benefit expense, which are also included in the respective total amounts disclosed separately above for each of these types of expenses.

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7. FINANCE COSTS

An analysis of finance costs from continuing operations is as follows:

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
			(Unaudited)	
Interest on lease liabilities	1,517	1,167	621	282

8. DIRECTORS’ AND CHIEF EXECUTIVE’S REMUNERATION

Directors’ and chief executive’s remuneration (including those as employees of the entities now comprising the Group prior to being directors or chief executive of the Company) for the Relevant Periods and the six months ended 30 June 2023, disclosed pursuant to the Listing Rules, section 383(1)(a), (b), (c) and (f) of the Hong Kong Companies Ordinance and Part 2 of the Companies (Disclosure of Information about Benefits of Directors) Regulation, is as follows:

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
			(Unaudited)	
Directors’ fees	300	300	150	150
Other emoluments:				
Salaries, bonuses and allowances	7,492	6,509	3,268	2,398
Pension scheme contributions and social welfare	–	63	31	41
Share-based payment expenses	27,620	28,881	11,679	7,498
Subtotal	35,112	35,453	14,978	9,937
Total	35,412	35,753	15,128	10,087

During the Relevant Periods and the six months ended 30 June 2023, certain directors were granted share awards, in respect of their services to the Group, under the share incentive plan of the Company, further details of which are set out in note 25 to the Historical Financial Information. The fair value of such share awards, which has been recognised in profit or loss over the vesting period, was determined as at the date of grant and the amount included in the Historical Financial Information for the Relevant Periods and the six months ended 30 June 2023 is included in the above directors’ and chief executive’s remuneration disclosures.

(a) Independent non-executive directors

The fees paid to independent non-executive directors during the year were as follows:

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
			(Unaudited)	
Mr. Liu Shuo	100	100	50	50
Ms. Lu Xulei	100	100	50	50
Ms. Wang Yu	100	100	50	50
Total	300	300	150	150

There were no other emoluments payable to the independent non-executive directors during the Relevant Periods.

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(b) Executive directors, non-executive directors and the chief executive

	Salaries, bonuses and allowances	Pension scheme contributions and social welfare	Share-based payment expenses	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Year ended 31 December 2022				
Executive directors:				
Dr. Shih Cheng-Kon (<i>note (i)</i>)	3,448	–	4,938	8,386
Dr. Li Jia Kui (<i>note (i)</i>)	2,881	–	6,173	9,054
Subtotal.	<u>6,329</u>	<u>–</u>	<u>11,111</u>	<u>17,440</u>
Non-executive directors:				
Ms. Li Huiying.	–	–	1,773	1,773
Mr. Yu Lifeng	–	–	–	–
Mr. Song Wenlei	–	–	–	–
Subtotal.	<u>–</u>	<u>–</u>	<u>1,773</u>	<u>1,773</u>
Chief executive:				
Ms. Xu Yanjun	1,163	–	14,736	15,899
Total	<u>7,492</u>	<u>–</u>	<u>27,620</u>	<u>35,112</u>

	Salaries, bonuses and allowances	Pension scheme contributions and social welfare	Share-based payment expenses	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Year ended 31 December 2023				
Executive directors:				
Dr. Shih Cheng-Kon (<i>note (i)</i>)	2,654	–	3,193	5,847
Dr. Li Jia Kui (<i>note (i)</i>)	2,593	–	3,991	6,584
Subtotal.	<u>5,247</u>	<u>–</u>	<u>7,184</u>	<u>12,431</u>
Non-executive directors:				
Ms. Li Huiying.	–	–	1,773	1,773
Mr. Yu Lifeng	–	–	–	–
Mr. Song Wenlei	–	–	–	–
Subtotal.	<u>–</u>	<u>–</u>	<u>1,773</u>	<u>1,773</u>
Chief executive:				
Ms. Xu Yanjun	1,262	63	19,924	21,249
Total	<u>6,509</u>	<u>63</u>	<u>28,881</u>	<u>35,453</u>

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	Salaries, bonuses and allowances	Pension scheme contributions and social welfare	Share-based payment expenses	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Six months ended 30 June 2023				
Executive directors:				
Dr. Shih Cheng-Kon (<i>note (i)</i>)	1,337	–	–	1,337
Dr. Li Jia Kui (<i>note (i)</i>)	1,297	–	3,077	4,374
Subtotal.	<u>2,634</u>	<u>–</u>	<u>3,077</u>	<u>5,711</u>
Non-executive directors:				
Ms. Li Huiying.	–	–	879	879
Mr. Yu Lifeng	–	–	–	–
Mr. Song Wenlei	–	–	–	–
Subtotal.	<u>–</u>	<u>–</u>	<u>879</u>	<u>879</u>
Chief executive:				
Ms. Xu Yanjun	634	31	7,723	8,388
Total	<u>3,268</u>	<u>31</u>	<u>11,679</u>	<u>14,978</u>

	Salaries, bonuses and allowances	Pension scheme contributions and social welfare	Share-based payment expenses	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Six months ended 30 June 2024				
Executive directors:				
Dr. Shih Cheng-Kon (<i>note (i)</i>)	579	–	–	579
Dr. Li Jia Kui (<i>note (i)</i>)	1,229	–	–	1,229
Subtotal.	<u>1,808</u>	<u>–</u>	<u>–</u>	<u>1,808</u>
Non-executive directors:				
Ms. Li Huiying.	–	–	884	884
Mr. Yu Lifeng	–	–	–	–
Mr. Song Wenlei	–	–	–	–
Subtotal.	<u>–</u>	<u>–</u>	<u>884</u>	<u>884</u>
Chief executive:				
Ms. Xu Yanjun	590	41	6,614	7,245
Total	<u>2,398</u>	<u>41</u>	<u>7,498</u>	<u>9,937</u>

Note:

(i) In 2023, RSUs of Dr. Shih Cheng-Kon and Dr. Li Jia Kui, executive directors, have been unlocked.

There was no arrangement under which a director or the chief executive waived or agreed to waive any remuneration during the Relevant Periods and the six months ended 30 June 2023.

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9. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees during the Relevant Periods and the six months ended 30 June 2023 included three, three, two and two of the then directors, respectively, details of whose remuneration are set out in note 8 above. Details of the remuneration of the remaining two, two, three and three highest paid employees who are neither a director nor chief executive of the Company are as follows:

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000 (Unaudited)	RMB'000
Salaries, bonuses and allowances . . .	5,166	4,362	2,243	3,408
Pension scheme contributions and social welfare	115	126	92	81
Share-based payment expenses	10,251	10,824	6,792	13,760
Total	15,532	15,312	9,127	17,249

The number of non-director and non-chief executive highest paid employees whose remuneration fell within the following bands is as follows:

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
			(Unaudited)	
HKD2,000,001 to HKD2,500,000 . .	–	–	1	1
HKD2,500,001 to HKD3,000,000 . .	–	–	1	1
HKD5,000,001 to HKD5,500,000 . .	–	–	1	–
HKD6,000,001 to HKD6,500,000 . .	1	1	–	–
HKD10,500,001 to HKD11,000,000 .	–	1	–	–
HKD11,500,001 to HKD12,000,000 .	1	–	–	–
HKD13,500,001 to HKD14,000,000 .	–	–	–	1
Total	2	2	3	3

During the Relevant Periods and the six months ended 30 June 2023, RSUs were granted to the non-director and non-chief executive highest paid employees in respect of their services to the Group, further details of which are included in the disclosures in note 25 to the Historical Financial Information. The fair value of such RSUs, which has been recognised in profit or loss over the vesting period, was determined as at the date of grant and the amount included in the Historical Financial Information for the Relevant Periods and the six months ended 30 June 2023 is included in the above non-director and non-chief executive highest paid employees’ remuneration disclosures.

10. INCOME TAX

United States of America profits tax

Pursuant to Tax Cuts and Jobs Act (“TCJA”) enacted on 22 December, 2017, the USA federal statutory income tax rate for the subsidiary is 21%. The subsidiary in the USA was incorporated in the state of California and the State income tax rate is 8.84%. Taxes on profits assessable elsewhere have been calculated at the rates of tax prevailing in the countries (or jurisdictions) in which the Group operates.

Hong Kong

The subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the statutory rate of 16.5% on any estimated assessable profits arising in Hong Kong during the Relevant Periods and the six months ended 30 June 2023.

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Chinese Mainland

Pursuant to the Corporate Income Tax Law of the People’s Republic of China and the respective regulations (the “CIT Law”), the subsidiaries which operate in Chinese Mainland are subject to CIT at a rate of 25% on the taxable income during the Relevant Periods and the six months ended 30 June 2023.

One of the Group’s PRC subsidiaries, Shandong Xuanzhu Pharma Co., Ltd. was accredited as a “High and New Technology Enterprise” under the relevant tax rules and regulations in November 2019 and December 2022, and accordingly, was entitled to a reduced preferential CIT rate of 15% during the Relevant Periods. This qualification is subject to review by the relevant tax authority in the PRC for every three years.

The income tax expense of the Group for the Relevant Periods and the six months ended 30 June 2023 is analysed as follows:

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000
Current tax:				
Charge for the year/period	5	6	6	6
Deferred tax	–	–	–	–
Total tax charge for the year/period	<u>5</u>	<u>6</u>	<u>6</u>	<u>6</u>

A reconciliation of the tax expense applicable to loss before tax at the statutory rates for the jurisdictions in which the Company and its major subsidiaries are domiciled to the tax expense at the effective tax rates, and a reconciliation of the applicable rates (i.e., the statutory tax rates) to the effective tax rates, are as follows:

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000
Loss before tax	(512,260)	(300,556)	(187,184)	(110,971)
Tax at the statutory tax rate (25%)	(128,065)	(75,139)	(46,796)	(27,743)
Lower tax rate enacted by local authority	12,778	18,371	6,639	4,081
Expenses not deductible for tax purposes	803	887	526	81
Tax losses and temporary differences not recognised	160,642	110,318	59,896	30,024
Additional deductible allowance for research and development expenses	(38,976)	(54,431)	(20,259)	(6,437)
Tax losses utilised from previous periods	<u>(7,177)</u>	<u>–</u>	<u>–</u>	<u>–</u>
Tax charge at the Group’s effective rate	<u>5</u>	<u>6</u>	<u>6</u>	<u>6</u>

11. DIVIDENDS

No dividend was paid or declared by the Company during the Relevant Periods and the six months ended 30 June 2023.

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12. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amount is based on the loss attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 450,614,000, 450,614,000, 450,614,000 and 450,614,000 in issue during the Relevant Periods and the six months ended 30 June 2023, respectively.

The calculation of loss per share is based on:

(a) Basic

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
			<i>(Unaudited)</i>	
Loss				
Loss attributable to ordinary equity holders of the parent, used in the basic loss per share calculation (RMB’000)	(512,265)	(300,562)	(187,190)	(110,977)
Ordinary shares (’000)				
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation	450,614	450,614	450,614	450,614
Loss per share (RMB per share) . . .	(1.14)	(0.67)	(0.42)	(0.25)

(b) Diluted

Diluted loss per share amounts presented are the same as the basic loss per share amounts as there were no potentially dilutive ordinary shares in issue during each of the Relevant Periods and the six months ended 30 June 2023.

13. PROPERTY, PLANT AND EQUIPMENT

The Group

	Leasehold improvements	Buildings	Laboratory equipment	Office equipment	Electronic equipment	Motor vehicles	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>	<i>RMB’000</i>	<i>RMB’000</i>
As at 31 December 2022								
At 1 January 2022:								
Cost	3,640	114,918	77,077	5,170	2,287	966	–	204,058
Accumulated depreciation	(87)	(23,157)	(49,171)	(3,749)	(897)	(917)	–	(77,978)
Net carrying amount	<u>3,553</u>	<u>91,761</u>	<u>27,906</u>	<u>1,421</u>	<u>1,390</u>	<u>49</u>	<u>–</u>	<u>126,080</u>

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	Leasehold improvements	Buildings	Laboratory equipment	Office equipment	Electronic equipment	Motor vehicles	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>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2022, net of accumulated depreciation	3,553	91,761	27,906	1,421	1,390	49	–	126,080
Additions	–	–	38,930	524	429	–	829	40,712
Disposal	–	(460)	(40)	(2)	–	–	–	(502)
Depreciation provided during the year	<u>(1,195)</u>	<u>(5,262)</u>	<u>(10,373)</u>	<u>(414)</u>	<u>(680)</u>	<u>–</u>	<u>–</u>	<u>(17,924)</u>
At 31 December 2022, net of accumulated depreciation	<u>2,358</u>	<u>86,039</u>	<u>56,423</u>	<u>1,529</u>	<u>1,139</u>	<u>49</u>	<u>829</u>	<u>148,366</u>
At 31 December 2022:								
Cost	3,640	114,458	115,967	5,692	2,716	966	829	244,268
Accumulated depreciation	<u>(1,282)</u>	<u>(28,419)</u>	<u>(59,544)</u>	<u>(4,163)</u>	<u>(1,577)</u>	<u>(917)</u>	<u>–</u>	<u>(95,902)</u>
Net carrying amount	<u>2,358</u>	<u>86,039</u>	<u>56,423</u>	<u>1,529</u>	<u>1,139</u>	<u>49</u>	<u>829</u>	<u>148,366</u>
	Leasehold improvements	Buildings	Laboratory equipment	Office equipment	Electronic equipment	Motor vehicles	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>	<i>RMB'000</i>	<i>RMB'000</i>
As at 31 December 2023								
At 1 January 2023:								
Cost	3,640	114,458	115,967	5,692	2,716	966	829	244,268
Accumulated depreciation	<u>(1,282)</u>	<u>(28,419)</u>	<u>(59,544)</u>	<u>(4,163)</u>	<u>(1,577)</u>	<u>(917)</u>	<u>–</u>	<u>(95,902)</u>
Net carrying amount	<u>2,358</u>	<u>86,039</u>	<u>56,423</u>	<u>1,529</u>	<u>1,139</u>	<u>49</u>	<u>829</u>	<u>148,366</u>
At 1 January 2023, net of accumulated depreciation	2,358	86,039	56,423	1,529	1,139	49	829	148,366
Additions	17	–	949	43	150	–	810	1,969
Disposal	–	(4)	(11)	(2)	(2)	–	–	(19)
Depreciation provided during the year	<u>(1,197)</u>	<u>(5,219)</u>	<u>(14,369)</u>	<u>(469)</u>	<u>(585)</u>	<u>–</u>	<u>–</u>	<u>(21,839)</u>
At 31 December 2023, net of accumulated depreciation	<u>1,178</u>	<u>80,816</u>	<u>42,992</u>	<u>1,101</u>	<u>702</u>	<u>49</u>	<u>1,639</u>	<u>128,477</u>
At 31 December 2023:								
Cost	3,657	114,454	116,905	5,733	2,864	966	1,639	246,218
Accumulated depreciation	<u>(2,479)</u>	<u>(33,638)</u>	<u>(73,913)</u>	<u>(4,632)</u>	<u>(2,162)</u>	<u>(917)</u>	<u>–</u>	<u>(117,741)</u>
Net carrying amount	<u>1,178</u>	<u>80,816</u>	<u>42,992</u>	<u>1,101</u>	<u>702</u>	<u>49</u>	<u>1,639</u>	<u>128,477</u>

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	Leasehold improvements	Buildings	Laboratory equipment	Office equipment	Electronic equipment	Motor vehicles	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>	<i>RMB'000</i>	<i>RMB'000</i>
As at 30 June 2024								
At 1 January 2024:								
Cost	3,657	114,454	116,905	5,733	2,864	966	1,639	246,218
Accumulated depreciation	<u>(2,479)</u>	<u>(33,638)</u>	<u>(73,913)</u>	<u>(4,632)</u>	<u>(2,162)</u>	<u>(917)</u>	–	<u>(117,741)</u>
Net carrying amount	<u>1,178</u>	<u>80,816</u>	<u>42,992</u>	<u>1,101</u>	<u>702</u>	<u>49</u>	<u>1,639</u>	<u>128,477</u>
At 1 January 2024, net of accumulated								
depreciation	1,178	80,816	42,992	1,101	702	49	1,639	128,477
Additions	–	–	354	–	–	–	10,044	10,398
Disposal	–	–	(6)	(12)	–	–	–	(18)
Depreciation provided during the period	<u>(613)</u>	<u>(2,543)</u>	<u>(7,077)</u>	<u>(187)</u>	<u>(261)</u>	–	–	<u>(10,681)</u>
At 30 June 2024, net of accumulated								
depreciation	<u>565</u>	<u>78,273</u>	<u>36,263</u>	<u>902</u>	<u>441</u>	<u>49</u>	<u>11,683</u>	<u>128,176</u>
At 30 June 2024:								
Cost	3,657	114,454	117,253	5,721	2,864	966	11,683	256,598
Accumulated depreciation	<u>(3,092)</u>	<u>(36,181)</u>	<u>(80,990)</u>	<u>(4,819)</u>	<u>(2,423)</u>	<u>(917)</u>	–	<u>(128,422)</u>
Net carrying amount	<u>565</u>	<u>78,273</u>	<u>36,263</u>	<u>902</u>	<u>441</u>	<u>49</u>	<u>11,683</u>	<u>128,176</u>

The Company

	Leasehold improvements	Office equipment	Electronic equipment	Construction in progress	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
As at 31 December 2022					
At 1 January 2022:					
Cost	3,042	971	1,132	–	5,145
Accumulated depreciation	–	<u>(315)</u>	<u>(416)</u>	–	<u>(731)</u>
Net carrying amount	<u>3,042</u>	<u>656</u>	<u>716</u>	–	<u>4,414</u>
At 1 January 2022, net of accumulated					
depreciation	3,042	656	716	–	4,414
Additions	–	28	207	829	1,064
Depreciation provided during the year	<u>(1,043)</u>	<u>(172)</u>	<u>(322)</u>	–	<u>(1,537)</u>
At 31 December 2022, net of accumulated					
depreciation	<u>1,999</u>	<u>512</u>	<u>601</u>	<u>829</u>	<u>3,941</u>
At 31 December 2022:					
Cost	3,042	999	1,339	829	6,209
Accumulated depreciation	<u>(1,043)</u>	<u>(487)</u>	<u>(738)</u>	–	<u>(2,268)</u>
Net carrying amount	<u>1,999</u>	<u>512</u>	<u>601</u>	<u>829</u>	<u>3,941</u>

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	Leasehold improvements	Laboratory equipment	Office equipment	Electronic equipment	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>
As at 31 December 2023						
At 1 January 2023:						
Cost	3,042	–	999	1,339	829	6,209
Accumulated depreciation	(1,043)	–	(487)	(738)	–	(2,268)
Net carrying amount . .	<u>1,999</u>	<u>–</u>	<u>512</u>	<u>601</u>	<u>829</u>	<u>3,941</u>
At 1 January 2023, net of accumulated						
depreciation	1,999	–	512	601	829	3,941
Additions	15	16	3	148	811	993
Disposal	–	–	–	(3)	–	(3)
Depreciation provided during the year	(1,043)	–	(176)	(316)	–	(1,535)
At 31 December 2023, net of accumulated depreciation	<u>971</u>	<u>16</u>	<u>339</u>	<u>430</u>	<u>1,640</u>	<u>3,396</u>
At 31 December 2023:						
Cost	3,057	16	1,002	1,484	1,640	7,199
Accumulated depreciation	(2,086)	–	(663)	(1,054)	–	(3,803)
Net carrying amount . .	<u>971</u>	<u>16</u>	<u>339</u>	<u>430</u>	<u>1,640</u>	<u>3,396</u>
	Leasehold improvements	Laboratory equipment	Office equipment	Electronic equipment	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>
As at 30 June 2024						
At 1 January 2024:						
Cost	3,057	16	1,002	1,484	1,640	7,199
Accumulated depreciation	(2,086)	–	(663)	(1,054)	–	(3,803)
Net carrying amount . .	<u>971</u>	<u>16</u>	<u>339</u>	<u>430</u>	<u>1,640</u>	<u>3,396</u>
At 1 January 2024, net of accumulated						
depreciation	971	16	339	430	1,640	3,396
Depreciation provided during the period . . .	(537)	(1)	(85)	(166)	–	(789)
At 30 June 2024, net of accumulated depreciation	<u>434</u>	<u>15</u>	<u>254</u>	<u>264</u>	<u>1,640</u>	<u>2,607</u>
At 30 June 2024:						
Cost	3,057	16	1,002	1,484	1,640	7,199
Accumulated depreciation	(2,623)	(1)	(748)	(1,220)	–	(4,592)
Net carrying amount . .	<u>434</u>	<u>15</u>	<u>254</u>	<u>264</u>	<u>1,640</u>	<u>2,607</u>

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14. LEASES

The Group as a lessee

The Group has lease contracts for various items of buildings used in its operations. Lump sum payments were made upfront to acquire the leased land from the owners with lease periods of 50 years, and no ongoing payments will be made under the terms of these land leases. Leases of buildings generally have lease terms of 2.04 to 5.58 years. Generally, the Group is restricted from assigning and subleasing the leased assets outside the Group. Other rental agreements generally have lease terms of 12 months or less.

(a) Right-of-use assets

The carrying amounts of the Group’s right-of-use assets and the movements during the Relevant Periods are as follows:

	Leasehold land	Buildings	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
31 December 2022			
As at 1 January 2022	57,366	31,443	88,809
Disposal	–	(264)	(264)
Depreciation charge	(1,375)	(6,104)	(7,479)
As at 31 December 2022.	<u>55,991</u>	<u>25,075</u>	<u>81,066</u>
31 December 2023			
As at 1 January 2023	55,991	25,075	81,066
Disposal	–	(4,723)	(4,723)
Depreciation charge	(1,375)	(6,018)	(7,393)
As at 31 December 2023.	<u>54,616</u>	<u>14,334</u>	<u>68,950</u>
30 June 2024			
As at 1 January 2024	54,616	14,334	68,950
Disposal	–	(10,133)	(10,133)
Depreciation charge	(688)	(2,222)	(2,910)
As at 30 June 2024	<u>53,928</u>	<u>1,979</u>	<u>55,907</u>

(b) Lease liabilities

The carrying amounts of lease liabilities and the movements during the Relevant Periods are as follows:

	As at 31 December		As at 30 June
	2022	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Carrying amount at 1 January.	32,955	29,232	17,065
Disposal	(283)	(5,758)	(12,101)
Accretion of interest recognised during the year/period	1,517	1,167	282
Payments	(4,957)	(7,576)	(2,871)
Carrying amount at the end of the year/period . .	<u>29,232</u>	<u>17,065</u>	<u>2,375</u>
Analysed into:			
Current portion	6,519	5,148	2,375
Non-current portion	<u>22,713</u>	<u>11,917</u>	<u>–</u>

The maturity analysis of lease liabilities is disclosed in note 26 to the Historical Financial Information.

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(c) The amounts recognised in profit or loss in relation to leases are as follows:

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000 (Unaudited)	RMB'000
Interest on lease liabilities	1,517	1,167	621	282
Depreciation charge of right-of-use assets	7,479	7,393	3,697	2,910
Expenses relating to short-term leases	2,862	2,466	1,519	1,182
Total amount recognised in profit or loss	<u>11,858</u>	<u>11,026</u>	<u>5,837</u>	<u>4,374</u>

(d) The total cash outflow for leases is disclosed in note 26 to the Historical Financial Information.

The Company as a lessee

The Company has lease contracts for various items of buildings used in its operations. Lump sum payments were made upfront to acquire the leased land from the owners with lease periods of 50 years, and no ongoing payments will be made under the terms of these land leases. Leases of buildings generally have lease terms of 2.04 to 5.58 years. Generally, the Company is restricted from assigning and subleasing the leased assets outside the Company. Other rental agreements generally have lease terms of 12 months or less.

(a) *Right-of-use assets*

The carrying amounts of the Group’s right-of-use assets and the movements during the Relevant Periods are as follows:

	Leasehold land	Buildings	Total
	RMB'000	RMB'000	RMB'000
31 December 2022			
As at 1 January 2022	40,498	28,754	69,252
Disposal	–	(264)	(264)
Depreciation charge	(824)	(5,583)	(6,407)
As at 31 December 2022	<u>39,674</u>	<u>22,907</u>	<u>62,581</u>
31 December 2023			
As at 1 January 2023	39,674	22,907	62,581
Disposal	–	(4,722)	(4,722)
Depreciation charge	(824)	(5,498)	(6,322)
As at 31 December 2023	<u>38,850</u>	<u>12,687</u>	<u>51,537</u>
30 June 2024			
As at 1 January 2024	38,850	12,687	51,537
Disposal	–	(8,969)	(8,969)
Depreciation charge	(412)	(1,961)	(2,373)
As at 30 June 2024	<u>38,438</u>	<u>1,757</u>	<u>40,195</u>

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(b) Lease liabilities

The carrying amounts of lease liabilities and the movements during the Relevant Periods are as follows:

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
Carrying amount at 1 January	30,135	26,704	15,101
Disposal	(283)	(5,647)	(10,708)
Accretion of interest recognised during the year/period	1,295	1,066	246
Payments	(4,443)	(7,022)	(2,538)
Carrying amount at the end of the year/period	<u>26,704</u>	<u>15,101</u>	<u>2,101</u>
Analysed into:			
Current portion	5,956	4,558	2,101
Non-current portion	<u>20,748</u>	<u>10,543</u>	<u>–</u>

15. OTHER INTANGIBLE ASSETS

The Group

	Software	Patents and licences	Research and development costs	Total
	RMB'000	RMB'000	RMB'000	RMB'000
31 December 2022				
Cost at 1 January 2022, net of accumulated amortisation	1,396	6,462	266,565	274,423
Additions	1,646	–	166,481	168,127
Amortisation provided during the year	(535)	–	–	(535)
Disposal	–	–	(50,263)	(50,263)
At 31 December 2022	<u>2,507</u>	<u>6,462</u>	<u>382,783</u>	<u>391,752</u>
At 31 December 2022:				
Cost	4,258	6,462	382,783	393,503
Accumulated amortisation	(1,751)	–	–	(1,751)
Net carrying amount	<u>2,507</u>	<u>6,462</u>	<u>382,783</u>	<u>391,752</u>

	Software	Patents and licences	Research and development costs	Total
	RMB'000	RMB'000	RMB'000	RMB'000
31 December 2023				
Cost at 1 January 2023, net of accumulated amortisation	2,507	6,462	382,783	391,752
Additions	197	–	144,787	144,984
Amortisation provided during the year	(728)	(2,205)	–	(2,933)
Transfer	–	68,088	(68,088)	–
At 31 December 2023	<u>1,976</u>	<u>72,345</u>	<u>459,482</u>	<u>533,803</u>
At 31 December 2023:				
Cost	4,455	74,550	459,482	538,487
Accumulated amortisation	(2,479)	(2,205)	–	(4,684)
Net carrying amount	<u>1,976</u>	<u>72,345</u>	<u>459,482</u>	<u>533,803</u>

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	Software	Patents and licences	Research and development costs	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
30 June 2024				
Cost at 1 January 2024, net of accumulated amortisation	1,976	72,345	459,482	533,803
Additions	–	–	51,004	51,004
Amortisation provided during the period	(290)	(3,322)	–	(3,612)
Disposal	(235)	–	(13,958)	(14,193)
At 30 June 2024	<u>1,451</u>	<u>69,023</u>	<u>496,528</u>	<u>567,002</u>
At 30 June 2024:				
Cost	4,040	74,550	496,528	575,118
Accumulated amortisation	(2,589)	(5,527)	–	(8,116)
Net carrying amount	<u>1,451</u>	<u>69,023</u>	<u>496,528</u>	<u>567,002</u>

The Company

	Software	Research and development costs	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
31 December 2022			
Cost at 1 January 2022, net of accumulated amortisation	–	86,555	86,555
Additions	883	115,751	116,634
Amortisation provided during the year	(222)	–	(222)
Disposal	–	(50,263)	(50,263)
At 31 December 2022	<u>661</u>	<u>152,043</u>	<u>152,704</u>
At 31 December 2022:			
Cost	883	152,043	152,926
Accumulated amortisation	(222)	–	(222)
Net carrying amount	<u>661</u>	<u>152,043</u>	<u>152,704</u>

	Software	Research and development costs	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
31 December 2023			
Cost at 1 January 2023, net of accumulated amortisation	661	152,043	152,704
Additions	197	204,263	204,460
Amortisation provided during the year	(354)	–	(354)
At 31 December 2023	<u>504</u>	<u>356,306</u>	<u>356,810</u>
At 31 December 2023:			
Cost	1,080	356,306	357,386
Accumulated amortisation	(576)	–	(576)
Net carrying amount	<u>504</u>	<u>356,306</u>	<u>356,810</u>

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	Software	Research and development costs	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
30 June 2024			
Cost at 1 January 2024, net of accumulated amortisation	504	356,306	356,810
Additions	–	53,980	53,980
Amortisation provided during the period.	(104)	–	(104)
Disposal	(235)	(13,958)	(14,193)
At 30 June 2024	<u>165</u>	<u>396,328</u>	<u>396,493</u>
At 30 June 2024:			
Cost	845	396,328	397,173
Accumulated amortisation.	(680)	–	(680)
Net carrying amount	<u>165</u>	<u>396,328</u>	<u>396,493</u>

16. INVENTORIES

The Group

	As at 31 December		As at 30 June
	2022	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Raw materials	41,608	54,533	44,088
Work in progress	7,738	5,485	5,068
Finished goods	–	2,053	1,838
Others	101	246	255
Total	<u>49,447</u>	<u>62,317</u>	<u>51,249</u>

The Company

	As at 31 December		As at 30 June
	2022	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Raw materials	25,073	42,909	32,637
Work in progress	2,393	2,084	1,703
Others	45	28	33
Total	<u>27,511</u>	<u>45,021</u>	<u>34,373</u>

17. TRADE AND BILLS RECEIVABLES

	As at 31 December		As at 30 June
	2022	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Bills receivables	–	–	2,350
Trade receivables	–	–	827
Impairment allowance	–	–	(22)
Net carrying amount	<u>–</u>	<u>–</u>	<u>3,155</u>

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The Group’s trading terms with its customers are mainly payment in advance, except for certain customers who make small-volume purchases on an urgent basis. The payment term generally ranges from 30 to 180 days. The Group seeks to maintain strict control over its outstanding receivables. Overdue balances are reviewed regularly by senior management. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

An ageing analysis of the trade and bills receivables as at the end of each of the Relevant Periods, based on the transaction dates and net of loss allowance, is as follows:

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB’000	RMB’000	RMB’000
Within 3 months	–	–	3,155

An impairment analysis is performed at the end of each of the Relevant Periods using a provision matrix to measure expected credit losses. The Group uses the simplified method to calculate the credit impairment losses on trade receivables. Management’s estimate of the expected loss rate is based on the expected loss rate calculated by establishing the default rate of the corporate bonds in the recent three years and combining with forward-looking factors.

Set out below is the information about the credit risk exposure on the Group’s trade receivables as at the end of each of the Relevant Periods using a provision matrix:

As at 30 June 2024

	Within 3 months	3 to 6 months	6 to 12 months	More than 1 year	Total
Trade receivables (RMB’000).	827	–	–	–	827
Expected credit loss rate	2.66%	–	–	–	2.66%
Expected credit losses (RMB’000).	22	–	–	–	22

18. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

The Group

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB’000	RMB’000	RMB’000
Non-current:			
Prepayment for property, plant and equipment	10,414	10,044	–
Deductible value-added tax	19,573	36,238	39,566
Rental deposits.	2,244	1,062	–
Impairment allowance	–	–	–
Total	<u>32,231</u>	<u>47,344</u>	<u>39,566</u>

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	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
Current:			
Prepayments	28,118	12,847	15,241
Deposits	649	73	226
Other receivables	13,012	13,556	20,588
Deductible value-added tax	736	–	105
Deferred [REDACTED]	3,554	3,947	–
Impairment allowance	(226)	(27)	(134)
Total	<u>45,843</u>	<u>30,396</u>	<u>36,026</u>

The Company

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
Non-current:			
Deductible value-added tax	5,020	23,691	25,944
Rental deposits	2,243	1,061	–
Impairment allowance	–	–	–
Total	<u>7,263</u>	<u>24,752</u>	<u>25,944</u>
Current:			
Prepayments	18,024	10,500	13,999
Deposits	301	44	192
Other receivables	531,539	530,468	403,545
Deductible value-added tax	736	–	105
Deferred [REDACTED]	3,554	3,947	–
Impairment allowance	(55)	(25)	(21,930)
Total	<u>554,099</u>	<u>544,934</u>	<u>395,911</u>

The balances are interest-free and are not secured with collateral.

The financial assets included in the above balances relate to receivables for which there was no recent history of default and past due amounts.

19. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

The Group

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
Wealth management products	<u>482,180</u>	<u>306,832</u>	<u>332,376</u>

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The Company

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
Wealth management products	334,900	124,404	293,641

Note:

- (a) The wealth management products are purchased from creditworthy commercial banks in Chinese Mainland. They were mandatorily classified as financial assets at fair value through profit or loss as their contractual cash flows are not solely payments of principal and interest.

20. CASH AND CASH EQUIVALENTS

The Group

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
Cash and bank balances	219,312	140,637	19,954
Time deposits	4,800	2,254	5,385
Cash and cash equivalents	224,112	142,891	25,339

The Company

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
Cash and bank balances	191,414	136,152	10,159

Cash at banks earns interest at floating rates based on daily bank deposit rates. Short term time deposits are made for varying periods of between one month and three months depending on the immediate cash requirements of the Group, and earn interest at the respective short term time deposit rates. The bank balances and time deposits are deposited with creditworthy banks with no recent history of default.

The RMB is not freely convertible into other currencies, however, under Chinese Mainland’s Foreign Exchange Control Regulations and Administration of Settlement, and Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business.

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21. TRADE PAYABLES

The Group

An ageing analysis of the trade payables as at the end of each of the Relevant Periods, based on the invoice date, is as follows:

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
Within 1 year.	38,914	68,634	72,003
1 year to 2 years	177	7	850
2 years to 3 years	234	–	7
Over 3 years	411	571	571
Total	<u>39,736</u>	<u>69,212</u>	<u>73,431</u>

Trade payables are non-interest-bearing and are normally settled on terms of 30 to 180 days.

The Company

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
Within 1 year.	25,115	95,326	71,048
1 year to 2 years	–	–	377
Total	<u>25,115</u>	<u>95,326</u>	<u>71,425</u>

Trade payables are non-interest-bearing and are normally settled on terms of 30 to 180 days.

22. OTHER PAYABLES AND ACCRUALS

The Group

		As at 31 December		As at 30 June
		2022	2023	2024
		RMB'000	RMB'000	RMB'000
Non-current:				
Contract liabilities.	(a)	<u>–</u>	<u>55,719</u>	<u>55,138</u>
Current:				
Contract liabilities.	(a)	–	7,253	22,683
Other payables	(b)	18,934	39,612	38,602
Payroll payables		27,229	18,595	8,820
Other tax payables		1,323	1,647	5,997
Amounts due to related parties		–	1,660	2,385
Total		<u>47,486</u>	<u>68,767</u>	<u>78,487</u>

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The Company

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
Other payables	129,764	162,175	182,796
Payroll payables	11,552	8,348	3,384
Other tax payables	490	575	116
Total	<u>141,806</u>	<u>171,098</u>	<u>186,296</u>

(a) Details of contract liabilities are as follows:

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
<i>Short-term advances received from customers</i>			
Sales of medicines	–	664	13,930
Sales of distribution rights	–	62,308	63,891
Total	–	<u>62,972</u>	<u>77,821</u>

Contract liabilities include advances received for sales of pharmaceutical products and deferred revenue for sales of distribution rights. The increase in contract liabilities during the Relevant Periods was mainly due to the increase in short-term advances received from customers in relation to the provision of pharmaceutical products and deferred revenue for sales of distribution rights during the Relevant Periods.

(b) Other payables are non-interest-bearing.

23. SHARE CAPITAL

Shares

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
Issued and fully paid:			
Ordinary shares	<u>450,614</u>	<u>450,614</u>	<u>450,614</u>

A summary of movements in the Company’s share capital is as follows:

	Number of shares	Share capital
	'000	RMB'000
At 1 January 2022	450,614	450,614
At 31 December 2022 and 1 January 2023	450,614	450,614
At 31 December 2023 and 1 January 2024	450,614	450,614
At 30 June 2024	<u>450,614</u>	<u>450,614</u>

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24. RESERVES

The Group

The amounts of the Group’s reserves and the movements therein are presented in the consolidated statements of change in equity on pages I-7 to I-8 of the Historical Financial Information.

Share premium

The share premium represents the difference between the par value of the shares issued and the consideration received.

RSU reserve

The RSU reserve represents the reserve arising from share-based payment transactions, further details of which are included in note 25 to the Historical Financial Information.

Other reserve

Other reserve of the Group mainly includes the effect of the waiver of interests on loans from related parties.

The Company

	Share premium account	RSU reserve	Other reserve	Accumulated losses	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2022	1,765,573	39,304	111,987	(315,625)	1,601,239
Loss and total comprehensive loss for the year	–	–	–	(313,530)	(313,530)
Recognition of share-based payment expenses	–	49,611	–	–	49,611
At 31 December 2022 and 1 January 2023	1,765,573	88,915	111,987	(629,155)	1,337,320
Loss and total comprehensive loss for the year	–	–	–	(175,577)	(175,577)
Recognition of share-based payment expenses	–	56,337	–	–	56,337
At 31 December 2023 and 1 January 2024	1,765,573	145,252	111,987	(804,732)	1,218,080
Loss and total comprehensive loss for the period	–	–	–	(154,799)	(154,799)
Recognition of share-based payment expenses	–	29,881	–	–	29,881
At 30 June 2024	1,765,573	175,133	111,987	(959,531)	1,093,162

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25. SHARE-BASED PAYMENT TRANSACTIONS

First share-based payment

On the grant date of 24 August 2020, Xuanzhu (HK) Biopharmaceutical Limited (“Xuanzhu Biopharma”), the former shareholder of the Company, entered into an agreement with Ms. Xu Yanjun, Dr. Shih Cheng-Kon and Dr. Li Jia Kui, three senior executives of the Group, under which Xuanzhu Biopharma transferred 0.80% of the Company’s equity to Ms. Xu Yanjun, 1.30% of the Company’s equity to Dr. Shih Cheng-Kon and 1.00% of the Company’s equity to Dr. Li Jia Kui. The number of restricted shares granted to the incentive objects under this share incentive plan is 35,650,000 (Batch 1). The price is RMB1.3116 per share, and there is no binding clause related to the exercise, which can be exercised immediately.

On the grant date of 24 August 2020, the board of directors of the Company decided to approve the share incentive plan. The shareholder Xuanzhu Biopharma transferred its equity to the shareholding platforms, Tianjin Hongzekang, Tianjin Xuansheng, Tianjin Hongteng, Tianjin Zhenxuan, Tianjin Pusheng, Tianjin Guoding and Tianjin Huize (see note 1). The Company signed equity incentive grant agreements with 122 employees (Batch 1). A total of restricted shares corresponding to the registered capital of RMB43,276,800 were granted at an exercise price of RMB1.5739 per share.

Based on the asset appraisal report issued by Shanghai Dongzhou Asset Appraisal Co., Ltd. (“Dongzhou Consulting Report Zi [2021] No. 0334”) on the appraisal of the equity value on 31 August 2020 by market method, the fair value of the above share-based payment for senior executives and employees were RMB61,473,585 and RMB74,624,966, respectively. As the share incentive plan has a vesting period, it shall be amortised and recognised as share-based payment expenses within three years from the grant date.

Amendments to the first share-based payment

On 10 September 2021, the Company approved the amendment of the grant price of the first share-based payment through the resolution of the board of directors, which was uniformly adjusted to RMB0.263 per share, and the impact of the adjustment of the price was recognised in the remaining vesting period. In addition, the vesting period is agreed for the equity incentive granted to senior executives, which is amortised and recognised as share-based payment expenses within three years from the grant date.

Second share-based payment

On the grant date of 10 September 2021, the board of directors of the Company decided to approve the share incentive plan, and the employee stock ownership platforms, Tianjin Hongzekang, Tianjin Xuansheng, Tianjin Hongteng, Tianjin Zhenxuan, Tianjin Pusheng, Tianjin Guoding, Tianjin Huize, Beihai Keya and Beihai Jixin granted restricted shares to 60 employees and 1 executive. The number of restricted shares granted to the incentive objects under this share incentive plan is 65,305,500, and the exercise price of restricted shares granted this time is RMB0.263 per share (Batch 2-a). As the share incentive plan stipulates a vesting period, it shall be amortised and recognised as share-based payment expenses within three years from the grant date.

On the grant date of 10 September 2021, the board of directors of the Company decided to approve the share incentive plan. The Company had previously signed an equity transfer agreement with Beihai Baimei’en (see note 1), and the Company had signed an equity incentive grant agreement with 14 employees. A total of restricted shares corresponding to the registered capital of RMB49,642,307 were granted, and the price was RMB1.2343 per share (Batch 2-b). As the share incentive plan stipulates a vesting period, it shall be amortised and recognised as share-based payment expenses within three years from the grant date.

The Company took the asset appraisal report issued by Shanghai Dongzhou Asset Appraisal Co., Ltd. (“Dongzhou Zibao Zi [2022] No. 0376”) for reference, which evaluated the equity value on 31 August 2021 by market method. The fair values of the above share-based payment were RMB108,716,653 and RMB143,019,045, respectively. As the share incentive plan stipulates a vesting period, it shall be amortised and recognised as share-based payment expenses within three years from the grant date.

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Third share-based payment

On the grant dates of 31 March 2022 and 21 July 2022, the board of directors of the Company decided to approve the share incentive plan, and the employee stock ownership platforms, Tianjin Hongteng, Tianjin Zhenxuan, Tianjin Guoding, Beihai Jixin and Beihai Baimei’en granted restricted shares to 9 employees. The number of restricted shares granted to the incentive objects under this share incentive plan is 3,791,140. Among them, the exercise price of 3,667,020 restricted shares granted is RMB0.263 per share (Batch 3-a); and the exercise price of 124,120 restricted shares in Beihai Baimei’en is RMB1.2343 per share, which is reauthorised by the Company to 2 employees (Batch 3-b).

The fair value of the above share-based payment is RMB8,057,172 based on the asset appraisal report (“Dongzhou Zibao Zi [2022] No. 0376”) issued by Shanghai Dongzhou Asset Appraisal Co., Ltd. for the appraisal of the equity value on 31 August 2021 by market method. As the share incentive plan stipulates a vesting period, it shall be amortised and recognised as share-based payment expenses within three years from the grant date.

On the grant date of 30 November 2022, the board of directors of the Company decided to approve the share incentive plan, and the employee stock ownership platforms, Tianjin Hongteng, Tianjin Guoding and Beihai Keya granted restricted shares to 13 employees. The number of restricted shares granted to the incentive objects under this share incentive plan is 5,037,630, and the exercise price is RMB0.263 per share (Batch 3-a).

The fair value of the above share-based payment is RMB22,944,200 based on the asset appraisal report (“Dongzhou Zibao Zi [2023] No.0293”) issued by Shanghai Dongzhou Asset Appraisal Co., Ltd. on the appraisal of the equity value on 30 November 2022 by market method. As the share incentive plan stipulates a vesting period, it shall be amortised and recognised as share-based payment expenses within three years from the grant date.

The following restricted stocks were outstanding during the Relevant Periods:

	Weighted average exercise price per share	Number of shares authorised
	<i>RMB</i>	<i>'000</i>
As at 1 January 2022	0.924	169,887
Granted during the year	0.277	8,829
Forfeited during the year	0.611	<u>(15,465)</u>
As at 31 December 2022 and 1 January 2023	0.919	163,251
Forfeited during the year	0.263	<u>(6,678)</u>
As at 31 December 2023 and 1 January 2024	0.947	156,573
Exercised during the period	0.263	(3,847)
Forfeited during the year	0.263	<u>(2,120)</u>
As at 30 June 2024	0.974	<u>150,606</u>

The exercise prices and the fair values at grant dates of the restricted stocks outstanding as at the end of each of the Relevant Periods are as follows:

As at 31 December 2022

	Number of shares outstanding	Exercise price	Fair value at grant date
	<i>'000</i>	<i>RMB per share</i>	<i>RMB per share</i>
Batch 1	53,436	0.263	1.724
Batch 2-a	57,701	0.263	2.190
Batch 2-b	44,107	1.234	2.190
Batch 3-a	7,883	0.263	2.190
Batch 3-b	124	0.263	4.991
	<u>163,251</u>		

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As at 31 December 2023

	Number of shares outstanding	Exercise price	Fair value at grant date
	'000	RMB per share	RMB per share
Batch 1	50,681	0.263	1.724
Batch 2-a	54,599	0.263	2.190
Batch 2-b	44,107	1.234	2.190
Batch 3-a	7,062	0.263	2.190
Batch 3-b	124	0.263	4.991
	<u>156,573</u>		

As at 30 June 2024

	Number of shares outstanding	Exercise price	Fair value at grant date
	'000	RMB per share	RMB per share
Batch 1	46,834	0.263	1.724
Batch 2-a	52,972	0.263	2.190
Batch 2-b	44,107	1.234	2.190
Batch 3-a	6,569	0.263	2.190
Batch 3-b	124	0.263	4.991
	<u>150,606</u>		

The fair values of the restricted stocks granted to the employees and consultants during the grant dates were estimated as at the date of grant using the market-value model, taking into account the terms and conditions upon which the restricted stocks were granted. The following table lists the inputs to the model:

	2022	2021	2020
Expected volatility (%)	56.49	56.49	49.93
Risk-free interest rate (%)	2.55	2.55	2.93
Term (year)	2.3	3.3	4.3

The expected volatility reflects the assumption that the historical volatility is indicative of future trends, which may also not necessarily be the actual outcome.

The total share-based payment expenses recognised in profit or loss for restricted shares were approximately RMB70,129,000, RMB72,266,000, RMB30,095,000 and RMB49,105,000 (unaudited) during the Relevant Periods and the six months ended 30 June 2023.

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ACCOUNTANTS’ REPORT

26. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

During the Relevant Periods, the Group did not have non-cash additions to right-of-use assets and lease liabilities.

(b) Changes in liabilities arising from financing activities

	<u>Lease liabilities</u>
At 1 January 2022.	32,955
Changes in financing cash flows	(4,957)
Accretion of interest	1,517
Disposal	<u>(283)</u>
At 31 December 2022 and 1 January 2023.	29,232
Changes in financing cash flows	(7,576)
Accretion of interest	1,167
Disposal	<u>(5,758)</u>
At 31 December 2023 and 1 January 2024.	17,065
Changes in financing cash flows	(2,871)
Accretion of interest	282
Disposal	<u>(12,101)</u>
At 30 June 2024.	<u><u>2,375</u></u>

(c) Total cash outflow for leases

The total cash outflow for leases included in the consolidated statements of cash flows is as follows:

	<u>Year ended 31 December</u>		<u>Six months ended 30 June</u>	
	<u>2022</u>	<u>2023</u>	<u>2023</u>	<u>2024</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
	<i>(Unaudited)</i>			
Within operating activities.	2,862	2,466	1,519	1,182
Within financing activities.	4,957	7,576	3,733	2,871
Total	<u>7,819</u>	<u>10,042</u>	<u>5,252</u>	<u>4,053</u>

27. COMMITMENTS

The Group had the following capital commitments at the end of each of the Relevant Periods.

	<u>As at 31 December</u>		<u>As at 30 June</u>
	<u>2022</u>	<u>2023</u>	<u>2024</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Contracted, but not provided for:			
Acquisition of property, plant and equipment. . .	<u>2,345</u>	<u>1,059</u>	<u>–</u>

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28. RELATED PARTY TRANSACTIONS

Name and relationship of related parties

Name	Relationship
北京四環製藥有限公司 Beijing Sihuan Pharmaceutical Co., Ltd. (“Beijing Sihuan”).	Entity under common control of the ultimate holding company
北京惠之衡生物科技有限公司 Beijing Huizhiheng Biotechnology Co., Ltd. (“Beijing Huizhiheng”) . . .	Entity under common control of the ultimate holding company

(a) The Group had the following transactions with related parties during the Relevant Periods and the six months ended 30 June 2023:

	Note	Year ended 31 December		Six months ended 30 June	
		2022	2023	2023	2024
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i> <i>(Unaudited)</i>	<i>RMB’000</i>
Entities under common control of the ultimate holding company					
Purchases of products and services	(i)	268	702	545	–
Lease	(ii)	<u>1,476</u>	<u>898</u>	<u>751</u>	<u>767</u>

Notes:

- (i) The purchases of products and services include receiving domestic services for water, electricity and heating, packaging services from Beijing Sihuan for clinical trials, and processing services for XZP-3621 preparation.
- (ii) The Group rented a building from Beijing Sihuan for office use for the Relevant Periods and the six months ended 30 June 2023.

(b) Technology Transfer:

In August 2020, Beijing Xuanzhu entered into a technology transfer agreement with Beijing Huizhiheng, agreed to transfer the ownership of and rights relating to Janagliflozin to Beijing Huizhiheng. In consideration, Beijing Huizhiheng agreed to pay Beijing Xuanzhu (i) an one-off payment which has already been made before the Relevant Periods, (ii) the pre-determined royalties based on the net sales generated from the sales of Janagliflozin which had not been taken place during the Relevant Periods.

(c) Outstanding balances with related parties:

- (i) The Group had an outstanding balance due from an entity under common control of the ultimate holding company of RMB529,000, RMB23,000 and RMB17,000 as of 31 December 2022 and 2023 and 30 June 2024, respectively. This balance is unsecured, interest-free and has no fixed terms of repayment.
- (ii) The Group had an outstanding balance due to an entity under common control of the ultimate holding company of nil, RMB1,660,000 and RMB2,385,000 as of 31 December 2022 and 2023 and 30 June 2024, respectively. This balance is unsecured, interest-free and has no fixed terms of repayment.

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(d) Compensation of the key management personnel of the Group

	Year ended 31 December		Six months ended 30 June	
	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000 (Unaudited)	RMB'000
Salaries, bonuses and allowances. . .	11,806	11,260	6,443	3,875
Pension scheme contributions and social welfare	473	668	258	329
Share-based payment expenses	35,409	38,835	18,131	73
Total compensation paid to key management personnel.	<u>47,688</u>	<u>50,763</u>	<u>24,832</u>	<u>4,277</u>

Further details of directors’ and the chief executive’s emoluments are included in note 8 to the Historical Financial Information.

29. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of each of the Relevant Periods are as follows:

The Group

Financial assets

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
Financial assets at FVTPL:			
Wealth management products	<u>482,180</u>	<u>306,832</u>	<u>332,376</u>
Financial assets at amortised cost:			
Trade and bills receivables	–	–	3,155
Financial assets included in prepayments, other receivables and other assets	15,679	14,664	20,680
Cash and cash equivalents	<u>224,112</u>	<u>142,891</u>	<u>25,339</u>
Total	<u>239,791</u>	<u>157,555</u>	<u>49,174</u>

Financial liabilities

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
Trade payable	39,736	69,212	73,431
Financial liabilities included in other payables and accruals	<u>18,934</u>	<u>41,272</u>	<u>40,987</u>
Total	<u>58,670</u>	<u>110,484</u>	<u>114,418</u>

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ACCOUNTANTS’ REPORT

30. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

Management has assessed that the fair values of cash and cash equivalents, trade and bills receivables, financial assets included in prepayments, other receivables and other assets (in the current portion), trade payables, financial liabilities included in other payables and accruals and amounts due to related parties approximate to their carrying amounts largely due to the short-term maturities of these instruments.

The Group’s finance department headed by the finance manager is responsible for determining the policies and procedures for the fair value measurement of financial instruments. At the end of each of the Relevant Periods, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The directors review the results of the fair value measurement of financial instruments periodically for financial reporting.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale. The following methods and assumptions were used to estimate the fair values:

The fair values of the non-current portion of financial assets included in prepayments, other receivables and other assets have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities.

31. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group’s principal financial instruments comprise cash and cash equivalents, trade and bills receivables and financial assets included in prepayments, other receivables and other assets. The main purpose of these financial instruments is to raise finance for the Group’s operations. The Group has various financial assets and liabilities such as trade and bills receivables, trade payables, financial assets included in prepayments, other receivables and other assets and financial liabilities included in other payables and accruals, which arise directly from its operations.

The main risks arising from the Group’s financial instruments are credit risk and liquidity risk. The board of directors reviews and agrees policies for managing each of these risks and they are summarised below.

Credit risk

The Group trades only with recognised and creditworthy third parties. It is the Group’s policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and the Group’s exposure to bad debts is not significant.

The credit risk of the Group’s financial assets, which comprise cash and cash equivalents, trade receivables, bills receivables and financial assets included in prepayments, other receivables and other assets, arises from default of the counterparty, with a maximum exposure equal to the carrying amount of these instruments.

Maximum exposure and year-end staging

The tables below show the credit quality and the maximum exposure to credit risk based on the Group’s credit policy, which is mainly based on past due information unless other information is available without undue cost or effort, and year-end staging classification as at the end of each of the Relevant Periods.

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The amounts presented are gross carrying amounts for financial assets.

The Group

As at 30 June 2024

	12-month ECLs	Lifetime ECLs			Total
	Stage 1	Stage 2	Stage 3	Simplified approach	
	RMB'000	RMB'000	RMB'000	RMB'000	
Financial assets included in other receivables and other assets – normal**	20,680	–	–	–	20,680
Trade receivables*	805	–	–	–	805
Bills receivables	2,350	–	–	–	2,350
Cash and cash equivalents	25,339	–	–	–	25,339
Total	49,174	–	–	–	49,174

As at 31 December 2023

	12-month ECLs	Lifetime ECLs			Total
	Stage 1	Stage 2	Stage 3	Simplified approach	
	RMB'000	RMB'000	RMB'000	RMB'000	
Financial assets included in other receivables and other assets – normal**	14,664	–	–	–	14,664
Cash and cash equivalents	142,891	–	–	–	142,891
Total	157,555	–	–	–	157,555

As at 31 December 2022

	12-month ECLs	Lifetime ECLs			Total
	Stage 1	Stage 2	Stage 3	Simplified approach	
	RMB'000	RMB'000	RMB'000	RMB'000	
Financial assets included in other receivables and other assets – normal**	15,679	–	–	–	15,679
Cash and cash equivalents	224,112	–	–	–	224,112
Total	239,791	–	–	–	239,791

* For trade receivables to which the Group applies the simplified approach for impairment, information based on the provision matrix is disclosed in note 17 to the Historical Financial Information.

** The credit quality of the financial assets included in prepayments, other receivables and other assets is considered to be “normal” when they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk since initial recognition. Otherwise, the credit quality of the financial assets is considered to be “doubtful”.

APPENDIX I

ACCOUNTANTS’ REPORT

Further quantitative data in respect of the Group’s exposure to credit risk arising from trade receivables are disclosed in note 17 to the Historical Financial Information.

Since the Group trades only with recognised and creditworthy third parties, there is no requirement for collateral. There is no significant concentration of credit risk.

Liquidity risk

The Group monitors and maintains a level of cash and cash equivalents deemed adequate by the management of the Group to finance the operations and mitigate the effects of fluctuations in cash flows.

The maturity profile of the Group’s financial liabilities and lease liabilities as at the end of each of the Relevant Periods, based on the contractual undiscounted payments, is as follows:

The Group

	As at 30 June 2024			
	Less than 1 year or on demand	1 to 5 years	Over 5 years	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade payables	73,431	–	–	73,431
Financial liabilities included in other payables and accruals	40,987	–	–	40,987
Lease liabilities	2,871	–	–	2,871
Total	<u>117,289</u>	<u>–</u>	<u>–</u>	<u>117,289</u>

	As at 31 December 2023			
	Less than 1 year or on demand	1 to 5 years	Over 5 years	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade payables	69,212	–	–	69,212
Financial liabilities included in other payables and accruals	41,272	–	–	41,272
Lease liabilities	5,742	12,442	–	18,184
Total	<u>116,226</u>	<u>12,442</u>	<u>–</u>	<u>128,668</u>

	As at 31 December 2022			
	Less than 1 year or on demand	1 to 5 years	Over 5 years	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade payables	39,736	–	–	39,736
Financial liabilities included in other payables and accruals	18,934	–	–	18,934
Lease liabilities	7,686	24,340	–	32,026
Total	<u>66,356</u>	<u>24,340</u>	<u>–</u>	<u>90,696</u>

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ACCOUNTANTS’ REPORT

Capital management

The primary objectives of the Group’s capital management are to safeguard the Group’s ability to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximise shareholders’ value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the Relevant Periods.

The gearing ratios as at the end of each of the Relevant Periods are as follows:

	As at 31 December		As at 30 June
	2022	2023	2024
	RMB’000	RMB’000	RMB’000
Total equity	1,338,543	1,110,247	1,029,365
Total liabilities	116,454	210,763	209,431
Gearing ratio (<i>note</i>)	8.7%	19.0%	20.3%

Note: The gearing ratio is calculated by dividing total liabilities by total equity and multiplying the product by 100%.

32. EVENTS AFTER THE RELEVANT PERIODS

In recognition of the contributions of its employees and to incentivize them to further promote its development, the board of directors of the Company approved an Equity Incentive on 17 November 2024. Pursuant to the equity transfer agreement entered into by Xuanzhu Biopharma, its Controlling Shareholder, and two of its Incentive Platforms, namely Tianjin Zhenxuan and Tianjin Guoding, Xuanzhu Biopharma agreed to transfer 34,467,544 Shares and 1,581,600 Shares to Tianjin Zhenxuan and Tianjin Guoding for share incentive purposes at consideration of RMB34,467,544 and RMB1,581,600, respectively.

33. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Company, the Group or any of the companies now comprising the Group in respect of any period subsequent to 30 June 2024.

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II

UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX IIA

[REDACTED]

[REDACTED]

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

TAXATION IN THE PRC

Taxation on dividend

Individual Investors

Under PRC Individual Income Tax Law (《中華人民共和國個人所得稅法》) (the “IIT Law”), promulgated on 10 September 1980 and amended on 31 August 2018, and its implementation rules (《中華人民共和國個人所得稅法實施條例》), effective on 1 January 2019, dividends paid by PRC companies to individual investors are generally subject to a tax at a rate of 20%.

In accordance with the Notice on Issues Concerning Differentiated IIT Policies for Dividends and Bonuses of Listed Companies (《關於上市公司股息紅利差別化個人所得稅政策有關問題的通知》) (Cai Shui [2015] No. 101), issued on 7 September 2015, where an individual acquires stocks of a listed company from public offering market or from the stock transfer market and holds the stocks for more than one year, the income from dividends is exempt from IIT; where an individual holds the stocks for one month or less, the full amount of such income from dividends shall be included in taxable income; if the individual holds the stocks for one month to one year, 50% of such income from dividends shall be included in taxable income; the aforesaid income is subject to a flat rate of 20%.

HK Individual Investors

Pursuant to the Arrangement between the Mainland PRC 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), signed on 21 August 2006, tax on dividends paid by PRC companies to Hong Kong individuals will not exceed 10% of the total amount of the dividends.

Enterprise Investors

Foreign 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》) (the “EIT Law”), effective on 29 December 2018, and its implementation rules (《中華人民共和國企業所得稅法實施條例》), effective on 23 April 2019, a non-resident enterprise is generally subject to a 10% enterprise income tax on PRC-sourced income, if a non-resident enterprise does not establish an institution or premise in the PRC or has an institution or premise in the PRC but the PRC-sourced income is not connected with such institution or premise in the PRC.

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

The Notice of the Issues Concerning Withholding EIT on the Dividends Distributed by PRC Resident Enterprises to Overseas H-share Non-PRC Resident Enterprise Shareholders (《國家稅務總局關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》) (Guo Shui Han [2008] No. 897), came into effect on 6 November 2008, stipulates that with regard to dividends paid for 2008 onwards, PRC resident enterprises must withhold tax at a rate of 10% on dividends distributed to H-share non-PRC resident enterprise shareholders. The Reply of the Imposition of Enterprise Income Tax on B-share and Other Dividends of Non-resident Enterprises (《國家稅務總局關於非居民企業取得B股等股票股息徵收企業所得稅問題的批覆》) that was promulgated on 24 July 2009, further provides that any PRC resident enterprise listed on any overseas stock exchange must withhold enterprise income tax at a rate of 10% on dividends distributed to non-PRC resident enterprise shareholders. The above tax rates may be further amended in accordance with tax treaties or agreements between China and relevant jurisdictions (if applicable).

HK Enterprise Investors

Pursuant to the Arrangement between the Mainland PRC 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》) signed on 21 August 2006, tax on dividends paid by PRC companies to Hong Kong enterprises shall not exceed 10% of the total amount of the dividends. If Hong Kong enterprises directly holds 25% or more of the equity interest in PRC companies, such tax shall not exceed 5% of the total dividends paid by the PRC companies.

Tax agreements

Non-PRC resident investors residing in countries which have entered into agreements for the avoidance of double taxation with the PRC are entitled to a reduction of the withholding taxes imposed on the dividends received from PRC companies. The PRC has entered into Avoidance of Double Taxation Arrangements with a number of countries and regions including but not limited to Hong Kong, Macau, 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 income tax treaties or arrangements are required to apply to the Chinese tax authorities for a refund of the withholding tax in excess of the agreed tax rate, and the refund payment is subject to approval by the Chinese tax authorities.

Taxation on income from transfer of equity

Individual Investors

According to the IIT Law and its implementation regulations, individuals shall pay the IIT at the rate of 20% on their income from the sale of equity in PRC resident enterprises.

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In accordance with the Circular of the Declaring that IIT Continues to Be Exempted over Income of Individuals from Transfer of Shares (《財政部、國家稅務總局關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) (Cai Shui Zi [1998] No. 61), promulgated on 30 March 1998, from 1 January 1997, income of individuals from the transfer of shares of listed companies remain exempt from IIT. According to the Announcement about the Catalogue of Preferential IIT Policies with Continued Effect (《財政部、國家稅務總局關於繼續有效的個人所得稅優惠政策目錄的公告》) (MOF SAT Announcement [2018] No. 177), promulgated on 29 December 2018, the Circular of the Declaring that IIT Continues to Be Exempted over Income of Individuals from Transfer of Shares will remain effective.

Foreign Enterprise Investors

In accordance with the EIT Law and its implementation provisions, a non-PRC resident enterprise is generally subject to a 10% enterprise income tax 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 the PRC-sourced income is not connected in reality with such establishment or premise. Such income tax for non-resident enterprises shall be deducted at source, where the payer of the income is required to withhold the enterprise income tax from the amount to be paid to the non-resident enterprise when such payment is made or due. Such withholding tax may be reduced or exempted to avoid double taxation in accordance with applicable agreements or protocols.

Tax policies for Shanghai — Hong Kong Stock Connect

Individual Investors

Taxation on income from transfer of equity

Pursuant to Announcement on Continuation of Implementation of Individual Income Tax Policies Relating to Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect and Mutual Recognition of Funds between Mainland China and Hong Kong (《關於延續實施滬港、深港股票市場交易互聯互通機制和內地與香港基金互認有關個人所得稅政策的公告》) (MOF Announcement [2023] No. 23), effective on 21 August 2023, the income from the transfer price difference obtained by Mainland PRC individual investors investing in stocks listed on the Hong Kong Stock Exchange through Shanghai-Hong Kong Stock Connect is exempt from IIT.

Taxation on dividend

Pursuant to the Circular of the MOF, SAT and China Securities Regulatory Commission on the Relevant Taxation Policies for the Pilot Interconnected Mechanism for Trading in the Stock Markets of Hong Kong and Shanghai (《財政部、國家稅務總局、證監會關於滬港股票市場交易互聯互通機制試點有關稅收政策的通知》) (Cai Shui [2014] No. 81), effective on 17 November 2014, in respect of dividends and bonuses received by mainland PRC individual

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investors from investing in the H shares listed on the Hong Kong Stock Exchange through the Shanghai-Hong Kong Stock Connect, the H share company should submit an application to CSDC, then CSDC will provide a list of the mainland PRC individual investors to the H share company, and the H share company shall withhold individual income tax based on 20% tax rate.

Enterprises Investors

Taxation on income from transfer of equity and dividend

Pursuant to the Circular of the MOF, SAT and China Securities Regulatory Commission on the Relevant Taxation Policies for the Pilot Interconnected Mechanism for Trading in the Stock Markets of Hong Kong and Shanghai (《財政部、國家稅務總局、證監會關於滬港股票市場交易互聯互通機制試點有關稅收政策的通知》) (Cai Shui [2014] No. 81), effective on 17 November 2014, the income derived from the difference in the price of the transfer of the stocks listed on the Hong Kong Stock Exchange obtained by mainland PRC enterprise investors through the Shanghai-Hong Kong Stock Connect shall be counted as part of their gross income and be subject to the enterprise income tax according to the law. Dividend and bonus income obtained by mainland PRC resident enterprises from their continuous holding of H shares for 12 months or more is exempted from enterprise income tax in accordance with the law. H share companies do not withhold dividend and bonus income tax on behalf of mainland PRC enterprises in respect of dividend and bonus income obtained by mainland PRC enterprises. The tax payable shall be declared and paid by the enterprise itself.

Tax policies for Shenzhen — Hong Kong Stock Connect

Individual Investors

Taxation on income from transfer of equity

Pursuant to Announcement on Continuation of Implementation of Individual Income Tax Policies Relating to Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect and Mutual Recognition of Funds between Mainland China and Hong Kong (《關於延續實施滬港、深港股票市場交易互聯互通機制和內地與香港基金互認有關個人所得稅政策的公告》) (MOF Announcement [2023] No. 23), effective on 21 August 2023, the income from the transfer price difference obtained by Mainland PRC individual investors investing in stocks listed on the Hong Kong Stock Exchange through Shenzhen-Hong Kong Stock Connect is exempt from IIT.

Taxation on income from dividend

Pursuant to the Circular on the Relevant Taxation Policy for the Pilot Programme of an Interconnection Mechanism for Transactions in the Shenzhen and Hong Kong Stock Markets (《關於深港股票市場交易互聯互通機制試點有關稅收政策的通知》) (Cai Shui [2016] No. 127) which came into effect on 5 December 2016, for dividends and bonus obtained by

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individual investors of mainland PRC investing in the H shares listed on the Stock Exchange through Shenzhen — Hong Kong Stock Connect, the H share companies shall apply to CSDC for provision by CSDC to the H-share companies the register of mainland PRC individual investors, and the H-share companies shall withhold IIT at a rate of 20%.

Enterprises Investors

Taxation on income from transfer of equity and dividend

Pursuant to the Circular on the Relevant Taxation Policy for the Pilot Programme of an Interconnection Mechanism for Transactions in the Shenzhen and Hong Kong Stock Markets (《關於深港股票市場交易互聯互通機制試點有關稅收政策的通知》) (Cai Shui [2016] No. 127) which came into effect on 5 December 2016, the income from the transfer price difference obtained by enterprise investors of mainland PRC investing in stocks listed on the Stock Exchange through Shenzhen — Hong Kong Stock Connect shall be included in their total income, and the EIT shall be levied on such income in accordance with the law.

Dividend and bonus income obtained by mainland PRC enterprise residents from their continuous holding of H shares for 12 months or more is exempted from enterprise income tax in accordance with the law. H share companies do not withhold dividend and bonus income tax on behalf of mainland PRC enterprises in respect of dividend and bonus income obtained by mainland PRC enterprises. The tax payable shall be declared and paid by the enterprise itself.

Stamp duty in the PRC

In accordance with the Stamp Duty Law of the PRC (《中華人民共和國印花稅法》) which came into effect on 1 July 2022, (i) entities and individuals that conclude taxable certificates, or conduct securities transactions within the territory of the PRC shall be taxpayers of stamp duty, and shall pay the PRC stamp duty; (ii) entities and individuals who are located outside the territory of the PRC and conclude taxable certificates that are to be used within the territory of the PRC shall pay the PRC stamp duty.

Estate Duty

The PRC currently has not imposed any estate duty yet.

Enterprise income tax

According to the EIT Law, the EIT rate in the PRC is 25%, which is in line with the rate applicable to foreign-invested enterprises and foreign enterprises. According to the Administrative Measures for Recognition of High and New-Technology Enterprises (《高新技術企業認定管理辦法》) that was promulgated by the Ministry of Science and Technology, the MOF and the SAT on 14 April 2008, amended on 29 January 2016 and came into effect on 1 January 2016, enterprises which are recognized as high and new-tech enterprises could apply for a preferential EIT rate of 15% in accordance with the EIT Law.

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Value-added tax ("VAT")

Pursuant to the Provisional Regulations on VAT of the PRC (《中華人民共和國增值稅暫行條例》), came into effect on 19 November 2017, all organizations and individuals engaged in sales of goods, provision of processing, repairs and replacement services, or import of goods etc. within the territory of the PRC are subject to VAT.

Pursuant to the Notice on the Implementation of the Pilot Programme of Replace the Business Tax with VAT (《關於全面推開營業稅改徵增值稅試點的通知》) (Cai Shui [2016] No. 36) and its appendix the Measures for the Implementation of the Pilot Programme of Replacing Business Tax with VAT (《營業稅改徵增值稅試點實施辦法》), effective on 1 May 2016, the tax rates applied to the taxpayer for the different goods it sells and different services it provides shall be 17%, 11%, 6% and zero, respectively. Pursuant to the Notice on Adjusting VAT Rates (《關於調整增值稅稅率的通知》) (Cai Shui [2018] No. 32), promulgated on 4 April 2018 and came into effect on 1 May 2018, for taxpayers engaging in taxable sales or import of goods, the previously applicable VAT rates are adjusted to 16% and 10%, respectively. Pursuant to the Announcement on Relevant Policies for Deepening the VAT Reform (《關於深化增值稅改革有關政策的公告》) (MOF SAT GACC Announcement [2019] No. 39), promulgated on 20 March 2019 and came into effect on 1 April 2019, for taxpayers engaging in taxable sales or import of goods, the previously applicable VAT rates of 16% and 10% are adjusted to 13% and 9%, respectively.

TAXATION IN HONG KONG

Tax on dividends

Under the current practice of the Inland Revenue Department of Hong Kong, no tax is payable in Hong Kong in respect of dividends paid by us.

Capital gains and profit tax

No tax is imposed in Hong Kong in respect of capital gains from the sale of H Shares. However, trading gains from the sale of H Shares by persons carrying on a trade, profession or business in Hong Kong, where such gains are derived from or arise in Hong Kong from such trade, profession or business will be subject to Hong Kong profits tax, which is currently imposed at the maximum rate of 16.5% on corporations and at the maximum rate of 15% on unincorporated businesses. Certain categories of taxpayers (for example, financial institutions, insurance companies and securities dealers) are likely to be regarded as deriving trading gains rather than capital gains unless these taxpayers can prove that the investment securities are held for long-term investment purposes.

Trading gains from sales of H Shares effected on the Stock Exchange will be considered to be derived from or arise in Hong Kong. Liability for Hong Kong profits tax would thus arise in respect of trading gains from sales of H Shares effected on the Stock Exchange realized by persons carrying on a business of trading or dealing in securities in Hong Kong.

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Stamp duty

Hong Kong stamp duty, currently charged at the ad valorem rate of 0.1% on the higher of the consideration for or the market value of H Shares, will be payable by the purchaser on every purchase and by the seller on every sale of Hong Kong securities, including H Shares (in other words, a total of 0.2% is currently payable on a typical sale and purchase transaction involving H Shares). In addition, a fixed duty of HK\$5.00 is currently payable on any instrument of transfer of H Shares. Where one of the parties is a resident outside Hong Kong and does not pay the ad valorem duty due by it, the duty not paid will be assessed on the instrument of transfer (if any) and will be payable by the transferee. If no stamp duty is paid on or before the due date, a penalty of up to ten times the duty payable may be imposed.

Estate duty

The Revenue (Abolition of Estate Duty) Ordinance 2005 abolished estate duty in respect of deaths occurring on or after February 11, 2006.

FOREIGN EXCHANGE

The lawful currency of the PRC is the RMB, which is currently subject to foreign exchange control and is not freely convertible into foreign exchange.

Pursuant to the Regulations of the People’s Republic of China on Foreign Exchange Administration (《中華人民共和國外匯管理條例》) (the “Foreign Exchange Administration Regulations”), effective on 1 April 1996, all international payments and transfers are classified into current items and capital items, with most of the current items no longer subject to the approval of the foreign exchange administration agencies, while capital items are still subject to its approval. The latest Foreign Exchange Administration Regulations, amended on 5 August 2008, clarifies that the State does not impose restriction on international current item payments and transfers.

According to the “Regulations on the Administration of Settlement, Sale and Payment of Foreign Exchange” (《結匯、售匯及付匯管理規定》) (Yin Fa [1996] No. 210), issued on 20 June 1996, the existing restrictions on foreign exchange transactions under capital items were retained, while the residual restrictions under current items were abolished.

Pursuant to the Announcement on Reforms to Improve the Exchange Rate Formation Mechanism of Renminbi (《關於完善人民幣匯率形成機制改革的公告》) (PBOC Announcement [2005] No. 16), effective on 21 July 2005, the PRC began to implement a managed floating exchange rate system, under which the exchange rate is determined according to market demand and supply and adjusted with reference to a basket of currencies. The exchange rate of RMB is no longer pegged to the U.S. dollar. The PBOC will announce the closing price of foreign currencies, such as the U.S. dollar, against the RMB in the interbank foreign exchange market after the close of market on each business day, which will be used as the mid-rate for RMB transactions on the following business day.

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On 23 October 2014, the State Council promulgated 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》)(Guo Fa [2014] No. 50), which canceled the administrative approval by 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.

On 26 December 2014, the SAFE issued 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》) (Hui Fa [2014] No. 54), pursuant to which, a domestic company shall, within 15 business days from the date of the completion of its overseas listing and issuance, register the overseas listing with the SAFE's local branch 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 documents as publicly disclosed by the document.

According to the Notice of the State Administration of Foreign Exchange on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》) (Hui Fa [2015] No. 13), promulgated on February 13 2015, banks shall directly examine and handle foreign exchange registration under domestic direct investment and overseas direct investment, and the SAFE and its branch offices shall indirectly regulate the foreign exchange registration of direct investment through banks.

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》) (Hui Fa [2016] No. 16), effective on 9 June 2016, foreign currency earnings in capital account that relevant policies of willingness exchange settlement have been clearly implemented on (including the recalling of raised capital by overseas listing) may undertake foreign exchange settlement in the banks according to actual business needs of the domestic institutions. The tentative percentage of foreign exchange settlement for foreign currency earnings in capital account of domestic institutions is 100%. The SAFE may adjust the above proportion in due time according to balance of payments.

On 26 January 2017, the SAFE issued the Circular of State Administration of Foreign Exchange on Further Promoting Foreign Exchange Management Reform and Improving the Verification of True Compliance (《國家外匯管理局關於進一步推進外匯管理改革完善真實合規性審核的通知》) (Hui Fa [2017] No. 3) to further expand the scope of settlement of domestic and overseas foreign exchange loans by allowing the settlement of domestic foreign exchange loans with a background of exporting goods for trading, the redeployment of the funds under the domestic guaranteed foreign loans to be used in the domestic market, and the settlement of domestic foreign exchange accounts of foreign institutions in the pilot free trade zones; and implementing the full-scale external loan management in local and foreign

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currencies, where a domestic institution handles overseas lending business, the total balance of overseas lending in local currency and the balance of overseas lending in foreign currency shall not exceed the maximum of 30% of the owner's equity in its audited financial statements of the previous year.

On 23 October 2019, the SAFE issued the Circular of the State Administration of Foreign Exchange on Further Promoting Cross-border Trade and Investment Facilitation (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》) (Hui Fa [2019] No. 28), pursuant to which, on the basis that the foreign invested enterprises with an investment nature (including foreign invested companies with an investment nature, foreign-invested venture capital enterprises and foreign-invested equity investment enterprises) may make equity investments in the PRC with capital fund in accordance with the law, foreign invested enterprises without an investment nature are allowed to make equity investments in the PRC with capital in accordance with the law on the premise of not violating the existing special administrative measures for access to foreign investment (the Negative List), and that the projects they invest in the PRC are genuine and in compliance with the law.

According to the Circular of the State Administration of Foreign Exchange on Optimising Foreign Exchange Management to Support the Development of Foreign-Related Businesses (《國家外匯管理局關於優化外匯管理支持涉外業務發展的通知》) (Hui Fa [2020] No. 8), effective on 10 April 2020, eligible enterprises are not required to provide proofs of truthfulness to the banks beforehand for each and every payment when they use the income from capital, foreign debts and overseas listings in the domestic market, provided that the use of the funds is genuine and regulation-abiding, and in compliance with the existing regulations on the use of income from capital items. The handling banks shall manage and control the relevant business risks in accordance with the principle of prudent business development and conduct retrospective random checks on the facilitation of capital item receipts and payments in accordance with the relevant requirements.

Pursuant to SAFE Notice on Further Deepening the Reform to Facilitate Cross-border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》), effective on 4 December 2023, for the purpose of facilitating the payment and use of funds from equity transfer under domestic reinvestment and funds raised from overseas listing of foreign direct investment, the asset realization account under the capital item shall be adjusted to the settlement account under the capital item. Where a domestic equity transferor (including institutions and individuals) receives funds from equity transfer consideration paid by a domestic entity in a foreign currency and foreign exchange funds raised from overseas listing of a domestic enterprise, such funds may be directly remitted to the settlement account under the capital account. Funds in the settlement account under the capital item may be settled and used on its own. The funds from equity transfer consideration paid by a foreign-invested enterprise with RMB funds from income from foreign exchange settlement (sourced from income from direct foreign exchange settlement or RMB funds in the foreign exchange settlement account pending for payment) received by a domestic equity transferor may be directly transferred to the RMB account of the domestic equity transferor.

APPENDIX IV SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

THE PRC LEGAL SYSTEM

The PRC legal system is based on the Constitution of the People’s Republic of China (《中華人民共和國憲法》, the “**Constitution**”), which was adopted on September 20, 1954 and subsequently amended on January 17, 1975, March 5, 1978, December 4, 1982, April 12, 1988, March 29, 1993, March 15, 1999, March 14, 2004 and March 11, 2018. The PRC legal system is made up of written laws, administrative regulations, local regulations, autonomous regulations, separate regulations, rules and regulations of State Council departments, rules and regulations of local governments, laws of special administrative regions and international treaties of which the PRC government is a signatory and other regulatory document. Court judgments do not constitute legally binding precedents, although they are used for the purposes of judicial reference and guidance.

The NPC and its Standing Committee are empowered to exercise the legislative power of the State in accordance with the Constitution and the Legislation Law of the People’s Republic of China (《中華人民共和國立法法》, the “**Legislation Law**”), which was adopted on March 15, 2000 and amended on March 15, 2015 and March 13, 2023. The NPC has the power to formulate and amend basic laws governing state authorities, civil, criminal 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 parts of the laws enacted by the NPC during the adjournment of the NPC, provided that such supplements and amendments are not in conflict with the basic principles of such laws.

The State Council is the highest organ of state administration and has the power to formulate administrative regulations based on the Constitution and laws.

The people’s congresses of the provinces, autonomous regions and municipalities and their respective standing committees may formulate local regulations based on the specific circumstances and actual needs of their respective administrative areas, provided that such local regulations do not contravene any provision of the Constitution, laws or administrative regulations. The people’s congresses of cities divided into districts and their respective standing committees may formulate local regulations on aspects such as urban and rural construction and management, environmental protection and historical cultural protection based on the specific circumstances and actual needs of such cities, provided that such local regulations do not contravene any provision of the Constitution, laws, administrative regulations and local regulations of their respective provinces or autonomous regions. If the law provides otherwise on the matters concerning formulation of local regulations by cities divided into districts, those provisions shall prevail. Such local regulations will become enforceable after being reported to and approved by the standing committees of the people’s congresses of the relevant provinces or autonomous regions 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 ethnic groups in the areas concerned.

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The ministries and commissions of the State Council, the People's Bank of China, National Audit Office and the subordinate institutions with administrative functions directly under the State Council may formulate departmental rules within the jurisdiction of their respective departments based on the laws and administrative regulations, and the decisions and orders of the State Council. Provisions of departmental rules should be the matters related to the enforcement of the laws and administrative regulations, and the decisions and orders of the State Council. The people's governments of the provinces, autonomous regions, municipalities and cities or autonomous prefectures divided into districts may formulate rules and regulations based on the laws, administrative regulations and local regulations of such provinces, autonomous regions and municipalities.

The Constitution has supreme legal authority and no laws, administrative regulations, local regulations, autonomous regulations or separate regulations or rules may contravene the Constitution. The authority of laws is greater than that of administrative regulations, local regulations and rules. The authority of administrative regulations is greater than that of local regulations and rules. The authority of the rules enacted by the people's governments of the provinces and autonomous regions is greater than that of the rules enacted by the people's governments of the cities divided into districts within their respective administrative regions.

The NPC has the authority to alter or annul any inappropriate laws enacted by the SCNPC, and to annul any autonomous regulations and separate regulations that have been approved by the SCNPC but contravene the Constitution and the Legislation Law; the SCNPC has the authority to annul administrative regulations that contravene the Constitution and laws, to annul local regulations that contravene the Constitution, laws and administrative regulations, and to annul autonomous regulations and separate regulations that 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 contravene the Constitution and the Legislation Law; the State Council has the authority to alter or annul any inappropriate ministerial rules and rules of local governments; the people's congresses of provinces, autonomous regions and municipalities directly under the Central Government have the authority to alter or annul any inappropriate local regulations enacted or approved by their respective standing committees; the standing committees of the local people's congresses have the authority to annul inappropriate rules enacted by the people's governments at the corresponding level; the people's governments of provinces and autonomous regions have the authority to alter or annul any inappropriate rules enacted by the people's governments at a lower level.

According to the Constitution and the Legislation Law, the power to interpret laws is vested in the SCNPC. Pursuant to the Resolution of the SCNPC Providing an Improved Interpretation of the Law (《全國人民代表大會常務委員會關於加強法律解釋工作的決議》) implemented on June 10, 1981, issues related to the application of laws and decrees in a court trial shall be interpreted by the Supreme People's Court; and issues related to the application of laws and decrees in a prosecution process of a procuratorate should be interpreted by the Supreme People's Procuratorate. If there is any disagreement in principle between Supreme People's Court's interpretations & Supreme People's Procuratorate's interpretations, such

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issues shall be reported to the SCNPC for interpretation or judgment. The other issues related to laws and decrees that do not pertain to the court trial or prosecution process should be interpreted by the State Council and the competent authorities. The State Council and its ministries and commissions are also vested with the power to give interpretations of the administrative regulations and departmental rules which they have promulgated. At the regional level, the power to interpret regional laws and administrative regulations is vested in the regional legislative and administrative authorities which promulgate such laws and administrative regulations.

THE PRC JUDICIAL SYSTEM

Under the Constitution and the Law of Organization of the People’s Courts of the People’s Republic of China (《中華人民共和國人民法院組織法》), which is adopted on September 21, 1954 and subsequently amended on July 5, 1979, September 2, 1983, December 2, 1986, October 31, 2006 and October 26, 2018, the people’s courts of the PRC are divided into 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 primary people’s courts may set up certain people’s tribunals based on the facts of the region, population and cases. The intermediate people’s courts and primary people’s courts have similar structures, and may set up other special divisions if needed. The Supreme People’s Court is the highest judicial authority in the PRC. The Supreme People’s Court shall supervise the administration of justice by the people’s courts at all levels and special people’s courts, and the people’s courts at a higher level shall supervise the administration of justice of the people’s courts at lower levels.

According to the Constitution and the Law of Organization of the People’s Procuratorate of the PRC (《中華人民共和國人民檢察院組織法》) which is adopted on July 1, 1979, and subsequently amended September 2, 1983, December 2, 1986, and October 26, 2018 and taking effect on January 1, 2019, the People’s Procuratorate is the law supervision organ of the state. The people’s procuratorates of the PRC are divided into the Supreme People’s Procuratorate, the local people’s procuratorates at all levels, Military Procuratorates and other special people’s procuratorates. The Supreme People’s Procuratorate shall be the highest procuratorial organ and it shall direct the work of the local people’s procuratorates at all levels and of the special people’s procuratorates; the people’s procuratorates at higher levels shall direct the work of those at lower levels.

Under the Civil Procedure Law of the People’s Republic of China (《中華人民共和國民事訴訟法》) (the “**PRC Civil Procedure Law**”, which is adopted on April 9, 1991 and subsequently amended on October 28, 2007, August 31, 2012, June 27, 2017, and September 1, 2023, which became effective from January 1, 2024), a people’s court takes the rule of the second instance as the final rule. A party may appeal against the judgment or ruling of the first instance of a local people’s court. The people’s procuratorate may present a protest to the people’s court at the next higher level in accordance with the procedures stipulated by the laws. In the absence of any appeal by the parties and any protest by the people’s procuratorate within

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the stipulated period, the judgments or rulings of the people's court are final. Judgments or rulings of the second instance of the intermediate people's courts, the higher people's courts and the Supreme People's Court, and judgments or rulings of the first instance of the Supreme People's Court are final. However, if the Supreme People's Court finds some definite errors in a legally effective judgment, ruling or conciliation statement of the people's court at any level, or if the people's court at a higher level finds such errors in a legally effective judgment, ruling or conciliation statement of the people's court at a lower level, it has the authority to review the case itself or to direct the lower-level people's court to conduct a retrial. If the chief judge of all levels of people's courts finds some definite errors in a legally effective judgment, ruling or conciliation statement, and considers a retrial is preferred, such case shall be submitted to the judicial committee of the people's court at the same level for discussion and decision.

The PRC Civil Procedure Law prescribes the conditions for instituting a civil action, the jurisdiction of the people's courts, the procedures for conducting a civil action, and the procedures for enforcement of a civil judgment or ruling. All parties to a civil action conducted within the PRC must abide by the PRC Civil Procedure Law. Generally, a civil case is initially heard by the court located in the defendant's place of domicile. The court of jurisdiction in respect of a civil action may also be chosen by explicit agreement among the parties to a contract, provided that the people's court having jurisdiction should be located at places substantially connected with the disputes, such as the plaintiff's or the defendant's place of domicile, the place where the contract is executed or signed or the place where the object of the action is located, provided that the provisions regarding the level of jurisdiction and exclusive jurisdiction shall not be violated.

A foreign individual, a person without nationality, a foreign enterprise or a foreign organization is typically given the same litigation rights and obligations as a citizen, a legal person or other organizations of the PRC when initiating actions or defending against litigations at a PRC court. Should a foreign court limit the litigation rights of PRC citizens or enterprises, the PRC court may apply the same limitations to the citizens and enterprises of such foreign country. A foreign individual, a person without nationality, a foreign enterprise or a foreign organization must engage a PRC lawyer in case he or it needs to engage a lawyer for the purpose of initiating actions or defending against litigations at a PRC court. In accordance with the international treaties to which the PRC is a signatory or participant or according to the principle of reciprocity, a people's court and a foreign court may request each other to serve documents, conduct investigation, collect evidence and conduct other actions on its behalf. A people's court shall not accommodate any request made by a foreign court which will result in the violation of sovereignty, security or public interests of the PRC. All parties to a civil action shall perform the legally effective judgments and rulings. If any party to a civil action refuses to abide by a judgment or ruling made by a people's court or an award made by an arbitration tribunal in the PRC, the other party may apply to the people's court for the enforcement of the same within two years subject to application for postponed enforcement or revocation. If a party fails to satisfy within the stipulated period a judgment which the court has granted an enforcement approval, the court may, upon the application of the other party, mandatorily enforce the judgment on the party.

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THE PRC SECURITIES LAWS AND REGULATIONS

The PRC has promulgated a series of regulations relating 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 offering 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 merged and restructured the two departments into the CSRC.

On April 22, 1993, the State Council promulgated 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》), governing the 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 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 principally govern the issue, subscription, trading and declaration of dividends and other distributions of domestic listed foreign shares and disclosure of information of joint stock limited companies having domestic listed foreign shares.

The Securities Law of the People’s Republic of China (《中華人民共和國證券法》), the “**PRC Securities Law**”, which took effect on July 1, 1999, was revised on August 28, 2004, October 27, 2005, June 29, 2013, August 31, 2014 and December 28, 2019, respectively, and came into effect on March 1, 2020) is divided into 14 chapters and 226 articles, regulating, among other things, the issue and trading of securities, the listing of securities, takeovers of listed companies, and the duties and responsibilities of the securities exchanges, securities companies, securities clearing institutions and securities regulatory authorities.

Article 224 of the PRC Securities Law provides that domestic enterprises which, directly or indirectly, issue securities or list and trade their securities outside the PRC shall comply with the relevant regulations of the State Council. Currently, the issue and trading of foreign issued securities (including H shares) are principally governed by the regulations and rules promulgated by the State Council and the CSRC.

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On November 14, 2019, the CSRC promulgated the Guidance for the Application for the “Full Circulation” of the Domestic Unlisted Shares of H-share Companies (《H股公司境內未上市股份申請“全流通”業務指引》), which came into effect on the same day and was partly revised on August 10, 2023 according to the Decision on Revising and Abolishing Part of Securities and Futures Policy Documents by the CSRC (《中國證券監督管理委員會關於修改、廢止部分證券期貨制度文件的決定》). This guidance is to regulate the listing and circulation (hereinafter referred to as “**Full Circulation**”) of unlisted domestic shares of domestic joint-stock limited companies (hereinafter referred to as H-share Companies) listed on the Stock Exchange (including unlisted domestic shares held by domestic shareholders before overseas listing, unlisted domestic shares issued in China after overseas listing and unlisted shares held by foreign shareholders).

H-share Companies applying for “Full Circulation” shall submit the application to the CSRC for filing procedures. H-share companies may submit the application for “Full Circulation” separately or simultaneously when applying for overseas refinancing. Unlisted domestic joint stock limited companies may submit the application for “Full Circulation” simultaneously when applying for overseas initial public offering and listing.

ARBITRATION AND ENFORCEMENT OF ARBITRAL AWARD

The Arbitration Law of the People’s Republic of China (《中華人民共和國仲裁法》) (the “**PRC Arbitration Law**”) was enacted by the SCNPC on August 31, 1994, which became effective on September 1, 1995 and was amended on August 27, 2009 and September 1, 2017, respectively. It is applicable to, among other matters, economic disputes involving foreign parties where all parties have entered into a written agreement to resolve disputes by arbitration before an arbitration committee constituted in accordance with the PRC Arbitration Law. The PRC Arbitration Law provides that an arbitration committee may, before the promulgation of arbitration regulations by the PRC Arbitration Association, formulate interim arbitration rules in accordance with the PRC Arbitration Law and the PRC Civil Procedure Law. Where the parties have agreed to settle disputes by means of arbitration, a people’s court will refuse to handle a legal proceeding initiated by one of the parties at such people’s court, unless the arbitration agreement is invalid.

Under the PRC Arbitration Law and the PRC Civil Procedure Law, an arbitral award shall be final and binding on the parties involved in the arbitration. If any party fails to comply with the arbitral award, the other party to the award may apply to a people’s court for its enforcement. The people’s court can issue a ruling prohibiting the enforcement of an arbitral award made by an arbitration commission after verification by collegial bench formed by the people’s court if there is any procedural irregularity (including but not limited to irregularity in the composition of the arbitration tribunal or arbitration proceedings, the jurisdiction of the arbitration commission, or the making of an award on matters beyond the scope of the arbitration agreement).

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Any party seeking to enforce an award of a foreign affairs arbitral body of the PRC against a party who or whose property is not located within the PRC shall apply to a foreign court with jurisdiction over the case for recognition and enforcement of the award. Likewise, an arbitral award made by a foreign arbitral body may be recognized and enforced by a PRC court in accordance with the principle of reciprocity or any international treaties concluded or acceded to by the PRC.

The PRC acceded to the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (《承認及執行外國仲裁裁決公約》), the “**New York Convention**”) adopted on June 10, 1958 pursuant to a resolution passed by the SCNPC on December 2, 1986. The New York Convention provides that all arbitral awards made in a state which is a party to the New York Convention shall be recognized and enforced by other parties thereto subject to their rights to refuse recognition and enforcement under certain circumstances, including where the recognition or enforcement of the arbitral award is against the public policy of that state. At the time of the PRC’s accession to the Convention, the SCNPC declared that (i) the PRC will only apply the Convention to the recognition and enforcement of arbitral awards made in the territories of other parties based on the principle of reciprocity; and (ii) the New York Convention will only be applied to disputes deemed under PRC laws to be arising from contractual or non-contractual mercantile legal relations.

An arrangement for mutual enforcement of arbitral awards between Hong Kong and the Supreme People’s Court of China was reached. The Supreme People’s Court of China adopted the Arrangements on the Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region (《關於內地與香港特別行政區相互執行仲裁裁決的安排》) on June 18, 1999, which took effect on February 1, 2000. The arrangement reflects the spirit of the New York Convention. Under the arrangement, the awards by the Mainland arbitral bodies in accordance with the PRC Arbitration Law may be enforced in Hong Kong, and the awards by the Hong Kong arbitral bodies according to the Arbitration Ordinance of Hong Kong SAR may also be enforced in the Mainland China. If the Mainland court finds that the enforcement of awards made by the Hong Kong arbitral bodies in the Mainland will be against public interests of the Mainland, or the court of Hong Kong SAR decides that the enforcement of the arbitral awards in Hong Kong SAR will be against public policies of Hong Kong SAR, the awards may not be enforced. The Supreme People’s Court of China adopted the Supplementary Arrangements on the Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region (《最高人民法院關於內地與香港特別行政區相互執行仲裁裁決的補充安排》) (the “**Supplementary Arrangements**”) on November 26, 2020. According to the Supplementary Arrangements, before or after the acceptance of an application for enforcement of an arbitration award, the relevant court may, upon application and in accordance with the law of the place where the arbitration award is enforced, adopt preservation or enforcement measures.

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JUDICIAL JUDGMENT AND ITS ENFORCEMENT

According to the Arrangement on Mutual Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland China and of the Hong Kong Special Administrative Region Pursuant to Agreed Jurisdiction by Parties Concerned (《最高人民法院關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “**Arrangement**”) promulgated by the Supreme People’s Court on July 3, 2008 and implemented on August 1, 2008, in the case of final judgment, defined with payment amount and enforcement power, made between the court of Mainland China and the court of the Hong Kong Special Administrative Region in a civil and commercial case with written jurisdiction agreement, any party concerned may apply to the People’s Court of China or the court of the Hong Kong Special Administrative Region for recognition and enforcement based on this arrangement. “Written jurisdiction agreement” refers to a written agreement defining the exclusive jurisdiction of either the People’s Court of China or the court of the Hong Kong Special Administrative Region in order to resolve any dispute with particular legal relation occurred or likely to occur by the party concerned. Therefore, the party concerned may apply to the People’s Court of China or the court of the Hong Kong Special Administrative Region to recognize and enforce the final judgment made in China or Hong Kong that meets certain conditions of the aforementioned regulations. On 18 January 2019, a further arrangement was reached between Hong Kong Special Administrative Region and the Supreme People’s Court, Arrangements for Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Cases between Courts of the Mainland and Hong Kong Special Administrative Region (《最高人民法院關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “**New Arrangement**”), which became effective and replace the Arrangement on 29 January 2024, privileged that “Written Agreement on Jurisdiction” reached under the Arrangement before 29 January 2024 will still apply. This New Arrangement further stipulates the scope and content of judgments applicable to the reciprocal recognition and enforcement and corresponding procedures and methods for applying, the circumstances concerning review, non-recognition and enforcement upon the jurisdiction of the court of first instance and the means of remedy. Non-monetary judgments and judgments on some intellectual property cases are included in the reciprocal recognition and enforcement of judgments in accordance with this New Arrangement.

THE PRC COMPANY LAW, THE TRIAL MEASURES AND THE GUIDELINES

The Company Law of the People’s Republic of China (《中華人民共和國公司法》) (the “**PRC Company Law**”) was adopted by the SCNPC on December 29, 1993 and came into effect on July 1, 1994, subsequently amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013, October 26, 2018, and December 29, 2023, and took effect on July 1, 2024.

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The Trial Administrative Measures for 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》) (the “**Trial Measures**”) which were promulgated by the CSRC on February 17, 2023 and came into effect on March 31, 2023, are applicable to the overseas offering and listing of PRC domestic companies’ securities.

The Guidelines for Articles of Association of Listed Companies (《上市公司章程指引》) 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, provide 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 PRC Company Law, the Trial Measures and the Guidelines applicable to the Company.

GENERAL

A joint stock limited company refers to an enterprise legal person incorporated in China under the PRC Company Law with independent legal person properties and entitlements to such legal person properties and with its registered capital divided into shares of equal par value. The liability of the company for its own debts is limited to all the properties it owns and the liability of its shareholders for the company is limited to the extent of the shares they subscribe for.

A joint stock limited company must conduct its business in accordance with laws and administrative regulations. A joint stock limited company may invest in other limited liability companies and joint stock limited companies. The liabilities of the joint stock limited company to such invested companies are limited to the amount invested.

INCORPORATION

A joint stock limited company may be established by promotion or subscription. A joint stock limited company shall have a minimum of one but no more than 200 people as its promoters, and over half of the promoters must be resident within the PRC. The registered capital of a joint stock limited company is the total share capital of the issued shares as registered with the company’s registration authorities. No share offering shall be made to others before the shares subscribed for by the promoters are fully paid up.

For companies incorporated by way of promotion, the promoters shall fully subscribe for the shares that shall be issued at the time of the incorporation of the company as provided under the articles of association. For companies incorporated by way of subscription, the promoters shall subscribe for no less than 35% of the shares that shall be issued at the time of the incorporation of the company as provided under the articles of association; provided that, if laws and administrative regulations provide otherwise, such provisions shall prevail. Promoters shall make full payment for the shares they have subscribed for prior to the incorporation of the company.

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After the subscription monies for subscription of the public offering shares have been paid in full, a capital verification institution established under PRC laws must be engaged to conduct a capital verification and furnish a certificate thereof. The promoters of the joint stock limited company incorporated by way of subscription shall preside over and convene an inauguration meeting within 30 days from the date of the full payment of subscription monies of the shares that shall be issued at the time of the incorporation of the company. For the joint stock limited company incorporated by way of promotion, the convening and voting procedures of its inauguration meeting shall be stipulated by the articles of association or the promoters' agreement. Where the shares that shall be issued at the time of the incorporation of the company remain undersubscribed by the cut-off date stipulated in the share offering document, or where the promoter fails to convene an inauguration meeting within 30 days of the subscription monies for the shares issued being fully paid up, the subscribers may demand that the promoters refund the subscription monies so paid together with the interest at bank rates of a deposit for the same period. Within 30 days of the conclusion of the inauguration meeting, the board of directors shall authorize a representative to apply to the company registration authority for registration of the establishment of the company. A company is formally established and has the capacity of a legal person after the relevant company registration authority has approved the registration and issued a business license.

SHARE CAPITAL

The promoters or shareholder of a company may make a capital contribution in currencies, or non-monetary assets such as in kind, intellectual property rights, land use rights, equity interests and creditor's 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 and verification of the fair value of the assets contributed must be carried out.

The issuance of shares shall be conducted in a fair and equitable manner. The same class of shares must carry equal rights. For shares issued at the same time and within the same class, the conditions and price per share must be the same. The same price shall be paid for each share subscribed for by the subscribers. The share offering price of the par value share may be equal to or greater than the nominal value of the share but may not be lower than the nominal value.

A PRC domestic company must file with the CSRC before offering its shares to the overseas public. According to the Trial Measures, target investors of overseas offering and listing by domestic companies shall be overseas investors, unless prescribed in the Trial Measures or otherwise stipulated by the state.

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INCREASE IN SHARE CAPITAL

Under the PRC Company Law, where a company is issuing new shares, resolutions shall be passed at shareholder's meeting in accordance with the articles of association in respect of the class and amount of the new shares, the issue price of the new shares, the commencement and end dates for the issue of the new shares and the class and amount of the new shares proposed to be issued to existing shareholders.

Where an increase in registered capital of a company is made by means of an issue of new shares, the subscription of new shares by shareholders shall be made in accordance with the relevant provisions on the payment of subscription monies for the incorporation of a company.

Where a company intends to make public offering of shares, it shall go through the registration with the securities regulatory authority of the State Council and announce the prospectus. After the subscription monies that a company making offering of shares has been paid up, a public announcement shall be made accordingly.

REDUCTION OF SHARE CAPITAL

When a company reduces its registered capital, it shall prepare a statement of financial position and a property list. The company shall inform its creditors within 10 days, from the date of resolution on reduction in registered capital, and publish an announcement in newspapers or on the national enterprise credit information publicity system within 30 days after the resolution approving the reduction of registered capital has been passed. Creditors may 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 guarantees covering the debts. The company shall apply to the relevant company registration authority for the registration of the reduction in registered capital.

REPURCHASE OF SHARES

A company shall not purchase its own shares except under any of the following circumstances:

- (1) reducing the registered capital of the company;
- (2) merging with another company that holds its shares;
- (3) using shares for employee stock ownership plan or equity incentives;
- (4) acquiring its shares at the request of its shareholder who objects to a resolution of the shareholders' meeting on the merger or division of the company;
- (5) using shares for converting convertible corporate bonds issued by the company;
- (6) where it is necessary for a listed company to protect the corporate value and the rights and interests of shareholders.

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A company purchasing its own shares under any of the circumstances set forth in items (1) and (2) of the preceding paragraph shall be subject to a resolution of the shareholders' meeting; and a company purchasing its own shares under any of the circumstances set forth in items (3), (5) and (6) of the preceding paragraph may, pursuant to the articles of association or the authorization of the shareholders' meeting, be subject to a resolution of a meeting of the board of directors at which more than two-thirds of directors are present.

After purchasing its own shares pursuant to the above, a company shall, under the circumstance set forth in item (1), cancel them within 10 days after the purchase; while under the circumstance set forth in either item (2) or (4), transfer or cancel them within six months; and while under the circumstance set forth in item (3), (5) or (6), aggregately hold not more than 10% of the total shares that have been issued by the company, and transfer or cancel them within three years.

A listed company purchasing its own shares shall perform the obligation of information disclosure according to the provisions of the PRC Securities Law. A listed company purchasing its own shares under any of the circumstances set forth in items (3), (5) and (6) shall carry out trading in a public and centralized manner.

No company may accept the shares of its own as the subject matter of a pledge.

TRANSFER OF SHARES

Shares held by shareholders may be transferred legally. Under the PRC Company Law, a shareholder should effect a transfer of his shares on a stock exchange established in accordance with laws or by any other means as required by the State Council. Shares may be transferred by endorsement of the shareholders or in any other manner specified by the laws or administrative regulations. Following the transfer, the company shall enter the names and domiciles of the transferees into its register of shareholders. No changes shall be made to the register of shareholders during a period of 20 days prior to convening a shareholders' meeting or five days prior to the record date for the purpose of determining entitlements to dividend distributions, however, if laws, administrative regulations, or the securities regulatory authority of the State Council has different provisions on the changes in the register of shareholders of listed companies, those provisions shall prevail.

Under the PRC Company Law, shares of the company issued prior to the public issuance of shares may not be transferred within one year of the date on which the shares of a company are listed and traded on a stock exchange. Where it is otherwise provided for by laws, administrative regulations or the securities regulatory authority of the State Council on the transfer of shares held by the shareholders or actual controllers of a listed company, such provisions shall prevail. Directors, supervisors and the senior management of a company shall declare to the company their shareholdings in the company and any changes in such shareholdings. During their terms of office as determined when they assume the posts, they may transfer no more than 25% of the total number of shares they hold in the company every year. They shall not transfer the shares they hold within one year of the date of the company's listing on a stock exchange, nor within six months after they leave their positions in the company. The articles of association may set out other restrictive provisions in respect of the transfer of shares in the company held by its directors, supervisors and the senior management.

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SHAREHOLDERS

Under the PRC Company Law and the Guidelines, the rights of shareholders of a joint stock limited company include the rights:

- (1) to receive dividends and profit distributions in any other form in proportion to their shareholdings;
- (2) to lawfully require, convene, preside over or attend shareholders' meetings either in person or by proxy and exercise the corresponding voting right;
- (3) to supervise, present suggestions on or make inquiries about the operations of the Company;
- (4) to transfer, gift or pledge their shares in accordance with the laws, administrative regulations, and the articles of association;
- (5) to acquire relevant information, including the duplicate of the articles of association, register of shareholders, minutes of shareholders' meetings, resolutions of the meeting of the board of directors, resolutions of the supervisory board, financial and accounting statements of the company, and to bring forward suggestions or raise inquiries about the business operation of the company;
- (6) in the event of the termination or liquidation of the company, to participate in the distribution of the remaining property of the company in proportion to the shares held by them;
- (7) to require the company to buy their shares in the event of their objection to resolutions of the shareholders' meeting concerning merger or division of the company; and
- (8) any other shareholders' rights provided in laws, administrative regulations, other regulatory documents and the articles of association.

The obligations of shareholders include the obligation to abide by the articles of association, to pay the subscription monies according to the number of shares subscribed for and the method of subscription, to be liable for the company to the extent of the amount of his or her subscribed shares and any other shareholder obligation specified in the articles of association.

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SHAREHOLDERS' MEETINGS

The shareholders' meeting is the organ of authority of the company, which exercises its powers in accordance with the PRC Company Law. The shareholders' meeting may exercise the following powers:

- (1) to elect and remove the directors and supervisors and to decide on the matters relating to the remuneration of directors and supervisors;
- (2) to review and approve the reports of the board of directors;
- (3) to review and approve the reports of the supervisory board;
- (4) to review and approve the company's profit distribution proposals and loss recovery proposals;
- (5) to decide on any increase or reduction of the company's registered capital;
- (6) to decide on the issue of corporate bonds;
- (7) to decide on merger, division, dissolution and liquidation of the company or change of its corporate form;
- (8) to amend the articles of association; and
- (9) to exercise other authorities stipulated in the articles of association.

A shareholders' meeting is required to be held once every year. An extraordinary meeting is required to be held within two months of the occurrence of any of the following:

- (1) the number of directors is less than the number stipulated by the PRC Company Law or less than two-thirds of the number specified in the articles of association;
- (2) the outstanding losses of the company amounted to one-third of the company's total share capital;
- (3) shareholders individually or in aggregate holding 10% or more of the company's shares request the convening of an extraordinary meeting;
- (4) the board of directors deems necessary;
- (5) the supervisory board proposes to hold; or
- (6) any other circumstances as provided for in the articles of association.

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A shareholders' meeting shall be convened by the board of directors and presided over by the chairperson of the board of directors. In the event that the chairperson is incapable of performing or is not performing his duties, the meeting shall be presided over by the vice chairperson. In the event that the vice chairperson is incapable of performing or is not performing his duties, a director nominated by half or more of the directors shall preside over the meeting. Where the board of directors is incapable of performing or is not performing its duties to convene the shareholders' meeting, the supervisory board shall convene and preside over shareholders' meeting in a timely manner. If the supervisory board fails to convene and preside over shareholders' meeting, shareholders individually or in aggregate holding 10% or more of the company's shares for 90 days or more consecutively may unilaterally convene and preside over shareholders' meeting.

In accordance with the PRC Company Law, a notice of the shareholders' meeting stating the date and venue of the meeting and the matters to be considered at the meeting shall be given to all shareholders 20 days before the meeting. A notice of extraordinary meeting shall be given to all shareholders 15 days prior to the meeting.

Under the PRC Company Law, shareholders present at a shareholders' meeting have one vote for each share they hold, save that the company's shares held by the company are not entitled to any voting rights.

An accumulative voting system may be adopted for the election of directors and supervisors at the shareholders' meeting pursuant to the provisions of the articles of association or a resolution of the shareholders' meeting. Under the accumulative voting system, each share shall be entitled to the number of votes equivalent to the number of directors or supervisors to be elected at the shareholders' meeting, and shareholders may consolidate their votes for one or more directors or supervisors when casting a vote.

Under the PRC Company Law, resolutions of the shareholders' meeting must be passed by more than half of the voting rights held by shareholders present at the meeting, with the exception of matters relating to merger, division or dissolution of the company, increase or reduction of registered share capital, change of corporate form or amendments to the articles of association, which in each case must be passed by at least two-thirds of the voting rights held by the shareholders present at the meeting.

Minutes shall be prepared in respect of matters considered at the shareholders' meeting and the chairperson and directors attending the meeting shall endorse such minutes by signature. The minutes shall be kept together with the shareholders' attendance register and the proxy forms.

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BOARD OF DIRECTORS

A company shall have a board, which shall consist of no less than 3 members. The term of a director shall be stipulated in the articles of association, provided that no term of office shall last for more than three years. After the term of a director expires, the director may serve consecutive terms if re-elected. A director shall continue to perform his/her duties as a director in accordance with the laws, administrative regulations and the articles of association until a duly newly-elected director takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of directors results in the number of directors being less than the quorum.

Under the PRC Company Law, the board of directors may exercise the following powers:

- (1) to convene shareholders' meetings and report on its work to the shareholders' meetings;
- (2) to implement the resolutions passed by the shareholders at the shareholders' meetings;
- (3) to decide on the company's operational plans and investment proposals;
- (4) to formulate the company's profit distribution proposals and loss recovery proposals;
- (5) to formulate proposals for the increase or reduction of the company's registered capital and the issue of corporate bonds;
- (6) to formulate proposals for the merger, division or dissolution of the company or change of corporate form;
- (7) to decide on the setup of the company's internal management organs;
- (8) to appoint or dismiss the company's manager and decide on his/her remuneration and, based on the manager's recommendation, to appoint or dismiss any deputy general manager and financial officer of the company and to decide on their remunerations;
- (9) to formulate the company's basic management system; and
- (10) to exercise any other authority stipulated in the articles of association or granted by the shareholders' meeting.

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According to the PRC Company Law, meetings of the board of directors shall be convened at least twice each year. Notices of meeting shall be given to all directors and supervisors 10 days before the meeting. Interim board meetings may be proposed to be convened by shareholders representing more than 10% of the voting rights, more than one-third of the directors or the supervisory board. The chairperson shall convene the meeting within 10 days of receiving such proposal, and preside over the meeting. The board may otherwise determine the means and the period of notice for convening an interim board meeting. Meetings of the board of directors shall be held only if more than half of the directors are present. Resolutions of the board shall be passed by more than half of all directors. Each director shall have one vote for a resolution to be approved by the board. Directors shall attend board meetings in person. If a director is unable to attend for any reason, he/she may appoint another director to attend the meeting on his/her behalf by a written power of attorney specifying the scope of authorization.

If a resolution of the board of directors violates the laws, administrative regulations or the articles of association or resolutions of the shareholders' meeting, and as a result of which the company sustains serious losses, the directors participating in the resolution are liable to compensate the company. However, if it can be proved that a director expressly objected to the resolution when the resolution was voted on, and that such objection was recorded in the minutes of the meeting, such director shall be relieved from that liability.

Under the PRC Company Law, the following person may not serve as a director in a company: (i) a person who is unable or has limited ability to undertake any civil liabilities; (ii) a person who has been convicted of an offense of corruption, bribery, embezzlement, misappropriation of property or destruction of the socialist market economic order, or who has been deprived of his political rights due to his crimes, in each case where less than five years have elapsed since the date of completion of the sentence, or the person who has been sentenced to a probation, due to his crimes, where less than two years have elapsed since the date of expiration of the probation term; (iii) 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; (iv) a person who has been a legal representative of a company or an enterprise that has had its business license revoked due to violations of the law or has been ordered to close down by law and the person was personally responsible, where less than three years have elapsed since the date of such revocation; (v) a person who has been listed as a dishonest defaulter by a people's court due to failure to repay a relatively large amount of overdue debts.

Where a company elects or appoints a director to which any of the above circumstances applies, such election or appointment shall be null and void. A director to which any of the above circumstances occurs during his/her term of office shall be released of his/her duties by the company.

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Under the PRC Company Law, the board shall appoint a chairperson and may appoint a vice chairperson.

The chairperson and the vice chairperson shall be elected with approval of more than half of all the directors. The chairperson shall convene and preside over board meetings and review the implementation of board resolutions. The vice chairperson shall assist the chairperson to perform his/her duties. Where the chairperson is incapable of performing or is not performing his/her duties, the duties shall be performed by the vice chairperson. Where the vice chairperson is incapable of performing or is not performing his/her duties, a director nominated by more than half of the directors shall perform his/her duties.

SUPERVISORY BOARD

A joint stock limited company shall have a supervisory board composed of not less than three members; provided that, a joint stock limited company with a relatively small scale or relatively few shareholders may opt not to set up a supervisory board and instead set up a single supervisor to exercise the powers as stipulated by the PRC Company Law for the supervisory board; a joint stock limited company that has established an audit committee composed of directors in accordance with the provisions of its articles of association may delegate the powers of the supervisory board as stipulated by the PRC Company Law to the audit committee, and may not establish a supervisory board or a supervisor.

The supervisory board shall consist of shareholders' representatives and an appropriate proportion of the company's staff representatives, of which the proportion of staff representatives shall not be less than one-third, and the specific proportion shall be determined in the articles of association. Staff Representatives at the supervisory board shall be democratically elected by the company's staff at the staff representative assembly, general staff meeting or otherwise. Directors and senior management shall not concurrently serve as supervisors.

Each term of office of a supervisor is three years and he/she may serve consecutive terms if re-elected. A supervisor shall continue to perform his/her duties as a supervisor in accordance with the laws, administrative regulations and the articles of association until a duly newly-elected supervisor takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of the supervisor results in the number of supervisors being less than the quorum.

The supervisory board may exercise the following powers:

- (1) to review the company's financial position;
- (2) to supervise the directors and senior management in their performance of their duties and to propose the removal of directors and senior management who have violated laws, administrative regulations, the articles of association or resolutions of the shareholders' meetings;

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- (3) when the acts of a director or senior management personnel are detrimental to the company's interests, to require the director and senior management to correct these acts;
- (4) to propose the convening of extraordinary shareholders' meetings and to convene and preside over shareholders' meetings when the board fails to perform the duty of convening and presiding over shareholders' meetings under the PRC Company Law;
- (5) to submit proposals to the shareholders' meetings;
- (6) to bring actions against directors and senior management personnel pursuant to the relevant provisions of the PRC Company Law; and
- (7) to exercise any other authority stipulated in the articles of association.

Supervisors may be present at board meetings and make inquiries or proposals in respect of the resolutions of the board. The supervisory board may investigate any irregularities identified in the operation of the company and, when necessary, may engage an accounting firm to assist its work at the cost of the company.

The supervisory board shall appoint a chairperson and may appoint a vice chairperson. The chairperson and the vice chairperson of the supervisory board shall be elected by more than half of the supervisors. The chairperson of the supervisory board shall convene and preside over supervisory board meetings. Where the chairperson of the supervisory board is incapable of performing or is not performing his/her duties, the vice chairperson of the supervisory board shall convene and preside over supervisory board meetings. Where the vice chairperson of the supervisory board is incapable of performing or is not performing his/her duties, a supervisor recommended by more than half of the supervisors shall convene and preside over supervisory board meetings.

MANAGER AND SENIOR MANAGEMENT

Under the PRC Company Law, a joint stock limited company shall have a manager who shall be appointed or removed by the board of directors. The manager shall be responsible to the board of directors, and exercise his/her powers according to the articles of association or the authorization of the board of directors. The manager shall be present at meetings of the board of directors.

Under the PRC Company Law, senior management refers to the manager, deputy manager(s), financial officer, secretary of the board of directors of a listed company and other personnel as stipulated in the articles of association.

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DUTIES OF DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Under the PRC Company Law, directors, supervisors and senior management are required to comply with the relevant laws, administrative regulations and the articles of association, and owe the duties of loyalty and diligence towards the company.

Directors and senior management are prohibited from:

- (1) embezzling company properties and misappropriating company funds;
- (2) depositing company funds into accounts under their own names or the names of other individuals;
- (3) giving bribes or accepting any other illegal proceeds by taking advantage of his/her powers;
- (4) accepting commissions paid by a third-party for transactions conducted with the company to oneself;
- (5) unauthorized divulgence of confidential information of the company; and
- (6) other acts in violation of their duty of loyalty to the company.

Where any director, supervisor or senior management directly or indirectly enters into a contract or conducts a transaction with the company, he/she shall report the matters relating to the contract or transaction to the board of directors or shareholders' meeting, which shall be subject to the resolution of the board of directors or shareholders' meeting according to the articles of association. Where any of the close relatives of the directors, supervisors or senior management, or any of the enterprises directly or indirectly controlled by the directors, supervisors or senior management or any of their close relatives, or any of the related parties who has any other related relationship with the directors, supervisors or senior management, enters into a contract or conducts a transaction with the company, the aforementioned provision shall apply.

No director, supervisor or senior management may take advantage of his/her position to seek any business opportunity that belongs to the company for himself/herself or any other person except under any of the following circumstances:

- (1) where he/she has reported to the board of directors or the shareholders' meeting and has been approved by a resolution of the board of directors or the shareholders' meeting according to the articles of association; or
- (2) where the company cannot make use of the business opportunity as stipulated by laws, administrative regulations or the articles of association.

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Without reporting to the board of directors or the shareholders' meeting and obtaining an approval by resolution of the board of directors or the shareholders' meeting according to the articles of association, no director, supervisor or senior management may engage in any business that is similar to that of the company where he/she holds office, for himself/herself or for any other person.

Income generated by directors or senior management in violation of aforementioned paragraphs shall be returned to the company.

A director, supervisor or senior management who contravenes law, administrative regulation or articles of association in the performance of his/her duties resulting in any loss to the company shall be liable to the company for compensation.

Where a director, supervisor or senior management is required to attend a shareholders' meeting, such director, supervisor or senior management shall attend the meeting and answer the inquiries from shareholders. The supervisory board may require directors and senior management to submit reports on the performance of their duties. Directors and senior management shall furnish all true information and data to the supervisory board, without impeding the discharge of duties by the supervisory board or supervisors.

Where a director or senior management contravenes law, administrative regulation or articles of association in the performance of his/her duties resulting in any loss to the company, shareholder(s) holding individually or in aggregate no less than 1% of the company's shares consecutively for at least 180 days may request in writing that the supervisory board institute litigation at a people's court on its behalf. Where the supervisor violates the laws or administrative regulations or the articles of association in the discharge of its duties resulting in any loss to the company, such shareholder(s) may request in writing that the board of directors institute litigation at a people's court on its behalf. If the supervisory board or the board of directors refuses to institute litigation after receiving this written request from the shareholder(s), or fails to institute litigation within 30 days of the date of receiving the request, or in case of emergency where failure to institute litigation immediately will result in irrecoverable damage to the company's interests, such shareholder(s) shall have the power to institute litigation directly at a people's court in its own name for the company's benefit. For other parties who infringe the lawful interests of the company resulting in loss to the company, such shareholder(s) may institute litigation at a people's court in accordance with the procedure described above. Where a director or senior management contravenes any laws, administrative regulations or the articles of association in infringement of shareholders' interests, a shareholder may also institute litigation at a people's court.

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FINANCE AND ACCOUNTING

A company shall establish its own financial and accounting systems according to the laws, administrative regulations and the regulations of the competent financial departments of the State Council. At the end of each financial year, a company shall prepare a financial report which shall be audited by an accounting firm in accordance with the laws. The financial and accounting reports shall be prepared in accordance with the laws, administrative regulations and the regulations of the financial departments of the State Council.

The company's financial reports shall be made available for shareholders' inspection at the company 20 days before the convening of an annual shareholders' meeting. A joint stock limited company that makes public stock offerings shall publish its financial reports.

When distributing each year's profits after taxation, the company shall set aside 10% of its profits after taxation for the company's statutory common reserve fund until the fund has reached 50% or more of the company's registered capital. When the company's statutory common reserve fund is not sufficient to make up for the company's losses for the previous years, the current year's profits shall first be used to make up for the losses before any allocation is set aside for the statutory common reserve fund. After the company has made allocations to the statutory common reserve fund from its profits after taxation, it may, upon passing a resolution at a shareholders' meeting, make further allocations from its profits after taxation to the discretionary common reserve fund. After making up for its losses and making allocations to its discretionary common reserve fund, the joint stock limited company shall distribute the remaining profits after taxation in proportion to the number of shares held by the shareholders, unless otherwise provided by the articles of association.

Profits distributed to shareholders by the company in violation of the provisions of the PRC Company Law must be returned to the company; if losses are incurred to the company, shareholders and responsible directors, supervisors and senior management shall be liable for compensation. The company shall not be entitled to any distribution of profits in respect of shares held by it.

The premium over the nominal value of the shares of the company earned from the issue of share, the amount of proceeds from the issue of no-par value shares that is not calculated in the registered capital, and other income as required by CSRC to be treated as the capital reserve fund shall be accounted for as the capital reserve fund. The common reserve fund of a company shall be applied to make up for the company's losses, expand its business operations or increase its capital. Where the common reserve fund of a company is applied to make up for the company's losses, the discretionary common reserve fund and statutory common reserve fund shall be firstly applied; and if losses still cannot be made up, the capital reserve can be used in accordance with the relevant provisions. Upon the transfer of the statutory common reserve fund into capital, the balance of the fund shall not be less than 25% of the registered capital of the company before such transfer.

The company shall have no accounting books other than the statutory books. The company's assets shall not be deposited in any account opened under the name of an individual.

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APPOINTMENT AND RETIREMENT OF AUDITORS

Pursuant to the PRC Company Law, the engagement or dismissal of an accounting firm responsible for the company's auditing shall be determined by the shareholders' meeting, the board of directors, or the supervisory board in accordance with the articles of association. The accounting firm should be allowed to make statements when the shareholders' meeting, the board of directors, or the supervisory board conduct a vote on the dismissal of the accounting firm. The company should provide true and complete accounting evidence, accounting books, financial and accounting reports and other accounting information to the engaged accounting firm without any refusal, withholding or falsification of information.

PROFIT DISTRIBUTION

Under the PRC Company Law, a company shall not distribute profits before losses are covered and the statutory common reserve fund is provided.

AMENDMENTS TO THE ARTICLES OF ASSOCIATION

Under the PRC Company Law, the resolution of a shareholders' meeting regarding any amendment to a company's articles of association requires affirmative votes by at least two-thirds of the votes held by shareholders attending the meeting.

DISSOLUTION AND LIQUIDATION

Under the PRC Company Law, a company shall be dissolved for any of the following reasons:

- (1) the term of its operation set out in the articles of association has expired or other events of dissolution specified in the articles of association have occurred;
- (2) the shareholders' meeting has resolved to dissolve the company;
- (3) the company is dissolved by reason of its merger or division;
- (4) the business license of the company is suspended or the company is ordered to close down or to be revoked in accordance with the laws;
- (5) the company is dissolved by a people's court in response to the request of shareholders holding shares that represent more than 10% of the voting rights of all shareholders of the company, on the grounds that the operation and management of the company has encountered serious difficulties that cannot be resolved through other means, rendering ongoing existence of the company a cause for significant losses to the shareholders.

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In the event of paragraph (1) or (2) above, the company may carry on its existence by amending its articles of association or upon a resolution of the shareholders' meeting under the condition that the company has not distributed the assets to its shareholders. The amendments to the articles of association in accordance with the provisions described above shall require the approval of more than two-thirds of voting rights of shareholders attending a shareholders' meeting.

Where the company is dissolved under the circumstances set forth in paragraph (1), (2), (4), or (5) above, it should establish a liquidation committee within 15 days of the date on which the dissolution matter occurs. The liquidation committee shall be composed of directors or any other person determined by a shareholders' meeting or as stipulated in the articles of association. If a liquidation committee fails to be established within the prescribed period or fails to carry out the liquidation after its establishment, interested parties may file an application with a people's court to appoint relevant personnel to form a liquidation committee to administer the liquidation. The people's court should accept such application and form a liquidation committee to conduct liquidation in a timely manner.

The liquidation committee may exercise following powers during the liquidation:

- (1) to sort out the company's assets and to prepare a statement of financial position and an inventory of assets, respectively;
- (2) to notify creditors by notice or public announcement;
- (3) to deal with any outstanding business related to the liquidation;
- (4) to pay outstanding tax together with any tax arising during the liquidation process;
- (5) to settle claims and liabilities;
- (6) to distribute the company's remaining assets after its debts have been paid off;
- (7) to represent the company in any civil procedures.

The liquidation committee shall notify the company's creditors within 10 days of its establishment and publish an announcement in newspapers or on the national enterprise credit information publicity system within 60 days.

A creditor shall lodge his claim with the liquidation committee within 30 days of receipt of the notification or within 45 days of the date of the announcement if he has not received any notification. A creditor shall report all matters relevant to his claimed creditor's rights and furnish relevant evidence. The liquidation committee shall register such creditor's rights. The liquidation committee shall not make any settlement to creditors during the period of the claim.

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Upon disposal of the company's property and preparation of the required statement of financial position and inventory of assets, the liquidation committee shall draw up a liquidation plan and submit this plan to a shareholders' meeting or a people's court for confirmation. The remaining part of the company's assets, after payment of liquidation expenses, employee wages, social insurance expenses and statutory compensation, outstanding taxes and the company's debts, shall be distributed to shareholders in proportion to shares held by them. The company shall continue to exist during the liquidation period, although it cannot conduct operating activities that are not related to the liquidation. The company's assets shall not be distributed to shareholders before repayments are made in accordance with the requirements described above.

Upon liquidation of the company's property and preparation of the required statement of financial position and inventory of assets, if the liquidation committee becomes aware that the company does not have sufficient assets to meet its liabilities, it must apply to a people's court for a bankruptcy liquidation in accordance with the laws. After the people's court accepts the application for bankruptcy, the liquidation committee shall hand over the liquidation matters to the bankruptcy administrator designated by the people's court.

Upon completion of the liquidation, the liquidation committee shall prepare a liquidation report and submit it to the shareholders' meeting or a people's court for confirmation. Following such confirmation, the report shall be submitted to the company registration authority to cancel the company's registration. Members of the liquidation committee performing their liquidation obligations have the duties of loyalty and diligence. Members of the liquidation committee are liable for indemnifying the company in respect of the losses arising from their negligent performance of their liquidation duties; members of the liquidation committee are liable to indemnify the creditors in respect of any losses arising from their willful or gross negligence.

Liquidation of a company declared bankrupt according to law shall be processed in accordance with the laws on corporate bankruptcy.

OVERSEAS LISTING

Pursuant to the Trial Measures, where an issuer makes an overseas initial public offering or listing, it shall file with the CSRC within three PRC business days after such overseas listing application is submitted.

MERGER AND DIVISION

For companies to merge, a merger agreement shall be signed by merging companies, and the companies shall prepare respective statements of financial position and inventory of assets. The companies shall within 10 days of the date of passing the resolution approving the merger notify their respective creditors and publicly announce the merger in newspapers or the national enterprise credit information publicity system within 30 days. A creditor may, within 30 days of receipt of the notification, or within 45 days of the date of the announcement if he/she has not received the notification, request the company to settle any outstanding debts or provide relevant guarantees. In case of a merger, the credits and debts of the merging parties shall be assumed by the surviving company or the new company.

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In case of a division, the company’s assets shall be divided, and a statement of financial position and an inventory of assets shall be prepared. When a resolution regarding the company’s division is approved, the company should notify all its creditors within 10 days of the date of passing such resolution and publicly announce the division in newspapers or on the national enterprise credit information publicity system within 30 days. Unless an agreement in writing is reached with creditors before the company’s division in respect of the settlement of debts, the liabilities of the company which have accrued prior to the division shall be jointly borne by the divided companies.

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SHARES

Issuance of Shares

The shares of the Company shall take the form of registered share. The Company shall issue shares in an open, fair and just manner, and each share of the same class shall enjoy the equal rights.

Shares of the same class in the same issue shall be listed under the same conditions and at the same price; any subscriber shall pay the same price for each share subscribed.

Ordinary shares issued by the Company (domestic unlisted shares and overseas listed shares) shall enjoy the same rights in any distribution by way of dividends (including distribution in cash or in kind) or in other forms.

The overseas listed shares issued by the Company shall be collectively deposited in the local share registrar.

The domestic unlisted shares issued by the Company shall be collectively deposited in the domestic securities depository and clearing organization. After [REDACTED] with the securities regulatory authority under the State Council and consent of Hong Kong Stock Exchange, all or part of the domestic unlisted shares of the Company may be converted to overseas [REDACTED] shares, and the converted overseas [REDACTED] shares may be [REDACTED] and traded in overseas stock exchange. In case the converted shares are [REDACTED] and traded in overseas stock exchange, the Company shall also comply with the regulatory procedures, regulations and requirements of foreign securities market.

For the conversion of domestic unlisted shares to overseas [REDACTED] shares and being [REDACTED] as well as traded in overseas stock exchange, voting at shareholders' meeting is not required.

Increase/Reduction of Shares

The Company may, based on its operational and developmental needs and in accordance with laws and regulations, upon resolutions separately adopted at the shareholders' meeting, increase the capital in the following ways:

- (1) public issuance of shares;
- (2) non-public issuance of shares;
- (3) distribution of bonus share to existing shareholders;
- (4) transfer of capital reserve into capital stock;
- (5) other means stipulated by law and administrative regulations and approved by the CSRC and the Hong Kong Stock Exchange.

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The Company shall increase its capital and issue new shares in comply with the procedures stipulated by laws, administrative regulations, and the securities regulatory rules of the place where the Company's shares are listed, after having been approved in accordance with the articles of association and the securities regulatory rules of the place where the Company's shares are listed.

According to the articles of association, the Company may reduce its registered capital. The Company shall reduce its registered capital in accordance with the procedures set out in the Company Law as well as other relevant regulations, the Hong Kong Listing Rules, and other securities regulatory rules of the place where the Company's shares are [REDACTED], and the articles of association.

When the Company reduces its registered capital, a balance sheet and a list of assets should be prepared. The Company shall notify its creditors within ten days and publish an announcement in newspapers or on the National Enterprise Credit Information Publicity System within 30 days after the resolution approving the reduction has been made at the shareholders' meeting. The creditors shall have the right to require the Company to repay its debts or provide corresponding guarantees within 30 days after receiving the notice or within 45 days after the announcement if the creditors have not received the notice.

The Company's registered capital after reduction shall not be less than the statutory minimum amount.

Share Repurchase

The Company shall not acquire its own shares, except for one of the following circumstances:

- (1) reducing the Company's registered capital;
- (2) merging with another company that holds shares in the Company;
- (3) using the shares for employee stock ownership plan or equity incentives;
- (4) acquiring shares held by shareholders (upon their request) who vote against any resolution proposed in any shareholders' meeting on the merger or division of the Company;
- (5) using the shares for conversion of corporate bonds issued by the Company that are convertible into shares;
- (6) where it is necessary to safeguard the corporate value and shareholders' interests;
and
- (7) other circumstances permitted by the laws and administrative regulations.

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Where the Company acquires its own shares under the circumstances set out in items (1) and (2) above, it shall be subject to the resolution of the shareholders' meeting; where the Company acquires its own shares under the circumstances set out in items (3), (5) and (6) above, it may be resolved at the board meeting attended by more than two-thirds of the directors in accordance with the provisions of the articles of association or the authorization of the general meeting. Unless otherwise stipulated by the Hong Kong Listing Rules.

After the Company has acquired its own shares, such shares shall be cancelled within ten days from the date of acquisition in the case of item (1); such shares shall be transferred or cancelled within six months in the case of items (2) and (4); the total shares held by the Company shall not exceed 10% of the total issued shares of the Company and such shares shall be transferred or cancelled within three years in the case of items (3), (5) and (6).

After the Company acquires its own shares, it should perform its information disclosure obligation in accordance with the law, administrative regulations, rules, normative documents, and the Hong Kong Listing Rules. If the relevant regulatory rules at the place where the shares of the Company are listed have different provisions regarding the cancellation and treasury shares concerning the share repurchase, such provisions shall prevail.

Transfer of Shares

The Company's shares can be transferred pursuant to the law. The Company shall not accept its own shares as the subject of a pledge.

Shares issued by the Company before its public offering cannot be transferred within 1 year of the listing date of its shares in a stock exchange. If the laws, administrative regulations or the securities regulatory authority of the State Council have other provisions on the transfer of the Company's shares held by the shareholders and actual controllers of listed companies, such provisions shall prevail. The directors, supervisors and senior management personnel of the Company shall declare to the Company the shares (including preference shares (if any)) in the Company they hold and the changes in such shares, and the shares transferred each year during the term of office determined at the time of appointment shall not exceed 25% of the total number of the Company's shares held by them; the Company's shares held by them shall not be transferred within one year of the listing date of the Company's shares. The aforesaid persons shall not transfer the Company's shares held by them within half year from their resignation. If the Hong Kong Listing Rules or the relevant provisions of the securities regulatory authorities at the place where the shares of the Company are [REDACTED] have other provisions on the transfer restriction of overseas [REDACTED] shares, such provisions shall prevail.

Where the Company's shareholders, directors, supervisors and senior management personnel holding more than 5% of shares sell the Company's shares or other securities with equity nature held by them within six months after purchase or purchase the same within six months after sale, the proceeds thereof shall belong to the Company, and the board of directors of the Company will take back such proceeds. Except when a securities company holds more

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SUMMARY OF ARTICLES OF ASSOCIATION

than 5% of the Company's shares due to purchase of any remaining shares after a package sale, or under any other circumstances stipulated by the CSRC or the securities regulatory authorities at the place where the Company's shares are listed. The aforesaid shares or other securities with equity nature held by directors, supervisors, senior management personnel and natural-person shareholders include shares or other securities with equity nature held by their spouses, parents, children, and held by them by using other's accounts.

Where the board of directors of the Company fails to perform the aforesaid provisions, the shareholders shall have the right to require the board of directors to perform the duties within 30 days. Where the board of directors of the Company fails to perform the duties within the aforesaid period, the shareholders shall have the right to file a lawsuit directly in a people's court in their own name for the benefit of the Company. Where the board of directors of the Company fails to perform the aforesaid provisions, the directors who take responsibility shall bear joint liability pursuant to the law.

SHAREHOLDERS AND SHAREHOLDERS' MEETINGS

Register of Shareholders

The Company shall set up a register of shareholders based on the evidence provided by the securities registration agency. The register of shareholders is sufficient evidence proving the shareholders' holding of the Company's shares.

The Company shall keep a complete register of shareholders. The register of shareholders shall include the following: (1) the register of shareholders other than those stipulated in items (2) and (3) of this paragraph to be kept at the premises of the Company; (2) the register of shareholders of the H shares of the Company to be kept at the location of the Hong Kong Stock Exchange; and (3) the register of shareholders to be kept at another premises as the board of directors may decide necessary for the purposes of listing of the Company's shares. Alteration or correction of any part of a register of shareholders shall be carried out in accordance with the laws of the places where those parts of the register of shareholders are kept.

A duplicate copy of the Company's register of shareholders of overseas listed shares shall be kept at the premises of the Company. The entrusted overseas agency shall ensure the consistency of the original and duplicate copies of the register of shareholders of overseas listed shares at all times. The register of shareholders kept in Hong Kong shall be available for inspection by members but shall allow the Company to suspend registration of members under provisions equivalent to those under the Companies Ordinance (Cap 622).

Where the Company needs to confirm the identity of shareholders for convening shareholders' meetings, distribution of dividends, liquidation or other activities, the date of record shall be determined by the board of directors or the convenor of the shareholders' meeting. Shareholders in the register after market closing on the date of record shall be shareholders who enjoy the relevant rights and interests.

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In the case of loss of share certificate of a shareholder holding overseas listed shares, application for reissue may be handled in accordance with the laws of the place where the original register of shareholders of overseas listed shares is kept, the rules of the securities exchange, or other relevant provisions.

Rights and Obligations of Shareholders

Shareholders shall enjoy rights and bear obligations according to the class of shares they hold; shareholders holding share(s) of the same class shall enjoy equal rights and bear equal obligations.

The Company's shareholders are entitled to the following rights:

- (1) the right to receive dividends and benefits distributed in other forms in proportion to the number of shares they hold;
- (2) the right to legally request, convene, preside over, participate in or send proxies of shareholders to attend shareholders' meeting and to exercise the corresponding right to speak and vote (except for waiver of voting rights on certain matters pursuant to the provisions of laws and regulations and the securities regulatory rules of the place where the Company's shares are listed);
- (3) the right to supervise, make suggestions on or make inquiries on the Company's operations;
- (4) the right to transfer, donate or pledge their shares according to the law, administrative regulations and the articles of association;
- (5) the right to inspect and copy the articles of association, the register of shareholders, minutes of shareholders' meetings, board of directors' resolutions, board of supervisors' resolutions and financial accounting report, and inspect corporate bond stubs;
- (6) the right to participate in the distribution of the Company's residual assets in proportion to the number of shares they held when the Company terminates or liquidates;
- (7) any shareholder who has a different view on a resolution on the merger or division of the Company made by a shareholders' meeting has the right to require the Company to acquire his/her/its shares; and
- (8) other rights provided by laws, administrative regulations, departmental rules, the Hong Kong Listing Rules and the regulatory rules of the place where the Company's shares are listed or the Company's articles of association.

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Where a shareholder demands to inspect the relevant information or obtain any of the aforesaid materials, he/she/it shall submit to the Company written documents proving the class and number of shares he/she/it holds, and the Company shall provide the relevant information or materials as demanded by the shareholder after verifying the shareholder's identity.

Any shareholder of the Company shall assume the following obligations:

- (1) to comply with the law, administrative regulations, departmental rules, regulatory rules of the place where the Company's shares are listed and the Company's articles of association;
- (2) to pay monies according to the shares subscribed for and the method of shares subscription;
- (3) not to withdraw shares, except for the circumstances stipulated by laws and regulations;
- (4) not to abuse their shareholders' rights to damage the interests of the Company or other shareholders; not to abuse the independent legal person status of the Company or the limited liabilities of shareholders to damage the interests of the Company's creditors; and
- (5) to perform any other obligation as provided by the law, administrative regulations, regulatory rules of the place where the Company's shares are listed and the Company's articles of association.

Any shareholder of the Company who abuses his/her/its shareholders' rights and thereby causes losses to the Company or any other shareholder shall be liable for compensation according to the law. Any shareholder of the Company who abuses the independent legal person status of the Company or the limited liability of shareholders in order to evade debts and thereby seriously damages the interests of the Company's creditors shall assume joint and several liability for the Company's debts.

Where the shareholders holding more than 5% of shares with voting rights in the Company pledges their shares, a written report shall be made to the Company on the day of such occurrence.

Shareholders' Meeting

The shareholders' meeting is the authority of power of the Company and exercises the following functions and powers in accordance with the law:

- (1) determining the operational policy and investment plan of the Company;
- (2) electing and replacing directors and supervisors who are not staff representatives, and deciding on the remunerations of directors and supervisors;

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- (3) reviewing and approving the reports of the board of directors;
- (4) reviewing and approving the reports of the board of the supervisors;
- (5) reviewing and approving the profit distribution plan and loss compensation plan of the Company;
- (6) making resolutions on the increase or reduction of the registered capital of the Company;
- (7) making resolutions on the issuing of bonds and any class of shares of the Company;
- (8) making resolutions on the merger, division, spin-off, dissolution, voluntary winding-up, liquidation, or change of the Company's corporate form;
- (9) amending the Company's articles of association;
- (10) making resolutions on the hiring and dismissal of accounting firms that make regular and statutory audits of the Company's financial reports;
- (11) reviewing and approving the external guarantees which should be approved by the shareholders' meeting as provided in the articles of association;
- (12) reviewing any purchase and sale of significant assets within one (1) year exceeding 30% of the most recently audited total assets of the Company; if the total amount of assets involved in transaction contain both a book value and an evaluation value, the higher value shall be used for calculation;
- (13) reviewing and approving changes in usage of raised funds;
- (14) reviewing equity incentives plan and employee stock ownership plan; and
- (15) reviewing and approving other matters which shareholders' meeting should decide in accordance with laws, administrative regulations, departmental rules, Hong Kong Listing Rules and other securities regulatory rules of the place where the Company's shares are [REDACTED] or its articles of association.

Any of the following external guarantees (including mortgages, pledges or guarantees) provided by the Company shall be subject to review and approval by the shareholders' meeting (except when the Company accepts or provides its controlled subsidiary with guarantee):

- (1) any guarantee provided after the total amount of external guarantees of the Company and its controlled subsidiaries exceeds 50% of the latest audited net assets of the Company;

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- (2) any guarantee provided after the total amount of external guarantees of the Company exceeds 30% of the latest audited total assets of the Company;
- (3) any guarantee with a total amount within one (1) year that exceeds 30% of the latest audited total assets of the Company;
- (4) any guarantee provided to any entity whose liability to asset ratio exceeds 70%;
- (5) any single guarantee, the amount of which exceeds 10% of the latest audited net assets of the Company;
- (6) any guarantee provided to the shareholders, actual controller and their related parties; and
- (7) any other external guarantee which requires the approval by the shareholders' meeting in accordance with laws, regulations, normative documents, Hong Kong Listing Rules and other securities regulatory rules of the place where the Company's shares are [REDACTED] or its articles of association.

The above external guarantees that require the approval of the shareholders' meeting shall be submitted to the shareholders' meeting for approval after being reviewed and approved by the board of directors. The board of directors shall have the right to review and approve the external guarantees that are not subject to the approval of the shareholders' meeting.

Where the shareholders' meeting is considering a resolution on guarantees to be provided to shareholders, actual controllers and their related parties, such shareholders, or shareholders under the control of such actual controllers, shall abstain from voting. Such resolution is subject to the approval of more than half of the voting rights held by the other shareholders present at the meeting.

The shareholders' meeting shall be divided into annual and extraordinary shareholders' meeting. Annual shareholders' meeting shall be convened once every accounting year within 6 months after the end of the preceding accounting year.

The Company shall convene an extraordinary general meeting within 2 months of the occurrence of any of the following circumstances:

- (1) when the number of directors is less than two thirds of the number prescribed in the Company Law or the articles of association;
- (2) when the uncovered losses of the Company reach one third of the total amount of paid-up capital;
- (3) when the shareholders individually or together holding more than 10% of the shares of the Company request;

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- (4) when the board of directors deems it necessary;
- (5) when the board of supervisors proposes such a meeting;
- (6) when more than half of the independent directors of the Company propose such a meeting; and
- (7) other circumstances prescribed in laws, administrative regulations, departmental rules, Hong Kong Listing Rules and other securities regulatory rules of the place where the Company’s shares are [REDACTED] or its articles of association.

The venue of the shareholders’ meeting shall be the domicile of the Company or specified in the notice of the shareholders’ meeting. The shareholders’ meeting will have a venue and will be held on site. The Company shall also provide means of communication or other methods to facilitate the shareholders’ attendance. The shareholders who attend the meeting by the aforesaid means are deemed to be present.

Once the notice of the shareholders’ meeting is issued, the venue of the shareholders’ meeting shall not be changed without any justifiable reasons. In the case of a necessary change, the convener shall publicly inform every shareholder and explain the reasons at least 2 working days before the date of the meeting.

If laws, administrative regulations, departmental rules, Hong Kong Listing Rules and other securities regulatory rules of the place where the Company’s shares are [REDACTED] explicitly require the presence of lawyers and provision of legal opinions during the shareholders’ meeting of the Company, the Company shall, when the shareholders’ meeting is being held, engage lawyers to provide legal opinions and make announcement on the following issues:

- (1) whether the convening and meeting procedures comply with laws, administrative regulations, and the Company’s articles of association;
- (2) whether the qualifications of the attendees and the convener are lawful and valid;
- (3) whether the voting procedures and results of the meeting are lawful and valid; and
- (4) legal opinions on other related issues issued at the request of the Company.

Convening of Shareholders’ meeting

Independent directors are authorized to propose to the board of directors to convene an extraordinary meeting. Concerning the independent directors’ proposal to convene an extraordinary meeting, the board of directors should, in accordance with the laws, administrative regulations, Hong Kong Listing Rules and the Company’s articles of association, provide a written feedback opinion to agree or disagree to convene an extraordinary meeting within 10 days of receipt of the proposal. If the board of directors agrees to convene an extraordinary meeting, it will issue a notice of shareholders’ meeting within 5 days of the resolution of the board of directors. If the board of directors does not agree to convene an extraordinary meeting, it shall state reasons and make an announcement.

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The board of supervisors is authorized to propose to the board of directors to convene an extraordinary meeting, and shall put forward the proposal to the board of directors in writing. In accordance with laws, administrative regulations and the Company's articles of association, the board of directors should, within 10 days of receipt of the proposal, provide a written feedback opinion to agree or disagree to convene an extraordinary meeting.

If the board of directors agrees to convene an extraordinary meeting, it shall issue a notice of shareholders' meeting within 5 days of the resolutions of the board of directors; any change to the original proposal in the notice shall be subject to the consent of the board of supervisors.

If the board of directors does not agree to convene an extraordinary meeting, or does not reply within 10 days of receipt of the proposal, it shall be deemed that the board of directors is unable or fails to perform its duty to convene a shareholders' meeting, and the board of supervisors may convene and preside over an extraordinary meeting itself.

Shareholders individually or jointly holding 10% or more of the shares of the Company are authorized to request to the board of directors to convene an extraordinary meeting and submit proposals or to add proposals to the meeting agenda, which should be put forward to the board of directors in writing. According to the laws, administrative regulations, Hong Kong Listing Rules, other securities regulatory rules of the place where the Company's shares are [REDACTED] and the Company's articles of association, the board of directors should, within 10 days of receipt of the request, provide a written feedback opinion to agree or disagree to convene an extraordinary meeting.

If the board of directors agrees to convene an extraordinary meeting, it shall issue a notice of shareholders' meeting within 5 days of the resolution of the board of directors; any change to the original request in the notice shall be subject to the consent of the relevant shareholders. If the board of directors does not agree to convene an extraordinary general meeting, or does not reply within 10 days of receipt of the request, shareholders individually or jointly holding 10% or more of the shares of the Company are authorized to propose to the board of supervisors to hold an extraordinary meeting, which should be put forward to the board of supervisors in writing.

If the board of supervisors agrees to convene an extraordinary meeting, it shall issue a notice of shareholders' meeting within 5 days of receipt of the request; any change to the original request in the notice shall be subject to the consent of the relevant shareholders. If the board of supervisors does not issue the notice of shareholders' meeting within the prescribed period, it shall be deemed that the board of supervisors will not convene or preside over a shareholders' meeting, and shareholders who individually or jointly hold more than 10% of the shares for more than 90 days continuously can convene and hold the shareholders' meeting by themselves. When the board of supervisors or shareholders decide to convene a shareholders' meeting by themselves, they should inform the board of directors in writing. Before publicly announcing the resolutions of the shareholders' meeting, the convening shareholders should not hold less than 10% of the shares. When a shareholders' meeting is convened by the board of supervisors or the shareholders, the board of directors and the secretary of the board of

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directors shall cooperate therewith. The board of directors should provide the register of shareholders on the date of record. Where a shareholders’ meeting is convened by the board of supervisors or shareholders, the Company shall bear all necessary expenses incurred therefor.

Proposal and Notice of Shareholders’ meeting

A proposal shall fall within the scope of authority of the shareholders’ meeting, have specific topics and matters to be decided and comply with the law, administrative regulations, Hong Kong Listing Rules and other securities regulatory rules of the place where the Company’s shares are [REDACTED], and the articles of association.

When the Company holds a shareholders’ meeting, the board of directors, the board of supervisors or shareholders holding individually or jointly more than 1% of the shares of the Company, have the right to submit proposals to the Company. Shareholders, individually or jointly, holding more than 1% of the shares of the Company, can submit temporary proposals and submit them in writing to the convener 10 days before the holding of the shareholders’ meeting. The convener shall issue a supplementary shareholders’ meeting notice of the content of the temporary proposals within 2 days of the receipt of such proposal, unless the temporary proposal is in violation of the provisions of laws, administrative regulations or the articles of association, or does not fall within the scope of authority of the shareholders’ meeting.

Except as provided in the preceding paragraph, the convener shall not modify or add new proposals to the proposals listed in the notice of the shareholders’ general meeting after sending such notice out.

The shareholders’ meeting cannot vote or pass any resolution on any proposals not specified in the notice of shareholders’ meeting or inconsistent with Article 52 of the articles of association.

The convener shall notify all shareholders in writing 21 days prior to the holding of annual shareholders’ meeting, and notify all shareholders in writing 15 days prior to the holding of an extraordinary meeting.

The notice of shareholders’ meeting includes the following:

- (1) time, venue and duration of the meeting;
- (2) issues and proposals submitted to the meeting for review;
- (3) clearly specifying that all shareholders are entitled to attend the shareholders’ meeting and may appoint a proxy in writing to attend the meeting and vote on their behalf. The proxy need not be a shareholder of the Company;
- (4) the shareholding registration date of the shareholders entitled to attend the shareholders’ meeting;

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- (5) the name and telephone number of the permanent contact person for the meeting;
- (6) time and procedure of voting by Internet or other means (if any); and
- (7) other requirements as required by the law, administrative regulations, departmental rules, Hong Kong Listing Rules and other securities regulatory rules of the place where the shares of the Company are [REDACTED] and the articles of association of the Company.

The notice of shareholders' meeting and supplemental notice shall contain full and complete disclosure of all specific details of all proposals, as well as all information or explanations required to enable shareholders to make their reasonable discretion on the issues to be discussed. If the issues to be discussed require the opinion given by independent directors, the opinions and reasons of the independent directors will be disclosed at the same time when the notice of shareholders' meeting or supplementary notice is published.

The voting by Internet or other means (if any) shall not commence earlier than 3:00 pm of the previous day of the shareholders' meeting and not later than 9:30 am on the day of the shareholders' meeting, and shall not be concluded earlier than 3:00 pm of the day of conclusion of the shareholders' meeting.

The interval between the shareholding registration date and the day of meeting shall be no more than 7 working days. The shareholding registration date shall not be changed once confirmed.

No amendment of the register of shareholders as a result of any share transfer may be made within 5 days prior to the shareholders' meeting or the reference date determined by the Company for the distribution of dividends. Where the relevant laws, regulations, normative documents, the securities regulatory authority of the place where the shares of the Company are [REDACTED], or the Hong Kong Stock Exchange provide otherwise with respect to the suspension of registration of amendments of the register of shareholders prior to the shareholders' meeting or the reference date determined by the Company for the distribution of dividends, such provisions shall prevail.

If the shareholders' meeting proposes to discuss the election of directors or supervisors, the notice of shareholders' meeting shall contain full information of the candidates for the directors and supervisors, including at least the following:

- (1) personal information such as the educational background, working experience, and concurrent positions, etc.;
- (2) whether the candidate has any related relationship with the Company or the controlling shareholder or the actual controller of the Company;
- (3) the number of shares of the Company held by him/her; and

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- (4) whether the candidate has been penalized by the relevant securities regulatory authorities and other relevant departments and sanctioned by any stock exchange.

Unless the cumulative voting system is adopted to elect the directors and supervisors, each candidate of director or supervisor should be individually proposed.

Once the notice of shareholders' meeting is issued, it shall not be postponed or cancelled without any valid reason. Proposals specified in the notice of shareholders' meeting shall not be cancelled. In the case of postponement or cancellation of a shareholders' meeting, the convener shall notify the shareholders and explain the reasons at least 2 working days prior to the original date of the shareholders' meeting. In the case of any change in the manner of holding a shareholders' meeting or the venue of the shareholders' meeting, the convener shall notify all shareholders and explain the reasons in writing at least 1 working day prior to the original date of the shareholders' meeting. If the securities regulatory rules of the place where the Company's shares are listed have special provisions with respect to the postponement or cancellation of shareholders' meeting, those provisions shall prevail.

Convening of Shareholders' Meeting

The board of directors and other conveners of the Company will take necessary actions to ensure the proper order of the shareholders' meeting. Measures shall be taken to halt any interference with the shareholders' meeting, provocations or infringement of the shareholders' legitimate rights and interest and any such actions will be promptly reported to the relevant authorities for investigation.

All shareholders registered on shareholding registration date or their proxies are entitled to attend the shareholders' meeting and exercise their voting rights in accordance with laws, regulations and the articles of association. Shareholders may attend the shareholders' meeting in person or authorize proxies to attend and vote on their behalf. A corporate shareholder may appoint a representative to attend and vote at any shareholders' meeting of the Issuer, and such company shall be deemed as attending in person. A company may sign a proxy form through its duly authorized person.

If an individual shareholder attends the shareholders' meeting in person, he/she shall present his/her identity card or other valid certificates or share certificates that can prove his/her identity; proxies attending the shareholders' meeting on behalf of shareholders shall present their own valid identity documents and authorization letter from the shareholder.

A corporate shareholder/institutional shareholder should attend a meeting through its legal representative/executive partner or proxy appointed by legal representative/executive partner. If the legal representative/executive partner attends the meeting, he/she shall present his/her identity card and valid certificates that can identify his/her qualification as the legal

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representative/executive partner; if a proxy attends the meeting on his/her behalf, the proxy shall present his/her identity card and the written authorization letter issued by the legal representative/executive partner of the corporate shareholder/institutional shareholder in accordance with the law.

A shareholder which is a recognized clearing house (or its proxy) as such term is defined in the relevant Hong Kong Ordinances from time to time may authorize its corporate representative or one or more persons it deems proper to act as its representative at any shareholders' meeting; provided, however, that if more than one person is so authorized, the power of attorney or authorization shall specify the number and class of shares in respect of which each such person is authorized, and shall be signed by a person authorized by the recognized clearing house. A person so authorized may attend meetings on behalf of the recognized clearing house (or its proxy) (without providing share certificates, notarial authority and/or further evidence establishing that he/she is duly authorized) and exercise the same legal rights as any other shareholder, including the right to speak and vote, as if that person were an individual shareholder in the Company.

The power of attorney issued by a shareholder for appointing another person to attend a shareholders' meeting on his/her behalf shall include:

- (1) name of the proxy;
- (2) whether the proxy is authorized to vote (including the voting rights in respect of provisional proposals);
- (3) respective instructions on affirmative, negative or abstention voting on each issue listed in the meeting agenda;
- (4) the issuance date and the valid period of the authorization letter; and
- (5) the signature (or seal) of the shareholder. In the case of a corporate/other institutional shareholder, the seal of the corporate/other institution shall be affixed.

The power of attorney shall indicate whether the shareholder's proxy may vote at his/her own discretion in the absence of specific instructions from the shareholder.

Where a shareholder authorizes another person to sign a power of attorney for proxy, the authorization letter or other authorization documents shall be notarized. The notarized authorization letter or other authorization documents, and the power of attorney shall be kept at the Company's domicile or any other place specified in the notice convening the meeting at least before the commencement of the relevant meeting or the designated time of the shareholders' meeting.

In the case of a corporate/institution shareholder, its legal representative/executive partner or other person authorized by resolution of the board of directors or other decision-making authority shall attend the shareholders' meeting of the Company.

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The Company shall prepare a meeting register of attendees, which includes the names of the persons (or names of the organizations) attending the meeting, their identity card numbers, residential addresses, the number of voting shares held or represented by them, and the names of shareholders with proxies, etc.

The convener and the attorney engaged by the Company (if any) shall, based on the register of shareholders provided by the securities depository and clearing organization, jointly verify the legality of the shareholders' qualification and record the names of shareholders and the number of voting shares they hold. Registration for the meeting shall cease prior to the announcement made by the one presiding over the meeting on the number of shareholders and proxies in attendance and the total number of voting shares they hold.

When the shareholders' meeting is held, all directors, supervisors and secretaries to the board of directors shall attend the meeting, and general managers and other senior management personnel shall be present on the meeting.

The chairman of the board of directors shall preside over the shareholders' meeting. If the chairman of the board of directors is unable or fails to carry out his/her duties, more than half of the directors shall jointly nominate a director to preside over the meeting. If the board of supervisors convenes the shareholders' meeting by themselves, the chairman of the board of supervisors shall preside over the meeting. If the chairman of the board of supervisors is unable or fails to carry out his/her duties, the vice chairman of the board of supervisors shall preside over the meeting. If the vice chairman is unable or fails to carry out his/her duties, more than half of the supervisors shall nominate a supervisor to preside over the meeting. If a shareholders meeting is convened by the shareholders themselves, the convener shall nominate a representative to preside over the meeting. When the shareholders meeting is being held, if the presiding officer of the meeting violates meeting procedures so that the shareholders meeting fails to continue, the shareholders meeting may nominate one person to become the presiding officer of the meeting to continue with the meeting with the agreement of the shareholders with more than half of voting rights present at the meeting.

The meeting host shall, before voting, announce the number of shareholders and their proxies attending the meeting as well as the total number of shares with voting rights they hold. The number of shareholders and their proxies attending the meeting, as well as the total number of shares with voting rights they hold, shall be based on those registered at the meeting.

The shareholders' meeting shall have minutes prepared by the secretary to the board of directors. The minutes shall contain:

- (1) time, venue, agenda of the meeting, and the name of the convener;
- (2) names of the meeting host, directors, supervisors, general managers and other senior management personnel attending or present at the meeting;

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- (3) the number of shareholders and proxies attending the meeting, the total number of shares with voting rights they hold, and the proportion of such shares to the total number of Company shares;
- (4) the review, main points of address and voting results of each proposal;
- (5) shareholders' inquiries or suggestions and the corresponding replies or explanations;
- (6) names of lawyers (if any), tellers and scrutineer; and
- (7) other details specified by the articles of association to be included in the minutes.

The convener shall ensure that the details recorded in the meeting minutes are true, accurate and complete. The directors, the supervisors, the secretary to the board of directors, the convener or his/her representative and the meeting host shall sign the meeting minutes. The meeting minutes shall be kept together with the signature book for the shareholders attending the meeting, proxy authorization letter, valid information on voting via the Internet and by any other means for no less than 10 years.

The convener shall ensure that the shareholders' meeting is held continuously until final decisions are made. Where the shareholders' meeting is suspended or a decision cannot be made due to force majeure or other special reasons, necessary procedures shall be taken as soon as possible to resume the meeting or to directly terminate that meeting with a public timely announcement.

Voting and Resolutions of the Shareholders' meeting

Resolutions at the shareholders' meeting consist of ordinary resolutions and special resolutions. An ordinary resolution of the shareholders' meeting shall be passed by an absolute majority of the voting rights represented by shareholders (including shareholder proxies) attending the shareholders' meeting. Any special resolution of the shareholders' meeting shall be passed by more than two-thirds of the voting rights represented by shareholders (including shareholder proxies) attending the shareholders' meeting.

The following shall be passed by an ordinary resolution of the shareholders' meeting:

- (1) work reports of the board of directors and the board of supervisors;
- (2) plans drafted by the board of directors to distribute profits or cover losses;
- (3) the appointment and dismissal of members of the board of directors and the board of supervisors, as well as the remuneration of and payments to such members;
- (4) annual report of the Company;

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- (5) hiring, dismissal or non-appointment of an accounting firm by the Company and the remunerations of the accounting firm;
- (6) any matters other than those that are required to be decided by special resolutions under the law, administrative regulations, the Hong Kong Listing Rules or other securities regulatory rules of the place where the Company's shares are [REDACTED], or the articles of association of the Company.

The following shall be passed by a special resolution of the shareholders' meetings:

- (1) any increase or reduction in the registered capital of the Company;
- (2) any merger, division, spin-off, dissolution, voluntary winding-up, liquidation, or change of the Company's corporate form;
- (3) any amendment to the Company's articles of association;
- (4) any purchase or sale of major assets or any provision of guarantee within one year for an amount exceeding 30% of the Company's total assets as audited in the latest period;
- (5) any equity incentive plan; and
- (6) other matters required by the law, administrative regulations, the Hong Kong Listing Rules or other securities regulatory rules of the place where the Company's shares are [REDACTED], or the articles of association of the Company, and determined by ordinary resolutions at the shareholders' meeting to have a significant impact on the Company and thus requiring a special resolution.

Shareholders (including shareholder proxies) shall exercise their voting rights based on the number of voting shares they represent. Each share is entitled to one vote. When voting by ballot, a shareholder (including the proxy) with two or more voting rights need not cast all votes as affirmative or negative votes.

Where a shareholder is required to abstain from voting on an issue pursuant to the provisions of the Hong Kong Listing Rules or is restricted to casting affirmative or negative votes only, the shareholder shall abstain from voting on such matter pursuant to such provisions; any shareholder's votes or votes of proxy that violate such provisions or restrictions shall not be included in the voting results.

When the shareholders' meeting reviews important issues affecting the interests of minority investors, it shall count the votes of these investors separately. The results of separate counting shall be disclosed in a timely manner.

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The shares held by the Company itself have no voting right and shall not be included in the total voting shares held by the shareholders attending the meeting.

The Company's board of directors, independent directors, shareholders holding more than 1% of the voting shares or the investor protection institutions set up in accordance with the laws, administrative regulations or the provisions of the securities regulatory authorities of the place where the Company's shares are [REDACTED], may publicly solicit shareholders' voting rights. When soliciting shareholders' voting rights, the specific voting intention and other information shall be fully disclosed to the shareholders whose voting rights are solicited. It is prohibited to solicit shareholders' voting rights with payment or in a disguised form of payment. The Company may not set the limit of minimum shareholding ratio for the solicitation of voting rights except for the statutory conditions.

Where the shareholders' meeting reviews any issue relating to a connected transaction, the related shareholder(s) shall not participate in the voting, and number of voting shares they represent shall not be included in the total number of valid votes; and the result of voting by non-related shareholders shall be fully disclosed in the announcement of the resolution of the shareholders' meeting.

Prior to reviewing issues relating to a connected transaction by a shareholders' meeting, the Company shall determine the scope of related shareholders pursuant to the provisions of relevant laws and regulations, the Hong Kong Listing Rules, and the regulatory requirements of the securities regulatory authority of the place where the Company's shares are [REDACTED]. A related shareholder or his/her authorised representative may attend a shareholders' meeting, and articulate his/her views to the shareholders present at the meeting pursuant to the meeting procedures, but shall abstain from voting at the time of voting.

When a shareholders' meeting reviews issues relating to a connected transaction, the related shareholders shall voluntarily abstain from voting. Where the related shareholder does not voluntarily abstain from voting, the other shareholders present at the meeting shall have the right to request him/her to abstain from voting. Upon abstention by the related shareholder, the other shareholders shall vote based on their voting rights, and the corresponding resolution shall be passed pursuant to the provisions of the Company's articles of association. The abstention of the related shareholder and the voting procedures shall be notified by the chairman of the shareholders' meeting, and recorded in the minutes of the meeting.

Any resolution of a shareholders' meeting with respect to a connected transaction shall be valid only when such resolution is passed by more than half of the votes cast by the non-related shareholders present at the shareholders' meeting. However, in respect of any connected transaction involving any issues requiring a special resolution in accordance with the provisions of the Company's articles of association, the resolution shall be valid only when such issues are passed by no less than two-thirds of the voting rights held by the non-related shareholders present at the shareholders' meeting.

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Unless the Company is in a crisis or other special circumstances, the Company will not, without an approval by a special resolution of the shareholders’ meeting, enter into a contract with a person other than a director, general manager, or other senior management personnel that places the management of all or an important part of the Company’s business in the person’s charge.

The lists of candidates for directors and supervisors shall be proposed to the shareholders’ meeting for voting. When the shareholders’ meeting votes to elect directors and supervisors, it can adopt a cumulative voting system according to the articles of association or a resolution of the shareholders’ meeting. The term cumulative voting system shall mean that when the shareholders’ meeting elects directors or supervisors, each share has voting rights equivalent to the number of directors or supervisors to be elected, and the voting rights of a shareholder may be collectively exercised. The board of directors shall publicly announce to the shareholders the resumes and basic circumstances of the candidates for directors and supervisors. Except for issues involving the privacy, the directors and supervisors shall truthfully make their statements; however, the shareholders may not disclose their details to any third party. The candidates for directors and supervisors must have the professional qualifications required by laws and regulations, the Hong Kong Listing Rules, and the securities regulatory authority of the place where the Company’s shares are [REDACTED], as well as the level of professional expertise and knowledge required to perform their duties.

The shareholders’ meeting will vote on all proposals item by item, except for proposals under the cumulative voting system, and if there are different proposals on the same issue, the proposals will be voted according to the sequence in which they were submitted. The shareholders’ meeting will not set aside or withhold voting on the proposals, except when the shareholders’ meeting is suspended or unable to reach a resolution due to special reasons such as force majeure.

When a proposal is reviewed at a shareholders’ meeting, no modifications may be made to the proposal; otherwise, the modification in question shall be deemed to be a new proposal and cannot be voted at this shareholders’ meeting.

If a network or other means of voting is set up, one voting right can be exercised once through one method of on-site, Internet voting or any other means of voting. The first voting result shall prevail in the event of a duplicate voting for the same voting right.

The shareholders’ meeting shall vote by open ballot. Before the shareholders’ meeting votes on a proposal, two representatives of shareholders shall be elected to participate in the counting and monitoring of the cast of ballots. In case any matter to be reviewed has any relation with any shareholder, neither the related shareholder nor his/her proxy shall participate in the counting or monitoring of the cast of ballots. When the shareholders’ meeting votes on a proposal, the lawyers (if any), representatives of shareholders and supervisors shall be jointly responsible for the counting and monitoring of votes and shall announce the voting results on

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the spot. The voting results shall be recorded in the minutes. The Company's shareholders or their proxies who vote via the Internet or by any other means (if any) are entitled to check their own voting results through the corresponding voting system.

The on-site shareholders' meeting shall end no earlier than the Internet or other means (if any), and the presiding officer of the meeting shall announce the voting and results of each proposal and declare whether the proposal has been adopted or not based on the voting results. Prior to the formal announcement of the voting results, the relevant parties involved in the shareholders' meeting by on-site, online and other voting means (if any), such as the Company, the tellers, the scrutineers, the major shareholders, and the network service provider (if any), shall be under a duty of confidentiality with respect to the voting.

The shareholders attending the shareholders' meeting shall deliver any of the following opinions on any proposal put forward for voting: affirmative, negative or abstention. The securities depository and clearing organization shall be the nominee holder of the shares under the Transaction Interconnection Mechanism for the Mainland and Hong Kong Stock Markets, except where declarations are made in accordance with the actual holder's intention. Where any ballot is not filled in, wrongly filled in or unintelligible or has no vote recorded, the voter shall be deemed to have waived his/her voting rights and the voting result of his/her shares shall be deemed as an "abstention".

Where the meeting host has any doubts on the resolution result submitted for voting, he/she may organize a recounting of the cast votes. Where the meeting host has not yet counted the votes, shareholders or their proxies attending the meeting who object to the result announced by the meeting host may request a recounting of the votes after the announcement of the voting result, and the meeting host shall immediately organize for a recounting of votes.

Resolutions of the shareholders' meeting shall be announced in a timely manner. The announcement shall specify the number of shareholders and shareholder proxies attending the meeting, the total number of shares with voting rights they hold and their proportion to the total number of voting shares in the Company, the method of voting, the voting result for each proposal and details of each resolution passed.

Where a resolution is not passed, or a resolution made at a previous shareholders' meeting is modified at the shareholders' meeting, a special note shall be included in the resolution of the shareholders' general meeting.

Where any proposal for the election of a director or supervisor is adopted at a meeting, the newly elected director or supervisor shall take office on date which the resolution of the shareholders' meeting is passed.

Where a shareholders' meeting adopts a proposal to pay cash dividends, gift shares or convert capital reserve funds into share capital, the Company shall implement the specific plan within two months of the closing of the shareholders' meeting.

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BOARD OF DIRECTORS

Directors

The Company's directors are natural persons. A natural person shall not serve as a company director if any of the following circumstances applies:

- (1) a person without civil capacity or with restricted civil capacity;
- (2) a person who has been sentenced due to corruption, bribery, embezzlement or misappropriation of property or sabotaging the socialist market economic order, with less than five years have elapsed since the completion date of the execution of the penalty, or deprived of his/her political rights due to any crime, with less than five years have elapsed since the completion date of the execution of the penalty, or granted a probation, with less than two years have elapsed since the completion date of the probation period;
- (3) a former director, factory director, manager of a company or enterprise which has been bankrupt or liquidated, whereby he/she was personally responsible for the bankruptcy of such company or enterprise, and less than three years have elapsed since the date of completion of the bankruptcy or liquidation of such company or enterprise;
- (4) a former legal representative of a company or enterprise, but the business license of this company or enterprise was revoked or this company or enterprise was ordered to close due to a violation of the law, whereby he/she was personally responsible for the revocation or closure, and less than three years have elapsed since the date of the revocation of the business license or the order to close;
- (5) a person who has failed to repay a relatively large amount of his/her due and unpaid debts, and has been listed as a dishonest person subject to enforcement by the people's court;
- (6) a person who has been prohibited from entering into securities market by CSRC, and the period has not expired;
- (7) other circumstances required by the applicable law, administrative regulations, departmental rules, other normative documents, the Hong Kong Listing Rules, and other securities regulatory rules of the place where the shares of the Company are [REDACTED].

In the case of an election or appointment of a director in contravention of this Article, such election, appointment or engagement shall be invalid. If any of the circumstances stated in this Article occurs during the term of office of a director, the Company shall remove such director from office.

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Director shall be elected or replaced by a shareholders' meeting, and may be removed by an ordinary resolution adopted by a shareholders' meeting before the expiry of his/her term of office (such removal shall not affect a claim by that director for damages under any contract). Each term of office of a director shall be 3 years. Upon expiry of a director's term of office, he/she may be re-elected. The term of office of a director shall be calculated from the date he/she takes up the appointment until the current term of office of the board of directors expires. If a director is not yet subject to re-election upon expiry of his/her term of office, before the newly elected director takes up appointment, the original director shall still carry out his/her duties according to the law, administrative regulations, departmental rules, and the articles of association. The general manager or other senior management personnel can concurrently hold the position of director. However, the aggregate number of directors concurrently serving as general manager or other senior management personnel may not exceed 1/2 of the total number of directors. The board of directors will not have staff representative director.

A director should comply with the law, administrative regulations, and the articles of association, and owe the following duties of loyalty to the Company:

- (1) not to make use of his/her position to receive bribes or other illegal income, and cannot embezzle the Company's assets;
- (2) not to misappropriate the Company's funds;
- (3) not to use his own name or other individuals' names to open accounts to deposit the Company's assets or funds;
- (4) without the consent of the shareholders' meeting or the board of directors, not to violate the articles of association by loaning the Company's funds to other persons or using the Company's assets to provide guarantee for other persons;
- (5) not to enter into any contract or trade with the Company without the consent of the shareholders' meeting or in violation of the articles of association of the Company;
- (6) without the consent of the shareholders' meeting, not to make use of his/her position to obtain business opportunities that should belong to the Company for himself or others, and not to trade with oneself or others in the same type of business of the Company;
- (7) not to accept commissions for transactions with the Company for his/her own;
- (8) not to disclose secrets of the Company without authorization;
- (9) not to make use of his/her related-party relationship to damage the Company's interests; and
- (10) other duties of loyalty stated in the law, administrative regulations, departmental rules, Hong Kong Listing Rules, and other securities supervision regulations of the place where the Company's shares are [REDACTED], and the articles of association of the Company.

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Any income obtained by a director in violation of this Article should belong to the Company. In case it has caused losses to the Company, he/she should be responsible for compensation.

A director should comply with the law, administrative regulations and the articles of association, and owe the following duties of diligence towards the Company:

- (1) prudently, earnestly and diligently exercise his/her rights conferred by the Company in order to ensure that the business activities of the Company comply with the requirements of the State laws, administrative regulations and various national economic policies, and the business activities cannot exceed the scope of activities specified in the business license;
- (2) treat all shareholders fairly;
- (3) understand the business operation and management circumstances of the Company in a timely manner;
- (4) sign and endorse the regular reports of the Company. He/she should ensure the truthfulness, accuracy and completeness of information disclosed by the Company;
- (5) provide the relevant information and materials to the board of supervisors truthfully, and should not obstruct the board of supervisors or the supervisors from exercising their functions and powers;
- (6) ensure that he/she has adequate time and energy to participate in the affairs of the Company, and make prudent judgment on the risks and benefits that may arise from the matters being deliberated; in principle, he/she should attend the board meeting in person, but if he/she authorizes another director to attend the meeting on his/her behalf, he/she should select the proxy prudently, the authorized matters and decision-making intent should be specific, and he/she should not entrust the proxy with sole discretion;
- (7) pay attention to the business status and other matters of the Company and timely report to the board of directors of relevant issues and risks, and should not claim exemption of liability on the grounds that he/she is not familiar with the Company's business or does not understand the relevant matters;
- (8) actively promote the standardized operation of the Company, promptly correct the irregularities of the Company, and support the performance of social responsibilities by the Company; and

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- (9) other duties of diligence stipulated in the law, administrative regulations, departmental rules, Hong Kong Listing Rules, and other securities supervision regulations of the place where the Company's shares are [REDACTED], and the articles of association of the Company.

Where a director neither attends two consecutive board meetings nor entrusts another director to attend the board meetings, he/she shall be deemed unable to perform his/her duties, and the board of directors shall propose to the shareholders' meeting to replace the director.

A director may resign prior to the expiration of his/her term. A resigning director shall submit a written resignation report to the board of directors. The board of directors should disclose the relevant situations within 2 days. If the number of directors falls below the minimum legal requirement as a result of a director's resignation, before a newly elected director commences the appointment, the original director shall still carry out his/her duties according to the law, administrative regulations, departmental rules, and the articles of association. Except as specified in the preceding paragraph, the resignation of a director shall become effective when his/her resignation report is delivered to the board of directors.

When the resignation of a director takes effect or his/her term of office expires, he/she shall complete all handover procedures with the board of directors. His/her duty of loyalty towards the Company and the shareholders will not be released after the termination of his/her term of office. His/her duty to keep the Company's trade secrets confidential will still be valid after the termination of his/her term of office until those secrets become public information. The duration of other duties shall be determined in accordance with the principle of fairness and will depend on the length between the occurrence of relevant events and his/her departure, and the situation and condition under which his/her relation with the Company was terminated.

Unless otherwise specified in the articles of association or legally authorized by the board of directors, no director shall represent the company or the board of directors to act in his/her own name. When a director acts in his/her own name, but a third party reasonably thinks that the director acts on behalf of the Company or the board of directors, the director shall declare in advance his position and capacity.

If a director contravenes the law, administrative regulations, departmental rules or the articles of association in performing his duties, thereby causing losses to the Company, he/she shall be responsible for compensating.

Independent Directors

The Company shall have independent directors. Matters such as the qualification, nomination and election procedures, term of office, resignation and authorities of the independent directors shall be implemented in accordance with laws, administrative regulations, departmental rules, the Hong Kong Listing Rules and other securities regulatory rules of the place where the Company's shares are [REDACTED]. An independent director is

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a director who does not hold any position other than director in the Company and who does not have any relationship with the Company or its major shareholders that could prevent him/her from exercising independent and objective judgment.

The Company shall have independent directors among the members of the board of directors. The number of independent directors shall be no less than 1/3 of the board of directors and no less than 3, and at least one independent director must have appropriate professional qualifications complying with the supervisory requirements or have appropriate accounting or related financial management expertise.

The term of office of the independent directors is the same as that of other directors. Upon expiration of his/her term, he/she may be re-elected.

The independent directors should perform their duties independently, and shall not be influenced by the Company's major shareholders, the actual controlling persons, or other entities or individuals that have an interest in the Company, its major shareholders, or the actual controlling persons.

An independent director shall ensure that he/she has sufficient time and energy to perform his/her duties effectively.

Board of Directors

The Company shall have a board of directors. The board of directors shall consist of 9 directors. The board of directors shall have one chairman. The board of directors shall consist of executive directors, non-executive directors and independent directors.

The board of directors shall exercise the following functions and powers:

- (1) convene shareholders' meeting, and report to the shareholders' meeting on its work;
- (2) implement resolutions of the shareholders' meeting;
- (3) determine the operational plans and investment programs of the Company;
- (4) review and approve the Company's proposed annual financial budgets and final accounts;
- (5) prepare the Company's profit distribution plans and loss compensation plans;
- (6) prepare plans for increasing or reducing the Company's registered capital, for issuing bonds or other securities as well as for the listing of the Company;

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- (7) prepare plans concerning the Company's significant acquisition, merger, division, spin-off, dissolution, voluntary winding-up, liquidation or change of the Company's corporate form;
- (8) prepare plans concerning the Company's share buyback as described in Article 23 paragraph 1 (1) and (2) of its articles of association;
- (9) make resolutions concerning the Company's share buyback as described in Article 23 paragraph 1 (3), (5) and (6) of its articles of association;
- (10) within the scope authorized by the shareholders' meeting, decide the Company's external investment, purchase and sale of assets, pledge of assets, external guarantee, appointment to manage wealth and connected transactions, etc.;
- (11) decide to establish the Company's internal management organizations;
- (12) appoint or dismiss the Company's general manager and secretary to the board of directors, and decide on their remuneration, reward and punishment; according to the general manager's nomination, appoint or dismiss senior management personnel such as deputy general manager or chief financial officer, and decide on their remuneration, reward and punishment;
- (13) prepare the Company's basic management system;
- (14) prepare plans on any amendment of the Company's articles of association;
- (15) manage the Company's information disclosure;
- (16) propose to the shareholders' meeting on the appointment or replacement of the accounting firms that make regular and statutory audits of the Company's financial reports;
- (17) hear the general manager's work report and inspect the general manager's work; and
- (18) other functions as conferred by laws, administrative regulations, departmental rules, the Hong Kong Listing Rules, and other securities regulatory rules of the place where the Company's shares are [REDACTED] or the Company's articles of association.

Matters beyond the scope of such authorization shall be submitted to the shareholders' meeting for consideration.

The board of directors of the Company shall establish an audit committee, a remuneration and appraisal committee and a nomination committee, and may establish other relevant special committees based on needs. Special committees shall be responsible to the board of directors, perform duties in accordance with the articles of association of the Company and the

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authorization of the board of directors, and submit proposals to the board of directors for deliberation and decision. Each special committee shall be composed entirely of directors. In particular, the audit committee shall be composed entirely of non-executive directors and shall have at least three members, including at least one independent director who meets the relevant supervisory requirements with appropriate professional qualification or has appropriate accounting or relevant financial management expertise. The audit committee shall comprise a majority of independent directors, and the chairman (or convener) of the audit committee shall be an independent director. The nomination committee shall comprise a majority of independent directors, and the chairman (or convener) of the nomination committee shall be an independent director or the chairman of the board of directors. The remuneration and appraisal committee shall comprise a majority of independent directors, and the chairman (or convener) of the remuneration and appraisal committee shall be an independent director. The chairman (or convener) of each special committee will be appointed or dismissed by the board of directors. The board of directors shall be responsible for formulating the procedural rules and working procedures of the special committees, stipulating the composition, authority, procedures and other matters of the special committees, and regulating the operation of the special committees.

The board of directors shall have one chairman. The chairman of the board of directors shall be elected by more than half of all the directors. The chairman of the board of directors shall exercise the following functions and powers:

- (1) to preside over shareholders' meetings, and to convene and preside over meetings of the board of directors;
- (2) to supervise, urge and inspect the implementation of resolutions of the board of directors;
- (3) to organize and formulate various systems for the operation of the board of directors, and coordinate the operation of the board of directors;
- (4) to sign the shares certificates, corporate bonds and other valuable securities of the Company;
- (5) to propose the name list of general manager and secretary to the board of directors of the Company;
- (6) to sign important documents of the board of directors, and other documents which should be signed by the legal representative of the Company;
- (7) to exercise the functions and powers of the legal representative;
- (8) when a force majeure event such as a very serious natural disaster occurs, to exercise special disposal power, which complies with the law and in the interest of the Company, to deal with the Company's affairs, and thereafter to report to the board of directors and shareholders' meeting; and

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- (9) other functions and powers delegated by the board of directors.

If the chairman of the board of directors cannot or does not carry out his/her duties, the duties shall be performed by a director jointly nominated by more than half of the board of directors.

Meetings of the board of directors include regular meetings and extraordinary meetings. The board of directors shall convene at least 4 times a year and once each quarter. Regular meetings are convened by the chairman of the board of directors. Written notice shall be sent to all directors and supervisors 14 days before the meeting is held and necessary information shall be provided 3 days before the meeting is held. Extraordinary meetings of the board of directors shall be convened by the chairman of the board of directors. Written notice shall be sent to all directors and supervisors 3 days before the meeting is held and necessary information shall be provided. In the event of emergency, if an extraordinary meeting of the board of directors is required to be convened as soon as possible, the meeting notice can at any time be made by telephone or other oral method. However, the convener should explain at the meeting.

The board of directors should convene an extraordinary meeting under one of the following circumstances:

- (1) shareholders representing more than 1/10 of the voting rights propose;
- (2) more than 1/3 of the directors propose;
- (3) the board of supervisors proposes;
- (4) more than 1/2 of the independent directors propose;
- (5) the chairman of the board considers necessary;
- (6) other circumstances as stipulated by the articles of association.

A notice of a board of directors meeting includes the following contents:

- (1) date and place of meeting;
- (2) duration of the meeting;
- (3) subject matter and topic;
- (4) date of issuance of notice; and
- (5) contact person and contact details.

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An oral meeting notice should at least include the above mentioned items (1) and (2) and the explanation that due to emergency, an extraordinary board meeting needs to be convened as soon as possible.

After the written notice of a regular board of directors meeting is issued, if the time, place or other matters of the meeting need to be changed, or if the meeting topics need to be added, changed or cancelled, a written change notice should be issued 3 days in advance of the original meeting date in order to explain the situation and relevant contents and relevant materials of the new topics. If there is less than 3 days, the date of the meeting should be postponed correspondingly or the meeting will be convened as scheduled after approval by all attending directors. After the notice of an extraordinary board of directors meeting is issued, if the time, place or other matters of the meeting need to be changed, or if the meeting topics need to be added, changed or cancelled, prior approval by all attending directors must be obtained and relevant minutes must be taken.

A board of directors meeting can be held only after exceeding half of the directors attend. Each director has one vote. When a board of directors makes a resolution, it must be passed by exceeding half of all the directors. When a director is connected with a board of directors resolution or related enterprise, such director must not vote on that resolution, and cannot vote on behalf of other directors. That board meeting can be held only if exceeding half of the unrelated directors attend. Resolutions of the board of directors must be passed by exceeding half of the unrelated directors. If the number of unrelated directors attending the meeting is less than three (3), the matter should be submitted to the shareholders meeting for discussion.

The voting methods for passing a resolution at a board meeting are open ballot or by means of communication. Resolutions may be passed at an extraordinary board meeting through means of communication provided that the directors are able to fully express their views and opinions. Such resolutions shall be signed by the directors present at the meeting. If a substantial shareholder or a director is considered by the board of directors to be materially interested in the matter to be considered at the board meeting, the matter must be conducted by a board meeting (rather than by a written resolution). Independent non-executive directors (themselves and their close associates) who do not have a material interest in the transaction should attend the relevant board meeting.

Directors should attend the board meeting in person. If a director is however unable to attend due to any reason, he/she can appoint in writing another director to attend the meeting on his/her behalf. Independent directors cannot authorize non-independent directors to attend board meetings on their behalf. A director cannot accept the appointment of more than two other directors to attend a board meeting on their behalf. When considering matters related to connected transactions, an unconnected director cannot authorize a connected director to attend the meeting on his/her behalf. The power of attorney should contain the name of the representative, the matters represented, scope of authority and valid period and should be signed or stamped by the person making the appointment. The director representing another

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person at the board meeting should exercise the director's rights within the authorized scope. If a director does not attend a board meeting in person or by proxy, such director is deemed to abstain from voting in that meeting.

The board of directors should prepare minutes of decisions on matters discussed at the board meeting. The directors attending the meeting should sign on the minutes. Minutes of board meetings is kept as a company file for not less than 10 years. If any director gives reasonable notice, relevant minutes of the board meeting shall be made available for inspection by that director at any reasonable time.

Minutes of a board meeting shall contain the following contents:

- (1) time and place of the meeting as well as the name of the convener;
- (2) names of directors attending the meeting and names of directors (proxies) appointed by other directors to attend;
- (3) agenda of the meeting;
- (4) main points of directors' speeches;
- (5) methods and results of voting on each resolution (the number of votes consenting, objecting and abstaining should be clearly set forth in the voting results); and
- (6) other matters that the directors attending the meeting consider necessary to be recorded.

Directors should be responsible for resolutions of the board of directors. If a resolution of the board of directors is in violation of laws, regulations, the articles of association or resolutions of the shareholders' meeting, which causes losses to the Company, the directors who participated in the adoption of such resolution are responsible for compensating the Company. However, if a director can prove that he/she expressed his/her objection to the resolution and that such objection was recorded in the minutes, then this director can be exempted from such responsibility.

GENERAL MANAGER AND OTHER SENIOR MANAGEMENT PERSONNEL

The Company shall have one general manager who is appointed or removed by the board of directors. The Company shall have a deputy general manager who is appointed or removed by the board of directors. The general manager, deputy general manager, chief financial officer, secretary of the board of directors and other persons recognized by the board of directors as senior management personnel shall be deemed as the Company's senior management personnel.

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The circumstances stipulated in the articles of association regarding disqualification for the position of director also apply to senior management personnel. The duty of loyalty of directors as set forth in Article 96 of the articles of association also applies to senior management personnel. The duty of diligence as set forth in Article 97 (4), (5) and (6) of the articles of association also applies to senior management personnel. Any person holding a post, other than a director or supervisor, in the organization of the controlling shareholder or the actual controller of the Company cannot hold the position of senior management personnel of the Company. The senior management personnel receive salary only from the Company, and the salary of the senior management personnel is not paid by the controlling shareholder on behalf of the Company.

Each term of service for the general manager is 3 years. The general manager may serve consecutive terms upon re-appointment. The general manager is responsible to the board of directors and exercises the following functions and powers:

- (1) be in charge of the Company's production, operation and management, implement decisions of the board of directors and report his/her work to the board of directors;
- (2) implement the Company's annual operation plans and investment plans;
- (3) draft the Company's internal management structure plan;
- (4) draft the Company's basic management system;
- (5) set down the Company's specific rules and regulations;
- (6) propose the board of directors to appoint or remove deputy general manager, chief financial officer and other senior management personnel;
- (7) appoint or remove management personnel other than those required to be appointed or removed by the board of directors;
- (8) review and approve other connected transactions outside the approval scope of the board of directors or shareholders' meeting;
- (9) determine the salary, welfare, rewards and punishment for the Company's staff, and decide on the employment and removal of the Company's staff;
- (10) decide on other external investment, asset acquisition and sale, asset mortgage and pledge, external guarantee, entrusted management of wealth and connected transactions, except for transactions subject to approval of the shareholders' meeting or the board of directors in accordance with the Articles of Association; and
- (11) other functions authorized by the articles of association or the board of directors.

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The Company's general manager shall comply with the law, administrative regulations, and the Company's articles of association, and shall perform his/her duties of loyalty and diligence. In the event that the general manager ceases to engage in the Company's business due to discharge, resignation, removal or other reasons, and the Company agrees to pay the general manager according to his/her average income in the previous year, the general manager shall not, during the period of time paid by the Company, hold any post in any other company that may be in competition with the Company's business or provide other companies with consulting help or advice. The general manager may resign office before the expiration of his/her term of service. The specific procedure and method for the general manager's resignation shall be specified in the employment contract entered into between the general manager and the Company.

The deputy general manager shall assist the general manager and be responsible to the general manager, take charge of other relevant matters as delegated by the general manager, and sign and issue relevant business documents within his/her scope of duties. If the general manager is unable to exercise his/her duties, the deputy general manager can be delegated by the general manager to exercise the duties of the general manager.

The Company shall have a secretary to the board of directors, who shall be responsible for the preparation of shareholders' meetings and board of directors' meetings, document keeping, management of shareholders' information of the Company and handling information disclosure matters, etc. The secretary to the board of directors shall comply with the law, administrative regulations, departmental rules, and the Company's articles of association.

If a senior management violates the law, administrative regulations, departmental rules, Hong Kong Listing Rules or other securities regulatory rules of the place where the Company's shares are [REDACTED], or the Company's articles of association in the performance of his/her duties to the Company, thereby causing losses to the Company, he/she shall be liable to compensate. The Company's senior management personnel shall faithfully carry out their duties and safeguard the best interests of the Company and all shareholders. If a senior management fails to faithfully carry out his/her duties or violates his/her duty of good faith, thereby causing losses to the interests of the Company and the shareholders of the public society, he/she shall be liable to compensate according to the laws.

SUPERVISORS AND THE BOARD OF SUPERVISORS

Supervisors

The relevant provisions in the Company's articles of association regarding disqualification for appointment as a director shall also apply to supervisors. Directors, the general manager and other senior management personnel cannot concurrently serve as supervisors. A supervisor shall comply with the law, administrative regulations, Hong Kong Listing Rules, and other securities regulatory rules of the place where the Company's shares are [REDACTED], and the Company's articles of association. A supervisor has the duties of loyalty and diligence towards the Company. He/she shall not make use of his/her position to receive any bribe or other illegal income, nor shall he embezzle any of the Company's assets.

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Each term of service of a supervisor is 3 years. Upon expiration of a supervisor’s term of service, he/she can be re-elected. If a new supervisor is not yet appointed upon expiry of the term of service of a supervisor, or if a supervisor resigns during his/her term of service, leading to the number of members in the board of supervisors falling below the statutory number, before the newly appointed supervisor takes up his/her appointment, the original supervisor shall still carry out his/her duties according to the law, administrative regulations, and the Company’s articles of association. A supervisor should ensure that the information disclosed by the Company is true, accurate and complete. He/she should also sign a written confirmation opinion on the regular report. A supervisor may attend board of director’s meetings. He/she can question or make suggestions regarding proposed resolutions at the meeting. A supervisor must not make use of his/her connected relations to damage the Company’s interests. If he/she causes losses to the Company, he/she shall be liable to compensate. If a supervisor contravenes the law, administrative regulations, departmental rules, or the Company’s articles of association while performing his/her duties to the Company, resulting in losses to the Company, he/she shall be liable to compensate.

Board of Supervisors

The Company shall have a board of supervisors. The board of supervisors shall consist of 3 supervisors. The board of supervisors has one chairman. The chairman shall be elected by exceeding half of all the supervisors. The chairman convenes and presides over meetings of the board of supervisors. If the chairman is unable to or fails to carry out his/her duties, a majority of the supervisors shall nominate a supervisor to convene and preside over the meeting.

The board of supervisors should include shareholders’ representatives and an appropriate proportion of the Company’s staff representatives. The proportion of the staff representative should not be less than one third. The staff representatives in the board of supervisors shall be democratically elected by the staff of the Company through the staff representatives’ meeting, staff meeting or other means.

The board of supervisors exercises the following functions and powers:

- (1) review and provide written opinions on the Company’s periodical reports prepared by the board of directors;
- (2) check the Company’s financial status;
- (3) monitor the performance of duties to the Company by directors and senior management personnel, and propose to remove directors or senior management personnel who have violated the law, administrative regulations, Hong Kong Listing Rules, other securities supervision regulations of the place where the Company’s shares are [REDACTED], the Company’s articles of association or resolutions of shareholders’ meetings;

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- (4) require directors or senior management personnel to correct their actions that damage the Company's interests;
- (5) propose to convene extraordinary shareholders' meetings, and convene and preside over a shareholders' meeting when the board of directors does not convene or preside over a shareholders' meeting as required by the Company Law;
- (6) present proposals to the shareholders' meeting;
- (7) initiate litigation against directors and senior management personnel in accordance with the Company Law;
- (8) conduct investigations upon discovering abnormalities in the Company's operations; if necessary, hire professional firms such as accounting firms or law firms to assist with its work at the expenses of the Company; and
- (9) other duties prescribed by the law, administrative regulations, departmental rules, Hong Kong Listing Rules, other securities supervision regulations of the place where the Company's shares are [REDACTED], the Company's articles of association, or authorized by the shareholders' meeting.

Meetings of the board of supervisors include regular meetings and extraordinary meetings. Regular meetings of the board of supervisors should be convened once every 6 months. Under any of the following circumstances, the board of supervisors should convene an extraordinary meeting within 10 days:

- (1) any supervisor proposes to convene an extraordinary meeting;
- (2) the shareholders' meeting or the board meeting has passed a resolution which violates the laws, regulations, departmental rules, Hong Kong Listing Rules, other securities supervision regulations of the place where the Company is [REDACTED], the Company's articles of association, the resolution of a shareholders' meeting or other relevant provisions;
- (3) the improper conduct of the directors and senior management personnel may cause great damage to the Company or cause adverse impact on the market;
- (4) the shareholders file a lawsuit against the Company, its directors, supervisors, or senior management personnel;
- (5) the Company, its directors, supervisors, or senior management personnel are punished by the securities regulatory authorities or condemned by the stock exchange; and
- (6) other circumstances as required by the Company's articles of association.

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SUMMARY OF ARTICLES OF ASSOCIATION

Resolutions of the board of supervisors should be adopted by more than half of all the supervisors.

The board of supervisors should maintain the minutes of its decisions on the matters under its consideration. Supervisors present at the meeting should sign the minutes of the meeting. Supervisors should have the right to require the minutes to record the explanatory statements for their speeches made at the meeting. The minutes of the board of supervisors’ meetings should be kept in the Company’s archives for at least 10 years.

FINANCIAL ACCOUNTING SYSTEM

The Company should formulate the financial accounting system according to the law, administrative regulations, and the rules of relevant state departments. If the Hong Kong Listing Rules or the rules of securities regulatory authorities at the place where the Company’s shares are [REDACTED] provide otherwise, the rules shall prevail.

The Company should prepare an annual financial accounting report within 4 months after the end of each accounting year. A half-yearly financial accounting report should be prepared within 2 months after the end of the first 6 months of each accounting year. The above financial accounting reports should be prepared according to the relevant law, administrative regulations, department rules, the Hong Kong Listing Rules, and other securities regulatory rules of the place where the Company’s shares are [REDACTED].

Other than the legally prescribed accounting books, the Company should not establish another accounting book. The Company’s funds will not be deposited in an account opened in the name of any individual.

After the Company is distributing the after-tax profits of the year, it should allocate 10% of the profits as the Company’s statutory reserve fund. If the Company’s accumulative statutory reserve fund exceeds 50% of the registered capital of the Company, no further allocation is required. If the Company’s statutory reserve fund is not sufficient to compensate for the Company’s losses in the previous year, such losses should first be compensated before the allocation mentioned in the preceding paragraph is made. After the Company has allocated the statutory reserve fund from the after-tax profits, if resolved by the shareholders’ meeting, it may also allocate a discretionary reserve fund from the after-tax profits. After the Company has made up losses and allocated reserves, the balance of the after-tax profits should be distributed in proportion to the shares held by shareholders, unless the articles of association provide otherwise. If the shareholders’ meeting contravenes the provisions of the preceding paragraph, and distributes the profits of the Company to shareholders before losses have been made up and statutory reserves have been allocated, the profits distributed in violation of the provisions must be returned to the Company. If losses have been incurred as a result of such distribution, the shareholders and the responsible directors, supervisors, and senior managers shall be liable for compensation. Shares of the Company held by its own do not participate in profit distribution.

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The Company’s reserve fund is for the purposes of loss compensation, business expansion, or registered capital increase. When the reserve fund is used to compensate the Company’s losses, the discretionary reserve fund and statutory reserve fund should be used first. If these fail, the capital reserve fund may be used according to the regulations. When the statutory reserve fund is converted into the increased registered capital, the remaining balance of the reserve fund cannot be less than 25% of the Company’s registered capital prior to the conversion.

After the shareholders’ meeting of the Company has resolved on the profit distribution plan, the board of directors of the Company should complete the distribution of dividend (or bonus shares) within 2 months of the meeting.

The Company’s profit distribution policy is to distribute dividend in cash or stock according to its actual operation performance in that year and in accordance with applicable law, administrative regulations, departmental rules, the Hong Kong Listing Rules and other securities regulatory rules of the place where the Company’s shares are [REDACTED].

Internal Audit

The Company shall implement an internal audit system. It will be staffed with full-time auditors to conduct internal audit and monitoring on the financial income and expense as well as economic activities of the Company and its subsidiary institutions.

The internal audit system of the Company and the responsibilities of the audit personnel should be implemented after being approved by the board of directors. The audit personnel shall be responsible to and report their work to the board of directors.

Accounting Firm

The Company shall appoint an accounting firm which conforms to the provisions of the Securities Law, the Hong Kong Listing Rules and other securities regulatory rules of the place where the Company’s shares are [REDACTED] to conduct the auditing of its accounting statements, the verification of its net assets and other relevant consultancy services. The term of appointment is one year and may be renewed.

The Company shall appoint an accounting firm to conduct the auditing of its accounting statements and other relevant businesses. The appointment of an accounting firm by the Company shall be decided by the shareholders’ meeting. The board of directors shall not appoint an accounting firm prior to the decision of the shareholders’ meeting. The Company shall appoint an accounting firm or renew its appointment at each annual shareholders’ meeting. The appointment shall last until the end of the next annual shareholders’ meeting.

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The Company shall guarantee that the accounting vouchers, account books, financial accounting reports and other accounting information that it provides to the accounting firm are true and complete and shall not refuse to provide information, hide or provide false information.

The auditing fees of the accounting firm shall be decided by the shareholders' meeting.

The Company shall notify the accounting firm 15 days in advance of the termination of its appointment or non-renewal of appointment and shall comply with the procedures stipulated in the Hong Kong Listing Rules and other securities regulatory rules of the place where the Company's shares are [REDACTED]. When the shareholders' meeting votes on the termination of appointment of the accounting firm, the accounting firm shall be allowed to state its opinion. If an accounting firm proposes to resign, it shall inform the shareholders' meeting whether the Company has any irregularities.

NOTICES AND ANNOUNCEMENTS

Notices of the Company shall be made in the following manners:

- (1) delivered by hand;
- (2) sent by mail or email;
- (3) made by publishing on the website designated by the Stock Exchange of Hong Kong, subject to compliance with laws, administrative regulations and the Hong Kong Listing Rules;
- (4) made by telephone, SMS or WeChat;
- (5) made by announcement; and
- (6) other manners provided by laws, administrative regulations, rules or the articles of association of the Company.

In respect of the manner in which the Company is required to provide or send corporate communications to its shareholders in accordance with the Hong Kong Listing Rules, subject to the laws and regulations and the listing rules of the place where the shares are [REDACTED] and the articles of association of the Company, a corporate communication may be sent to its shareholders on the website designated by the Company and/or on the Stock Exchange of Hong Kong or by electronic means. The aforesaid corporate communication means any document sent or to be sent by the Company for reference or action by any shareholder or other person as required by the Hong Kong Listing Rules, including without limitation, an annual report (including an annual financial report), an interim report (including an interim financial report and notice of the interim report), a report of the directors (together with a balance sheet and a profit and loss statement), a notice relating to meetings, listing documents, circulars and other communications. Where the Company exercises the powers

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provided for in the Company’s articles of association to give notice in the form of announcement, such announcement shall be published in accordance with the methods provided for in the Hong Kong Listing Rules.

Subject to the prerequisite of compliance with laws and regulations, normative documents, listing rules of the place where the Company’s shares are listed and the Company’s articles of association, where a notice sent by the Company is made by way of announcement, upon announcement, all relevant personnel shall be deemed to have received the notice.

The notice of a shareholders’ meeting convened by the Company shall be made by way of announcement or any other method provided in the Company’s articles of association. The notice of a board meeting convened by the Company shall be delivered by hand, sent by mail, sent by email, telephone, SMS or WeChat or any other effective method. The notice of a board of supervisors meeting convened by the Company shall be delivered by hand, sent by mail, sent by email, telephone, SMS or WeChat or any other effective method.

Where a notice is delivered by hand, the party being served shall sign (or affix seal) on the return receipt, and the date of signature by the party being served shall be the date of service of the notice; where a notice is sent by mail, the date of service of the notice shall be the 15th day from posting at the post office; where a notice is sent by email, the date of service of the notice shall be the date on which the email reaches the email address of the party being served; where a notice is sent by way of SMS or WeChat, the date of service of the notice shall be the date on which the notice is sent; where a notice is served by way of announcement, the date of service of the notice shall be the date on which the announcement is first published.

If a notice of meeting is not delivered due to accidental omission to those entitled to receive it or if such persons do not receive the notice of meeting, the meeting and the resolutions passed by the meeting shall not be rendered invalid as a result thereof.

The Company shall make announcements and disclose information to holders of non-listed shares in China through information disclosure newspapers and websites designated by laws, administrative regulations or the relevant domestic regulatory authorities. Where an announcement is required to be made to holders of H shares in accordance with the articles of association of the Company, the relevant announcement shall simultaneously be published on designated newspapers, websites and/or the Company’s website in accordance with the method stipulated in the Hong Kong Listing Rules. All notices or other documents required to be transmitted by a company to the Hong Kong Stock Exchange under Chapter 13 of the Hong Kong Listing Rules shall be written in English or be accompanied by a signed and certified English translation.

MERGER, DIVISION, INCREASE IN CAPITAL AND CAPITAL REDUCTION

Mergers of companies may take the form of mergers by absorption or mergers by new establishment. Mergers by absorption shall mean that one company absorbs one or more other companies into its own company, whereby the absorbed company or companies are dissolved.

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Mergers by new establishment shall mean that two or more companies merge to establish a new company, whereby each party to the merger is dissolved. The parties to a merger shall enter into a merger agreement for a company merger, and formulate a balance sheet and an inventory list for assets. The Company shall notify its creditors within ten days from passing of the resolution on merger, and make an announcement on the newspapers or the National Enterprise Credit Information Publicity System within 30 days. The creditors may, within 30 days from receipt of the notification, or within 45 days from the date of the announcement if they do not receive the notification, require that the Company settles the debts or provides the corresponding guarantee. The surviving company or the newly-established company of a merger shall succeed to the creditor's rights and debts of the parties to the merger.

In the event of a division, the assets of the Company shall be divided correspondingly. A company which proposes a division shall formulate a balance sheet and an inventory list for assets. The Company shall notify its creditors within ten days from passing of the resolution on division, and make an announcement on the newspapers or the National Enterprise Credit Information Publicity System within 30 days. The surviving company of a division shall bear joint liability for the debts of the Company prior to its division. Except where the written agreement between the Company and its creditors on repayment of debts prior to the division stipulates otherwise.

The Company which proposes to reduce its registered capital shall formulate a balance sheet and an inventory list for assets. The Company shall notify its creditors within ten days from passing of the resolution on reduction of registered capital, and make an announcement on the newspapers or the National Enterprise Credit Information Publicity System within 30 days. The creditors may, within 30 days from receipt of the notification, or within 45 days from the date of the announcement if they do not receive the notification, require that the Company settles the debts or provides the corresponding guarantee. The reduced registered capital of the Company shall not be lower than the minimum amount stipulated by the law.

Where the Company merges or divides, and the registered particulars change, it shall vary its registration at the company registration authority in accordance with the law. Where the Company is wound up, it shall cancel its registration in accordance with the law. Where a new company is established, it shall be registered in accordance with the law. Where the Company increases or reduces its registered capital, it shall vary its registration at the company registration authority in accordance with the law.

DISSOLUTION AND LIQUIDATION

The Company may be dissolved due to the following reasons:

- (1) expiry of the operation period as specified in the articles of association, or occurrence of other matters for dissolution as specified in the articles of association;
- (2) a shareholders' meeting resolves to dissolve the company;

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- (3) the Company is wound up as a result of merger or division;
- (4) the business license of the Company is revoked, or the Company is ordered to be closed down or to be dissolved in accordance with the law; and
- (5) the operation and management of the Company experience a great difficulty, the interest of the shareholders will suffer significant losses if the Company continues to exist, and the difficulty cannot be solved by other means. Shareholders holding more than 10% of the voting rights may request a people's court to dissolve the Company.

If any of the aforementioned dissolution matters occurs, the Company shall announce to the general public through the National Enterprise Credit Information Publicity System within ten days.

If the Company falls into circumstances as provided in items (1) or (2) above, and has not distributed its assets to the shareholders, the Company may continue to exist only by amending its articles of association or by a resolution made at the shareholders' meeting. Amendment to the articles of association or resolution made at the shareholders' meeting pursuant to the aforementioned paragraph, must be passed by shareholders representing more than two thirds of the voting rights present at the meeting.

Where the Company is dissolved pursuant to items (1), (2), (4), or (5) above, a liquidation group shall be established within 15 days of the occurrence of the event of dissolution, and liquidation shall be carried out. The liquidation group shall be composed of directors, except as otherwise provided in the articles of association, or as otherwise selected by a resolution of the shareholders' meeting. Directors shall be the obligors of the liquidation. If the obligors fail to discharge their liquidation obligations in a timely manner, thereby causing losses to the Company or creditors, they shall be liable to compensate.

Where the Company is dissolved pursuant to item (4) above, the authority or company registration authority that made the decision to revoke the business license, order it to close down, or order it to be dissolved may request a people's court to designate relevant personnel to establish a liquidation group, and conduct liquidation.

The liquidation group shall perform the following duties during liquidation:

- (1) liquidate the Company's assets; and prepare a balance sheet and an inventory list of assets, respectively;
- (2) notify creditors by notice or public announcements;
- (3) dispose of and liquidate relevant unfinished business of the Company;

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- (4) pay off all outstanding tax and tax arising from the process of liquidation;
- (5) pay off claims and debts;
- (6) dispose of remaining assets after all debts are paid; and
- (7) participate in civil litigations on behalf of the Company.

The liquidation group shall notify creditors within ten (10) days upon its establishment, and make a public announcement in newspapers or the National Enterprise Credit Information Publicity System within sixty (60) days. Creditors shall declare their claims to the liquidation group within thirty (30) days upon receipt of the notice, or within forty-five (45) days upon announcement of the public announcement if such creditors do not receive the notice. When declaring their claims, creditors shall provide details relevant to the claims, and supporting materials. The liquidation group shall register the claims. During the period of declaration of claims, the liquidation group shall not pay off any of the creditors. After the liquidation group has liquidated the Company's assets, and prepared a balance sheet and an inventory list of assets, it shall formulate a liquidation plan, and submit it to the shareholders' meeting or the people's court for confirmation.

The remaining assets after the Company's assets have been applied to the payment of liquidation expenses, employees' wages, social insurance premiums, statutory compensation, outstanding taxes, and the Company's debts, shall be distributed to the shareholders in proportion to their respective shareholdings.

During liquidation, the Company shall continue to exist, but shall not carry out any business activities unrelated to the liquidation. The Company's assets shall not be distributed to shareholders before full payments have been made in accordance with the aforesaid provisions.

After the liquidation group has liquidated the Company's assets, and prepared a balance sheet and an inventory list of assets, and discovers that the Company's assets are insufficient to pay off its debts, it shall apply to the people's court for bankruptcy liquidation. After the Company accepts the application for bankruptcy, the liquidation group shall hand over the liquidation matters to the bankruptcy administrator appointed by the people's court. After the completion of liquidation, the liquidation group shall prepare a liquidation report, and submit it to the shareholders' meeting or the people's court for confirmation, and submit it to the company registration authority to apply for deregistration. The liquidation group members shall perform liquidation duties, and have the duties of loyalty and diligence. The liquidation group members shall not use their authority to receive bribes or other illegal income, and cannot embezzle the Company's assets. If the liquidation group members are negligent in performing their liquidation duties, thereby causing losses to the Company, they shall be liable to compensate. If the Company or creditors suffer losses due to intentional misconduct or gross negligence, they shall be liable to compensate.

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AMENDMENT OF ARTICLES OF ASSOCIATION

The Company shall amend its articles of association in any of the following circumstances:

- (1) following any revision of the Company Law or relevant laws, administrative regulations, the Hong Kong Listing Rules and other securities regulatory rules of the place where the Company's shares are [REDACTED], the provisions of the articles of association conflict with the revised laws, administrative regulations, the Hong Kong Listing Rules and other securities regulatory rules of the place where the Company's shares are [REDACTED];
- (2) the circumstances of the Company have been changed, and are inconsistent with the contents of the articles;
- (3) the shareholders' meeting decides to amend the articles of association.

Any amendment to the articles that has been passed by resolution of the shareholders' meeting, which requires examination and approval by the administrative department in charge, shall be submitted to the administrative department in charge for approval. Any amendment involving company registration shall amend the registration according to the law.

The board of directors shall amend the articles of association according to the resolutions of the shareholders' meeting and the opinion provided after examination by the administrative department in charge.

Amendments to the articles which involve information to be disclosed as required by law or regulation, shall be publicly announced according to the requirements.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

FURTHER INFORMATION ABOUT OUR GROUP

Incorporation of Our Company

Our Company was established as a limited liability company in the PRC on September 5, 2018, and converted into a joint stock limited company on November 22, 2021.

As of the date of this document, our registered office is located at Beijing-Tianjin-Hebei Collaborative Innovation Demonstration Park, No. 769 Taihang Street, Hi-Tech District, Shijiazhuang City, Hebei Province, PRC and our head office is at 9/F, North Tower of CP Center, No. 20 Jin He East Avenue, Chaoyang District, Beijing, PRC. 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 the Articles of Association are set out respectively in “Appendix IV — Summary of Principal Legal and Regulatory Provisions” and “Appendix V — Summary of Articles of Association”.

Our Company has established a principal place of business in Hong Kong at 46/F, Hopewell Centre, 183 Queen’s Road East, Wan Chai, Hong Kong. We [were] registered with the Registrar of Companies in Hong Kong as a non-Hong Kong company under Part 16 of the Companies Ordinance on [●]. Mr. Ng Tung Ching Raphael 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 the service of process is the same as our principal place of business in Hong Kong.

Changes in the Share Capital of Our Company

Save as disclosed in “History and Corporate Structure,” there has been no alteration in our share capital within two years immediately preceding the date of this document.

Changes in the Share Capital of Our Subsidiaries

Details of our subsidiaries are set out in Note 1 to the Accountants’ Report in Appendix I.

There has been no other alteration in the share capital of our subsidiaries during the two years immediately preceding the date of this document.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

Shareholders’ Resolutions

At the general meeting of our Company held on November 17, 2024, the following resolutions, among others, were passed by the Shareholders:

- (i) the issuance by our Company of H Shares of the nominal value of RMB1.0 each and such H Shares be [REDACTED] on the Stock Exchange;
- (ii) the number of H Shares to be issued pursuant to the [REDACTED] shall be no more than [REDACTED]% of total issued share capital of our Company immediately following completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), and the grant of the [REDACTED] in respect of no more than [REDACTED]% of the number of H Shares issued pursuant to the [REDACTED];
- (iii) subject to the approval by the CSRC, upon completion of the [REDACTED], [REDACTED] Unlisted Shares in aggregate held by our Shareholders will be converted into H Shares on a one-for-one basis;
- (iv) subject to the completion of the [REDACTED], the granting of a general mandate to the Board to allot and issue Shares at any time within a period up to the date of the conclusion of the next annual general meeting of the Shareholders or the date on which the Shareholders pass a special resolution to revoke or change such mandate, whichever is earlier, upon such terms and conditions and for such purposes and to such persons as the Board in their absolute discretion deem fit, and to make necessary amendments to the Articles of Association, provided that, the number of H Shares to be issued shall not exceed [REDACTED]% of the number of Shares in issue as of the [REDACTED] Date;
- (v) subject to the completion of the [REDACTED], the conditional adoption of the Articles of Association, which shall become effective on the [REDACTED] Date, 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
- (vi) authorization of the Board and its authorized persons to handle all matters relating to, among other things, the [REDACTED], the issue and [REDACTED] of the H Shares.

Reorganization

We have not gone through any corporate reorganization for the purpose of the [REDACTED]. For details of the history and development of our Company, see “History and Corporate Structure.”

APPENDIX VI STATUTORY AND GENERAL INFORMATION

FURTHER INFORMATION ABOUT OUR BUSINESS

Summary of Material Contracts

The following contracts (not being contract entered into in the ordinary course of business) [have been] entered into by members of our Group within the two years preceding the date of this document and are or may be material:




- (i) the [REDACTED].

Intellectual Property Rights


Trademarks

Registered Trademarks

As of the Latest Practicable Date, we had registered the following trademarks which we consider to be or may be material to our business:

No.	Trademark	Place of Registration	Registered Owner	Class	Registration Number	Registration Date	Expiry Date
1.	轩竹	PRC	Shandong Xuanzhu	5	36914719	November 14, 2019	November 13, 2029
2.	Xuanzhu	PRC	Shandong Xuanzhu	5	36914713	December 14, 2019	December 13, 2029
3.	Xuanzhu Biopharma	PRC	Shandong Xuanzhu	5	36914720	November 14, 2019	November 13, 2029
4.	 Xuanzhu Biopharm	PRC	Shandong Xuanzhu	5	38962567	March 7, 2020	March 6, 2030
5.		PRC	Shandong Xuanzhu	5	38963950	March 7, 2020	March 6, 2030
6.	安久卫	PRC	Beijing Xuanzhu	5	47258736	February 7, 2021	February 6, 2031
7.	轩竹生物	PRC	Shandong Xuanzhu	5	48217364	August 28, 2021	August 27, 2031
8.		PRC	Beijing Xuanzhu	5	64517641	November 28, 2022	November 27, 2032
9.	轩悦宁	PRC	Our Company	5	64689137	November 7, 2022	November 6, 2032
10.	Xuanzhu	PRC	Shandong Xuanzhu	5	70186984	December 21, 2023	December 20, 2033

APPENDIX VI STATUTORY AND GENERAL INFORMATION

No.	Trademark	Place of Registration	Registered Owner	Class	Registration Number	Registration Date	Expiry Date
11.		PRC	Shandong Xuanzhu	5	70182692	September 14, 2023	September 13, 2033
12.	轩菲宁	PRC	Our Company	5	77207854	September 7, 2024	September 6, 2034

Patents

Registered Patents

As of the Latest Practicable Date, we had registered the following patents which we consider to be or may be material to our business:

No.	Patents	Type of Patent	Place of Registration	Patent Number	Owner	Application Date	Expiry Date
1.	Kinase inhibitor and uses thereof	Invention	Australia	AU2014375500	Our Company	December 30, 2014	December 29, 2034
2.	Crystal form targeting CDK4/6 kinase inhibitor	Invention	Australia	AU2018404690	Our Company	December 27, 2018	December 26, 2038
3.	Crystal form targeting CDK4/6 kinase inhibitor	Invention	Canada	CA3089243C	Our Company	December 27, 2018	December 26, 2038
4.	Kinase inhibitor and uses thereof	Invention	Canada	CA2935103C	Shandong Xuanzhu	December 30, 2014	December 29, 2034
5.	Benzimidazole derivatives and pharmaceutical compositions and uses thereof	Invention	European Patent Office	EP2532665	Shandong Xuanzhu	January 31, 2011	January 30, 2031
6.	Kinase inhibitor and uses thereof	Invention	European Patent Office	EP3091008	Our Company	December 30, 2014	December 29, 2034
7.	Polycyclic anaplastic lymphoma kinase inhibitor	Invention	European Patent Office	EP3202765	Our Company	September 25, 2015	September 24, 2035
8.	Crystal form targeting CDK4/6 kinase inhibitor	Invention	European Patent Office	EP3747880	Our Company	December 27, 2018	December 26, 2038
9.	Benzimidazole derivatives and pharmaceutical compositions and uses thereof	Invention	Hong Kong	HK1177933	Shandong Xuanzhu	April 24, 2013	January 30, 2031
10.	Kinase inhibitor and uses thereof	Invention	Hong Kong	HK1223089	Our Company	August 15, 2016	December 29, 2034

APPENDIX VI STATUTORY AND GENERAL INFORMATION

No.	Patents	Type of Patent	Place of Registration	Patent Number	Owner	Application Date	Expiry Date
11.	Polycyclic anaplastic lymphoma kinase inhibitor	Invention	Hong Kong	HK1235786	Our Company	September 22, 2017	September 24, 2035
12.	Crystal form targeting CDK4/6 kinase inhibitor	Invention	Hong Kong	HK40033772	Our Company	December 31, 2020	December 26, 2038
13.	Benzimidazole derivatives, and pharmaceutical compositions and uses thereof (벤즈이미다졸誘導體、並びにその醫藥組成物及び使用)	Invention	Japan	JP5948252	Shandong Xuanzhu	January 31, 2011	January 30, 2031
14.	Kinase inhibitor and uses thereof (キナーゼ阻害劑及びその使用)	Invention	Japan	JP6263269	Our Company	December 30, 2014	December 29, 2034
15.	Polycyclic inhibitor of anaplastic lymphoma kinase (未分化リンパ腫キナーゼの多環狀阻害劑)	Invention	Japan	JP6554538	Our Company	September 25, 2015	September 24, 2035
16.	Crystal form targeting CDK4/6 kinase inhibitors (CDK4/6キナーゼ阻害劑を標的とする結晶形)	Invention	Japan	JP6972390	Our Company	December 27, 2018	December 26, 2038
17.	Crystal form of a polycyclic inhibitor of anaplastic lymphoma kinase (未分化リンパ腫キナーゼの多環狀阻害劑の結晶形態)	Invention	Japan	JP7494435	Our Company	January 15, 2021	January 14, 2041
18.	Kinase inhibitor and uses thereof (발명의 명칭 키나아제 억제제 및 이의 용도)	Invention	Korea	KR101787680	Shandong Xuanzhu	December 30, 2014	December 29, 2034
19.	Polycyclic inhibitor of anaplastic lymphoma kinase (역형성 림프종 키나제의 폴리사이클릭 저해제)	Invention	Korea	KR101909404	Shandong Xuanzhu	September 25, 2015	September 24, 2035
20.	Crystal form targeting CDK4/6 kinase inhibitors (CDK4/6 키나아제 억제제를 타겟팅하는 결정형)	Invention	Korea	KR102531772	Our Company	December 27, 2018	December 26, 2038

APPENDIX VI STATUTORY AND GENERAL INFORMATION

No.	Patents	Type of Patent	Place of Registration	Patent Number	Owner	Application Date	Expiry Date
21.	Pyrimidine derivatives of mesenchymal lymphoma kinase inhibitors (嘧啶衍生物類間變性淋巴瘤激酶抑制劑)	Invention	PRC	ZL201810442695.7	Our Company	March 6, 2014	March 5, 2034
22.	Crystallization of targeted CDK4/6 kinase inhibitors (靶向CDK4/6激酶抑制劑的晶型)	Invention	PRC	ZL201910077459.4	Our Company	January 28, 2019	January 27, 2039
23.	Benzimidazole derivatives and pharmaceutical compositions and applications thereof (苯並咪唑衍生物及其藥物組合物和應用)	Invention	PRC	ZL201180006795.1	Beijing Xuanzhu	January 31, 2011	January 30, 2031
24.	Kinase Inhibitors and uses thereof (激酶抑制劑及其用途)	Invention	PRC	ZL201480065837.2	Our Company	December 30, 2014	December 29, 2034
25.	Polycyclic mesenchymal lymphoma kinase inhibitors (多環類間變性淋巴瘤激酶抑制劑)	Invention	PRC	ZL201580052631.0	Our Company	September 25, 2015	September 24, 2035
26.	Crystallization of Targeted CDK4/6 Kinase Inhibitors (靶向CDK4/6激酶抑制劑的晶型)	Invention	PRC	ZL201880087850.6	Our Company	December 27, 2018	December 26, 2038
27.	Crystallization of inhibitors targeting serine/threonine kinases (靶向絲/蘇氨酸激酶抑制劑的晶型)	Invention	PRC	ZL201910470296.6	Our Company	May 31, 2019	May 30, 2039
28.	An enteric-coated tablet of an andazole sodium and a method of preparing thereof (一種安納拉唑鈉的腸溶片及其製備方法)	Invention	PRC	ZL202210159337.1	Beijing Xuanzhu	February 22, 2022	February 21, 2042
29.	Novel uses of kinase inhibitors (激酶抑制劑的新用途)	Invention	PRC	ZL201910893109.5	Shandong Xuanzhu and Our Company	September 20, 2019	September 19, 2039
30.	A pharmaceutical composition for the prevention and/or treatment of cancer (一種預防和/或治療癌症的藥物組合物)	Invention	PRC	ZL202110021418.0	Our Company and Shandong Xuanzhu	January 8, 2021	January 7, 2041

APPENDIX VI STATUTORY AND GENERAL INFORMATION

No.	Patents	Type of Patent	Place of Registration	Patent Number	Owner	Application Date	Expiry Date
31.	A pharmaceutical composition for the prevention and/or treatment of cancer (一種預防和/或治療癌症的藥物組合物)	Invention	PRC	ZL202110021508.X	Our Company and Shandong Xuanzhu	January 8, 2021	January 7, 2041
32.	Crystalline forms of polycyclic mesenchymal lymphoma kinase inhibitors (多環類間變性淋巴瘤激酶抑制劑的晶型)	Invention	PRC	ZL202110052053.8	Our Company	January 15, 2021	January 14, 2041
33.	Uses of kinase inhibitors (激酶抑制劑的用途)	Invention	PRC	ZL202080033803.0	Shandong Xuanzhu and Our Company	May 7, 2020	May 6, 2040
34.	A method of preparing anandrazole (一種安納拉唑的製備方法)	Invention	PRC	ZL202110746758.X	Beijing Xuanzhu	July 2, 2021	July 1, 2041
35.	Pill box (藥盒)	Design	PRC	ZL202330457883.9	Beijing Xuanzhu	July 20, 2023	July 19, 2038
36.	Crystal form targeting CDK4/6 kinase inhibitors (КРИСТАЛЛИЧЕСКАЯ ФОРМА ИНГИБИТОРА, НАЦЕЛЕННОГО НАКИНАЗУ CDK4/6)	Invention	Russia	EA042455B1	Our Company	December 27, 2018	December 26, 2038
37.	PYRIMIDINO AMINOPYRIDINE BENZOIMIDAZOLE DERIVATIVES USEFUL FOR CANCER THERAPY (ПРОИЗВОДНЫЕ ПИРИМИДИНОАМИНОПИРИДИН БЕНЗОИМИДАЗОЛА, ПОЛЕЗНЫЕ ДЛЯ ЛЕЧЕНИЯ РАКА)	Invention	Russia	RU2670762C2	Our Company	December 30, 2014	December 29, 2034
38.	Benzimidazole derivatives and their pharmaceutical compositions and uses	Invention	the United States	US9315513B2	Shandong Xuanzhu	January 31, 2011	April 30, 2032
39.	Kinase inhibitor and uses thereof	Invention	the United States	US9796701B2	Our Company	December 30, 2014	December 29, 2034
40.	Kinase inhibitor and uses thereof	Invention	the United States	US9949976B2	Our Company	September 14, 2017	December 29, 2034

APPENDIX VI STATUTORY AND GENERAL INFORMATION

No.	Patents	Type of Patent	Place of Registration	Patent Number	Owner	Application Date	Expiry Date
41.	Polycyclic inhibitor of anaplastic lymphoma kinase	Invention	the United States	US10011592B2	Our Company	September 25, 2015	September 24, 2035
42.	Crystal form targeting CDK4/6 kinase inhibitor	Invention	the United States	US11299474B2	Our Company	December 27, 2018	December 26, 2038

Patent under Application

As of the Latest Practicable Date, we had applied for the registration of the following patents which we consider to be or may be material to our business:

No.	Patent	Type of patent	Place of Registration	Application Number	Applicant	Application Date
1.	A novel use for a kinase inhibitor (一種激酶抑制劑的新用途)	Invention	PRC	CN202210773530.4	Our Company	July 1, 2022
2.	Preparation of CDK4/6 kinase inhibitor compounds (CDK4/6激酶抑制劑化合物的製備方法)	Invention	PRC	CN202211323710.9	Our Company	October 27, 2022
3.	Crystal form of polycyclic anaplastic lymphoma kinase inhibitor	Invention	European Patent Office	EP21741695.7	Our Company	January 15, 2021
4.	Crystalline form of polycyclic anaplastic lymphoma kinase inhibitor (다환 역형성 림프종 키나아제 억제제의 결정형)	Invention	Korea	KR1020227028083	Shandong Xuanzhu and our Company	January 15, 2021
5.	Crystalline forms of polycyclic interstitial lymphoma kinase inhibitors	Invention	the United States	US17/793,275	Shandong Xuanzhu and our Company	January 15, 2021
6.	Crystalline forms of polycyclic interstitial lymphoma kinase inhibitors (Кристаллические формы ингибиторов киназы полициклической интерстициальной лимфомы)	Invention	Russia	RU2022122281	Shandong Xuanzhu and our Company	January 15, 2021

APPENDIX VI STATUTORY AND GENERAL INFORMATION

No.	Patent	Type of patent	Place of Registration	Application Number	Applicant	Application Date
7.	Crystal form of polycyclic anaplastic lymphoma kinase inhibitor	Invention	Hong Kong	HK62023068386.9	Shandong Xuanzhu and our Company	February 14, 2023
8.	An enteric-coated tablet of anaprazole sodium and a preparation method thereof (一種安納拉唑鈉腸溶片及其製備方法)	Invention	Taiwan	TW112106544	Beijing Xuanzhu	February 22, 2023
9.	Pharmaceutical compositions of CDKs inhibitors and methods of preparing the same (CDKs抑制劑的藥物組合物及製備方法)	Invention	PRC	CN202311534116.9	Our Company	November 17, 2023
10.	Pharmaceutical compositions of CDKs inhibitors and methods of preparing the same	Invention	World Intellectual Property Organization	PCT/CN2023/132177	Our Company	November 17, 2023
11.	Pharmaceutical compositions of CDKs inhibitors and methods of preparing the same (CDKs抑制劑之藥物組合物及製備方法)	Invention	Taiwan	TW112144492	Our Company	November 17, 2023
12.	Pharmaceutical compositions of kinase inhibitors for mesenchymal lymphoma and methods of preparation thereof (間變性淋巴瘤激酶抑制劑的藥物組合物及其製備方法)	Invention	PRC	CN202311832278.0	Our Company	December 28, 2023
13.	Polycyclic mesenchymal lymphoma kinase inhibitors (多環類間變性淋巴瘤激酶抑制劑)	Invention	PRC	CN202311841260.7	Our Company	December 28, 2023
14.	A pharmaceutical composition for the treatment of cancer (一種治療癌症的藥物組合物)	Invention	PRC	CN202180085717.9	Our Company and Shandong Xuanzhu	December 31, 2021
15.	A pharmaceutical composition for the treatment of cancer	Invention	the United States	US18/270,495	Our Company and Shandong Xuanzhu	December 31, 2021

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No.	Patent	Type of patent	Place of Registration	Application Number	Applicant	Application Date
16.	Salt and crystal form of polycyclic mesenchymal lymphoma kinase inhibitors (多環類間變性淋巴瘤激酶抑制劑的鹽及晶型)	Invention	PRC	CN202410344023.8	Our Company	March 25, 2024
17.	Preparation of benzimidazole-based CDK4/6 kinase inhibitor compounds (苯並咪唑類CDK4/6激酶抑制劑化合物的製備方法)	Invention	PRC	CN202410372949.8	Our Company	March 29, 2024
18.	A pharmaceutical composition for the treatment of prostate cancer (一種治療前列腺癌的藥物組合物)	Invention	PRC	CN202410509102.X	Our Company	April 26, 2024
19.	CDK kinase selective inhibitors (CDK激酶選擇性抑制劑)	Invention	PRC	CN202410509103.4	Our Company	April 26, 2024
20.	Salts and crystal forms of polycyclic mesenchymal lymphoma kinase inhibitors (多環類間變性淋巴瘤激酶抑制劑的鹽及晶型)	Invention	PRC	CN202411444120.0	Our Company	October 16, 2024
21.	A pharmaceutical composition for treating cancer (一種治療癌症的藥物組合物)	Invention	PRC	CN202280068953.4	Our Company	December 12, 2022

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Copyrights

As of the Latest Practicable Date, we had registered the following copyrights which we consider to be or may be material to our business:

<u>No.</u>	<u>Name of Software</u>	<u>Place of Registration</u>	<u>Registered Owner</u>	<u>Registration Number</u>	<u>Registration Date</u>
1.	Xuanzhu Pharmaceuticals Main Logo (軒竹醫藥主Logo)	PRC	Beijing Xuanzhu	2019-F-00950431	December 9, 2019

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:

<u>No.</u>	<u>Domain Name</u>	<u>Registration Owner</u>	<u>Registration date</u>	<u>Expiry Date</u>
1.	xuanzhubio.com	Our Company	March 21, 2019	March 21, 2025
2.	xzenithbio.com	Our Company	November 2, 2021	November 2, 2025
3.	xuanzhupharm.com	Shandong Xuanzhu	May 13, 2013	May 13, 2025
4.	58.59.12.106	Shandong Xuanzhu	May 13, 2013	May 13, 2025

Save as aforesaid, as of the Latest Practicable Date, there were no other trade or service marks, patents, intellectual or industrial property rights that were material in relation to our business.

FURTHER INFORMATION ABOUT OUR DIRECTORS, SUPERVISORS, CHIEF EXECUTIVE AND SUBSTANTIAL SHAREHOLDERS

Directors, Supervisors and Chief Executive

Disclosure of Interests

Saved as disclosed below, immediately following completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), so far as our Directors are aware, none of our Directors, Supervisors or chief executive has any interests or short positions in the Shares, underlying Shares and debentures of our Company or any associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which they are taken or deemed to have under such provisions of the SFO) or which will be required, pursuant to Section 352 of the SFO, to be recorded in the register referred to

APPENDIX VI STATUTORY AND GENERAL INFORMATION

therein or which will be required to be notified to our Company and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Companies contained in the Listing Rules (for this purpose, the relevant provisions of the SFO will be interpreted as if they apply to the Supervisors).

Name	Position	Nature of Interest	Shares held immediately following the completion of the [REDACTED] and the Conversion of Unlisted Shares into H Shares (assuming the [REDACTED] is not exercised)		
			Number and description ⁽¹⁾	% of shareholding in the H Shares	% of shareholding in the total issued share capital ⁽¹⁾
Ms. Xu Yanjun (徐艷君)	Chairperson of the Board and executive Director	Beneficial owner	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Li Jia Kui (李嘉達)	Executive Director and the general manager	Beneficial owner	[REDACTED]	[REDACTED]	[REDACTED]
Dr. Shih Cheng-Kon (史澈空)	Executive Director	Beneficial owner	[REDACTED]	[REDACTED]	[REDACTED]

Note:

(1) All interests stated are long positions.

Particulars of Service Contracts

Pursuant to Rules 19A.54 and 19A.55 of the Listing Rules, our Company [has entered into] a service agreement with each of the Directors and Supervisors which contains provisions in relation to, among other things, compliance of relevant laws and regulations, observations of Articles of Association and provisions on arbitration.

The principal particulars of these service agreements are: (a) each of the agreements is for a term of three years following his/her respective effective date of his/her appointment; (b) each of the agreements is subject to termination in accordance with their respective terms.

Save as disclosed above, our Company has not entered, and does not propose to enter, into any service contracts with any of the Directors or Supervisors in their respective capacities as Directors or Supervisors (other than contracts expiring or determinable by the employer within one year without the payment of compensation (other than statutory compensation)).

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

Directors’ and Supervisors’ remuneration

For details of the Directors’ and Supervisors’ remuneration, see “Directors, Supervisors and Senior Management — Remuneration of Directors, Supervisors and Five Highest Paid Individuals” and Note 8 to the Accountants’ Report as set out in Appendix I.

Substantial Shareholders

Save as disclosed in the section headed “Substantial Shareholders” in this document, as of the Latest Practicable Date, our Directors were not aware of any persons who would, immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), have or be deemed or taken to have the beneficial interests or short position in our Shares or underlying Shares which would fall to be disclosed to our Company under the provisions of Divisions 2 and 3 of Part XV of the SFO, or directly or indirectly be interested in 10% or more of the voting power at any general meeting of any member of our Group.

Disclaimers

Save as disclosed in this document,

- (i) none of our Directors, Supervisors or any of the parties listed in “— Other Information — Consents of Experts” in this appendix:
 - (a) is interested in our promotion, or in any assets which, within the two years immediately preceding the date of this document, have been acquired or disposed of by or leased to us, or are proposed to be acquired or disposed of by or leased to our Company; or
 - (b) is materially interested in any contract or arrangement subsisting at the date of this document that is significant in relation to our business;
- (ii) none of our Directors or Supervisors or their close associates or any Shareholders of our Company who, to the knowledge of our Directors, owns more than 5% of our issued share capital has any interest in our top five customers or suppliers; and
- (iii) none of our Directors, Supervisors and the chief executive of our Company has any interests or short positions in the Shares, underlying Shares or debentures of our Company or its associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he is taken or deemed to have under such provisions of the SFO) or which will be required, pursuant to section 352 of the SFO, to be entered into the register referred to therein, or will be required, pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix C3 to the Listing Rules, to be notified to our Company and the Stock Exchange.

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STATUTORY AND GENERAL INFORMATION

Share Incentive Scheme

In recognition of the contributions of, the employees and other key stakeholders of our Group, and to incentivize them to further promote our development, we adopted the Share Incentive Scheme. We established ten limited partnerships in the PRC as our Incentive Platforms, namely Beihai Baimei'en, Beihai Jixin, Beihai Keya, Tianjin Hongzekang, Tianjin Xuansheng, Tianjin Hongteng, Tianjin Zhenxuan, Tianjin Pusheng, Tianjin Guoding and Tianjin Huize. Under the Share Incentive Scheme, eligible participants were granted (i) incentive awards over the Shares in our Company (“**Incentive Shares**”) or (ii) partnership interest in the Incentive Platforms (“**Partnership Interest**”) (collectively, the “**Incentive Awards**”). As of the Latest Practicable Date, (i) three grantees, namely Ms. Xu Yanjun, Dr. Li Jia Kui, and Dr. Shih Cheng-Kon, held an aggregate of 9,435,200 Incentive Shares, representing approximately 2.09% of our total issued Shares; and (ii) our Incentive Platforms, in aggregate, held 71,391,644 Shares, representing approximately 15.84% of our total issued Shares. For details of our Incentive Platforms, see “History and Corporate Structure — Incentive Platforms.”

The Share Incentive Scheme does not involve any grant of share options or awards after the [REDACTED] and therefore is not subject to the provisions of Chapter 17 of the Listing Rules. Given the underlying Shares under the Share Incentive Scheme have already been issued, there will not be any further dilution effect to the issued Shares arising from the Share Incentive Scheme.

Below is a summary of the principal terms and provisions of Share Incentive Scheme.

Purpose

The Share Incentive Scheme aims to further enhance corporate governance, establish the long-term incentive mechanism, strengthen corporate cohesion, uphold the direction of our Company’s long-term development, and align the interests of our Company and employees.

Eligible Participants

Persons eligible to participate in the Share Incentive Scheme include the employees and external consultants of our Group, and any other person whom the Professional Committee (as defined below) considers appropriate.

Administration

The Share Incentive Scheme is administered and interpreted by the Board and implemented by a professional committee composed of five members appointed by the Board (the “**Professional Committee**”). The Board will consider and determine the grantees, the number of the Incentive Awards to be granted to each grantee, the corresponding terms and conditions of each grant, the circumstances where the grantees may exit the Share Incentive Scheme, as well as the transfer and disposal of the Incentive Awards.

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Save for Ms. Xu Yanjun, Dr Li Jia Kui and Dr. Shih Cheng-kon, all or part of the awards granted to whom are in the form of Incentive Shares, each of the grantees is registered as a partner of the Incentive Platforms or a partner of the sole limited partner of the Incentive Platforms (as the case may be) upon grant of the Partnership Interest and is able to indirectly receive economic interest in the *pro rata* portion of the underlying Shares held by such Incentive Platform.

Term

The Share Incentive Scheme shall be valid and effective until the date when all Incentive Awards granted have been disposed or the date on which our Company’s Shareholders resolve to terminate the Share Incentive Scheme by way of a general meeting.

Grants under the Share Incentive Scheme

As of the Latest Practicable Date, all Incentive Awards representing 80,826,844 underlying Shares under the Share Incentive Scheme have been granted and vested to 55 grantees, including five Directors, two Supervisors, three senior management members (excluding Dr. Li who is also our executive Director), and two external consultants, and are not subject to any additional lock-up restrictions other than those provided in applicable laws and regulations. No further grants will be made under the Share Incentive Scheme following the [REDACTED]. Except for Ms. Xu Yanjun, Dr. Li Jia Kui, and Dr. Shih Cheng-Kon, who directly hold Incentive Shares, and the grantees who are acting as the general partners of the Incentive Platforms, the other grantees under the Share Incentive Scheme are not able to exercise any voting rights attaching to the underlying Shares.

For details of the Incentive Awards granted to Directors or Supervisors of our Company under the Share Incentive Scheme, see “History and Corporate Structure — Our Corporate History — Establishment and Major Shareholding Changes of Our Company,” and “History and Corporate Structure — Incentive Platforms” and “History and Corporate Structure — Our Capitalization.”

OTHER INFORMATION

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.

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 us, that would have a material adverse effect on our financial condition or results of operations.

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Sole Sponsor

The Sole Sponsor has made an application on behalf of our Company to the Stock Exchange for the [REDACTED] of, and permission to [REDACTED], our H Shares to be converted from Unlisted Shares and our H Shares to be issued pursuant to the [REDACTED]. The Sole Sponsor satisfies the independence criteria applicable to sponsor as set out in Rule 3A.07 of the Listing Rules.

The Sole Sponsor will be paid by our Company a fee of US\$1,000,000 to act as a sponsor to our Company in connection with the [REDACTED], among which US\$100,000 had been paid and US\$900,000 was payable by our Company to the Sole Sponsor as of the Latest Practicable Date.

Compliance Advisor

Our Company has appointed First Shanghai Capital Limited as our Compliance Advisor in compliance with Rule 3A.19 of the Listing Rules.

Preliminary Expenses

We did not incur any material preliminary expenses in relation to the incorporation of our Company.

Taxation of holder of H Shares

The sale, purchase and transfer of H Shares are subject to Hong Kong stamp duty if such sale, purchase and transfer are effected on the H Share register of members of our Company, including in circumstances where such transaction is effected on the Stock Exchange. The current rate of Hong Kong stamp duty for such sale, purchase and transfer is a 0.1% of the consideration or, if higher, the fair value of the H Shares being sold or transferred. For further information in relation to taxation, see “Appendix III — Taxation and Foreign Exchange.”

Potential [REDACTED] in the [REDACTED] are urged to consult their professional tax advisors if they are in any doubt as to the taxation implications of [REDACTED] for, purchasing, holding or disposing of or [REDACTED] our H Shares (or exercising rights attached to them). None of our Company, our Directors, the Sole Sponsor, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED] and the [REDACTED], or any other person or party involved in the [REDACTED] accepts responsibility for any tax effects on, or liabilities of, any person, resulting from the [REDACTED], purchase, holding or disposal of, [REDACTED] or the exercise of any rights in relation to our H Shares.

APPENDIX VI STATUTORY AND GENERAL INFORMATION

Consents of Experts

The following experts have each given and have not withdrawn their respective written consents to the issue of this document with copies of their reports, letters, opinions or summaries of opinions (as the case may be) and the references to their names included herein in the form and context in which they are respectively included.

Name	Qualification
China International Capital Corporation Hong Kong Securities Limited	A licensed corporation to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 4 (advising on securities), Type 5 (advising on futures contracts) and Type 6 (advising on corporate finance) regulated activities under the SFO
Fangda Partners	Legal advisor to our Company as to PRC law
China Insights Industry Consultancy	Independent industry consultant
Ernst & Young	Certified Public Accountants Registered Public Interest Entity Auditor

Save as disclosed in this document and in connection with the [REDACTED], none of the experts named above has any shareholding interests in any member of our Group 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.

Promoters

The promoters of our Company are as follows:

No.	Name of promoters of our Company
1.	Xuanzhu Biopharma
2.	Metropolitan Industrial Investment Fund (京津冀產業協同發展投資基金(有限合夥))
3.	Future Industry Investment Fund II (先進製造產業投資基金二期(有限合夥))
4.	Beihai Baimei'en
5.	Shijiazhuang Keshuo Investment Centre (Limited Partnership) (石家莊科碩投資中心(有限合夥))
6.	Beijing Tonghe Yinxing Innovative Asset Management Centre (Limited Partnership) (北京同合銀杏創新資產管理中心(有限合夥))
7.	Dr. Li Jia Kui (李嘉達)
8.	Tianjin Hongzekang
9.	Tianjin Xuansheng

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No.	Name of promoters of our Company
10.	Dr. Shih Cheng-Kon (史澂空)
11.	Ms. Xu Yanjun (徐艷君)
12.	Tianjin Hongteng
13.	Beijing SL Pharmaceutical Co., Ltd. (北京雙鷺藥業股份有限公司)
14.	Tianjin Zhenxuan
15.	Beihai Jixin
16.	Tianjin Pusheng
17.	Tianjin Guoding
18.	Tianjin Huize

Save as disclosed in this document, within the two years immediately preceding the date of this document, no cash, securities, amount or benefit has been paid, allotted or given, or has been proposed to be paid, allotted or given, to any of the promoters named above in connection with the [REDACTED] or the related transactions described in this document.

Bilingual Document

The English language and Chinese language versions of this document are being published separately in reliance upon the exemption provided by section 4 of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

Binding Effect

This document shall have the effect, if an application is made in pursuance of this document, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of Sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

No Material Adverse Change

Our Directors confirm that there has been no material adverse change in our financial, trading position or prospects since June 30, 2024, being the date of our combined financial statements as set out in “Appendix I — Accountants’ Report,” up to the date of this document.

Miscellaneous

- (i) Save as disclosed in this document and in connection with the [REDACTED], within the two years immediately preceding the date of this document:
 - (a) no share or loan capital of our Company or any of our subsidiaries has been issued nor agreed to be issued fully or partly paid either for cash or for a consideration other than cash;

APPENDIX VI **STATUTORY AND GENERAL INFORMATION**

- (b) no commissions, discounts, brokerage fee or other special terms have been granted in connection with the issue or sale of any share or loan capital of our Company or any of our subsidiaries;
 - (c) no share or loan capital of our Company or any of our subsidiaries is under option or is agreed conditionally or unconditionally to be put under option; and
 - (d) no commission has been paid or is payable for subscribing or agreeing to subscribe, or procuring or agreeing to procure the subscriptions of any share in our Company or any of our subsidiaries.
- (ii) We have not issued nor agreed to issue any founder shares, management shares or deferred shares.
 - (iii) There are no arrangements under which future dividends are waived or agreed to be waived.
 - (iv) There have been no interruptions in our business which may have or have had a significant effect on our financial position in the last 12 months.
 - (v) There are no restrictions affecting the remittance of profits or repatriation of capital by us into Hong Kong from outside Hong Kong.
 - (vi) No equity or debt securities of our Group is currently listed on or dealt in on any stock exchange or trading system, and no such listing or permission to list on any stock exchange other than the Hong Kong Stock Exchange is currently being or agreed to be sought.
 - (vii) Our Company has no outstanding convertible debt securities or debentures.

**APPENDIX VII DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES AND AVAILABLE ON DISPLAY**

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG

The documents attached to the copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were, among other documents:

- (a) the written consents referred to in “Appendix VI — Statutory and General Information — Other Information — Consents of Experts”; and
- (b) a copy of the material contracts referred to in “Appendix VI — Statutory and General Information — Further Information about Our Business — Summary of Material Contracts.”

DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be available on display on the Stock Exchange’s website at www.hkexnews.hk and our Company’s website at www.xuanzhubio.com during a period of 14 days from the date of this document:

- (a) the Articles of Association;
- (b) the Accountants’ Report from Ernst & Young, the text of which is set out in Appendix I to this document;
- (c) the audited financial statements of our Group for the two years ended December 31, 2023, and the six months ended June 30, 2024;
- (d) the report on unaudited [REDACTED] financial information of our Group from Ernst & Young, the text of which is set out in Appendix II to this document;
- (e) the legal opinions issued by Fangda Partners, our PRC Legal Advisor in respect of certain matters of our Group in the PRC;
- (f) the industry report prepared by CIC, the summary of which is set forth in “Industry Overview;”
- (g) a copy of each of the PRC Company Law, the PRC Securities Law, the Guidelines on the Bylaws of Listed Companies, the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies and the Guidelines for Articles of Association together with their unofficial English translations;
- (h) the material contracts referred to in “Appendix VI — Statutory and General Information — Further Information about Our Business — Summary of Material Contracts;”

**APPENDIX VII DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES AND AVAILABLE ON DISPLAY**

- (i) the written consents referred to in “Appendix VI — Statutory and General Information — Other Information — Consents of Experts”; and

- (j) the service contracts referred to in “Appendix VI — Statutory and General Information — Further Information about Our Directors, Supervisors, Chief Executive and Substantial Shareholders — Directors, Supervisors and Chief Executive — Particulars of Service Contracts.”