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Post Hearing Information Pack of



PegBio Co., Ltd.

派格生物醫藥(杭州)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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PegBio Co., Ltd.

派格生物醫藥(杭州)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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**the [REDACTED]
Number of [REDACTED] : [REDACTED] H Shares (subject to
reallocation)**

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

**[REDACTED] : HK\$[REDACTED] per [REDACTED],
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transaction levy of 0.0027%, AFRC
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EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

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SUMMARY

This summary aims to give you an overview of the information contained in this Document. As this is a summary, it does not contain all the information that may be important to you. You should read the entire document 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 on the basis that we are unable to 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 such as ours. In addition, we have incurred significant operating losses since our inception, and we expect to remain loss making in the near term. We had negative net cash flow from operating activities during the Track Record Period. We did not declare or pay any dividends during the Track Record Period and do not intend to pay any dividends in the near future. Your [REDACTED] decision should be made in light of these considerations.

OVERVIEW

Founded in 2008, we are a biotechnology company focused on the in-house discovery and development of innovative therapies, primarily peptide and small molecule drugs, for chronic diseases with a particular emphasis on metabolic disorders. We have self-developed one Core Product and other five product candidates to capture the market potential in prevalent chronic and metabolic diseases, including type 2 diabetes mellitus (“**T2DM**”, also known as type 2 diabetes), obesity, non-alcoholic steatohepatitis (“**NASH**”), opioid-induced constipation (“**OIC**”, a gastrointestinal disorder induced by the usage of opioid drugs) and congenital hyperinsulinemia (a rare endocrine disease whose patients experience constant hypoglycemia). Our Core Product, PB-119, is a self-developed, near-commercialized, long-acting glucagon-like peptide 1 (“**GLP-1**”, a peptide hormone that decreases blood sugar levels) receptor agonist. GLP-1 receptor agonist is an agent that activates the GLP-1 receptor to simulate the receptor activation functions of GLP-1, which primarily include insulin secretion promotion, glucagon secretion inhibition, suppressing gastric motility and appetite, glucose uptake and fat degradation. PB-119 is primarily designed for the first-line treatment of T2DM and obesity. It has demonstrated multiple benefits in glycemic control, cardiovascular health, and a good efficacy profile in weight management across several clinical trials. According to CIC, long-acting GLP-1 receptor agonists referred to products that require an once-weekly dosing schedule such as that of PB-119, as compared to the frequent once- or multiple-daily dosing schedule required by short-acting GLP-1 receptor agonists. The new drug application (“**NDA**”) for PB-119 in China for T2DM was accepted by the NMPA in September 2023, marking a key milestone for its upcoming commercialization.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCT.

We are developing our Core Product and other product candidates in highly competitive markets with intense competition from multi-national and domestic pharmaceutical companies with multiple approved drugs and similar drug candidates at similar or more advanced clinical stages. For more details, see “Risk Factors — We may face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates.”

SUMMARY

The following chart summarizes the development status of our drug candidates as of the Latest Practicable Date. We strategically prioritize our resources for the clinical development and/or commercialization of certain pipeline candidates, including our Core Product PB-119 and key product PB-718.

Drug candidates	Moa/Target	Development origin	Indications	Predclinical	Phase I	Phase II	Phase III	Rights	Commercialization region	NDA date	Current status/Future milestones
PB-119 ⁹ ★	Long-acting GLP-1 receptor agonist	In-house	T2DM (Monotherapy) first-line	China (NMPA)				Global 	China	Submitted and accepted in September 2023 ⁷	Expected to be approved for marketing in China in 1H 2025
			T2DM (+Metformin) first-line	China (NMPA)					China		
			Overweight or obesity first-line	U.S. (FDA)					U.S.		Phase I and II clinical trials completed in July 2016 and July 2019, respectively, in the United States. Phase III clinical trial plan is to be finalized ⁸
			Overweight or obesity first-line	China (NMPA)					China		Phase Ib/IIa clinical trial is being initiated in China, participant enrollment completed in June 2024
			T2DM (Cardiovascular benefits)	China (NMPA)							IND approved by the NMPA in August 2021 and Phase III clinical trial to be initiated in 2026 in China ³
			T2DM (+ Basal insulin) first-line	China (NMPA)					China		To prepare IND and commence a Phase III clinical trial in China in 2026
PB-718 ⁸ ☆	Long-acting GLP-1/GCG dual receptor agonist	In-house	T2DM (+SGLT-2 inhibitor) first-line	China (NMPA)				Global 			To prepare IND and commence a Phase III clinical trial in China in 2026
			Overweight or obesity	China (NMPA)					China		Completed participant follow-up for a Phase Ib/IIa clinical trial in China and Phase IIb clinical trial is expected to commence in China following a communication with the NMPA to be conducted in 2025
				U.S. (FDA/IEU (EMA))					U.S., EU		Phase III MRCT trial is expected to commence following a communication with the FDA and the EMA to be conducted in 2026
				China (NMPA)/U.S. (FDA)					China, U.S.		Phase I clinical trial completed in May 2022 in the United States, and IND for a Phase II clinical trial in China is expected to be submitted in 2H 2025
				China (NMPA)					China		Phase I clinical trials completed in January 2022 in China, and Phase II clinical trial is expected to commence in China in 2025
				China (NMPA)					China		IND approved by the NMPA in May 2023 and Phase I clinical trial to be initiated in China in 2026
PB-1902 ⁵	Opioid receptor antagonist	In-house	NASH	China (NMPA)/U.S. (FDA)					China		IND submission in China expected in 2026
PB-722 ⁶	GCG receptor agonist	In-house	OIC	China (NMPA)					China		IND submission in China expected in 2025
PB-2301	GLP-1/GIP dual receptor agonist	In-house	Congenital hyperinsulinemia								
PB-2309	GLP-1/GIP/GCG triple receptor agonist	In-house	T2DM/Overweight or obesity/NASH								

★ Core Product ☆ Key Product

■ Metabolic diseases ■ Digestive disease

SUMMARY

Abbreviations: MoA = mechanism of action; GCG = glucagon (a peptide hormone that raises blood sugar levels); GIP = glucose-dependent insulintropic polypeptide (a hormone that affects energy intake and energy expenditure); OIC = opioid-induced constipation; IND = investigational new drug; U.S. = the United States

Notes:

1. Both T2DM (monotherapy) and T2DM (+metformin) are expected to be the lead indications of PB-119. The other indications are expansions of indications. PB-119 is primarily designed for the first-line treatment of T2DM and obesity. In recent years, GLP-1 receptor agonists have been increasingly recommended for the treatment of T2DM and obesity as a result of their favored treatment outcomes demonstrated in various clinical studies and real-world applications. For additional information, see “Industry Overview — Overview of T2DM drug market — Current treatment regimen and medical needs” and “Industry Overview — Overview of obesity drug market — Current treatment regimen and medical needs.”
2. We also completed two clinical trials in the United States, namely a Phase I clinical trial to evaluate the safety, tolerability, PK and PD of PB-119 in T2DM patients, as well as a Phase II clinical trial to evaluate efficacy and safety of PB-119 in T2DM patients not well-controlled by metformin monotherapy. We intend to finalize the clinical development plan in the United States and conduct Phase III clinical trials of PB-119 for the treatment of T2DM. For additional information, see “Business — Core Product — Core Product PB-119, a near-commercialized, long-acting GLP-1 receptor agonist.”
3. Based on the existing good clinical efficacy and safety data of PB-119 from our completed clinical trials, we plan to further test its multiple beneficial effects in potentially reducing the risk of cardiovascular events through a Phase III cardiovascular outcome clinical trial (PB119-305). We filed IND application with the NMPA for PB119-305 in June 2021 as we did not need to conduct such Phase I or II clinical trials since the clinical trial methods including the patient population and the dosage of PB-119 would be same as our completed Phase III clinical trials. In August 2021, we received the IND approval from the NMPA for this clinical trial.
4. We irrevocably granted to TSL HK the right of first refusal of exclusive commercialization rights of PB-718 in Mainland China.
5. The Phase I clinical trial of PB-1902 was registered by Shanghai Hanmai, a subsidiary of us.
6. PB-722 has been granted the Orphan Drug Designation by the FDA.
7. We submitted one NDA of PB-119 for the treatment of T2DM (containing relevant clinical trial results of PB-119 as a monotherapy or in combination with metformin) in July 2023 which was accepted by the NMPA in September 2023.

Our Business Model

Our core business model is to discover and develop in-house innovative therapies for chronic diseases to address medical needs. All drug candidates listed in the above chart are developed by us. To complement our internal efforts, we may seek collaborative opportunities on the clinical development and commercialization of our drug candidates to better capture market opportunities through out-licensing, co-commercialization or other strategic collaborations.

SUMMARY

CORE PRODUCT

Overview

Our Core Product, PB-119, is a self-developed, near-commercialized, long-acting GLP-1 receptor agonist primarily designed for the first-line treatment of T2DM and obesity. In the last decade, GLP-1 receptor agonists have been recommended as the first-line treatment for T2DM, with clear evidenced benefits of improved glucose control, weight loss, and cardiovascular protection. We have conducted a series of clinical trials to assess the safety and efficacy of PB-119. These trials have revealed its broad-ranging benefits, good safety profile, rapid and sustained effectiveness, and potentially a high level of patient compliance. With our PEGylation technology, we extended the half-life (the time required for the concentration of a compound to fall to 50% of its peak value) of PB-119 to enable a weekly dosing regimen. PB-119 also does not require titration given its good tolerability and effectiveness at relatively low dosage levels, resulting in enhanced administration convenience and improved patient compliance. We successfully completed two Phase III registrational clinical trials in China for PB-119 by early 2023. The clinical results regarding both monotherapy and combination therapy for T2DM have underpinned our NDA for PB-119 in China, which was accepted by the NMPA in September 2023, making it one of the earliest clinical-stage long-acting GLP-1 receptor agonists in China, according to CIC. We expect to receive the NDA approval and commercially launch PB-119 for the treatment of T2DM in China in 2025. We plan to initiate two more Phase III clinical trials in China for combination therapies of PB-119 with either basal insulin or with SGLT-2 inhibitor to evaluate the efficacy and safety of PB-119 in T2DM patients, and we were preparing IND applications for these two Phase III clinical trials as of the Latest Practicable Date and we plan to submit the IND applications to the NMPA in the second half of 2025. We also plan to initiate one Phase III clinical trial in China for PB-119 to evaluate cardiovascular outcomes in T2DM patients in 2026. We also completed a Phase II clinical trial of PB-119 for the treatment of T2DM in the United States in July 2019, and we intend to finalize the clinical development plan in the United States and conduct Phase III clinical trials of PB-119 for the treatment of T2DM in collaboration with a reputable local partner, paving the way for expanding the territory of PB-119 beyond China.

In light of the remarkable weight-loss efficacy of PB-119 observed in its Phase III clinical trials for T2DM, we also plan to assess the efficacy of PB-119 in the treatment of obesity. In June 2021, the NMPA approved our IND application of PB-119 for the treatment of obesity in China. We finalized the clinical trial protocol in February 2024 and received the approval from the NMPA to commence the clinical trial in April 2024. We are initiating a Phase Ib/IIa clinical trial to evaluate the safety, tolerability and PK profiles of PB-119 in Chinese obese participants, and we completed participant enrollment in June 2024. Subject to the Phase Ib/IIa clinical trial results, we intend to further advance the clinical development of PB-119 for the treatment of obesity in China by conducting potential Phase II and/or Phase III clinical trials in accordance with the plan that we will formulate. Our clinical development of PB-119 for obesity is still at early stage and it may fail to meet the primary and secondary endpoints at the late-stage clinical trials. Additionally, after the launch of PB-119 upon regulatory approval of its lead indication T2DM, it may be used for purposes beyond its labelled use, such as for the

SUMMARY

treatment of obesity before this indication receives regulatory approval. For details, see “Risk Factors — Risks relating to development, clinical trials and regulatory approval of our drug candidates — Negative results from off-label drug use of our drug products could negatively impact our business, financial condition, results of operations and prospects and expose us to liability.” and “Risk Factors — Risks relating to development, clinical trials and regulatory approval of our drug candidates — Results of earlier clinical trials may not be predictive of results of later-stage clinical trials.” In addition to T2DM and obesity, we expect to explore therapeutic potentials for combination therapies and further indication expansions for PB-119. We plan to commercialize PB-119 in China and beyond.

Addressable Markets and Competitive Landscape of the Core Product

T2DM is a disease characterized with elevated blood glucose levels. Insulin is a hormone produced by pancreas and regulates the metabolism of glucose from food intake. Obesity is defined as abnormal or excessive fat accumulation that presents comprehensive health concerns, such as cardiovascular diseases (“CVDs”), T2DM, musculoskeletal disorders, and carcinogenesis. A body mass index (“BMI”) over 24 kg/m² is considered overweight, and over 28 kg/m² is considered obese in China.

We face fierce competition from existing products and product candidates under development in the T2DM and obesity market. Such fierce competition may limit the anticipated market size for PB-119 and therefore negatively affect our anticipated growth. In addition to alternative treatment methods and prevention methods, such as adopting a healthier lifestyle that facilitates weight management, there are various marketed drugs with new modalities available to patients with T2DM or obesity. In China and the United States, GLP-1-based therapeutic options for T2DM and/or obesity mainly include exenatide, liraglutide, exenatide ER, albiglutide, dulaglutide, lixisenatide, semaglutide, tirzepatide, insulin degludec/liraglutide and insulin glargine/lixisenatide. In addition, the market competition may be fierce with the potential development of generic medications once the relevant patents of brand name drugs have expired. While we believe PB-119 is adequately protected by our intellectual property rights, the patent expiration of certain other GLP-1 receptor agonists may lead to the entry of generic drug products, subject to market conditions, regulatory trends and the strategic focus of market players. In addition to GLP-1-based therapeutics, prevalent treatment options for T2DM in China and the United States mainly include metformin, SGLT-2i, DPP-4i, GKA, among others, and prevalent treatment options for obesity in China and the United States mainly include orlistat, phentermine and naltrexone. In China, traditional Chinese medicines are also used for the treatment of T2DM and/or obesity, among which Mulberry Twig Alkaloids Tablet was approved by the NMPA for the treatment of T2DM. In addition to approved treatment options for T2DM and obesity, there are a large number of competing drug candidates currently under different clinical stages. For additional information, see “Industry Overview.”

SUMMARY

We intend to develop PB-119 as an affordable, quality domestic alternative option for patients in need in China. In light of the multiple benefits demonstrated in the clinical trials of PB-119, we anticipate it to be a competitive product in the marketplace. Once PB-119 is approved for additional indications, such as obesity, we expect it to capture market share in those corresponding markets as well. However, as the market evolves rapidly and our prediction is forward-looking in nature and based on assumptions that may turn out to be inaccurate, the aforementioned projected market share of PB-119 in China may not be accurate and should not be unduly relied upon. See “Risk Factors — Risk relating to the manufacturing and commercialization of our drug candidates — The market size of our drug candidates might be smaller than we expected.” In addition, while we believe in the potential of PB-119 for the treatment of T2DM, obesity, overweight and even NASH, for instance, it has potential to be included in the standard treatment recommendations for these disease which help to change the treatment paradigms, according to CIC, however, it is premature at this stage to accurately predict the knock-on impact of PB-119 in the relevant markets. We may also consider conducting head-to-head clinical studies of PB-119 in the future against then-major competing products on the market to demonstrate the comparative advantages of PB-119. For additional information, see “Business — Core Product” and “Future Plans and Use of [REDACTED].”

The following table summarizes the addressable patients and number of competing pipelines for our Core Product.

Core Product	Target Indication	Addressable Patients (million)				Number of Competitors ¹	
		China		Global		China	United States ²
		2023	2032E	2023	2032E		
PB-119 . .	T2DM	125.4	141.8	533.8	609.6	13 ³	Over 15 ⁴
PB-119 . .	Obesity	268.3	330.3	972.5	1,261.0	Over 15	Over 10

Notes:

1. “Competitors” refer only to pipelines with the same target for the same indication registered at CDE or ClinicalTrials.gov as our Core Product.
2. With active clinical trials in the United States.
3. Number of pipelines with NDA submitted to the NMPA and pipelines in Phase III clinical-stage in China.
4. Number of pipelines undergoing Phase II or Phase III clinical trials in the United States.

For details of the market opportunity and the competitive landscape, see “Industry Overview” in this Document.

SUMMARY

CLINICAL STAGE CANDIDATES

- **Our key product PB-718** is a dual receptor agonist that activates both the GLP-1 receptor and the glucagon (“GCG”) receptor and embodies the industry evolution from single-target agonists. GLP-1 and glucagon exhibit functions, such as promoting weight loss, through distinct mechanisms of action, and the dual activation of their respective receptors is associated with several beneficial effects, such as suppressed appetite and significant weight loss. These outcomes create a synergistic effect that is superior to the impact of either receptor agonist acting in isolation. The innovative design of PB-718 positions it as an important candidate in our pipeline for the treatment of obesity and NASH. Indeed, clinical studies of PB-718 have demonstrated its encouraging efficacy in weight loss and liver fat content reduction based on preliminary results.

We have completed a Phase I clinical trial of PB-718 on healthy participants in the United States in May 2022 which showed good safety and PK profiles of PB-718. We initiated a Phase Ib/Ia clinical trial in July 2023 to evaluate PB-718 for the treatment of obesity in China, and we completed the participant follow-up of the trial in April 2024. We plan to communicate with the NMPA in 2025 regarding our Phase IIb clinical trial plan to seek their further suggestions, if any, before commencing such Phase IIb clinical trial of PB-718 for the treatment of obesity in China. We also plan to communicate with the FDA and the EMA in as early as in 2026 regarding the plans for conducting a Phase III MRCT of PB-718 for the treatment of obesity.

We also plan to submit an IND application to the NMPA in the second half of 2025 to conduct a Phase II clinical trial of PB-718 for the treatment of NASH in China. We intend to evaluate the results of such Phase II clinical trial and formulate our plan for potentially conducting Phase II and Phase III clinical trials of PB-718 for the treatment of NASH in the United States. In the future we may also consider conducting head-to-head clinical studies of PB-718 against then-major competing products on the market to demonstrate its comparative advantages. For additional information, see “Business — Clinical-stage Products — PB-718, a long-acting GLP-1/GCG dual receptor agonist.”

- **PB-1902** is the first and one of the only two domestically developed clinical-stage oral μ -opioid receptor antagonist drug candidates for the treatment of opioid-induced constipation (“OIC”) under clinical trials in China as of the Latest Practicable Date, according to CIC. It relieves the opioid-induced bowel dysfunction without compromising the analgesic effect, making it an ideal option for the treatment of OIC. We have completed two Phase I clinical studies in October 2021 and January 2022, respectively, which showed good safety, tolerability, pharmacokinetics (“PK”) and pharmacodynamics (“PD”) profiles of PB-1902 in healthy participants in China. In October 2022, the NMPA responded in writing with no objection for us to conduct a Phase II clinical trial of PB-1902 for the treatment of OIC in China. We plan to commence the Phase II clinical trial in China in 2025. We expect to complete this Phase II clinical trial in 2027 and commence a Phase III clinical trial after obtaining results for Phase II trial.

SUMMARY

- **PB-722** is a GCG receptor agonist being developed for the treatment of congenital hyperinsulinemia and has been granted the Orphan Drug Designation by the FDA in May 2021. PB-722 has demonstrated its safety in several animal models and its efficacy in raising and maintaining blood glucose levels in a hypoglycemic animal model. In May 2023, the NMPA approved our IND application to conduct clinical trial of PB-722 for the treatment of congenital hyperinsulinemia in China, rendering PB-722 the first drug candidate with IND approval for the treatment of congenital hyperinsulinemia in China. We plan to initiate a randomized, double-blind, placebo-controlled, dose-escalating Phase I clinical trial to test the safety, tolerability, PK and PD profiles of PB-722 single dose subcutaneous injection in 2026. We expect to initiate a Phase II clinical trial in 2027.

SELECTED PRECLINICAL STAGE CANDIDATES

- **PB-2301** is a GLP-1/glucose-dependent insulintropic polypeptide (“**GIP**”) dual receptor agonist for the treatment of T2DM, NASH and obesity. We are conducting multiple preclinical studies to test the safety and efficacy profiles of PB-2301. We believe PB-2301 has the potential to further enhance the performance of current GLP-1 receptor agonist candidates. We plan to advance PB-2301 to clinical development for the treatment of T2DM, NASH and obesity and submit the IND applications to the NMPA in 2026.
- **PB-2309** is a GLP-1/GIP/GCG triple receptor agonist for the treatment of T2DM, NASH and obesity. We are conducting multiple preclinical studies to test the safety and efficacy profiles of PB-2309. We believe PB-2309 has the potential to further enhance the performance of current GLP-1 receptor agonist candidates. We plan to advance PB-2309 to clinical development for the treatment of T2DM, NASH and obesity and submit the IND applications to the NMPA in 2025.

STRENGTHS

We believe the following strengths differentiate us from our competitors:

- A leading player in the chronic and metabolic disease market with a competitive and balanced drug portfolio
- Advanced R&D and translational medicine capabilities, underpinned by our deep insight and understanding of the chronic and metabolic disease industry, to safeguard our future growth
- Core Product PB-119, a differentiated long-acting GLP-1 receptor agonist with multiple clinical benefits
- PB-718, a long-acting GLP-1/GCG dual receptor agonist, with potential to treat obesity and NASH
- Commercial prospect evidenced by our commercialization plan and arrangement
- Seasoned senior management team and shareholder support

SUMMARY

STRATEGIES

We plan to pursue the following significant opportunities and execute our key strategies accordingly. We also strategically prioritize our resources for the clinical development and/or commercialization of certain pipeline candidates.

- Fast-tracking the commercialization and indication expansion of PB-119
- Promote the development and clinical trial progress of our product candidates
- Enhance brand awareness and industry impact
- Continue to grow our Company into a reputable enterprise

RESEARCH AND DEVELOPMENT

We have established an R&D team with strong expertise, deep understanding and broad development experience in chronic and metabolic diseases. As of the Latest Practicable Date, we had 19 R&D team members conducting drug discovery, clinical development and regulatory affairs. Our drug discovery team consisted of 10 members, many of whom with over a decade of relevant work experience. We have worked on our product candidates’ advancement for more than 13 years and developed our product candidates in-house. The majority of our drug discovery team members have obtained post-graduate degrees, with respective expertise in biology, medicinal chemistry, drug metabolism and pharmacokinetics, chemistry and early clinical areas, which together support our product development. Our proprietary in-house drug discovery capabilities comprise (i) identifying medical needs and integrating real-world data, network pharmacology, known and established molecules with desired therapeutic benefits to design novel, multifunctional drug candidates; (ii) performing *in vitro* and *in vivo* assays of drug candidates including but not limited to pharmacological activities, pharmacokinetics and toxicities; and (iii) developing formulations, and analytical assays for quality control and assurance. During the drug discovery stage, our R&D chemistry team carries out synthesis and optimization of the target molecules for potential drug candidates. During the drug evaluation stage, our drug discovery team coordinates and accomplishes preclinical R&D activities in relation to the product candidates’ pharmacology, pharmacokinetics and toxicology.

As of the Latest Practicable Date, our clinical development team consisted of seven members, including scientists and physicians with strong drug development experience, who participate in clinical development strategy development, clinical trial protocol design, clinical trial operation organization, drug safety monitoring, and clinical trial quality control. Many of our clinical development team members had over a decade of relevant work experience. Among our clinical development team members, 29% have obtained post-graduate degrees. Our clinical development team is generally responsible for the development of our Core Product and other pipeline products.

SUMMARY

We have developed our pipeline leveraging our proprietary Highly Effective Target Screening & Molecule Modifier Platform (HECTOR[®]), a core technology platform supporting our research and development. HECTOR[®] encompasses a metabolic disease data collection, a drug molecular design platform, and a compound screening platform. Through the metabolic disease data collection, we integrate vast publicly available information and our research team’s in-depth understanding of target mechanisms, as well as their rich practical know-how in the rational design of drug molecules with ideal properties. The drug molecular design platform features our polyethylene glycol (“PEG”) technology that enables innovation and brings multiple benefits, including prolonged half-lives of compounds, enhanced long-acting efficacy, improved compound stability, reduced immunogenicity and lowered research costs. It underpins our pursuit of precise structural design and modification of drug molecules to enhance key physicochemical properties and achieve significant differentiation as compared to existing therapeutic options. The PEGylation technology enables reduced renal clearance and enhanced water solubility of the PEGylated molecules, thereby extending their half-lives. In addition, the steady release of PEGylated molecules enables less titration frequency and minimizes fluctuations of drug levels. There are other technologies to achieve similar effects, for instance, lipidation also extends the half-lives of molecules by enhancing their stability. Additionally, we leverage the efficient compound screening platform to adeptly identify promising lead compounds based on a range of critical parameters, setting a solid foundation for our future drug development. We are leveraging the AI-powered drug discovery in the development of our new products pipeline. For more details, see “Business — Research and Development — Drug Discovery — Our Platforms.”

We collaborate with CROs to conduct and support our preclinical and clinical studies in line with industry practice. Such CROs provide an array of services from preclinical toxicity and safety evaluations to various clinical trial tasks, and typically the duration of a single project lasts for a few months. For the years ended December 31, 2023 and 2024, we recorded R&D expenses of RMB236.7 million and RMB95.4 million, respectively, representing 81.0% and 34.0% of the total R&D and administrative expenses recorded in the periods, respectively, with R&D expenses of RMB60.5 million and RMB33.5 million, representing 25.6% and 35.1% of R&D expenses, attributable to the Core Product, respectively. The decrease of our R&D expenses incurred on our Core Product was in line with our advancement of the Core Product PB-119 from the Phase III clinical stage to the NDA filing in 2023. All of our R&D expenses for the Core Product during the Track Record Period were used for its clinical studies and regulatory filings.

SUMMARY

INTELLECTUAL PROPERTY RIGHTS

As of the Latest Practicable Date, we held 83 patents and patent applications, including 13 patents and 15 patent applications in relation to our Core Product. As of the Latest Practicable Date, all of our material patents and patent applications were self-owned and all of our clinical-stage drug candidates were derived out of our HECTOR[®] platform and PEGylation technologies. The following table sets forth an overview of our material granted patents and filed patent applications in connection with our Core Product as of the Latest Practicable Date:

Product	Name of Patent ⁽¹⁾	Jurisdiction	Status	Expiry Date of Granted Patent ⁽²⁾	Commercial Rights of the Company
PB-119	Novel exendin variant and conjugate thereof	Mainland China, United States, Korea, Japan, Germany, Russia, South Africa, Great Britain, France, Brazil, Italy	Granted	Mainland China: 2030/4/22 United States, Korea, Japan, Germany, Russia, South Africa, Great Britain, France, Brazil, Italy: 2030/4/23	Ownership
	Preparation method of exenatide variant and polyethylene glycol conjugate thereof	Mainland China	Filed	N/A	Ownership

SUMMARY

Product	Name of Patent ⁽¹⁾	Jurisdiction	Status	Expiry Date of Granted Patent ⁽²⁾	Commercial Rights of the Company
	Pharmaceutical composition containing pegylated exenatide variant and application thereof	Mainland China, Taiwan, The United Arab Emirates, Brazil, Eurasian, Egypt, Europe, Indonesia, Mexico, Malaysia. The Philippines, Saudi Arabia, Thailand, United States, Vietnam, South Africa	Mainland China: Filed Taiwan: Granted The United Arab Emirates, Brazil, Eurasian, Egypt, Europe, Indonesia, Mexico, Malaysia. The Philippines, Saudi Arabia, Thailand, United States, Vietnam: Filed South Africa: Granted	Mainland China: N/A Taiwan: 2042/9/13 The United Arab Emirates, Brazil, Eurasian, Egypt, Europe, Indonesia, Mexico, Malaysia. The Philippines, Saudi Arabia, Thailand, United States, Vietnam: N/A South Africa: 2042/9/13	Ownership

Notes:

- (1) Unless otherwise indicated, patents and patent applications within the same family are disclosed once.
- (2) The patent expiration date is estimated without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

We conduct our business under the brand name of “PegBio.” As of the Latest Practicable Date, we held 101 trademarks and trademark applications in Mainland China and Hong Kong. We are also the owner of one copyright and one domain name. 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 material 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.

SUMMARY

CHEMISTRY, MANUFACTURING & CONTROLS

As of the Latest Practicable Date, our Chemistry, Manufacturing & Controls (“**CMC**”) team consisted of 13 professionals with extensive experience in process development, production and quality management from well-known biopharmaceutical and pharmaceutical companies. Many of our CMC team members had over a decade of relevant work experience. Our CMC team specialized in preclinical and clinical support throughout the drug development process. The CMC function in our Company plays a critical role in drug development. It is responsible for developing safe, robust, and economically sound production processes for our drug substances and drug products, and ensuring their quality meets regulatory requirements.

As of the Latest Practicable date, we did not have commercialization-scale manufacturing facility. Currently we do not have any plans to establish our own manufacturing facilities to support our preclinical and clinical studies or produce future commercial supplies. We collaborate with contract development and manufacturing organizations (“**CDMOs**”) (including contract manufacturing organizations (“**CMOs**”)) to conduct and support our preclinical and clinical studies in line with industry practice. In terms of the involvement and contributions of each of the major CDMO partners (including CMOs) to the development of our product candidates, we collaborate with our CDMO partners to manufacture certain raw materials and drug substances of our product candidates to supply for preclinical studies and clinical trials. We did not experience any product quality issues in respect of the products manufactured by our CDMO partners during the Track Record Period. We currently plan to source future commercial supplies of our drugs following their marketing approval from CDMOs as well.

COMMERCIALIZATION

Our Marketing Strategy

During the Track Record Period and as of the Latest Practicable Date, we did not have any commercialized product. Our near-commercialized Core Product is one of the earliest domestically developed long-acting GLP-1 receptor agonists in China, according to CIC.

Competing with other industry participants in the rapidly growing GLP-1 market in China requires a well-thought-out strategy that leverages key strengths and addresses market dynamics. Establishing strong partnerships with local healthcare providers and institutions can be pivotal. Collaborating with renowned Chinese hospitals and healthcare professionals not only builds credibility but also facilitates access to a vast patient pool. Pricing strategies should be competitive yet sustainable, catering to the affordability factor in the Chinese market. Additionally, investing in extensive market research to understand the unique needs and preferences of Chinese patients and healthcare providers can guide product development and marketing efforts. Moreover, fostering innovation and differentiation in GLP-1 products by focusing on superior efficacy, ease of administration, and reduced side effects can provide compelling edges.

SUMMARY

Considering the marketing and sales cost, we will pursue the commercialization strategy of win-win cooperation to maximize the value of our Core Product, instead of establishing our in-house sales network. We plan to partner with pharmaceutical companies who have strong commercialization capability and rich experience in the therapeutical fields we are focusing on, to utilize their well-established sales networks and other resources to achieve mutually beneficial results and maximize the commercial value of our drug candidates.

On June 29, 2017, we entered into an agreement with TSL HK (the “**TSL Agreement**”), pursuant to which we irrevocably granted to TSL HK the right of first refusal of exclusive commercialization rights of PB-119 and PB-718 in Mainland China. Pursuant to the terms of the TSL Agreement, we are required to send a written notice to TSL HK after completion of Phase III clinical trials and prior to filing the marketing authorization applications with the NMPA for PB-119 and PB-718, respectively (the “**First Refusal Notice**”). The First Refusal Notice shall set forth terms and conditions of commercialization offered by a third party procured by us. TSL HK could exercise its right of first refusal within the agreed period after receipt of the First Refusal Notice, provided that it must match the terms and conditions offered by the third party as provided in the First Refusal Notice. In May 2023, in accordance with the TSL Agreement and based on mutual agreements, the right of first refusal of the exclusive commercialization of PB-119 of TSL HK was terminated. This was primarily due to commercial reasons and prioritization in strategic focus of TSL HK. TSL HK will not be involved in the commercialization of PB-119 in China thereafter.

On September 13, 2024, we entered into a commercialization collaboration arrangement with a leading domestic commercialization-stage pharmaceutical company in China for PB-119. With such commercialization arrangement, we expect to benefit from its decades of market experience and know-how in navigating through the rapidly evolving China healthcare landscape, market access ability to provide umbrella coverage for a portfolio of products and sales network covering both higher- and lower-tier markets to enable broad market penetration across China. We believe that the collaboration will establish a solid foundation for our future commercialization. For additional information, see “Business — Collaboration Agreement for Commercializing PB-119 in Mainland China.”

In the overseas markets, we plan to unlock the value of our assets through commercialization collaborations with local partners. We may also seek collaborations to conduct clinical development in the United States, Europe and explore other overseas jurisdictions amongst the “Belt and Road Initiative” countries, including countries in the Middle East and South Asia.

SUMMARY

Collaboration Agreement for Commercializing PB-119 in Mainland China

We entered into a commercialization collaboration arrangement (the “**Collaboration Agreement**”) on September 13, 2024 with a leading China-based pharmaceutical company (the “**Commercialization Partner**”) regarding the future marketing and commercialization activities of PB-119 in Mainland China (the “**Territory**”). The Commercialization Partner is an A-share listed company that has decades of experience in marketing and distributing drugs and medical equipment in China, covering all major markets and provinces in China, including first-tier cities such as Beijing, Shanghai and Guangzhou and other major cities, with established experience in chronic and metabolic diseases. Its direct sales channel covers a large amount of drug stores nationwide, and can access a wide range of terminal pharmacies nationwide. The Commercialization Partner has maintained long-standing partnerships with over 1,000 domestic and international suppliers. As of December 31, 2023, the Commercialization Partner had over 3,000 employees based on publicly available information.

Pursuant to the Collaboration Agreement, we granted the Commercialization Partner an exclusive, sublicensable license to promote and commercialize PB-119 in the Territory. We also granted the Commercialization Partner, among others, the right to use the technology secrets, patents and authorized brands (the “**granted IP rights**”) solely for purposes of commercializing PB-119 in the Territory. Other than the granted IP rights, we possess and retain all intellectual property rights related to PB-119 or any improvements thereto, regardless of whether created by us or the Commercialization Partner. Other than expressly provided, no license to the intellectual property related to PB-119 is granted by the Collaboration Agreement. During the term of the Collaboration Agreement, without prior written consent from us, the Commercialization Partner or any of its subsidiaries shall not directly or indirectly (including, but not limited to, through collaboration with third parties) market or promote any competing products within the Territory.

With respect to the promotion activities carried out by the Commercialization Partner, we agree to pay certain promotion service fee (the “**Promotion Service Fee**”) to the Commercialization Partner. The amount of the Promotional Service Fee will be calculated as a product of (a) the annual base amount of promotion service fee, (b) a specified fee rate and (c) the key performance indication (the “**KPI**”) achievement rate. The annual base amount of promotion service fee is calculated as a product of the winning bid price and the specified sales target. The KPI achievement rate is a weighted sum of the respective achievement rates of sales target, coverage of hospitals and pharmacies, hospital and pharmacy visits and promotion activities, respectively. The specified fee rate will be adjusted according to the status of NRDL inclusion of PB-119. Following the NRDL inclusion of PB-119, the specified rate will range between low- to mid-double digits, reflecting the time since such inclusion and whether PB-119 is also included in the national centralized procurement programs. Prior to the NRDL inclusion, the Promotion Service Fee is expected to be a majority of the annual base amount of promotion service fee, and depending on the KPI achievement rate, be adjusted upwards. Provided that the Commercialization Partner can meet all the KPI achievement rate, the Promotion Service Fee can reach up to substantially all of the annual base amount of promotion service fee. Taking into account the payments we are entitled to receive as specified in the Collaboration Agreement, the expected timetable of PB-119’s NRDL inclusion and the overall arrangement for the Promotion Service Fee payment, we believe the commercial arrangement is in line with industry practice for newly approved drugs, as confirmed by CIC.

SUMMARY

As part of the consideration for granting the commercialization rights to the Commercialization Partner and subject to the terms and conditions of the Collaboration Agreement, and provided that the drug registration certificate for PB-119 is received no later than a specified date, we are entitled to receive from the Commercialization Partner, within a specified period after we obtain the drug registration certificate for PB-119 issued by the NMPA, (i) a one-time upfront payment of slightly over RMB100 million (the “**Upfront Payment**”) and (ii) a one-time milestone payment (the “**Milestone Payment**”), the amount of which is based on the timing of obtaining such drug registration certificate, and the minimum amount of the Milestone Payment is low-double digit million RMB.

Unless terminated earlier, the Collaboration Agreement shall remain in effect until December 31, 2030 (the “**Initial Term**”). Subsequent terms shall automatically extend for five years following the expiration of the Initial Term and each subsequent term, unless either party provides prior written notice of non-renewal.

For additional information, see “Business — Collaboration Agreement for Commercializing PB-119 in Mainland China.”

Pricing

We will determine the prices of our products based on a number of factors, including our costs of production, prices of other similar products, our technology advantages, product quality, health economics, market trends and changes in the levels of supply and demand. In China, we intend to determine pricing based on the affordability to Chinese patients and the price of comparable peer products to not only ensure our products, once approved for commercialization, can be accessed by the vast patient population in China and also secure a sustainable revenue stream to support our future growth and R&D endeavors. The pricing in overseas markets may vary to suit specific conditions in each territory, and we will determine the prices based on a discussion with our local partners and taking into account, among other things, the pricing of multinational competitors in the same market. We endeavor to enhance our product affordability by pursuing reimbursement listings in the National Reimbursement Drug List (“**NRDL**”) and other government-sponsored medical insurance programs at appropriate pricing levels. Inclusion into the NRDL is evaluated and determined by the relevant government authorities and we may face significant competition for successful inclusion. If we fail to have our Core Product included in the NRDL after commercialization, we may need to seek alternatives such as commercial private insurance coverage of our Core Product.

PB-119 is expected to be commercialized in China in 2025. We expect that PB-119 will be priced at a competitive level that is closer to the lower end of our pricing estimates once included into the NRDL, which we believe would render PB-119 accessible and affordable for a broad range of patients, in particular who have limited medical or financial resources. For more details of the potential deeper-than-expected price reduction as a result of the inclusion of PB-119 in the NRDL, see “Risk Factors — Our drugs may not be covered by reimbursement programs or may become subject to unfavorable reimbursement practices, either of which could harm our business.”

SUMMARY

SUPPLIERS

During the Track Record Period, our major suppliers primarily consisted of CROs, SMOs and CDMOs and we did not experience any material disputes with our suppliers. In addition, we believe that adequate alternative sources for such supplies exist, and we have developed alternative sourcing strategies for these supplies. In 2023 and 2024, our purchases from our five largest suppliers in each period in aggregate amounted to RMB137.1 million and RMB32.6 million, respectively, representing 66.3% and 47.5% of our total corresponding purchases, and our purchases from the largest supplier in each period accounted for 33.0% and 16.0% of our total corresponding purchases, respectively.

None of our Directors, their respective associates or any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers during the Track Record Period. All of our five largest suppliers in each year during the Track Record Period are Independent Third Parties.

OUR SHAREHOLDING STRUCTURE

Our Single Largest Group of Shareholders

Our Single Largest Group of Shareholders comprises Dr. Michael Min XU, Dr. Xiangjun ZHOU, Dr. Yuhong XU (徐宇虹) and Shanghai Sujie. Such parties entered into a concert party agreement (the “**Concert Party Agreement**”) on April 2, 2021, pursuant to which they (i) acknowledged and confirmed their relationship of acting in concert as shareholders when exercising the voting rights of the Company and Pan-Asia (the holding company of our Group prior to September 2020, as the case may be) since they became shareholders of these companies, and (ii) agreed to continue such acting in concert relationship so long as they hold any Shares, unless termination is agreed among all parties to the agreement. Shanghai Sujie’s general partner, namely Ms. Xiaojun WANG (王小軍), plays an administrative role, and has been designated by the Company, upon which Dr. Michael Min XU exercises significant influence.

Immediately following the completion of the [REDACTED], our Single Largest Group of Shareholders will control approximately [REDACTED]% of our total issued share capital.

For details, see “History, Development and Corporate Structure — Concert Party Agreement.”

SUMMARY

[REDACTED] Investments

We completed nine rounds of [REDACTED] Investments since our inception with an aggregate amount of approximately US\$50.3 million and RMB1.05 billion raised. As of the Latest Practicable Date, we have utilized 89.76% of the proceeds from the [REDACTED] Investments. Our [REDACTED] Investors include Mingly, YuanBio Venture Capital, True Wing, Yingke PE, Nice Credit, Kaifeng VC, TSL HK, Shanghai Yaocui, Zhongxin Huiyuan, Share Link, Qianhai, Chelmsford, Huzhou Qiyuan, SIP Investment Fund, Tigermed, Suzhou Yipu, Beijing Agile, Asia Private and other experienced investors such as established funds as well as individual investors.

YuanBio Venture Capital, which made meaningful investment to us and will hold approximately [REDACTED]% of our total issued share capital upon the completion of the [REDACTED], is our Sophisticated Investor. Pursuant to PRC Company Law, Shares issued by our Company prior to the [REDACTED] (including those held by the [REDACTED] Investors) will be subject to a lock-up period of one year from the [REDACTED]. We utilized the proceeds from the [REDACTED] Investments for the principal business of our Group, including but not limited to research and development of our products, the growth and expansion of our business and general working capital purposes. For further details of the identity and background of the [REDACTED] Investors and the principal terms of the [REDACTED] Investments, see “History, Development and Corporate Structure — [REDACTED] Investments.”

SUMMARY OF KEY FINANCIAL INFORMATION

This summary of key financial information set forth below have been derived from, and should be read in conjunction with, our historical financial information, including the accompanying notes, set forth in the Accountants’ Report set out in Appendix I to this Document, as well as the information set forth in “Financial Information” of this Document. Our historical financial information was prepared in accordance with HKFRSs.

SUMMARY

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

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

	For the Year Ended December 31,	
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>
Other net income	14,635	7,007
Selling and marketing expenses	—	(7,150)
Research and development expenses	(236,731)	(95,427)
Administrative expenses	<u>(55,358)</u>	<u>(185,282)</u>
Loss from operations	(277,454)	(280,852)
Finance costs	(1,727)	(2,499)
Loss before taxation	(279,181)	(283,351)
Income tax	<u>—</u>	<u>—</u>
Loss for the year	<u>(279,181)</u>	<u>(283,351)</u>
Attributable to:		
Equity shareholders of the Company	(278,999)	(283,158)
Non-controlling interests	<u>(182)</u>	<u>(193)</u>
Loss and total comprehensive income for the year	<u>(279,181)</u>	<u>(283,351)</u>

We currently have no products approved for commercial sale and have not generated any revenue from product sales. We incurred operating losses during the Track Record Period. Our loss before taxation was RMB279.2 million and RMB283.4 million in 2023 and 2024, respectively. Substantially all of our loss resulted from research and development expenses and administrative expenses. Our research and development expenses decreased from RMB236.7 million in 2023 to RMB95.4 million in 2024. The decrease was in line with our advancement of Core Product from Phase III clinical stage to NDA filing.

SUMMARY

Summary of Consolidated Statements of Financial Position

	As of December 31,	
	2023	2024
	RMB'000	RMB'000
Total non-current assets	22,574	28,063
Total current assets	345,479	190,294
Total current liabilities	164,987	157,666
NET CURRENT ASSETS	180,492	32,628
Total assets less current liabilities	203,066	60,691
Non-current liabilities	7,713	3,221
NET ASSETS	195,353	57,470
CAPITAL AND RESERVES		
Share capital	366,672	366,672
Reserves	(176,792)	(314,482)
Total equity attributable to equity shareholders		
of the Company	189,880	52,190
Non-controlling interests	5,473	5,280
TOTAL EQUITY	195,353	57,470

We recorded net current assets of RMB32.6 million as of December 31, 2024 as compared to net current assets of RMB180.5 million as of December 31, 2023. The decrease in net current assets was primarily due to the decrease in financial assets at fair value through profit or loss (“FVPL”) of RMB109.4 million and the increase in interest-bearing borrowings of RMB34.2 million, partially offset by the trade and other payables of RMB41.4 million. Such changes were primarily due to our ongoing operating cash outflows, which was primarily driven by the progresses in our research and development activities.

We recorded net assets of RMB57.5 million as of December 31, 2024 as compared to net assets of RMB195.4 million as of December 31, 2023. The decrease in net assets was primarily due to our loss for the year of RMB283.4 million, partially offset by equity-settled share-based payments of RMB145.5 million credited to capital reserve.

SUMMARY

Summary of Consolidated Statements of Cash Flows

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

	For the Year Ended December 31,	
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>
Net cash used in operating activities	(233,283)	(183,442)
Net cash generated from investing activities . . .	101,622	114,353
Net cash generated from financing activities . . .	148,511	20,334
Net increase/(decrease) in cash and cash equivalents	16,850	(48,755)
Effects of foreign exchange rate changes	1	–
Cash and cash equivalents at the beginning of the year	60,296	77,147
Cash and cash equivalents at the ending of the year	<u>77,147</u>	<u>28,392</u>

Our primary use of cash was to fund preclinical and clinical research and development of our drug candidates. Our net cash used in operating activities was RMB233.3 million and RMB183.4 million in 2023 and 2024, respectively. Our negative cash flows from operating activities were primarily attributable to cash used in paying research and development expenses and administrative expenses we incurred during the Track Record Period while we had not generated any revenue from sales of our drug candidates. As our product candidates in pipeline advance further in clinical trials and obtain regulatory approvals for commercialization, we believe we will be able to generate operating cash inflow from an increasing number of drug products, thus improving our operating cash outflow position.

Our Directors are of the opinion that, taking into account the financial resources available to us, including cash and cash equivalents, wealth management product and negotiable certificate of deposits with banks and the estimated net [REDACTED] from the [REDACTED], and considering our cash burn rate, we have sufficient working capital to cover at least 125% of our costs, including research and development expenses and administrative expenses for at least the next 12 months from the expected date of this Document.

Our cash burn rate refers to the average monthly amount of net cash used in operating activities, capital expenditures and lease payments. We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] in the [REDACTED], based on an [REDACTED] of HK\$[REDACTED] per [REDACTED]. Assuming an average cash burn rate going forward of 1.0 time the level in 2023, we estimate that our cash at bank and on hand, wealth management products and negotiable certificate of deposits with banks as of December 31, 2024 will be able to maintain our financial viability for [REDACTED] from December 31,

SUMMARY

2024 taking into account the estimated net [REDACTED] from the [REDACTED]. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing, if needed, with a minimum buffer of 12 months.

Key Financial Ratios

The table below sets forth the current ratio of our Group as of the dates indicated:

	As of December 31,	
	2023	2024
Current Ratio ⁽¹⁾	<u>2.09</u>	<u>1.21</u>

Note:

(1) Current ratio equals current assets divided by current liabilities as of the dates indicated.

[REDACTED]

SUMMARY

DIVIDEND

We have never declared or paid any dividends on our ordinary shares or any other securities. As of the Latest Practicable Date, we did not have a formal dividend policy. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business and we do not intend to establish a dividend policy to declare or pay any dividends in the foreseeable future. [REDACTED] should not purchase our ordinary shares with the expectation of receiving cash dividends. Any future determination to pay dividends will be made at the discretion of our Shareholders’ meeting subject to our Articles of Association and the PRC Company Law, and may be based on a number of factors, including our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors may deem relevant. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. Regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits as determined in accordance with its articles of association and the accounting standards and regulations in China. As confirmed by our PRC Legal Adviser, according to the PRC law, any future net profit that we make will have to be first applied to make up for our historically accumulated losses, after which we will be obliged to allocate 10% of our net 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 net profit to our statutory common reserve fund as described above.

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], based on an [REDACTED] of HK\$[REDACTED] per [REDACTED]. We intend to use the net [REDACTED] we will receive from this [REDACTED] for the following purposes:

- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) to fund the commercialization and indication expansion of our Core Product PB-119;
- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) to fund further development of our key product PB-718;
- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) to fund ongoing and planned research and development of our other pipeline product candidates;

SUMMARY

- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used for business development activities and enhancing our overseas presence;
- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used for our working capital and other general corporate purposes.

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

RISK FACTORS

We believe that there are certain risks involved in our operations, many of which are beyond our control. These risks are set out in the section headed “Risk Factors” in this Document. Some of the major risks we face include:

- We may face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates.
- We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our drug candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.
- Our business, financial condition, results of operations and prospects for the next couple of years are substantially dependent upon the successful approval and sales of PB-119. If we are unable to successfully obtain regulatory approvals, achieve commercialization or complete clinical development to expand indications for PB-119 in our targeted markets, or if we experience significant delays or cost overruns in doing any of the foregoing, our business, financial condition, results of operations and prospects could be materially and adversely affected.
- Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may need to deprioritize certain drug candidates, and may be unable to commercialize our drug candidates at all.
- If our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or may ultimately be unable to complete, the development and commercialization of our drug candidates.
- Our drug candidates may cause undesirable adverse events.

SUMMARY

- Negative results from off-label drug use of our drug products could negatively impact our business, financial condition, results of operations and prospects and expose us to liability.
- We work with various third parties to develop our drug candidates. If these third parties fail to duly perform their contractual obligations or meet expected timelines, we may be unable to obtain regulatory approvals for, or commercialize, our drug candidates, and our business, financial condition and results of operations could be materially and adversely affected.
- We intend to work with third parties for the commercialization of our drug candidates. We may fail to identify competent third parties for such purposes, fail to achieve the expected synergies with the clinical development partners, and have little or no control over the marketing and sales efforts of the commercialization partners.
- We work with third parties to manufacture a portion of our drug candidates for clinical development and future commercialization. Our business could be harmed if those third parties fail to deliver sufficient quantities of products.
- The market size of our drug candidates might be smaller than we expected.
- We have incurred significant net losses since inception and we may continue to incur net losses and may fail to achieve or maintain profitability in the future. As a result, you may lose substantially all of your [REDACTED] in us if our business fails.

[REDACTED] EXPENSES

Our [REDACTED] expenses represent professional fees, [REDACTED] and other fees incurred in connection with the [REDACTED]. Based on an [REDACTED] of HK\$[REDACTED] per Share, we estimated that the total [REDACTED] expenses for the [REDACTED] are approximately HK\$[REDACTED], accounting for approximately [REDACTED]% of the gross [REDACTED] from the [REDACTED], of which approximately HK\$[REDACTED] is expected to be charged to our consolidated statements of profit or loss and other comprehensive income, and approximately HK\$[REDACTED] is expected to be accounted for as a deduction from equity upon the completion of [REDACTED]. The above expenses comprise of (i) [REDACTED] expenses, including [REDACTED] and other expenses, of HK\$[REDACTED]; and (ii) [REDACTED] expenses of HK\$[REDACTED], including (a) fee paid and payable to legal advisors and reporting accountants of HK\$[REDACTED], and (b) other fees and expenses of HK\$[REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

SUMMARY

RECENT DEVELOPMENTS

Impact of the COVID-19 Outbreak

The outbreak of the COVID-19 and its recurrence had caused temporary disruption to our operations to the extent that certain on-site meetings, deployment and technical support had to be delayed or cancelled. As of the Latest Practicable Date, however, COVID-19 had not had any material adverse impact on our R&D activities, clinical development, daily operation, supply chain and regulatory affairs. Given that the PRC government has substantially lifted its COVID-19 prevention and control policies since December 2022, our Directors are of the view that it is unlikely that the COVID-19 will have a material adverse impact on our business going forward.

Clinical Development

We successfully completed two Phase III registrational clinical trials in China for PB-119 by early 2023. The clinical results regarding both monotherapy and combination therapy for T2DM have underpinned our NDA for PB-119 in China, which was accepted by the NMPA in September 2023. As of the Latest Practicable Date, the NMPA had accepted the NDAs of seven GLP-1 receptor agonists for the treatment of T2DM, and PB-119 was the second earliest to receive NDA acceptance from the NMPA among such candidates, according to CIC. We expect to commercially launch PB-119 for the treatment of T2DM in China in 2025. We are also initiating the Phase Ib/IIa clinical trial of PB-119 for the treatment of obesity in China. We received the approval from the NMPA to commence the clinical trial in April 2024 and we completed participant enrollment for the clinical trial in June 2024. We also completed the participant follow-up of the Phase Ib/IIa clinical trial of PB-718 for the treatment of obesity in China in April 2024 and the final clinical study report is expected to be ready by the second half of 2025. With the development of PB-119 and PB-718, we were among the few companies with multiple clinical-stage GLP-1-based product candidates for the treatment of overweight/obesity in China as of the Latest Practicable Date, according to CIC.

On June 18, 2024, Wegovy (semaglutide), a GLP-1 receptor agonist developed by Novo Nordisk A/S, received marketing approval from the NMPA for the treatment of obesity or overweight patients in China with a BMI over 30 kg/m² or with a BMI between 27 to 30 kg/m² and least one weight-related comorbidity. As we are developing our Core Product PB-119 for indications including obesity or overweight, we may face competition with Wegovy in China in the future. However, we believe such an approval further demonstrates the momentum of gaining market acceptance by GLP-1-based products in the China market, and the positive perception of regulatory authorities towards such products in China. Such momentum and favorable regulatory attitude could benefit our Core Product PB-119 in obtaining NDA approvals and future marketing and commercialization efforts, especially considering the multiple advantages of PB-119 described throughout the Document. As of the Latest Practicable Date, there had been no new GLP-1-based product being approved in the markets that PB-119 and PB-718 intend to address, according to CIC.

SUMMARY

CSRC Filing

Pursuant to 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 five supporting guidelines promulgated by the China Securities Regulatory Commission (the “**CSRC**”) on February 17, 2023, which came into effect on March 31, 2023, overseas [REDACTED] and [REDACTED] by a joint-stock company registered and formed in China is identified as a direct overseas [REDACTED] and [REDACTED] by a domestic company, and such domestic company shall file with the CSRC in this regard. As advised by our PRC Legal Adviser, we are required to file with the CSRC in connection with the [REDACTED], as a direct overseas [REDACTED] and [REDACTED], within three business days after we submit the [REDACTED] for [REDACTED] overseas.

We have filed the required documents with the CSRC on February 28, 2024, and the CSRC has issued the filing notice dated July 25, 2024, confirming our completion of the filing for the [REDACTED], the conversion of certain Unlisted Shares into H Shares and the [REDACTED] of the H Shares on the Hong Kong Stock Exchange.

NO MATERIAL ADVERSE CHANGE

We expect to record a net loss for the year ending December 31, 2025, which is primarily due to our expectations that significant selling and marketing expenses and research and development expenses will be further incurred.

Our Directors confirm that up to the date of this Document, there has been no material adverse change in our financial, operational or trading positions or prospects since December 31, 2024, being the end of the period reported on as set out in the Accountants’ Report included in Appendix I to this Document.

DEFINITIONS

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

“Accountants’ Report”	the accountants’ report prepared by KPMG, details of which are set out in Appendix I
“affiliate(s)”	with respect to any specified person, any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“AFRC”	the Accounting and Financial Reporting Council of Hong Kong
“AIC”	Administration of Industry & Commerce (工商管理機關) of the PRC (now known as the Administration for Market Regulation (市場監督管理局)) or, where the context so requires, the State Administration for Industry & Commerce of the PRC (中華人民共和國工商管理總局) or its delegated authority at the provincial, municipal or other local level
“Articles of Association” or “Articles”	the articles of association of our Company, as amended, which shall become effective on the Listing Date, a summary of which is set out in Appendix III
“Asia Private”	Asia Private Equity Capital, formerly known as MediBIC Alliance, a limited company incorporated in Japan and wholly-owned by West Wood Capital, which is controlled by Mr. Takashi NISHIKI, a [REDACTED] Investor and an Independent Third Party
“associate(s)”	has the meaning ascribed to it under the Listing Rules
“Audit Committee”	the audit committee of the Board
“Board” or “our Board”	the board of Directors
“Business Day”	a day on which banks in Hong Kong are generally open for normal business to the public and which is not a Saturday, Sunday or public holiday in Hong Kong

DEFINITIONS

“BVI”	British Virgin Islands
[REDACTED]	
“CDE”	Center for Drug Evaluation (藥品審評中心) under the NMPA
“Chief Financial Officer”	chief financial officer of our Company, i.e. Ms. Xiaojun WANG (王小軍)
“China”, “Mainland China” or “PRC”	the People’s Republic of China which, for the purpose of this Document and for geographical reference only, excluding Hong Kong Special Administrative Region of the People’s Republic of China, Macau Special Administrative Region of the People’s Republic of China, and China’s Taiwan
“CIC”	China Insights Industry Consultancy Limited, a global market research and consulting company, which is an Independent Third Party
“CIC Report”	an independent market research report [REDACTED] 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”, “our Company”, or “the Company”	PegBio Co., Ltd. (派格生物醫藥(杭州)股份有限公司) (formerly known as PegBio Co., Ltd. (派格生物醫藥(蘇州)股份有限公司)), a limited liability company incorporated in the PRC on May 13, 2008 and converted into a joint stock company with limited liability on December 30, 2020

DEFINITIONS

“Compliance Adviser”	Rainbow Capital (HK) 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
“Core Product”	has the meaning ascribed thereto under Chapter 18A of the Listing Rules
“Corporate Governance Code”	the Corporate Governance Code set out in Appendix C1 to the Listing Rules
“CSRC”	the China Securities Regulatory Commission (中國證券監督管理委員會)
“Director(s)” or “our Director(s)”	the director(s) of our Company
“EIT”	the PRC enterprise income tax
“EIT Law”	the Enterprise Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法》), as amended, supplemented or otherwise modified from time to time

[REDACTED]

“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the government of Hong Kong
“FDA”	U.S. Food and Drug Administration

[REDACTED]

DEFINITIONS

“Group”, “our Group”, “our”, “we” or “us”	our Company and our subsidiaries
“Guide for New Listing Applicants”	the Guide for New Listing Applicants issued by the Hong Kong Stock Exchange effective from January 1, 2024
“H Share(s)”	[REDACTED] ordinary share(s) in the share capital of our Company with a nominal value of RMB1.00 each, which is/are to be [REDACTED] for and [REDACTED] in HK dollars and to be [REDACTED] on the Hong Kong Stock Exchange
	[REDACTED]
“HK\$” or “Hong Kong Dollars” or “HK Dollars” and “HK cents”	Hong Kong dollars, the lawful currency of Hong Kong
“HKFRSs”	Hong Kong Financial Reporting Standards

[REDACTED]

DEFINITIONS

[REDACTED]

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

[REDACTED]

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

“Hong Kong Takeovers Code”
or “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

[REDACTED]

“Independent Third Party(ies)” any entity(ies) or person(s) who is not a connected person of our Company within the meaning of the Hong Kong Listing Rules

DEFINITIONS

[REDACTED]

“Latest Practicable Date”	February 24, 2025, being the latest practicable date for the purpose of ascertaining certain information contained in this Document prior to its publication

[REDACTED]

“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time

“Main Board”	the stock exchange (excluding the option market) operated by the Hong Kong Stock Exchange which is independent from and operated in parallel with the GEM of the Hong Kong Stock Exchange

DEFINITIONS

“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))
“NMPA”	the National Medical Products Administration of China (國家藥品監督管理局) or, where the context so requires, its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局), or CFDA
“NPC”	the National People’s Congress of the PRC (中華人民共和國全國人民代表大會)
“Nomination Committee”	the nomination committee of the Board

[REDACTED]

“Overseas Listing Trial Measures”	The Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies and five supporting guidelines (《境內企業境外發行證券和上市管理試行辦法》及五項配套指引) promulgated by the CSRC on February 17, 2023 and became effective on March 31, 2023
“Pan-Asia”	Pan-Asia Bio Co., Ltd., a company incorporated in the BVI with limited liability on July 10, 2001, being the holding company of our Group prior to September 2020

DEFINITIONS

“PegBio Suzhou”	PegBio Xinrui Biotechnology Pharmaceutical (Suzhou) Co., Ltd. (派格欣銳生物醫藥科技(蘇州)有限公司), a limited liability company established in the PRC on January 21, 2025 and a subsidiary of the Company
“PBOC”	the People’s Bank of China (中國人民銀行), the central bank of the PRC
“PRC Company Law”	Company Law of the PRC (中華人民共和國公司法), as amended, supplemented or otherwise modified from time to time
“PRC GAAP”	generally accepted accounting principles in the PRC
“PRC Legal Adviser”	JunHe LLP, our legal adviser on PRC laws in connection with the [REDACTED]
“[REDACTED] Equity Incentive Plan”	the [REDACTED] equity incentive plan of our Company approved and adopted in March 2021, as amended from time to time, a summary of the principal terms of which is set forth in “Statutory and General Information — [REDACTED] Equity Incentive Plan” in Appendix IV
“[REDACTED] Investment(s)”	the investment(s) in our Group undertaken by the [REDACTED] Investors prior to this [REDACTED], the details of which are set out in “History, Development and Corporate Structure — [REDACTED] Investments”
“[REDACTED] Investor(s)”	the investor(s) making investments in our Group prior to this [REDACTED] as set out in “History, Development and Corporate Structure — [REDACTED] Investments”
“Document”	this document being issued in connection with the [REDACTED]
“Regulation S”	Regulation S under the U.S. Securities Act
“Remuneration and Appraisal Committee”	the remuneration and appraisal committee of the Board
“Renminbi” or “RMB”	the lawful currency of the PRC
“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)

DEFINITIONS

“SAIC”	the State Administration of Industry and Commerce of the PRC (中華人民共和國國家工商行政管理總局), the function of which has now been merged into the SAMR
“SAMR”	the State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局)
“SAT”	the State Taxation Administration of the PRC (中華人民共和國國家稅務總局)
“SFC”	the Securities and Futures Commission of Hong Kong
“SFO” or “Securities and Futures Ordinance”	the Securities and Futures Ordinance, Chapter 571 of the Laws of Hong Kong, as amended, supplemented or otherwise modified from time to time
“Shanghai Hanmai”	Shanghai Hanmai Biotech Co., Ltd. (上海瀚邁生物醫藥科技有限公司), a limited liability company established in the PRC on June 26, 2017 and a subsidiary of our Company
“Shanghai Maiji”	Shanghai Maiji Biotech Co., Ltd. (上海邁跡生物醫藥科技有限公司), a limited liability company established in the PRC on June 26, 2017 and a subsidiary of the Company
“Shanghai Sujie” or “Equity Incentive Platform”	Shanghai Sujie Business Management Consulting Partnership (Limited Partnership) (上海蘇頤企業管理諮詢合夥企業(有限合夥)), a limited partnership established in the PRC on August 28, 2020, the equity incentive platform of our Group of which Ms. Xiaojun WANG (王小軍), our executive Director and Chief Financial Officer, is the sole general partner
“Share(s)”	ordinary share(s) in the capital of our Company with a nominal value of RMB1.00 each
“Shareholder(s)”	holder(s) of our Share(s)
“Single Largest Group of Shareholders”	refers to Dr. Michael Min XU, Dr. Yuhong XU (徐宇虹), Dr. Xiangjun ZHOU and Shanghai Sujie

DEFINITIONS

“Sole Sponsor”	the sole sponsor of the [REDACTED] as named in “Directors, Supervisors and Parties Involved in the [REDACTED]”
“Sophisticated Investor(s)”	has the meaning ascribed to it under Chapter 2.3 of the Guide for New Listing Applicants
“State Council”	the State Council of the PRC (中華人民共和國國務院)
“Strategy and Development Committee”	the strategy and development committee of the Board
“subsidiary(ies)”	has the meaning ascribed to it in section 15 of the Companies Ordinance
“substantial shareholder(s)”	has the meaning ascribed to it under the Listing Rules
“Supervisor(s)”	supervisor(s) of the Company
“Supervisory Committee”	the committee of the Supervisors
“Track Record Period”	the period comprising the two years ended December 31, 2023 and 2024
“TSL HK”	Tasly (Hong Kong) Pharmaceuticals Limited (天士力(香港)藥業有限公司), a company established in Hong Kong on November 3, 2011 and a wholly-owned subsidiary of Tasly Pharmaceutical Group Co., Ltd. (天士力醫藥集團股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 600535), a [REDACTED] Investor and an Independent Third Party
“U.S. Government”	the federal government of the United States, including its executive, legislative and judicial branches
“U.S. persons”	U.S. persons as defined in Regulation S
“U.S. Securities Act”	United States Securities Act of 1933, as amended, supplemented or otherwise modified from time to time

DEFINITIONS

[REDACTED]

“United States”, “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
“US\$” or “U.S. dollars”	United States dollars, the lawful currency of the U.S.
“VAT”	value-added tax

[REDACTED]

“Xinfeng Biotech”	Xinfeng Biotech (Shanghai) Co., Ltd. (新峰生物科技(上海)有限公司), a limited liability company established in the PRC on September 17, 2001 and deregistered on December 23, 2021, and a former subsidiary of the Company
“%”	per cent

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

For ease of reference, the names of Chinese laws and regulations, governmental authorities, institutions, natural persons or other entities (including our subsidiary) have been included in this Document in both the Chinese and English languages and in the event of any inconsistency, the Chinese versions shall prevail. English translations of company names and other terms from the Chinese language are provided for identification purposes only.

GLOSSARY OF TECHNICAL TERMS

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

“5-HT”	5-hydroxytryptamine
“ADA”	American Diabetes Association
“AEs”	adverse events
“Agonist”	an agonist is an agent that activates a receptor to produce a biological response
“ALT”	alanine transaminase, an enzyme found in the liver that helps convert proteins into energy for the liver cells; the level of ALT increases when the liver is damaged, making it a biomarker commonly associated with injury or apoptosis of liver cells
“Alzheimer’s disease”	a brain disorder that leads to deposits of certain abnormal proteins in the brain and cause the brain to shrink and brain cells to eventually die; it is the most common cause of dementia, which is a gradual decline in memory, thinking, behavior and social skills
“apoptosis”	a type of programmed cell death
“AST”	aspartate aminotransferase, an enzyme found mostly in the liver, heart, muscles and kidneys; high levels of which in the blood may indicate hepatitis, cirrhosis, or other liver diseases
“BID”	from Latin “bis in die”, meaning two times a day
“biomarker”	a measurable indicator of a biological state or condition
“CAGR”	compound annual growth rate

GLOSSARY OF TECHNICAL TERMS

“CDMO”	contract development and manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
“CGM”	continuous glucose monitoring
“CHI”	congenital hyperinsulinemia
“CLCN2”	chloride voltage-gated channel 2
“clinical trial/study”	a type of research carried out on human for validating or finding the therapeutic effects and side effects of test drugs in order to determine the therapeutic value and safety of such drugs
“CMC”	chemistry, manufacturing, and controls
“CMO”	contract manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services for drug manufacturing
“cohort”	a group of participants as part of a clinical trial who share a common characteristic or experience within a defined period and who are monitored over time
“combination therapy”	treatment in which a clinical trial participant is given two or more drugs (or other therapeutic agents) for a single disease
“comorbidity”	the simultaneous presence of two or more diseases or medical conditions in a patient
“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
“CRU”	clinical research unit
“CV”	cardiovascular

GLOSSARY OF TECHNICAL TERMS

“CVD”	cardiovascular disease, conditions affecting the heart or blood vessels
“diabetes”	a complex, chronic metabolic disease characterized by elevated levels of blood glucose, which over time leads to serious damage to the heart, blood vessels, eyes, kidneys, nerves and other organs, comprised of two categories including type 1 diabetes mellitus and type 2 diabetes mellitus
“digestive diseases”	health conditions associated with the digestive system
“DPP-4”	dipeptidyl peptidase-4, also known as adenosine deaminase complexing protein 2 or CD26 (cluster of differentiation 26), an enzyme expressed on the surface of most cell types and associated with immune regulation, signal transduction, and apoptosis
“DDP-4i”	dipeptidyl peptidase-4 inhibitor
“ECG”	electrocardiogram; a test that records the electrical activity of your heart, including the rate and rhythm
“ESG”	environmental, social and governance; a collection of corporate performance evaluation criteria that assess the robustness of a company’s governance mechanisms and its ability to effectively manage its environmental and social impacts
“FIB-4”	fibrosis-4, an indicator of the severity of liver damage
“GABA”	gamma aminobutyric acid, the chief inhibitory neurotransmitter in the developmentally mature mammalian central nervous system
“GCG”	glucagon, the main catabolic hormone of the body, produced by alpha cells of the pancreas; it raises the concentration of glucose and fatty acids in the bloodstream
“GCGR”	glucagon receptor

GLOSSARY OF TECHNICAL TERMS

“GCP”	good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans
“GI”	gastrointestinal
“GIP”	glucose-dependent insulintropic polypeptide, also known as gastric inhibitory polypeptide; it is a hormone produced in the upper gut and secreted to the circulation in response to the ingestion of foods, especially fatty foods
“GIPR”	glucose-dependent insulintropic polypeptide receptor, or gastric inhibitory polypeptide receptor, found on beta-cells in the pancreas; its activation stimulates insulin secretion
“GMP”	good manufacturing practice, the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of products
“GLP-1”	glucagon-like peptide-1; a peptide hormone that decreases blood sugar levels in a glucose-dependent manner by enhancing the secretion of insulin
“GLP-1R”	glucagon-like peptide-1 receptor
“GLP-1RA”	glucagon-like peptide-1 receptor agonist
“glycemic control”	the management of blood sugar levels
“Grade”	term used to refer to the severity of adverse events according to Common Terminology Criteria for Adverse Events (CTCAE) v4.03, using Grade 1, Grade 2, Grade 3, etc.
“HbA1c”	glycated hemoglobin, formed when hemoglobin joins with glucose in the blood and becomes glycated
“HF”	heart failure

GLOSSARY OF TECHNICAL TERMS

“ <i>in vitro</i> ”	Latin for “within the glass”, referring to studies that are performed with microorganisms, cells, or biological molecules outside their normal biological context
“ <i>in vivo</i> ”	Latin for “within the living”, referring to studies in which the effects of various biological entities are tested on whole, living organisms or cells, usually animals, including humans, and plants, as opposed to a tissue extract or dead organism
“IND”	investigational new drug, an application in the drug review process required by a regulatory authority to decide whether a new drug is permitted to initiate clinical trials; also known as clinical trial application, or CTA, in China
“INSR”	insulin receptor
“LSM”	liver stiffness measurement
“MACE”	major adverse cardiovascular events
“metformin”	the main first-line medication for the treatment of T2DM; it is an FDA-approved antidiabetic agent that manages high blood sugar levels in patients
“MoA”	mechanism of action, the specific biochemical interaction through which a drug substance produces its pharmacological effect
“MRCT”	multi-regional clinical trials
“NAFLD” or “non-alcoholic fatty liver disease”	excessive fat build-up in the liver without another clear cause such as alcohol use, including two types: nonalcoholic fatty liver (NAFL) and non-alcoholic steatohepatitis, with the latter also including liver inflammation, also known as metabolic dysfunction-associated steatotic liver disease (MASLD)
“NAS”	NAFLD activity score, a sum of numerical score system applying to steatosis, hepatocellular ballooning, and lobular inflammation

GLOSSARY OF TECHNICAL TERMS

“NASH” or “non-alcoholic steatohepatitis”	the liver manifestation of a metabolic disorder, and the most severe form of non-alcoholic fatty liver disease, also known as metabolic dysfunction-associated steatohepatitis (MASH)
“NDA”	new drug application, a process required by an regulatory authority to approve a new drug for sale and marketing
“NE”	norepinephrine, also called noradrenaline or noradrenalin, an organic chemical that functions as a hormone, neurotransmitter and neuromodulator to mobilize the brain and body for action
“NRDL”	National Reimbursement Drug List, which names all the drugs covered by the medical insurance program in full or partially in China
“obesity”	abnormal or excessive fat accumulation in the body; defined as an individual having a body mass index over 28kg/m ² or more in China and 30 kg/m ² or more in the United States, respectively
“off-label”	related to the use of pharmaceutical drugs for an unapproved indication or in an unapproved age group, dosage or route of administration
“OIC”	opioid-induced constipation; opioid drugs inhibit gastric emptying and peristalsis in the gastrointestinal tract which results in delayed absorption of medications and increased absorption of fluid
“opioid”	a class of drugs used to reduce pain
“PAMORA”	peripherally acting μ -opioid receptor antagonists
“PD”	pharmacodynamics; the study of how a drug affects an organism, which, together with pharmacokinetics, influences dosing, benefit, and adverse effects of the drug
“PEG”	polyethylene glycol

GLOSSARY OF TECHNICAL TERMS

“PEGylation”	a process through which PEG chains are attached to proteins, peptides or other molecules to alter certain properties, such as molecular mass, solubility, stability and half-life in the body
“Phase I 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 efficacy
“Phase II clinical trial”	a study in which a drug is administered to a limited patient population to preliminarily evaluate the efficacy of the product for specific targeted diseases, to identify possible adverse effects and safety risks, and to determine optimal dosage
“Phase III 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 person(s) in charge of a clinical trial who prepares and carries out the clinical trial protocol, and analyzes the data and reports the results
“PK”	pharmacokinetics; the study of the bodily absorption, distribution, metabolism, and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit, and adverse effects of the drug
“placebo”	a medical treatment or preparation with no specific pharmacological activity
“p.o.”	from Latin “per os”, meaning oral administration
“preclinical study”	a study testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials

GLOSSARY OF TECHNICAL TERMS

“primary endpoint”	the specific key measurement upon which a clinical study is designed to assess the effect of the drugs being investigated
“QD”	from Latin “quaque die”, meaning once daily
“QT interval”	a measurement made on an electrocardiogram used to assess some of the electrical properties of the heart
“QW”	from Latin “quaque week”, meaning once weekly
“R&D”	research and development
“receptor agonist”	a receptor agonist is an agent that activates a receptor to produce a biological response
“registrational clinical trial”	a clinical trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval
“ROW”	rest of the world
“SAEs”	serious adverse events, an event or reaction that, in the view of either the investigator or sponsor, results in severe outcomes such as death, life-threatening adverse events, in-patient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, a congenital anomaly or birth defect
“SBM”	spontaneous bowel movements
“s.c.”	subcutaneous
“SDOH”	social determinants of health
“SGLT-2”	sodium-glucose cotransporter-2; SGLT-2 is the major cotransporter involved in glucose reabsorption in the kidney, responsible for reabsorption of 80-90% of the glucose filtered by the kidney glomerulus
“SGLT-2i”	sodium-glucose cotransporter-2 inhibitors, a class of prescription medicines that are FDA-approved for use with diet and exercise to lower blood sugar in adults with T2DM

GLOSSARY OF TECHNICAL TERMS

“SMO”	site management organization, an organization that has adequate infrastructure and staff to meet the requirements of the clinical trial protocol and provides clinical trial related services to a CRO, a pharmaceutical company, a biotechnology company, or a clinical site
“ $t_{1/2}$ ”	half-life, the time required for the concentration to fall to 50% of its peak value
“T1DM”	type 1 diabetes mellitus, an autoimmune disease that originates when cells that make insulin are destroyed by the immune system
“T2DM”	type 2 diabetes mellitus, a form of diabetes characterized by high blood sugar, insulin resistance and relative lack of insulin; the pancreas in T2DM patient makes less insulin, and the body becomes resistant to insulin
“TEAEs”	treatment-emergent adverse events, undesirable events not present prior to medical treatment or already present events that worsen in either intensity or frequency following the treatment
“TID”	from Latin “ter in die”, meaning three times a day
“ t_{max} ”	the amount of time that a drug is present at the maximum concentration in serum
“TZD”	thiazolidinediones, a class of drugs used in the treatment of T2DM

FORWARD-LOOKING STATEMENTS

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

This Document contains 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,” “aspire,” “believe,” “could,” “expect,” “going forward,” “intend,” “may,” “ought to,” “plan,” “project,” “schedule,” “seek,” “should,” “target,” “vision,” “will,” “would,” and the negative of these words and other similar expressions, as they relate to us or our management, are intended to identify forward-looking statements. Such statements reflect the current views of our management with respect to future events, operations, liquidity and capital resources, some of which may not materialize or may change. These statements are subject to certain risks, uncertainties and assumptions, including the risk factors as described in “Risk Factors” and elsewhere in this Document, some of which are beyond our control and may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. You are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The risks and uncertainties facing us which could affect the accuracy of forward-looking statements include, but are not limited to, the following:

- our operations and business prospects;
- future developments, trends and conditions in the industries and markets in which we operate or plan to operate;
- general economic, political and business conditions in the markets in which we operate, including but not limited to interest rates, foreign exchange rates;
- changes to the regulatory environment in the industries and markets in which we operate;
- our ability to maintain relationship with, and the actions and developments affecting, our major business partners, suppliers and future customers;
- our ability to maintain the market leading positions and the actions and developments of our competitors;
- our ability to effectively control costs and operating expenses;
- the ability of business partners to perform in accordance with contractual terms and specifications;
- our ability to retain senior management and key personnel and recruit qualified staff;

FORWARD-LOOKING STATEMENTS

- our business strategies and plans to achieve these strategies, including our drug development plans, commercialization strategies and geographic expansion plans; and
- all other risks and uncertainties described in “Risk Factors”.

By their nature, certain disclosures relating to these and other risks are only estimates and should one or more of these uncertainties or risks, among others, materialize, actual results may vary materially from those estimated, anticipated or projected, as well as from historical results. Specifically but without limitation, sales could decrease, costs could increase, capital costs could increase, capital investment could be delayed and anticipated improvements in performance might not be fully realized.

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

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

RISK FACTORS

[REDACTED] in our H Shares involves significant risks. You should carefully consider all of the information set out in this Document, including the risks and uncertainties described below, before making an [REDACTED] in our H Shares. In particular, we are a biopharmaceutical company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. Our operations and the biopharmaceutical industry involve certain risks and uncertainties, some of which are beyond our control and may cause you to lose all your [REDACTED] in our H Shares. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks and uncertainties. The [REDACTED] price of our H Shares could decline due to any of these risks, and you may lose all or part of your [REDACTED]. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations.

These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, which will not be updated after the date hereof, and is subject to the cautionary statements in the section headed “Forward Looking Statements” in this Document.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to development, clinical trials and regulatory approval of our drug candidates; (ii) risks relating to manufacturing and commercialization of our drug candidates; (iii) risks relating to our financial prospects; (iv) risks relating to our intellectual property rights; (v) risks relating to our business and industry; (vi) risks relating to doing business in the jurisdictions we operate; and (vii) risks relating to the [REDACTED].

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

RISK FACTORS

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

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

The pharmaceutical industry is subject to intense competition and we will face intense competition with respect to any drug candidates that we may seek to develop or commercialize in the future.

Many of our drug candidates will face competition from biologic drugs developed by major international and domestic pharmaceutical companies with the same targets as ours. For example, our Core Product, PB-119 long-acting glucagon-like peptide 1 (“GLP-1”) receptor agonist primarily designed for the first-line treatment of T2DM and obesity. As of the Latest Practicable Date, there were 16 GLP-1 receptor agonists approved in China and more than 20 GLP-1 receptor agonist candidates undergoing clinical trials for the treatment of T2DM in China. If and when we obtain regulatory approval for PB-119, we expect it will face (i) intense competition from approved drugs from multinational pharmaceutical companies, such as Exenatide and Lixisenatide; and (ii) potential competition from drug candidates under clinical development in China.

The ability of our drug candidates to successfully compete with other drugs of the same targets and gain market share will depend on various factors, including the timing of regulatory approval, the efficacy and safety profile of our drug candidates in comparison to other drugs, convenience of our dosing regimens, pricing and market coverage of our or our commercialization partner’s sales and distribution channels. However, we cannot guarantee you that we will be able to successfully compete on all or any of the aforementioned aspects against major pharmaceutical companies that operate on a global or national level, which may have stronger medical and technological capabilities, greater pricing flexibility, better track records, greater brand name recognition or greater financial, marketing and public relations resources than we do.

Furthermore, our drug candidates will also face competition from biologic drugs with different targets developed for the same indication. For example, in addition to other glucagon-like peptide 1 (“GLP-1”) receptor agonist, PB-119 will also compete with, among others, thiazolidinediones (“TZDs”), oral sulfonylureas, dipeptidyl peptidase-4 (“DPP-4”) inhibitors, sodium-glucose co-transporter-2 (“SGLT-2”) inhibitors, which are or will be approved by the NMPA for the treatment of T2DM in China. In addition, traditional non-biologic medications are widely prescribed for T2DM and obesity in China. The market competition may be further intensified with the potential development of generic medications once the relevant patents of brand name drugs have expired. We cannot guarantee you that biologic drugs will successfully replace these traditional therapies for the relevant patient population.

RISK FACTORS

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our drug candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

Our commercial success will depend, in large part, on our ability to obtain and maintain patent and other intellectual property protection with respect to our drugs and drug candidates. We cannot be certain that patents will be issued or granted with respect to our patent applications that are currently pending, or that issued or granted patents will not later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our drug candidates, or otherwise provide us with any competitive advantage. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. Patent applications we had applied may not be granted in the end. As such, we do not know the degree of future protection that we will have on our drugs and technology, if any, and a failure to obtain adequate intellectual property protection with respect to our drug candidates could have a material adverse impact on our business.

The scope of patent protection in various jurisdictions is uncertain. Changes in either the patent laws or their interpretation may diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patent rights. We cannot predict whether the patent applications we are currently pursuing and may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any future granted patents will provide sufficient protection from competitors.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been a common subject of litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

RISK FACTORS

Our business, financial condition, results of operations and prospects for the next couple of years are substantially dependent upon the successful approval and sales of PB-119. If we are unable to successfully obtain regulatory approvals, achieve commercialization or complete clinical development to expand indications for PB-119 in our targeted markets, or if we experience significant delays or cost overruns in doing any of the foregoing, our business, financial condition, results of operations and prospects could be materially and adversely affected.

We incurred significant expenses related to the research and development of our drug candidates during the Track Record Period. In 2023 and 2024, our research and development expenses amounted to RMB236.7 million and RMB95.4 million, respectively. We expect that we will continue to incur significant expenses related to the research and development and commercialization of our drug candidates in the future. To date, PB-119 is at the near-commercialized stage. We completed phase III clinical trials of PB-119 and its NDA was accepted in September 2023. We expected that our ability to generate significant revenue in the next several years will depend primarily on the successful regulatory approval, manufacture, marketing and commercialization of PB-119 in our targeted markets, which is subject to uncertainty on a global scale. Our ability to generate sales revenue from our drug candidates and our future profitability depends on a number of factors, including our ability to continue:

- obtaining regulatory approvals and marketing authorizations in our targeted markets for PB-119;
- obtaining market acceptance by hospitals, doctors, KOLs and others in the medical community for our drug candidates as viable treatment options;
- successful collaboration with third parties to launch and commercialize our drug candidates;
- setting appropriate and favorable prices for our drug candidates and obtaining adequate reimbursement from third-party payers, including government payers;
- maintaining commercially viable supply relationships with third parties;
- addressing any competing technological and market developments; and
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how.

In addition, because of the numerous risks and uncertainties on a global scale associated with regulatory approval in our targeted markets, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we are required to perform studies in addition to those that we currently anticipate. Even if our drug candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of these drugs.

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Our ability to become and remain profitable depends on our ability to generate revenue. Even if we are able to generate revenue from the sale of these drugs, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. Failure to become and remain profitable may adversely affect the market price of our H Shares and our ability to raise capital and continue operations. A decline in the value of our Company could also cause you to lose all or part of your [REDACTED].

Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may need to deprioritize certain drug candidates, and may be unable to commercialize our drug candidates at all.

We face uncertainties in clinical trial development which are subject to a variety of factors, including satisfactory safety and efficacy results from clinical trials, successful enrollment of patients, and performance of CROs and other parties involved in clinical trial development and others. In the past, we strategically deprioritized PB-201 to focus our resources on more promising pipeline programs. PB-201 is a candidate for the treatment of T2DM and was under Phase III clinical development in China when we decided to deprioritize it in 2023. Our decision was based on multiple factors including the anticipated competitive landscape and information about peer products leveraging the same underlying mechanism of action. We did not receive any regulatory objections or feedback that could not be addressed from the NMPA for the development of PB-201. We did not deprioritize other clinical-stage candidate or any indications of our current pipeline during the Track Record Period. In our future R&D efforts, we may experience numerous unexpected events during, or as a result of, clinical development that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including but not limited to the following events. Therefore, we cannot guarantee you that we will not deprioritize any of the drug candidates described in the “Business” section of this Document.

- regulators may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;

RISK FACTORS

- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or a finding that participants are being exposed to unacceptable health risks;
- regulators may require that we or our investigators suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements;
- the cost of clinical trials of our drug candidates may be greater than we anticipate; or
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate.

If we do not achieve one or more of these factors in a timely manner, we may be unable to commercialize our drug candidates at all which would materially harm our business, and we may fail to generate sufficient revenues or cash flows to continue our operations. These factors present uncertainty and material risks to our commercial success and may cause potential [REDACTED] to lose a substantial amount, or substantially all, of their [REDACTED] in our business.

In addition, two of our pipeline candidates, PB-2301 and PB-2309, are in the preclinical development stage. It is uncertain that we will be able to advance these preclinical-stage product candidates into clinical development, and as they have not been tested in human, they may experience longer development timelines, encounter greater uncertainty, and face higher clinical risks than our other clinical-stage product candidates.

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

Before obtaining regulatory approvals for the commercialization of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. If the results of the clinical trials of our drug candidates are not positive or only modestly positive for proposed indications, or if they raise safety concerns, any or some of the following would occur:

- regulatory approvals for our drug candidates would be delayed or denied;
- we may be required to conduct additional clinical trials or other testing of our drug candidates beyond our current development plan;

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

If our drug candidates ultimately fails to receive regulatory approvals due to unsatisfactory clinical trial results, our business, financial condition, results of operations and prospects would be materially and adversely affected.

Negative results from off-label drug use of our drug products could negatively impact our business, financial condition, results of operations and prospects and expose us to liability.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use beyond our control. Off-label drug use is prescribing a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. In particular, the NDA for PB-119 in T2DM has been accepted by the NMPA. While the NDA of PB-119 is for the treatment of T2DM, we also intend to investigate PB-119 for other indications, such as obesity. After its launch, PB-119 may be used for purposes beyond its labelled use, such as for the treatment of obesity before this indication receives regulatory approval. 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 PB-119 or our other drug candidates, upon regulatory approval for certain indications, are subject to off-label drug use, with indications, dosages or dosage forms that have not been approved by relevant regulatory authorities. The currently reported market of the treatment of obesity by GLP-1 receptor agonists may include off-label use. The occurrences of off-label use

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may render PB-119 or our other drug candidates less effective or entirely ineffective for those other indications at issue and may cause adverse effects, particularly if used at inappropriate dosage levels. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand name, commercial operations and financial condition. These occurrences may also expose us to liability of off-label use of PB-119 or our other drug candidates upon regulatory approval, which may subsequently cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our drug candidates. The illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our drug candidates, upon regulatory approval, and could have a negative impact on our business, financial condition, results of operations and prospects.

Our drug candidates may cause undesirable adverse events.

Undesirable adverse events caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the NMPA, FDA and other comparable regulatory authorities. Some of our pipeline products including our Core Product PB-119 are GLP-1-based candidates. The currently marketed GLP-1-based products and pipelines undergoing clinical trials have exhibited certain common adverse effects such as mild-to-moderate gastrointestinal disturbances. Results of our clinical trials could reveal a high and unacceptable severity or prevalence of adverse events. In such an event, our clinical trials could be suspended or terminated and the NMPA, FDA and other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. Drug-related adverse events could affect patient recruitment or the ability of enrolled subjects to complete the trial, and could result in potential product liability claims. Any of these occurrences may harm our reputation, business, financial condition, results of operations and prospects significantly.

Additionally, the recent shortage of GLP-1-based products has led to an increased consumption of compounded GLP-1-based medications — custom formulations that may contain the same active ingredients as the original drug but are not regulated for safety and efficacy. Compounded medications present a higher risk to patients compared to FDA-approved drugs. According to the FDA’s adverse event database, there have been reports of fatalities associated with compounded GLP-1-based products, although the specific cause of death has not been determined and may not be linked to the GLP-1-based products. While these reports are not directly related to and are not indicative of the safety profile of our drug candidates, any negative publicity surrounding the potential risks of compounded GLP-1 products could adversely affect our reputation, clinical trials, and overall business operations.

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Additionally if one or more of our drug candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such drugs, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of the drug;
- regulatory authorities may withdraw approvals of the drug;
- regulatory authorities may require additional warnings on the label;
- we may be required to develop risk evaluation and mitigation measures for the drug or, if risk evaluation and mitigation measures are already in place, to incorporate additional requirements under the risk evaluation and mitigation measures;
- we may be required to conduct post-market studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

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

We may not be able to obtain or maintain Orphan Drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the U.S., may designate drugs for relatively small patient populations as Orphan Drugs. In the U.S., Orphan Drug designation entitles a party to financial incentives such as tax advantages and user-fee waivers. In addition, if a product candidate that has Orphan Drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to Orphan Drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances, including if the FDA concludes that the later drug is clinically superior to the approved drug. The FDA has granted Orphan Drug designation for our PB-722 for congenital hyperinsulinemia.

If we obtain Orphan Drug exclusivity, we may lose such exclusivity if the FDA determines that the request for designation was materially defective or if we are unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Moreover, Orphan Drug exclusivity may not effectively protect our product candidates from competition because different drugs can be approved for the same condition. Even after an Orphan Drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve the same drug for the same condition if such regulatory authority

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concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process.

Results of earlier clinical trials may not be predictive of results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later phase clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial and early phase clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, for instance, the FDA’s rejection to the NDA of Ocaliva developed by Intercept in 2023. Future clinical trial results of PB-718 for the treatment of NASH may not be favorable for various reasons, and ultimately we may not be able to successfully develop PB-718 for NASH.

In some cases, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations including genetic differences, patient adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. As drug candidates are developed through preclinical to early- to late-stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. Any of these changes could make the results of planned clinical trials or other future clinical trials we may initiate less predictable and could cause our drug candidates to perform differently, which could delay completion of clinical trials, delay approval of our drug candidates and/or jeopardize our ability to commence commercialization of our drug candidates.

If we encounter delays or difficulties enrolling participants in our clinical trials, clinical development of our drug candidates could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients or participants who remain in the trial until their conclusion. We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients or participants to participate in these trials, or if there are delays in the

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enrollment of eligible patients or participants as a result of the competitive clinical enrollment environment. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including but not limited to:

- design and eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the drug candidate under study;
- our resources to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- availability of competing therapies also undergoing clinical trials;
- our investigators’ or clinical trial sites’ efforts to screen and recruit eligible patients or participants; or
- proximity and availability of clinical trial sites for prospective patients or participants.

In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients or participants 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.

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

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

As we have limited financial and managerial resources, we focus our product pipeline on research programs and drug candidates that we identify for selected indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. Our spending on current and future research and development programs and drug candidates for selected indications may not yield any commercially viable products. Furthermore, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through licensing, collaboration or royalty arrangements in cases where it would have been more advantageous

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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.

The regulatory approval processes of the NMPA, FDA and other comparable regulatory authorities depend on numerous factors, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The regulatory approval processes of the NMPA, FDA and other comparable regulatory authorities depend on numerous factors, some of which may be outside our control. Generally, such approvals take years to be obtained following the commencement of preclinical studies and clinical trials. For instance, it took us several years to develop our Core Product PB-119 between we initiated clinical development in early 2010s and before the NMPA accepted its NDA in September 2023, and we experienced the expedited clinical trial review and application process after the NMPA’s reformation of its approval policies in 2015. We expect the development of our current and prospective pipeline candidates would be expedited, given the NMPA’s reformation of its approval policies and support for the development of innovative drugs, as well as our accumulated experience. However, approval policies, regulations or the type and amount of clinical data necessary to gain approval may further change in the future during the course of a drug candidate’s clinical development and may vary among jurisdictions.

We cannot guarantee that we will be able to obtain regulatory approvals for our other existing drug candidates or any drug candidates we may discover, in-license or acquire and seek to develop in the future. Our drug candidates could fail to receive the regulatory approval of the NMPA, FDA or a comparable regulatory authority for many reasons, including but not limited to:

- 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;
- 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;

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- failure of the manufacturer of our drug candidates to pass GMP inspections during the regulatory review process or across the production cycle of our drug candidates;
- failure of our clinical sites to pass audits carried out by the NMPA, FDA or other comparable regulatory authorities, resulting in a potential invalidation of our research data;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for obtaining approvals; or
- failure of our clinical trial process to keep up with any scientific or technological advancements required by approval policies or regulations.

The NMPA, FDA 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 materially harm the commercial prospects of our drug candidates.

We work with various third parties to develop our drug candidates. If these third parties fail to duly perform their contractual obligations or meet expected timelines, we may be unable to obtain regulatory approvals for, or commercialize, our drug candidates, and our business, financial condition and results of operations could be materially and adversely affected.

We have worked with and may continue to work with third parties on our ongoing preclinical and clinical programs. For example, we rely on CROs, clinical trial sites, consultants and other third parties to monitor, support and/or conduct preclinical studies and clinical trials of our drug candidates. We work with these parties to execute our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocols, legal and regulatory requirements and scientific standards, and our collaboration with the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCPs, which are regulations and guidelines enforced by the NMPA, FDA and other comparable regulatory authorities for all of our drugs in clinical development. If we or any of our CROs or clinical investigators fail to comply with the applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA, FDA or other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with products produced under GMP regulations. Any failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. If CROs fail to duly perform their contractual obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approvals for, or successfully commercialize, our drug candidates. Switching or adding additional CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. Any of the foregoing events may cause cost increases, restrict our ability to generate revenue and have a material adverse effect on our business, financial condition, results of operations and prospects.

Our ability to generate future revenue is dependent on our ability to work effectively with collaborators to develop our drug candidates, including to obtain regulatory approvals. Our arrangements with collaborators will be critical to the successful commercialization of our drug candidates and future products. We rely on collaborators in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process, and to assist with our commercialization efforts. We do not control our collaborators, and therefore there can be no assurance that these third parties will adequately and timely perform all of their obligations under their agreements with us. If they fail to complete the remaining studies successfully, or at all, it could delay or adversely affect the obtaining of regulatory approvals. There can be no assurance of the satisfactory performance of any of our collaborators, and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the product which could materially and adversely affect our business, financial condition, cash flows and results of operations. In addition, we may rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately carried out and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on us until deficiencies are remedied.

If we cannot maintain or develop clinical collaborations and relationships with our principal investigators, key opinion leaders, physicians and experts, our results of operations and prospects could be adversely affected.

Our relationships with principal investigators (“PIs”), key opinion leaders (“KOLs”), physicians and 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 clinical needs and clinical practice trends, which is critical to our ability to develop new market-responsive drugs. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with our PIs and KOLs, physicians and experts, or that our efforts to maintain or strengthen such relationships will yield the successful development and marketing of new products. These industry participants may leave their roles, change their business or practice focus, choose to

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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. Moreover, we cannot assure you that our academic promotion and marketing strategy will continue to serve as an effective marketing strategy. 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 new drugs or generate returns from our relationships with industry participants as anticipated, or at all, our business, financial condition and results of operations may be materially and adversely affected.

All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated. Any failure to comply with relevant laws and regulations may adversely affect the business, financial condition, results of operations and prospects of our Group.

All jurisdictions in which we intend to conduct our biopharmaceutical industry activities regulate these activities in great depth and detail. These jurisdictions strictly regulate the pharmaceutical industry, and in doing so they employ extensive regulations governing the development, approval, manufacturing, marketing, sales and distribution of pharmaceutical products. Differences in regulatory regimes across jurisdictions may lead to a higher compliance burden.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process and approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include but are not limited to: refusal to approve pending applications; withdrawal of an approval; license revocation; clinical hold; mandatory product recalls; product seizures; total or partial suspension of production or distribution; injunctions, refusals of government contracts; injunctions, fines and other civil or criminal penalties. Failure to comply with these regulations could therefore have a material adverse effect on our business.

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

We may fail to identify drug candidates for clinical development for a number of reasons. For example, our research methodology may be unsuccessful in identifying potential drug candidates or those we identify may be shown to have harmful adverse effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. We have devoted significant resources to compound discovery efforts through our drug discovery approach, and we cannot guarantee that we will be successful in identifying potential drug candidates.

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Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and drug targets require substantial technical, financial and human resources. Our research programs may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including but not limited to:

- the research methodology used may not be successful in identifying potential indications and/or drug candidates;
- potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio.

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

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

The global biopharmaceutical market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. In 2023 and 2024, our research and development expenses were RMB236.7 million and RMB95.4 million, respectively. We intend to continue to strengthen our technical capabilities in the development and manufacture of our drug candidates, which requires substantial capital and time. We cannot assure you that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, or obtain sufficient or any patent or other intellectual property protection for such new or enhanced products in a timely and cost-effective manner. Any failure to do so may render our previous efforts obsolete, which could significantly reduce the competitiveness of our technology platforms and drug candidates, and harm our business and prospects.

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RISKS RELATING TO MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES

We intend to work with third parties for the commercialization of our drug candidates. We may fail to identify competent third parties for such purposes, fail to achieve the expected synergies with the clinical development partners, and have little or no control over the marketing and sales efforts of the commercialization partners.

We may pursue collaborative arrangements regarding the sales and marketing of our product candidates in China. We have entered into a commercialization agreement with TSL HK to promote the commercialization of PB-119 and PB-718 in Mainland China. After completion of Phase III clinical trials of PB-718, we and TSL HK shall confirm the commercialization arrangements of PB-718 in Mainland China, prior to filing the marketing authorization application with the NMPA. In May 2023, in accordance with the commercialization agreement and based on mutual agreements, the right of first refusal of the exclusive commercialization of PB-119 of TSL HK was terminated. We may also enter into commercialization agreements with other third parties. However, we may have little or no control over the marketing and sales efforts of those third parties beyond the contractual terms. Therefore, the actual revenue generated from the commercialization collaboration model may be lower than the anticipated revenue. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. We cannot assure you that we will be able to establish or maintain relationships with third-party collaborators at all, or within the desired timeframe, to successfully commercialize our product candidates, and as a result, we may not be able to generate product revenue.

On September 13, 2024, we entered into a commercialization collaboration arrangement with a leading domestic commercialization-stage pharmaceutical company in China for PB-119. Pursuant to the agreement, we are required to pay certain promotion service fee to the commercialization partner for its promotion activities carried out after PB-119 is being approved for commercialization. Depending on the status of PB-119’s NRDL inclusion and the commercialization partner’s ability to reach the various performance targets as set forth in the agreement, our promotion service fee may reach up to substantially all of the base amount of promotion service fee. As a result, we may not be able to generate profit from sales of PB-119 if we cannot cover the promotion service fee with our sales revenues and the payments we are entitled to receive as specified in the agreement. We cannot guarantee you that our commercialization efforts of PB-119 in mainland China will succeed. Furthermore, our commercialization efforts for PB-119 could be materially and adversely affected if we fail to obtain the required regulatory approval within the agreed timeline. Under the Collaboration Agreement, if we fail to obtain the drug registration certificate for PB-119 from the NMPA by March 31, 2025, our Commercialization Partner has the right to unilaterally terminate the agreement upon written notice. However, if such termination notice is not provided by the Commercialization Partner by June 30, 2025, the Collaboration Agreement will remain in effect, in which case both parties may need to engage in further negotiations regarding potential adjustments to the milestone events and payments. If our Commercialization Partner exercises its termination right, we would need to identify and secure a new commercialization

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partner or build our own commercialization infrastructure, which could result in significant delays and additional costs, materially impacting our ability to successfully commercialize PB-119 in mainland China. For details, please refer to “Business — Commercialization — Collaboration Agreement for Commercializing PB-119 in Mainland China.”

Beyond China, we may pursue collaborative arrangements regarding the future commercialization of our product candidates, including PB-119, in the United States and “Belt and Road Initiative” countries. As of the Latest Practicable Date, no overseas partners had been identified. However, we may not achieve the revenue and cost synergies expected from the collaboration. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. Even if we achieve the expected benefits, they may not be achieved within the anticipated timeframe. Also, the synergies from our collaboration with partners may be offset by other costs incurred in the collaboration, increases in other expenses, operating losses or problems in the business unrelated to our collaboration. As a result, there can be no assurance that these synergies will be achieved.

Also, disputes may arise between us and our collaboration partners. Such disputes may cause delay or termination of commercialization of our drug candidates after their market launch, or may result in costly litigation or arbitration that diverts management attention and resources.

The market size of our drug candidates might be smaller than we expected.

Our estimates regarding our eligible patient population, pricing and available coverage and reimbursement determine our estimated market size, which may differ significantly from the actual market addressable by our drug candidates. Our estimates of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and analysis. These estimates have been derived from a variety of sources, including patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the diseases we are targeting. The number of our target patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our drug candidates may be limited or may not be receptive to treatment with our drug candidates, and new patients may become increasingly difficult to identify or access. If the market opportunities for our drug candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

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Our Core Product has been developed for the indications of T2DM and obesity. However, given the presence of various prevention methods, such as adopting a healthier lifestyle that facilitates weight management, as well as existing and potential alternative treatment options (i.e. thiazolidinediones (“TZDs”), oral sulfonylureas, dipeptidyl peptidase-4 (“DPP-4”) inhibitors for T2DM and Wegovy or Ozempic for the treatment of obesity), for our targeted indications, the market potential of the Core Product may be limited. As a result, even though the number of patients of our targeted indications may be large, the actual addressable patients of our drug candidates may be limited and smaller than we expected. Additionally, the growth of the NASH market in China might potentially be less pronounced than the global trend given the relatively lower level of obesity in China as compared to other countries, which could affect the number of addressable patients of our other drug candidates being developed for the NASH indication.

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

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

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

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- the inclusion in the National Reimbursement Drug List (“NRDL”) (《國家醫保藥品目錄》) and other government-sponsored medical insurance programs, or by third-party payers;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; or
- the effectiveness of our sales and marketing efforts.

If our drug candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals or others in the medical community, we will not be able to generate significant revenue. Even if our drugs achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drugs, are more cost effective or render our drugs obsolete.

Our drugs may not be covered by reimbursement programs or may become subject to unfavorable reimbursement practices, either of which could harm our business.

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 and/or third-party payers, such as private health insurers and health maintenance organizations. The regulations that govern reimbursement for new therapeutic drugs vary substantially from country to country.

In China, the NRDL and Provincial Reimbursement Drug Lists (“PRDL”) (《省級醫保藥品目錄》) include drugs under the National Medical Insurance Catalogue, which affect the amounts reimbursable to program participants for those drugs. There can be no assurance that any of our drug candidates will be included in the NRDL or the PRDL after initial approval for commercial sale. Pharmaceutical products included in the NRDL or the PRDL are typically generic and essential drugs. Innovative drugs similar to our drug candidates have historically been more limited on their inclusion in the NRDL or the PRDL due to cost constraints. If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL or PRDL, our revenue from commercial sales will be highly dependent on patient self-payment, which can make our products less competitive.

In addition, a key trend in the global healthcare industry is cost containment. Government authorities and third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. As a result, even if our drug candidates are successfully approved by the NRDL or PRDL or any other reimbursement programs sponsored by government health administration authorities and third-party payers, our potential revenue from the sales of these products could still decrease as a result of the

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significantly lowered prices we may be required to charge or potential deeper-than-expected price reduction required for our products to be included in such reimbursement programs due to price control policies. Increasingly, third-party payers are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products.

We cannot assure you that reimbursement will be available for our drug candidates that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any approved drug candidate that we commercialize. Obtaining or maintaining reimbursement for approved drug candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate that we 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, FDA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Payment rates may vary according to the uses of the drugs and the clinical setting in which the drugs are used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices. Our inability to promptly obtain reimbursement coverage at intended payment rates from both government funded and private payers 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.

We work with third parties to manufacture a portion of our drug candidates for clinical development and future commercialization. Our business could be harmed if those third parties fail to deliver sufficient quantities of products.

We currently do not have in-house manufacturing facilities to produce our drug candidates independently. Currently and in the long term future, we plan to work with qualified CDMOs (including CMOs) to manufacture product candidates for preclinical, clinical and commercial supply. We also procure technical services, including CRO and CDMO services and consulting services that support our clinical trials and preclinical studies.

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Reliance on third-party manufacturers would expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited and the NMPA, FDA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates;
- our third-party manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- manufacturers are subject to ongoing periodic unannounced inspection and other government regulations by the NMPA, FDA or other comparable regulatory authorities to ensure strict compliance with GMP. We do not have control over third party manufacturers’ compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;
- manufacturers may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- manufacturers may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our contract manufacturers and suppliers may be subject to inclement weather, as well as natural or man-made disasters.

The manufacture of pharmaceutical products is a highly exacting and complex process, and if we encounter problems in manufacturing our products, our business could be materially and adversely affected.

The manufacturing of our drug candidates is complex. Problems may arise during manufacturing for a variety of reasons, including but not limited to equipment malfunction, failure to follow specific protocols and procedures, changes in product specification, low quality or insufficient supply of raw materials, changes in the types of products produced, physical limitations that could inhibit continuous supply, man-made or natural disasters and

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other environmental factors. Products with quality issues may have to be discarded, resulting in product shortages or additional expenses. This could lead to, among other things, increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

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

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

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors’ drugs and drug candidates. Currently, there are not any unfavorable guidelines, recommendations and studies published by various organizations in relation to our product candidates. However, any such guidelines, recommendations or studies that reflect negatively on our 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.

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

The quality of our products, including drug candidates manufactured by us for research and development purposes, will depend significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in our manufacturing facilities, the quality and reliability of equipment used, the quality of our staff and related training programs and our ability to ensure that our employees adhere to our quality control and quality assurance protocol. We operate a comprehensive quality control system which extends across all key stages of the research and development, manufacturing and commercialization processes. This system is established and refined in accordance with the rigorous regulations and guidelines in China, the U.S. and Europe. See “Business — Research and Development.” However, we cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from

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our quality standards or that our standard operating procedures will be complete or updated at all times. Any significant failure or deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, result in gaps in the audit of our processes, jeopardize any GMP certifications we may have and/or harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATING TO OUR FINANCIAL PROSPECTS

We have incurred significant net losses since inception and we may continue to incur net losses and may fail to achieve or maintain profitability in the future. As a result, you may lose substantially all of your [REDACTED] in us if our business fails.

[REDACTED] in pharmaceutical or biotechnology companies is highly speculative. It entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We have incurred significant expenses related to the research and development of our drug candidates. In 2023 and 2024, our research and development expenses amounted to RMB236.7 million and RMB95.4 million, respectively. In addition, we also incurred other expenses related to our operations including administrative expenses. As a result, we recorded net losses of RMB279.2 million and RMB283.4 million in 2023 and 2024, respectively.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we carry out certain activities relating to our development, including, but not limited to, the following:

- continue to advance the clinical trials and preclinical studies of our drug candidates;
- seek regulatory approvals for our drug candidates to complete clinical development and commence commercialization;
- commercialize any of our drug candidates for which we may obtain marketing approval;
- seek to identify additional drug candidates;
- address any competing technological and marketing developments, including new drugs developed by competitors;
- maintain, protect and expand our intellectual property portfolio; and
- create additional infrastructure to support our operations as a [REDACTED] and our drug development and future commercialization efforts.

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We cannot guarantee that we will be able to obtain regulatory approvals for any of our drug candidates in a timely manner, or at all. In addition, none of our drug candidates has been approved for marketing in China or any other jurisdictions yet. Substantial investments may be incurred before we generate any revenue from product sales. Considering the numerous risks and uncertainties associated with regulatory approval, we are unable to accurately predict the timing or amount of additional expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the NMPA, FDA or other applicable authorities to perform studies in addition to those that we currently anticipate. Even if our drug candidates are approved for commercial sale, we expect to continue incurring significant costs associated with the manufacturing and the commercial launch of the drug candidates.

We had net operating cash outflows during the Track Record Period.

Since our inception, our operations have consumed substantial amounts of cash. We had net cash used in operating activities of RMB233.3 million and RMB183.4 million in 2023 and 2024, respectively. Additionally, we are exposed to credit risk on the cash and cash equivalents deposited in financial institutions. In the event that any of them becomes insolvent and is taken into receivership by the relevant government agencies, there will be uncertainty as to the timing and extent to which we will be able to recover our cash on deposit at such financial institution.

While we believe we have sufficient working capital to fund our current operations for the next 12 months, we expect that we may experience net cash outflows from our operating activities for the foreseeable future. We may need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on reasonable terms, we could have to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts. Our inability to obtain additional funding when we need it could seriously harm our business.

We may incur impairment losses for prepayments and other receivables.

Our prepayments and other receivables primarily consist of prepayments to suppliers, and other debtors and deposits. However, there is no guarantee that the suppliers and service providers will perform their obligations in a timely manner and we are subject to credit risk in relation to prepayments and other receivables. The assessment of impairment losses involves a significant degree of management judgments as well as estimates in determining the key assumptions, and unpredictable adverse changes in the future may also result in decreases in the value of our prepayments and other receivables. Therefore, we cannot assure you that these assumptions and estimates would not result in outcomes that require a material adjustment to the carrying amounts of our prepayments and other receivables in the future, which may in turn result in impairment losses. Any significant impairment losses of prepayments and other receivables in the future could have an adverse effect on our business, financial condition and results of operations.

RISK FACTORS

We have never generated any revenue from sales of drug products, and our ability to generate revenue from sales of drug products and become profitable depends significantly on our success in a number of factors.

We have no drug products approved for commercial sale, have not generated any revenue from drug product sales, and do not anticipate generating any revenue from drug product sales until sometime after we have received regulatory approval for the commercial sale of our drug candidates. Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including but not limited to:

- completing research regarding, and nonclinical and clinical development of, our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical studies;
- developing a sustainable and scalable manufacturing process for our product candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new product candidates, intellectual property and technologies;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trademarks, trade secrets, and know-how; or
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the NMPA, FDA or other regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those we currently anticipate. If we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the market for the relevant product in China or the relevant jurisdictions, the accepted price for the product to be

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paid with out-of-pocket expenses and the ability to get reimbursement for any amount. If the number of patients with our addressable disease is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we may never become profitable.

We may need to obtain substantial additional financing to fund our operations and expansion with the potential effect of diluting our shareholders’ interest and restricting our operations, and if we fail to do so, we may be unable to complete the development and commercialization of our drug candidates.

During the Track Record Period, we financed our operations, including our research and development activities in relation to our preclinical studies and clinical trials, primarily through interest-bearing borrowings and equity financing. As of December 31, 2023 and 2024, our interest-bearing borrowings were RMB65.8 million and RMB100.0 million, respectively. We believe our current cash and cash equivalents and the estimated net [REDACTED] from the [REDACTED] will be sufficient to meet our anticipated cash needs for at least the next 12 months from the date of this Document. We expect to fund our future operations primarily with existing cash and cash equivalents, future potential payments received from our license and collaboration agreements, and net [REDACTED] from the [REDACTED]. Upon the successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with income generated from sales of our commercialized drug products. Changes in our ability to fund our operations may affect our cash flow and results of operations. Although we are conducting this [REDACTED], we may nevertheless require substantial additional capital to meet our continued operating cash requirements, especially to fund our research and development activities, commercialization of our drug candidates and development of manufacturing capabilities. Our future funding requirements will depend on many factors, including but not limited to:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely identify and enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our drug candidates;
- the progress, timing, scope and costs related to discovery and early development of additional drug candidates;
- the preparation required for anticipated commercialization of our drug candidates, and if regulatory approvals are obtained, to fund the product launch;
- the manufacturing requirements and capabilities related to clinical development and future commercialization for any approved drug candidates;

RISK FACTORS

- the amount and timing of any milestone and royalty payments we receive from or pay to our current or future collaborators;
- the cost of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights;
- the cash requirements of any future acquisitions and/or development of in-licensed pipeline drug candidates; and
- our headcount growth and the associated costs.

As our business continues to expand, we may seek additional funding through equity offerings, debt financings, license and collaboration arrangements and other sources, which may not be available on terms favorable or commercially reasonable to us or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that may adversely affect your rights as a holder of our H Shares. Incurring additional debt could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

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

In the event that we enter into collaboration or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future arrangements when we might be able to achieve more favorable terms.

We benefit from government grants, the expiration of or changes to which could adversely affect our profitability.

During the Track Record Period, we recognized RMB2.8 million and RMB0.3 million of government grants in other net income in 2023 and 2024, respectively. Some of the government financial incentives, grants or funding are granted on a project by project basis and/or are subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements, completion of the specific projects therein, and compliance with the conditions imposed including but not limited to maintaining operations or physical facilities. We cannot guarantee that we will satisfy all relevant conditions. If we fail to satisfy any such condition upon a corporate change or other difficulties to meet the conditions, we may

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be deprived of or be asked to return the relevant incentives, funding, and/or government grants, or we may be asked to repay our debt obligations early, if any, as the case may be. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives may have an adverse effect on our results of operations. In addition, we may not be able to receive government grants in the future, which may have an adverse effect on our financial condition and results of operations.

We are exposed to risks in connection with the fair value change of financial assets at FVPL.

During the Track Record Period, we invested in financial products which represent wealth management products and negotiable certificate of deposits with banks. Pursuant to the Guidance on Regulating Financial Institution’s Asset Management Business (《關於規範金融機構資產管理業務的指導意見》) promulgated by the People’s Bank of China, the China Banking and Insurance Regulatory Commission, the China Securities Regulatory Commission and the State Administration of Foreign Exchange on April 27, 2018, financial institutions selling wealth management products cannot guarantee the returns of principal and interest of such products. As a result, the returns of our investments in wealth management products were not guaranteed, and therefore were measured at fair value through profit or loss. Net changes in the fair value of our investments are recorded as our other income or losses, and therefore directly affect our results of operations. We may continue to invest in wealth management products in the future when we believe that we have surplus cash on-hand and the potential investment returns are stable and attractive. However, we cannot guarantee that we will not experience losses with respect to such investments in the future or that such losses or other potentially negative consequences due to such investments will not have material adverse effects on our results of operations. Furthermore, the respective fair value is determined by applying certain valuation techniques. Key valuation assumptions used to determine the fair value of the financial assets are subject to various uncertainties. Any change in the assumptions may lead to different valuation results and, in turn, changes in the fair value of these financial assets at FVPL.

We have granted, and may continue to grant, share-based awards, which may result in increased share-based payments and potential dilution of shareholding.

We have granted share-based payments to, among others, attract and retain outstanding individuals to serve the Company. We believe the granting of share-based payment is of significant importance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based payment to employees in the future. Our equity-settled share-based payment expenses were RMB35.1 million and RMB145.5 million in 2023 and 2024, respectively. See Note 22 of the Accountants’ Report set out in Appendix I to this Document. As a result, our expenses associated with share-based payment may increase, which may have an adverse effect on our 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 share incentive plans and any subsequently adopted share incentive plans from time to time. If we choose to do so, we may experience substantial change in our share-based payment charges. In addition, such share-awards may dilute the shareholding percentage of our existing Shareholders.

RISK FACTORS

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the China National Intellectual Property Administration (“CNIPA”), the United States Patent and Trademark Office (“USPTO”) and other patent agencies in other jurisdictions in several stages over the lifetime of a patent. The CNIPA, the USPTO and other governmental patent agencies also require compliance with a number of procedural, documentary, and other similar provisions during the patent application process. We work with our counsel and professionals to help us comply with these requirements with respect to our intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include the failure to respond to official actions within prescribed time limits, nonpayment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors or other third parties might be able to enter the market, which would have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

We focus on protecting our intellectual property rights in our target markets, primarily the China, United States and Europe. Filing, prosecuting, maintaining and defending patents on drug candidates in all other countries throughout the world could be prohibitively expensive for us. Our intellectual property rights in other jurisdictions, if obtained, can have a different scope and strength compared to those in our target markets. In addition, the laws of certain jurisdictions do not protect intellectual property rights to the same extent as the laws of other 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 jurisdictions where we have patent protection. Consequently, we may not be able to prevent third parties from using our inventions in all jurisdictions outside our target markets, or from selling or importing drugs made using our inventions into our target markets or other jurisdictions. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

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We may from time to time be involved in lawsuits to protect or enforce our patents and other intellectual property, which could be expensive, time-consuming and unsuccessful and may delay us from developing or commercializing our drug candidates. Our patent rights relating to our drug candidates could be found invalid or unenforceable if being challenged.

Litigation relating to patents and other intellectual property rights is common in the pharmaceutical industries, and is inherently uncertain. Even if successful, litigation may result in substantial costs and reputational harm, 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 inevitably compromised by disclosure during discovery.

Competitors may infringe our patents. 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, the defendant may be able to counterclaim that our patent is invalid and/or unenforceable, and a court may uphold such claims, or otherwise refuse to stop the opposing party from using the technology at issue, on the potential grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent application at risk of not being issued.

On the other hand, if a third party were to assert claims of patent infringement, misappropriation of trade secrets, or violation of other intellectual property rights against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents and rights are valid, enforceable and infringed, and the holders of any such patents and rights may be able to block our ability to commercialize the applicable product unless we obtained a license from them, or until such patents or rights expire or are finally determined to be invalid or unenforceable. Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could also be costly and time-consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs.

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or [REDACTED] perceive these announcements as negative, the perceived value of our drug candidates, future drugs, programs or intellectual property could be diminished. Accordingly, the market price of our H Shares may decline. Such announcements could also harm our reputation or the commercialization of our drug candidates, which could have a material adverse effect on our business. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials and continue our in-house research programs.

RISK FACTORS

Unfavorable outcomes in intellectual property litigation could limit our research and development activities and/or our ability to commercialize our drug candidates.

If third parties successfully assert their intellectual property rights against us, we might be barred from using certain aspects of our technology, or barred from developing and commercializing our drug candidates. Prohibitions against using certain technologies, or prohibitions against commercializing our drug candidates, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed.

We may face intellectual property disputes with our business partners or other third parties.

We may be subject to claims that former employees, collaborators, contractors or other third parties have an interest in our patents or other intellectual property, for example as an inventor or co-inventor. When enforcing our rights in our patents or other intellectual property, we may be subject to counterclaims that we do not own or possess clean title to one or more patents or patent applications that cover development, manufacture, and commercialization of one or more of our drug candidates. If we are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents, or our patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we are unsuccessful in any inventorship or ownership disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our patents.

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

We own registered trademarks. We may not always be able to obtain and ensure trademark protection in territories that we consider of significant importance to us. In addition, any of our trademarks or trade names, whether registered or unregistered, may be challenged, opposed, infringed, cancelled, circumvented or declared generic, or determined to be infringing on other marks, as applicable. We may not be able to protect our rights to these trademarks and trade names, which we will need in order to build name recognition by potential collaborators or customers in our markets of interest. Over the long term, 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.

RISK FACTORS

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

As it is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents and trademarks of our trade names. 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, or permit us to maintain our competitive advantage. The illustrative examples include but are not limited to:

- others may be able to make products that are similar to our drug candidates but that are not covered by the claims of the patents that we own;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patent applications not issuing or being invalidated after issuing;
- we might not have been the first to file patent applications covering certain of our inventions, which could result in the patent applications not issuing or being invalidated after issuing;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain compounds many years before we receive NDA approval for drugs containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related drugs, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for commercialization in our major markets;
- we may fail to develop additional proprietary technologies that are patentable;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate;

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- the patents of others may have an adverse effect on our business, for example by preventing us from commercializing one or more of our drug candidates for one or more indications; or
- our competitors might develop biosimilar drugs if the patent protection of our drug candidates will be expired.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

The life of patent protection is limited, and third parties could be able to circumvent our patents by developing similar or alternative products and technologies in a non-infringing manner, or develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially adversely affected.

The life of a patent and the protection it affords is limited. For example, in China, if all maintenance fees are timely paid, the invention patents, design patents and utility model patents are valid for 20 years, 15 years and 10 years from its filing date, respectively, with potential patent term compensation for invention patents under the current Patent Law of the PRC. Even if we successfully obtain patent protection for an approved product candidate, it may face competition from generic or biosimilar medications. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would materially adversely affect any potential sales of that product.

Patent terms may not be adequate to protect our competitive position on our product candidates in the absence of patent linkage, patent term extensions and other exclusivities. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product 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. Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities 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. The pending patent applications, if issued, for our product candidates are expected to expire on various dates as described in “Business — Intellectual Property.” Upon the expiration of our patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors, which would materially adversely affect our business, financial condition, results of operations and prospects. Additionally, the patent expiration of certain other peer products may lead to the entry of generic drug products, subject to market conditions, regulatory trends and the strategic focus of market players.

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According to Article 42 of the Patent Law of the PRC issued on October 17, 2020 and implemented on June 1, 2021, for the purpose of compensating for the time taken to evaluate and approve a new drug to be put on market, CNIPA shall grant compensation for duration of patent right for invention of a new drug approved to be put on market in China upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent right for a new drug approved to be put on market shall not exceed 14 years.

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

In addition to our patents, we rely on trade secrets and confidential information, including but not limited to unpatented know-how, technology and other proprietary information to maintain our competitive position and to protect our drug candidates. We seek to protect these trade secrets and confidential information, in part, by entering into confidentiality agreements with parties that have access to them, such as our employees, outside collaborators, CROs, consultants and other third parties. However, 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. Substantiating and winning a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we may have no means to prevent them from using that technology or information to compete with us, and our competitive position would be harmed.

Furthermore, many of our employees including our senior management, were previously employed at other pharmaceutical or biotechnology companies, which may include our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants and advisors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any of the former employers of such employees, consultants and advisors. We were not aware of any such claims threatened or pending as of the Latest Practicable Date, but there is no assurance that we will not be subject to such claims or involved in litigations to defend against such claims in the future. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and reputational harm, 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 every party who is actually involved in developing intellectual property that we regard as our own. Further, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any

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such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.

The laws and regulations governing patents could be revised from time to time that would affect our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Our existing patent rights and future patent applications may face certain potential influence. Such changes may impact the value of our patent rights or our other intellectual property rights. For instance, the United States has enacted wide-ranging patent reform legislation. The United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any.

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

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

As we seek to advance our drug candidates through clinical trials and eventually achieve commercialization, we will need to expand our development, regulatory, manufacturing, sales and marketing capabilities or contract with third parties to provide these capabilities for us. In addition, we may need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant additional responsibilities on our management. Our future financial performance and our ability to commercialize our drug candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We cannot assure you that we will be able to successfully develop and commercialize our drug candidates and build suitable manufacturing, sales, marketing and managerial teams to meet our growth targets. Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

We may be subject to product liability lawsuits that could cause us to incur substantial liabilities.

We face an inherent risk of product liability as a result of the clinical testing and any future commercialization of our drug candidates, subject to limited immunity that we may seek in connection with some of our product candidates. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may

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include allegations of defects in manufacturing, defects in design, improper, insufficient or improper labelling of products, insufficient or misleading disclosures of side effects or dangers inherent in the product, negligence, strict liability and a breach of warranties. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. There is also risk that third parties we have agreed to indemnify could incur liability. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates or any resulting products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our drug candidates; and
- a decline in our Share price.

If we are unable to defend ourselves against such claims, among other things, we may be subject to civil liability for physical injury, death or other losses caused by our products and to criminal liability and the revocation of our business licenses if our products are found to be defective. In addition, we may be required to recall the relevant products, suspend sales or cease sales. Even if we are able to successfully defend ourselves against any such product liability claims, doing so may require significant financial resources and the time and attention of our management.

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

From time to time, we may be involved in claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, environmental matters, breach of contract, employment or labor disputes and infringement of intellectual property rights. Any claims, disputes or legal proceedings initiated by us or brought against us, with or without merit, may result in substantial costs and diversion

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of resources, and if we are unsuccessful, could materially harm our reputation. Furthermore, claims, disputes or legal proceedings against us may be due to 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 Single Largest Group of Shareholders have had and will continue to have substantial influence over the outcome of shareholder actions in our Company. The interests of our Shareholder may not be aligned with the interests of our other Shareholders.

Upon completion of the [REDACTED], Single Largest Group of Shareholders will hold [REDACTED]% of our total issued and outstanding Shares, assuming [REDACTED] is not exercised. As a result, Single Largest Group of Shareholders, will have significant influence over our business, including decisions regarding mergers, consolidations, liquidations and the sale of all or substantially all of our assets, election of directors and other significant corporate actions.

It may take actions that are not in the best interest of us or our other Shareholders. This concentration of ownership may discourage, delay or prevent a change in control of our Company, which could have the effect of depriving our other Shareholders of the opportunity to receive a premium for their shares as part of a sale of our Company and may reduce the price of the Shares. This concentrated control will limit your ability to influence corporate matters and could discourage others from pursuing any potential merger, takeover or other change of control transactions that other holders of our ordinary shares may view as beneficial.

Our future success depends on our ability to retain key executives and to attract, hire, retain and motivate other qualified and highly skilled personnel.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as other key clinical and scientific personnel, and other key employees.

Competition for qualified employees in the biopharmaceutical industry is intense and the pool of qualified candidates is limited. In recent years, the average staff costs in the global biopharmaceutical market, particularly for highly skilled and experienced personnel, has been rising steadily. We cannot assure you that there will be no significant increase in our staff costs, especially as we continue to expand our business and operations. Despite an increase in staff costs, we may still not be able to retain the services of experienced senior management or key clinical and scientific personnel in the future. The departure of one or more of our senior management or key clinical and scientific personnel, whether or not they join a competitor or form a competing company, may subject us to risks relating to finding replacements in a timely manner or at all, which may disrupt our drug development progress and have a material and adverse effect on our business, financial condition, results of operations and prospects. We will also need to hire additional employees as we expand our commercialization and manufacturing teams.

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We may be subject to disasters, health epidemics, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

Natural disasters, acts of war, terrorism or other force majeure events beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations, and those of our third-party research institution collaborators, suppliers and other contractors and consultants, 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, force majeure events such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or potential wars or terrorist attacks.

The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments could materially disrupt our business and operations. For example, since the end of December 2019, the outbreaks of a novel strain of coronavirus COVID-19 have materially and adversely affected the global economy. Many countries and regions had been affected by the COVID-19 outbreaks. There is no assurance that such kind of health epidemic or even a more severe pandemic will not occur again in the future.

There also could occur serious natural disasters, which may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Damage or extended periods of interruption to our corporate, development, research or manufacturing facilities due to fire, disaster, epidemics, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of our drug candidates. As we rely on third parties on various services and supplies, the occurrence of any of the foregoing events could seriously harm ability to obtain services or supplies if such third parties are affected by disasters, epidemics, business interruptions and other force majeure events. In addition, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption. Acts of war or terrorism may also injure our employees, 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, results of operations and prospects.

Counterfeits of our products and the illegal and/or parallel import of competing drugs in the global market could negatively affect our sales and our reputation.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or are fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. Globally, the counterfeit pharmaceutical product control and

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enforcement system may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products can quickly erode our sales volume of the relevant products. Moreover, counterfeit products may or may not have the same chemical composition as our products do, which may make them less effective than our products, entirely ineffective or more likely to cause severe adverse side effects. This could expose us to negative publicity, reputational damage, fines and other administrative penalties, and may even result in litigation against us. The existence and prevalence of counterfeit pharmaceutical products, products of inferior quality and other unqualified products in the global market may negatively impact the reputation of participants in the pharmaceutical industry, like us. As a result of these factors, the continued proliferation of counterfeit pharmaceutical products and illegal anti-viral drugs in the global market could affect our sales and reputation and expose us to liability claims.

If we or our business partners fail to protect data and privacy of subjects in our clinical trials, or the medical institutions that we conduct clinical trials at or provide services to, our reputation will be damaged and we might be subject to fines or other regulatory punishments.

We or our business partners need to collect and store non-personally identifiable data and information of clinical trial participants, which require us and our business partners such as clinical trial institutions and medical institutions to maintain an effective control system to protect such data and information. The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every major target market in which we operate or intend to operate have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection.

Whilst we have adopted security policies and measures to protect our proprietary data and subjects’ privacy, misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of personal data might not be avoided due to human error, employee misconduct or system breakdown. We also cooperate with third parties including principal investigators, hospitals and other third parties for our clinical trials. 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 privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims. Although we have made efforts to ensure our compliance with the applicable privacy regulations in the relevant jurisdictions, we may not be capable of adjusting our internal policies in a timely manner and any failure to comply with applicable regulations could also result in regulatory enforcement actions against us.

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

We are subject to stringent privacy laws and information security policies related to data privacy and security, and we may be exposed to risks relating to personal or other sensitive information.

On December 28, 2021, the Cyberspace Administration of China (“CAC”), jointly with other 12 governmental authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “MCR”), which became effective from February 15, 2022. Pursuant to Article 2 of the MCR, if a critical information infrastructure operator purchases network products and services or a network platform operator conducts any data processing activity that affects or may affect national security, a cybersecurity review shall be carried out according to the MCR. In accordance with Article 7 of the MCR, a network platform operator possessing personal information of more than one million users must apply to the Cybersecurity Review Office for cybersecurity review when [REDACTED] abroad (國外[REDACTED]).

As of the Latest Practicable Date, (i) we had not been notified of the results of any determination that we have been identified as a critical information infrastructure operator by the relevant governmental authorities; (ii) we had been focused on the discovery and development of differentiated therapeutics for chronic diseases, and had not conducted any business involving the collection, usage, storage or processing of personal information of users through network information technology or via internet and had not possessed personal information of more than one million users; and (iii) we had not received any notification of cybersecurity review from the relevant governmental authorities, nor had we been involved in any investigations on cybersecurity review initiated by CAC or received any inquiry, notice, warning, or sanctions in such respect. Therefore, as advised by our PRC Legal Adviser, taking into consideration the above and provided that there is no material change to our current business and no further rules are introduced and no significant changes to the MCR is made by the relevant governmental authorities, our Directors believe cybersecurity review under the article 2 and article 7 of the MCR shall not be applicable to us.

However, the MCR was released recently, certain provisions of which are subject to clarification by the relevant governmental authorities. If we were deemed having conducted any data processing activity that “affects or may affect national security” by the relevant

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regulatory authorities, we may be subject to cybersecurity review under the MCR. If we fail to pass such cybersecurity review, our [REDACTED] may be impeded, our business operations may be adversely affected, and/or we may be subject to other penalties and/or actions by the competent governmental authorities.

On September 24, 2024, the State Council issued the Regulation on the Administration of Cyber Data Security (《網絡數據安全管理條例》) (the “**Cyber Data Security Regulation**”), which became effective from January 1, 2025. The Cyber Data Security Regulation stipulated certain requirements on network data processing activities, the security and protection of network data, and the reasonable and effective use of network data, and further shed light on the protection of personal information, security of important data, management of cross-border security of network data and obligations of network platform service providers. The Cyber Data Security Regulation required, among others, where network data processing activities carried out by a network data processor affect or may affect national security, national security review shall be conducted in accordance with relevant PRC regulations. However, as the Cyber Data Security Regulation provided no further explanation or interpretation for “affect or may affect national security”, if we were deemed having carried out any network data processing activities that “affect or may affect national security”, we may be subject to the national security review under article 13 of the Cyber Data Security Regulation, failing which may subject us to fines, penalties, suspension of relevant business and revocation of relevant business permits, and thus our business operations may be adversely affected.

On July 7, 2022, CAC promulgated the Measures for the Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》), which took effect on September 1, 2022 and required that the data processors providing data overseas and falling under any of the following circumstances shall apply for the security assessment of cross-border data transfer: (i) where a data processor intends to provide important data overseas; (ii) where a critical information infrastructure operator or a data processor processing personal information of more than 1,000,000 people intends to provide personal information overseas; (iii) where a data processor who has provided personal information of 100,000 people or sensitive personal information of 10,000 people overseas accumulatively since January 1, 2021 intends to provide personal information overseas; and (iv) other circumstances where the security assessment of cross-border data transfer is required by CAC. As of the Latest Practicable Date, as our business operations had not fallen under any of the above-mentioned circumstances, our Directors believed the security assessment of cross-border data transfer under the Measures for the Security Assessment of Cross-border Data Transfer shall not be applicable to us currently.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the “**Scientific Data Measures**”), which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at

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least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term state secret is not clearly defined, if and to the extent our research and development of drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, financial condition, results of operations and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities. In addition, according to the Administration of Human Genetic Resources (《人類遺傳資源管理條例》) promulgated in May 2019 and the PRC Biosecurity Law 《(生物安全法)》 promulgated in October 2020, if any scientific data falls within the scope of Chinese human genetic resources, any transfer of such data outside of China will be subject to the prior approval of the PRC Ministry of Science and Technology. There can be no assurance that we will be able to obtain such approval in a timely manner, or at all.

Our future investments or acquisitions may have a material adverse effect on our reputation, business, financial condition, results of operations and prospects.

We may in the future evaluate and consider a wide array of investments and acquisitions that we believe can augment our overall business strategy. We may be engaged in discussions or negotiations with respect to one or more of these types of transactions. These transactions involve significant challenges and risks, including but not limited to:

- difficulties integrating into our operations the personnel, operations, products and services;
- technology, internal controls and financial reporting of companies we acquire;
- disrupting our ongoing business, distracting our management and employees and increasing our expenses;
- losing skilled professionals as well as established client relationships of the businesses we invest in or acquire;
- for investments over which we do not obtain management and operational control, we may lack influence over the controlling partner or shareholder, which may prevent us from achieving our strategic goals in such investment;
- new regulatory requirements and compliance risks that we become subject to as a result of acquisitions in new industries or otherwise;

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- actual or alleged misconduct or non-compliance by any company we acquire or invest in (or by its affiliates) that occurred prior to our acquisition or investment, which may lead to negative publicity, government inquiry or investigations against such company or against us;
- unforeseen or hidden liabilities or costs that may adversely affect us following our acquisition of such targets;
- regulatory hurdles including the anti-monopoly and competition laws, rules and regulations in connection with any proposed investments and acquisitions;
- the risk that any of our pending or other future proposed acquisitions does not close;
- the costs of identifying and consummating investments and acquisitions;
- the use of substantial amounts of cash and potentially dilutive issuances of equity securities;
- the occurrence of significant goodwill impairment charges and amortization expenses for other intangible assets; or
- challenges in achieving the expected benefits of synergies and growth opportunities in connection with these acquisitions and investments.

Any such negative developments described above could disrupt our existing business and have a material adverse effect on our reputation, business, financial condition, results of operations and prospects.

If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or 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 or unforeseen liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

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- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products and pipeline products and regulatory approvals; and/or
- 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.

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

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

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There may be additional financial burdens on our Company if our subsidiaries are unable to obtain additional funds from their minority shareholders or if such minority shareholders exit.

As of the Latest Practicable Date, each of Shanghai Hanmai and Shanghai Maiji, our subsidiaries, was held as to approximately 64.77% by our Company, and as to approximately 35.23% by other seven minority shareholders in aggregate. See “History, Development and Corporate Structure — Our Subsidiaries” for further details of Shanghai Hanmai and Shanghai Maiji.

Shanghai Hanmai and Shanghai Maiji may require additional funds to meet their continued operating cash requirements in the future, especially to fund their R&D activities. There is no assurance that the minority shareholders of Shanghai Hanmai and Shanghai Maiji will be able or willing to contribute additional funds, failing which our Company may need to provide additional financial support to Shanghai Hanmai and Shanghai Maiji, which could result in increased financial burden on our Company. Moreover, there is a risk that the minority shareholders of Shanghai Hanmai and Shanghai Maiji may choose to exit their investments due to commercial considerations, financial considerations, or market conditions, under which circumstances our Company may need to either find new investors for such subsidiaries or increase its own investment therein to maintain the required funding levels for them, leading to additional financial burdens on our Company.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals materials, and may produce hazardous wastes. We may contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials and wastes, whether arising from our own operations or those of our CROs, CDMOs or other contractors and business partners, now or in the future. In the event of such contamination or injury, we could be held liable for any resulting damages, and such liabilities could exceed our resources. We could also incur significant costs associated with civil or criminal fines and penalties.

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

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

Healthcare providers, including physicians and others, play a primary role in the recommendation and prescription of products for which we may seek regulatory approval. If we obtain approval from the NMPA, FDA or other regulatory authorities for any of our drug candidates and if we then begin to market those drugs in the PRC or in the United States, our operations may be subject to federal and state fraud and abuse laws in the PRC, United States and other countries, including the federal Anti-Kickback Statute and the False Claims Act, as well as physician payment transparency laws and regulations, including the Federal Physician Payment Act. Our current and future operations also may be subject to regulation by U.S. federal, state and local authorities including, among others, the Centers for Medicare and Medicaid Services and other divisions within the U.S. Department of Health and Human Services such as the Office of the Inspector General and the Office for Civil Rights. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. There are ambiguities as to what is required to comply with any of these requirements, and if we fail to comply with any such requirements, we could be subject to applicable penalties.

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, financial condition, results of operations and prospects.

If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which may also adversely affect our business.

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If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations. We may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees or other third parties.

We are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing other improper advantages. In addition, although currently our primary business operations are in China, our future expansion of footprint beyond China may subject us to laws such as the Foreign Corrupt Practices Act of the United States, which generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Although we have policies and procedures designed to ensure that we, our employees, agents and intermediaries comply with anti-bribery laws, there is no assurance that such policies or procedures will always effectively prevent our employees, agents and intermediaries from engaging in bribery activities. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could significantly affect our business, financial condition, results of operations and prospects. We could also be adversely affected by any allegation that we violated such laws.

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

A number of governmental agencies or industry regulatory bodies in the PRC and other applicable jurisdictions impose strict rules, regulations and industry standards governing biopharmaceutical research and development activities, which apply to us. Our or our business partners' failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our reputation, business, financial condition, results of operations and prospects.

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or impose fines and penalties which could materially and adversely affect our business, financial condition, results of operations and prospects. If the interpretation or implementation of laws and regulations is adjusted in the future or new regulations come into effect, or the criteria used in

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reviewing applications for, or renewals of permits, licenses and certificates change to adapt to new developments, we may be required to obtain any additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, increase our costs, and in turn, adversely affect results of operations and prospects.

Any government investigation of alleged violations of laws could require us to expend significant time and resources in response and generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our Company and our results of operations will be adversely affected.

If we become a party or are subject to litigation, legal or contractual disputes, governmental investigations or administrative proceedings, our management’s attention may be diverted and we may incur substantial costs and liabilities.

We may also from time to time become a party to various litigation, legal disputes, claims, administrative proceedings or other administrative measures arising in the ordinary course of our business. On-going litigation, legal disputes, claims, administrative proceedings or other administrative measures may divert our management’s attention and consume their time and our other resources. Furthermore, any litigation, legal disputes, claims, administrative proceedings or other administrative measures which are initially not of material importance may escalate and become important to us, due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. Negative publicity arising from litigation, legal disputes, claims, administrative proceedings or other administrative measures may damage our reputation and adversely affect the image of our brands and products. In addition, if any verdict or award is rendered against us or we are imposed any fines or penalties, we could be required to pay significant monetary damages, assume other liabilities and even to suspend or terminate the related business ventures or projects. Consequently, our business, financial condition, results of operations and prospects may be materially and adversely affected.

Our business significantly depends on our reputation, and any negative publicity on us or failure to maintain and enhance our recognition and reputation may materially and adversely affect our business, financial condition, results of operations and prospects.

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. 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 contract sales organizations, 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.

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Any negative publicity, including disputes concerning us, our business partners or our affiliates, even if untrue, could adversely affect our reputation and prospects. Moreover, if we are unable to maintain a good reputation, our ability to attract and retain key employees and business partners could be harmed which, in turn, may materially and adversely affect our business, financial condition, results of operations and prospects.

Our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. Negative publicity about us, such as alleged misconduct or improper activities, or negative rumors relating to us, our management, employees, business partners or affiliates, can harm our business, financial condition, results of operations and prospects, even if they are unsubstantiated or are later satisfactorily addressed. Any regulatory inquiries or investigations or other actions against our management, any perceived unethical, fraudulent, or inappropriate business conduct by us or perceived wrong doing 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.

Moreover, any negative media publicity about the pharmaceutical industry in general, including issues and allegations solely involving other companies in the industry, may also negatively impact our reputation.

In the event that such negative publicity relates to our own products and business, the adverse impact on our financial condition or results of operations might be more significant. Any such negative publicity may undermine the public confidence in our products, reputation, brand image, business prospects, and impair the development and commercialization of our drug candidates, all of which may adversely affect our business operations and financial performance. Investigations and increasingly stringent regulations arising from such negative publicity, if any, may draw time and attention from our management team, which would have otherwise been devoted into our business operations, or may incur additional compliance expenses.

Our information technology systems, or those of our CROs, CDMOs or other contractors and business partners, may fail or suffer security breaches.

Despite the implementation of security measures, our information technology systems and those of our CROs, CDMOs, consultants and other service providers are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, 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

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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.

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

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

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

We maintain insurance policies that are required under the PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. In addition to employee social and medical insurances, our principal insurance policies also cover adverse events in clinical trials. We currently do not maintain insurance for environmental liability or property loss. For additional information, see “Business — Insurance.” According to CIC, our insurance policy is in line with the industry practice. Our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may negatively impact our product development and overall operations.

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Difficult conditions and turbulence in the global economic, political and financial environment may adversely affect our business, financial condition, results of operations and prospects.

Geopolitical, economic and market conditions, including factors such as the liquidity of the global financial markets, the level and volatility of debt and equity prices, interest rates, currency and commodities prices, [REDACTED] sentiment, inflation and the availability and cost of capital and credit have been and will continue to affect the countries where we operate. The stress experienced by the global financial markets in 2020 due to the COVID-19 pandemic, the series of measures taken by major economies in response and the consequences of such measures continue to impact the global economy in varying degrees in different regions over the years. The financial markets continue to be impacted by general uncertainty, and growth rates have declined recently. In addition, tighter monetary policy in the United States could further undermine financial stability in emerging market economies. Central banks around the world, including in the United States and several large emerging markets, have tightened monetary policy and have indicated that they would continue to do so in the near future. The financial conditions of banking institutions have come under severe pressure and deterioration, as exemplified by the proposed restructuring of Credit Suisse Group AG and the failures of Silicon Valley Bank and Signature Bank in the first quarter of 2023, driven by bank runs or simultaneous withdrawals by depositors due to various reasons, including lack of confidence in the banking system. The slow economic recoveries around the world and the high inflation, high interest environment have contributed to higher global volatility. These developments may adversely impact global liquidity, heighten market volatility and increase U.S. dollar funding costs resulting in tightened global financial conditions and fears of a recession. A prolonged period of extremely volatile and unstable market conditions would likely increase our funding costs and could also adversely affect the countries where we operate, which could in turn affect our business, financial condition, results of operations and prospects.

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

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

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certain countries. If any new tariffs, policies, legislation and/or regulations are announced or implemented, or if existing trade agreements are renegotiated, such changes could have an adverse effect on our business, financial condition, results of operations and prospects.

RISKS RELATING TO DOING BUSINESS IN THE JURISDICTIONS WE OPERATE

Changes in economic, social conditions and policies may impact our business, financial condition, results of operations and prospects.

Substantially all of our assets and operations are located in the PRC. Accordingly, our business, financial condition, results of operations and prospects to a significant degree rely on the economic and social conditions in the PRC generally.

The PRC economy has experienced significant growth over the past decades and we expect the PRC economy will continue to grow. Various measures have been implemented to encourage economic growth. Some of these measures may benefit the overall PRC economy, but may have an effect on us. In addition, certain measures implemented based on the overall economic situation may affect our business, financial condition, results of operations and prospects.

Furthermore, in recent years, the U.S.-China relations also give rise to uncertainties on the global economy. Since 2018, the United States government imposed several rounds of tariffs on Chinese products. In retaliation, the PRC government responded with tariffs on U.S. products. The trade tensions were accompanied with escalating economic restrictions and sanctions, which created further uncertainties and volatilities to the global markets. Since 2019, the United States government has imposed increasing restrictions on Chinese technology companies exporting sensitive U.S. goods. In 2021, the United States government blacklisted over 40 Chinese technology companies, citing activities contrary to the national security or foreign policy interests of the United States. The future development and lasting impact of the U.S.-China relations on the chronic disease therapeutics industry remain uncertain. Should the U.S.-China relations materially impact the global economy, the purchasing power of our customers may decrease, which will have an adverse effect on our business operation and financial performance.

There might be uncertainties in effecting service of legal process and enforcing foreign judgments against us and our management in the PRC.

We are a company incorporated under the laws of the PRC, and a significant portion of our assets and the majority of our Directors and senior management are located in the PRC. As a result, it may be difficult for the [REDACTED] to directly effect service of process within the United States or elsewhere outside the PRC upon us or most of our Directors and senior management in the PRC. Moreover, judgments rendered in jurisdictions with which the PRC does not have treaties that provide for the reciprocal recognition and enforcement of judicial rulings and awards may not be so recognized or enforced in the PRC.

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On July 14, 2006, the Supreme People’s Court of the PRC and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by Courts of the Mainland and the Hong Kong Special Administration Region Pursuant to Choice of Court Agreements between Parties Concerned 《(關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排)》 (the “**Arrangement**”). Under the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case pursuant to a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. A judgment rendered by a Hong Kong court may not be enforced in Mainland China if the parties in dispute have not agreed to enter into a choice of court agreement in writing.

On January 18, 2019, the Supreme People’s Court and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region 《(關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排)》 (the “**New Arrangement**”), which seeks to establish a mechanism with further clarification on and certainty for reciprocal recognition and enforcement of judgments in a wider range of civil and commercial matters between Mainland China and Hong Kong. The New Arrangement does not include the requirements for a choice of court agreement in writing by the parties. The New Arrangement has come into effect on January 29, 2024 and superseded the Arrangement. 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.

There may be new laws or regulations promulgated or interpretations of the laws and regulations in the future that may affect our business, financial condition, results of operations and prospects.

We are governed by the laws, rules and regulations in the jurisdictions we operate. Due to the rapid development and iteration of economic activities, there may be new laws or regulations promulgated or interpretations of laws and regulations in the jurisdictions we operate in the future. And we are thus required to understand and be familiar with the interpretation and implementation of relevant laws and regulations in a timely manner, or otherwise we may violate relevant laws and regulations.

Laws, regulations or implementation policies including those regulating the healthcare and pharmaceutical industry, are evolving to account for changes such as those in the industry and the global best practices. The pharmaceutical industry is subject to comprehensive regulation and many aspects of our business depend on the receipt of the relevant government authorities’ approvals and permits.

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In recent years, the regulatory framework regarding the pharmaceutical industry has undergone a series of changes, and we expect relevant healthcare regulatory authorities in the jurisdictions we operate to continue to promulgate rules and regulations to optimize the drug approval system. Any such new requirements or future changes or amendments may result in increased compliance costs on our business or cause us to spend more time than anticipated to develop and commercialize our drug candidates, thereby adversely affect our business, financial condition, results of operations and prospects.

Required procedures on the remittance of Renminbi into and out of the PRC may affect our ability to pay dividends and other obligations, and affect the value of your [REDACTED].

Procedures on the remittance of Renminbi into and out of the PRC are required under the relevant PRC laws and regulations. A substantial majority of our future revenue is expected to be denominated in Renminbi and we will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our H Shares. Shortages in the availability of foreign currency may affect our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency denominated obligations.

Under the relevant PRC laws and regulations, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from China’s State Administration of Foreign Exchange (“SAFE”), but we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. Approval from appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies.

Holders of our H Shares may be subject to PRC income tax obligations.

Under the current PRC tax laws and regulations, non-PRC resident individuals and non-PRC resident enterprises are subject to different tax obligations with respect to the dividends paid to them by us and the gains realized upon the sale or other disposition of H Shares.

Non-PRC resident individuals are required to pay PRC individual income tax at a 20% rate for the income derived in China under the PRC Individual Income Tax Law (the “IIT Law”) and its implementation guidelines. Accordingly, we are required to withhold such tax from dividend payments, unless applicable tax treaties between China and the jurisdiction in which the foreign individual resides reduce or provide an exemption for the relevant tax obligations. However, pursuant to the Circular on Certain Policy Questions Concerning Individual Income Tax (《財政部、國家稅務總局關於個人所得稅若干政策問題的通知》) (Cai Shui Zi [1994] No. 020) issued by the MOF and SAT on May 13, 1994, the income gained by individual foreigners from dividends and bonuses of enterprises with foreign investment are exempted from individual income tax for the time being. In addition, under the IIT Law and its implementation regulations, non-PRC resident individual holders of H shares are subject to

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individual income tax at a rate of 20% on gains realized upon the sale or other disposition of H shares. However, pursuant to the Circular of Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) (Cai Shui Zi [1998] No. 61) issued by the MOF and the SAT on March 30, 1998, from January 1, 1997, the income of individuals from the transfer of the shares of [REDACTED] enterprises continues to be exempted from individual income tax.

As of the Latest Practicable Date, no aforesaid provisions had expressly provided that individual income tax shall be levied on non-PRC resident individual holders on the transfer of shares in PRC resident enterprises [REDACTED] on overseas stock exchanges. However, there is no assurance that the PRC tax authorities will not levy income tax on non-PRC resident individual holders on gains from the sale of H shares.

For non-PRC resident enterprises that do not have establishments or premises in China, and for those that have establishments or premises in China but whose income is not related to such establishments or premises, under the PRC Enterprise Income Tax Law and its implementation regulations, dividends paid by us and gains realized by such foreign enterprises upon the sale or other disposition of H Shares are subject to PRC enterprise income tax at a 10% rate. In accordance with the Circular on Issues Relating to Withholding of Enterprise Income Tax by PRC Resident Enterprises on Dividends Paid to Overseas Non-PRC Resident Enterprise Shareholders of H Shares (《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) issued by SAT on November 6, 2008, the withholding tax rate for dividends payable to non-PRC resident enterprise holders of H Shares will be 10% and we intend to withhold tax at a rate of 10% from dividends paid to non-PRC resident enterprise holders of our H Shares (including HKSCC Nominees). Non-PRC resident enterprises (or other non-PRC owners holding H shares through non-PRC enterprises) that are entitled to be taxed at a reduced rate under an applicable income tax treaty or arrangement will be required to apply to the PRC tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, and payment of such refund will be subject to the PRC tax authorities’ approval.

Despite the arrangements mentioned above, the interpretation and application of applicable PRC tax laws and regulations by the competent tax authorities shall be in accordance with the then effective laws and regulations, and new taxes may be imposed which may materially and adversely affect the value of your [REDACTED] in our H Shares.

We are subject to risks in relation to our social insurance and housing provident fund contributions.

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), we are required to make contributions to the social insurance plans and the housing provident fund under the relevant PRC laws and regulations for our employees.

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During the Track Record Period, we engaged third-party human resources agencies to pay social insurance premium and housing provident funds, as requested by the relevant employees. Pursuant to the agreement entered into between such third-party human resources agencies and us, the third-party human resources agencies would pay social insurance premium and housing provident funds for such employees on behalf of us. As of the Latest Practicable Date, the third-party human resources agencies provided such funds for five of our employees. As of the Latest Practicable Date, (i) such employees had confirmed such arrangement that the third-party human resources agencies pay the social insurance premium and housing provident funds for them on behalf of us, and had raised no objections in relation thereto; (ii) there had been no disputes between us, such employees and the third-party human resources agencies with regard to such arrangement; and (iii) we had not received any notice of rectification from, or been imposed any administrative penalty by, the relevant governmental authorities as a result of such arrangement. As advised by our PRC Legal Adviser, taking into consideration the above, the risk of us being subject to material penalties as a result of paying the social insurance premium and housing provident funds for the relevant employees through third-party agencies which thus have a material adverse effect on our financial condition or results of operations taken as a whole is relatively low. However, if the relevant governmental authorities are of the view that such arrangement does not satisfy the requirements under the relevant PRC laws and regulations in respect of housing provident funds, we may be ordered to pay the outstanding balance to the relevant local authorities within a prescribed period of time, failing which the relevant governmental authorities could apply to the People’s Court for enforcement, but no penalties are provided under the relevant PRC laws and regulations; and, in respect of social insurance premium, we might be ordered to pay the outstanding balance within a certain period of time and a late fee that equals 0.05% of the total outstanding balance per day from the date of the failure to make payment, failing which we may be subject to a fine, ranging from one to three times the total outstanding balance. In the event that the relevant governmental authorities do not recognize the amount of social insurance premium and housing provident funds that we contributed through third-party agencies, it may be deemed a failure to make full contributions, with the social insurance premium and housing provident funds paid by third-party human resources agencies on behalf of us for 2023 and 2024 amounted to RMB609.4 thousand and RMB723.9 thousand, respectively. This in turn may adversely affect our financial condition and results of operations.

We have enhanced our internal control measures requiring social insurance and housing provident fund contributions to be made in compliance with relevant PRC laws and regulations. In particular, we plan to regularly review and monitor the reporting and contributions of social insurance premium and housing provident funds and consult our PRC Legal Adviser on a regular basis to keep us abreast of relevant regulatory developments. For details, see “Business — Employees.”

RISK FACTORS

We are subject to risks associated with our leased properties.

We have leased certain properties in China as our offices. 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. In practice, as the filing of the lease agreements requires the coordination of both lessors and lessees, we cannot assure you that the lessors will cooperate and complete the registration in a timely manner. 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 failed to register all five lease agreements with relevant governmental authorities due to various reasons, including without limitation, the failure or unwillingness of the lessors to provide relevant documents. Although failure to register the lease agreements does not in itself invalidate the leases, we may not be able to defend these leases against *bona fide* third parties, which may negatively affect our ability to operate our business covered under those leases. In addition, we may be required by relevant PRC governmental authorities to register such lease agreements within a prescribed timeframe, and failure to do so may subject us to fines. The penalty ranges from RMB1,000 to RMB10,000 for each unregistered lease agreement. As of the Latest Practicable Date, we had not been 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 the relevant governmental authorities to fulfill the registration requirements, which may increase our costs in the future.

In addition, as our leases expire, we may face difficulties renewing them, either on commercially acceptable terms or at all. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

We are subject to filing requirements by CSRC in connection with the [REDACTED].

Pursuant to the Overseas Listing Trial Measures, overseas [REDACTED] and [REDACTED] by a joint-stock company registered and formed in China is identified as a direct overseas [REDACTED] and [REDACTED] by a domestic company, and such domestic company shall file with CSRC in this regard according to the Overseas Listing Trial Measures. As such, we are required to file with CSRC in connection with the [REDACTED], as a direct overseas [REDACTED] and [REDACTED], within three business days after we submit the [REDACTED] for [REDACTED] overseas. We have filed the required documents with the CSRC, and the CSRC has issued the filing notice dated July 25, 2024, confirming our completion of the filing pursuant to the new filing regime introduced by the Overseas Listing Trial Measures for the [REDACTED], the conversion of certain Unlisted Shares into H Shares and the [REDACTED] of the H Shares on the Hong Kong Stock Exchange.

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RISKS RELATING TO THE [REDACTED]

There has been no prior public market for our H Shares and the liquidity and market price of our H Shares may be volatile.

Prior to the completion of the [REDACTED], there has been no public market for our H Shares. There can be no guarantee that an active [REDACTED] market for our H Shares will develop or be sustained after the completion of the [REDACTED]. The [REDACTED] is the result of negotiations between our Company and the [REDACTED] (for themselves and on behalf of the [REDACTED]), which may not be indicative of the price at which our H Shares will be [REDACTED] following the completion of the [REDACTED]. The market price of our H Shares may drop below the [REDACTED] at any time after completion of the [REDACTED].

The [REDACTED] price of our H Shares may be volatile, which could result in substantial losses to you.

The [REDACTED] price of our H Shares may be volatile and could fluctuate widely in response to factors beyond our control. In particular, the performance and fluctuation of the market prices of other companies with business operations located mainly in Mainland China that have [REDACTED] their securities in Hong Kong may affect the volatility in the price of and [REDACTED] volumes for our H Shares. A number of Mainland China-based companies have [REDACTED] their securities, and some are in the process of preparing for [REDACTED] their securities, in Hong Kong. The share price of some of these companies have experienced significant volatility, including significant price declines after their [REDACTED]. The [REDACTED] performances of the securities of these companies at the time of or after their [REDACTED] may affect the overall [REDACTED] sentiment towards Mainland China-based companies [REDACTED] in Hong Kong and consequently may impact the [REDACTED] performance of our H Shares. Pursuant to the applicable PRC law, within one year following the [REDACTED], all existing Shareholders (including the [REDACTED] Investors) could not dispose of any of the Shares held by them. Due to such lock-up requirement, the liquidity and [REDACTED] volume of the H Shares in the short term following the [REDACTED] may be significantly affected. These factors may significantly affect the market price and volatility of our H Shares, regardless of our actual operating performance.

Future sales or perceived sales of substantial amounts of our H Shares in the public market could have a material and adverse effect on the price of our H Shares and our ability to raise additional capital in the future.

The market price of our H Shares could decline as a result of future sales of a substantial number of our H Shares or other securities relating to our H Shares in the public market, the issuance of new shares or other securities, or the perception that such sales or issuances may occur. Future sales, or perceived sales, of substantial amounts of our securities, including any future [REDACTED], could also materially and adversely affect our ability to raise capital at

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a specific time and on terms favorable to us. In addition, our Shareholders may experience dilution in their holdings if we issue more securities in the future. New shares or shares-linked securities issued by us may also confer rights and privileges that take priority over those conferred by the H Shares.

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

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] consolidated net tangible asset value. To expand our business, we may consider [REDACTED] and issuing additional shares in the future. Purchasers of the [REDACTED] may experience dilution in the net tangible asset value per Share of their Shares if we issue additional shares in the future at a price that is lower than the net tangible asset value per Share at that time.

Our historical dividends may not be indicative of our future dividend policy, and there can be no assurance that we will declare and distribute any amount of dividends in the future

Our ability to declare future dividends will depend on the availability of dividends, if any, received from us and our subsidiaries. Under PRC law and the constitutional documents of our PRC operating subsidiaries, dividends may be paid only out of distributable profits, which refer to after-tax profits as determined under PRC GAAP less any recovery of accumulated losses and required allocations to statutory capital reserve funds. Any distributable profits that are not distributed in a given year are retained and become available for distribution in subsequent years. In addition, as stipulated by our Articles, distributable profits are recognized as our after-tax profit determined under PRC GAAP or HKFRSs, whichever is lower, less any recovery of accumulated losses and appropriations to statutory and other reserves that we are required to make. As a result, our Company and our subsidiaries may not be able to pay a dividend in a given year if our Company or our subsidiaries do not have distributable profits as determined under PRC GAAP even if they have profits as determined under HKFRSs. See “Financial Information — Dividend” for details of our dividend policy.

Our historical dividends may not be indicative of our future dividend policy, and there can be no assurance that we will declare and distribute any amount of dividends in the future. The declaration, payment and amount of any future dividends are subject to the discretion of our Directors, after taking into account our results of operations, financial conditions, cash requirements and availability, and other factors as they may deem relevant, and subject to the approval at a Shareholders’ meeting. We may not have sufficient or any profits to enable us to distribute dividends to our Shareholders in the future, even if our financial statements indicate that our operations have been profitable.

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Certain statistics contained in this Document are derived from a third-party report and publicly available official sources.

This Document, particularly the section headed “Industry Overview”, contains information and statistics relating to the biotech industry in China and internationally. Such information and statistics have been derived from various official governments and other publications and from a third-party report commissioned by us. We believe that the sources of such information are appropriate and we have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading in any material respect or that any fact has been omitted that would render such information false or misleading in any material respect. However, we cannot guarantee the quality or reliability of such information. The information and statistics from official governments have not been independently verified by the Company, the Sole Sponsor, any of our or their respective directors, officers or representatives or any other person involved in the [REDACTED] and no representation is given as to their accuracy. In any event, you should consider carefully the importance placed on such information or statistics.

You should read the entire Document carefully and should not rely on any information contained in press articles or other media regarding us and 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, our business, our industry and the [REDACTED]. There may be additional press and media coverage regarding us, our business, our industry and the [REDACTED] subsequent to the date of this Document but prior to the completion of the [REDACTED]. 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. None of us or any other person involved in the [REDACTED] has authorized the disclosure of any such information in the press or media coverage and none of us accepts 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], our Company has sought the following waivers from strict compliance with the relevant provisions of the Listing Rules and exemption from strict compliance with the Companies (Winding up and Miscellaneous Provisions) Ordinance.

WAIVER IN RESPECT OF MANAGEMENT PRESENCE IN HONG KONG

According to Rule 8.12 of the Listing Rules, a new applicant for a primary [REDACTED] on the Stock Exchange must have a sufficient management presence in Hong Kong. This normally means that at least two of our executive Directors must be ordinarily resident in Hong Kong. Rule 19A.15 of the Listing Rules further provides that the requirement in Rule 8.12 of the Listing Rules may be waived by having regard to, among other considerations, our arrangements for maintaining regular communication with the Stock Exchange.

We do not have a sufficient management presence in Hong Kong for the purpose of satisfying the requirement under Rule 8.12 and Rule 19A.15 of the Listing Rules. Our management headquarters, senior management, business operations and assets are primarily based outside Hong Kong. The Directors consider that either by means of relocation of our existing executive Directors or appointment of additional executive Directors who will be ordinarily resident in Hong Kong would not be beneficial to, or appropriate for, our Group and therefore would not be in the best interests of our Company or the Shareholders as a whole. As such, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us a waiver from strict compliance with Rule 8.12 and Rule 19A.15 of the Listing Rules. We will ensure that there is a regular and effective communication between us and the Stock Exchange by way of, among others, the following conditions:

- (a) pursuant to Rules 3.05 of the Listing Rules, we have appointed and will continue to maintain two authorized representatives, who will act as our principal channel of communication with the Stock Exchange and ensure that our Company complies with the Listing Rules at all times. The two authorized representatives appointed are Dr. Michael Min XU and Ms. Yuen Mui CHAN (陳婉梅) (“**Ms. CHAN**”) (the “**Authorized Representatives**”). Ms. CHAN is situated and based in Hong Kong, and will be available to meet with the Stock Exchange in Hong Kong within a reasonable time frame upon the request of the Stock Exchange. Both of the Authorized Representatives will be readily contactable by telephone and email to deal promptly with enquiries from the Stock Exchange. Our Company has provided contact details of the two Authorized Representatives to the Stock Exchange and will inform the Stock Exchange promptly in respect of any change in the authorized representatives;
- (b) both Authorized Representatives have means to contact all Directors (including the independent non-executive Directors) promptly at all times as and when the Stock Exchange wishes to contact our Directors on any matters. Our Company has implemented a policy whereby (1) each Director has provided their respective valid phone numbers or other means of communication to the Authorized Representatives; (2) in the event that a Director expects to travel or is otherwise out of office, he/she

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will endeavor to provide his/her phone number of the place of his/her accommodation to the Authorized Representatives or maintain an open line of communication via his/her mobile phone; and (3) each Director has provided his/her mobile phone number, office phone number, e-mail address and, where available, fax number to the Stock Exchange and will inform the Stock Exchange promptly if there are any changes to the contact details of the Directors;

- (c) pursuant to Rule 3.20 of the Listing Rules, each Director has provided his/her contact information to the Stock Exchange and to the Authorized Representatives. This will ensure that the Stock Exchange and the Authorized Representatives should have means for contacting all Directors promptly at all times as and when required;
- (d) all our Directors who are not ordinarily resident in Hong Kong have confirmed that they possess or can apply for valid travel documents to visit Hong Kong and will be able to meet with relevant members of the Stock Exchange in Hong Kong upon reasonable notice, when required;
- (e) pursuant to Rule 3A.19 of the Listing Rules, we have retained the services of Rainbow Capital (HK) Limited as compliance adviser (the “**Compliance Adviser**”) upon [REDACTED] for a period commencing on the [REDACTED] and ending 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], which will act as an additional channel of communication with the Stock Exchange and will be available to respond to enquiries from the Stock Exchange. The contact details of the Compliance Adviser has been provided to the Stock Exchange;
- (f) our Authorized Representatives, Directors and other officers of our Company will provide promptly such information and assistance as the Compliance Adviser may reasonably require in connection with the performance of the Compliance Adviser’s duties as set forth in Chapter 3A of the Listing Rules. There will be adequate and efficient means of communication between our Company, Authorized Representatives, Directors and other officers of our Company and the Compliance Adviser, and, to the extent reasonably practicable and legally permissible, we will keep the Compliance Adviser informed of all communications and dealings between the Stock Exchange and us; meetings between the Stock Exchange and our Directors could be arranged through our Authorized Representatives or the Compliance Adviser, or directly with our Directors within a reasonable time frame. We will inform the Stock Exchange as soon as practicable in respect of any change of Authorized Representatives and/or the Compliance Adviser;
- (g) we will appoint other professional advisors (including legal advisors in Hong Kong) after the [REDACTED] to assist us in dealing with any questions which may be raised by the Stock Exchange and to ensure that there will be prompt and effective communication with the Stock Exchange; and

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- (h) our Company has designated one of our staff members as the communication officer at our headquarters after the [REDACTED] who will be responsible for maintaining day-to-day communication with the Authorized Representatives and our Company’s professional advisors in Hong Kong, including our legal advisors in Hong Kong and the Compliance Adviser, to keep abreast of any correspondences and/or enquiries from the Stock Exchange and report to our executive Directors to further facilitate communication between the Stock Exchange and our Company.

WAIVER IN RESPECT OF JOINT COMPANY SECRETARIES

Pursuant to Rules 3.28 and 8.17 of the Listing Rules and Chapter 3.10 of the Guide for New Listing Applicants, a new applicant for listing on the Stock Exchange must appoint a company secretary who, by virtue of his/her academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of the company secretary.

Note 1 to Rule 3.28 of the Listing Rules provides that the Stock Exchange considers the following academic or professional qualifications to be acceptable:

- (a) a member of The Hong Kong Chartered Governance Institute;
- (b) a solicitor or barrister as defined in the Legal Practitioners Ordinance (Chapter 159 of the Laws of Hong Kong); and
- (c) a certified public accountant as defined in the Professional Accountants Ordinance (Chapter 50 of the Laws of Hong Kong).

Note 2 to Rule 3.28 of the Listing Rules further provides that the Stock Exchange considers the following factors in assessing the “relevant experience” of the individual:

- (a) length of employment with the issuer and other issuers and the roles he/she played;
- (b) familiarity with the Listing Rules and other relevant laws and regulations including the SFO, the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code;
- (c) relevant training taken and/or to be taken in addition to the minimum requirement under Rule 3.29 of the Listing Rules; and
- (d) professional qualifications in other jurisdictions.

Our Company has appointed Mr. Yifeng HUANG (黃一峰) (“**Mr. HUANG**”) and Ms. Yuen Mui CHAN (陳婉梅) as our joint company secretaries. See “Directors, Supervisors and Senior Management — Joint Company Secretaries” for their biographical details.

WAIVERS AND EXEMPTION

Mr. HUANG has extensive experience in legal and board matters. The Company believes that it would be in the best interests of the Company and the corporate governance of the Group to have as its joint company secretary a person such as Mr. HUANG, who is the secretary of the Board and has day-to-day knowledge of the Company’s affairs. Mr. HUANG has the necessary nexus to the Board and close working relationship with management of the Company in order to perform the function of a joint company secretary and to take the necessary actions in the most effective and efficient manner. However, Mr. HUANG presently does not possess any of the qualifications under Rules 3.28 and 8.17 of the Listing Rules, and may not be able to solely fulfill the requirements of the Listing Rules. Therefore, we have appointed Ms. CHAN, who is an associate member of The Hong Kong Chartered Governance Institute and fully meets the requirements stipulated under Rules 3.28 and 8.17 of the Listing Rules, to act as the other joint company secretary and to provide assistance to Mr. HUANG for an initial period of three years from the [REDACTED] to enable Mr. HUANG to acquire the “relevant experience” under Note 2 to Rule 3.28 of the Listing Rules so as to fully comply with the requirements set forth under Rules 3.28 and 8.17 of the Listing Rules.

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 such that Mr. HUANG may be appointed as a joint company secretary of our Company.

The waiver is valid for an initial period of three years from the [REDACTED], and is granted on the condition that Ms. CHAN, as a joint company secretary of our Company, will work closely with Mr. HUANG to jointly discharge the duties and responsibilities as company secretaries and assist Mr. HUANG in acquiring the relevant experience as required under Rules 3.28 and 8.17 of the Listing Rules. Ms. CHAN will also assist Mr. HUANG in organizing Board meetings and Shareholders’ meetings of our Company as well as other matters of our Company which are incidental to the duties of a company secretary. Ms. CHAN is expected to work closely with Mr. HUANG and will maintain regular contact with Mr. HUANG, the Directors and the senior management of our Company. In addition, Mr. HUANG will comply with the annual professional training requirement under Rule 3.29 of the Listing Rules and will enhance his knowledge of the Listing Rules during the three-year period from the [REDACTED]. Mr. HUANG will also be assisted by (a) the Compliance Adviser, particularly in relation to compliance with the Listing Rules; and (b) the Hong Kong legal advisors of our Company, on matters concerning our Company’s ongoing compliance with the Listing Rules and the applicable laws and regulations.

Pursuant to Chapter 3.10 of the Guide for New Listing Applicants, the waiver will be revoked immediately if Ms. CHAN ceases to provide assistance to Mr. HUANG as a joint company secretary for the three-year period after the [REDACTED] or where there are material breaches of the Listing Rules by our Company.

Prior to the expiration of the initial three-year period, the qualifications and experience of Mr. HUANG will be re-evaluated to determine whether the requirements as stipulated in Rules 3.28 and 8.17 of the Listing Rules can be satisfied and whether the need for ongoing

WAIVERS AND EXEMPTION

assistance will continue. We will liaise with the Stock Exchange to enable it to assess whether Mr. HUANG, having benefited from the assistance of Ms. CHAN for the preceding three years, will have acquired the skills necessary to carry out the duties of company secretary and the relevant experience within the meaning of Note 2 to Rule 3.28 of the Listing Rules so that a further waiver will not be necessary.

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

Section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires all documents to include matters specified in Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance (the “**Third Schedule**”), and set out the reports specified in Part II of the Third Schedule.

Paragraph 27 of Part I of the Third Schedule requires a company to include in its document a statement as to the gross trading income or sales turnover (as the case may be) of the company during each of the three financial years immediately preceding the issue of the document, including an explanation of the method used for the computation of such income or turnover and a reasonable breakdown between the more important trading activities.

Paragraph 31 of Part II of the Third Schedule further requires a company to include in its document a report by the auditors of the company with respect to (i) the profits and losses of the company for each of the three financial years immediately preceding the issue of the document and (ii) the assets and liabilities of the company of each of the three financial years immediately preceding the issue of the document.

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

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

Our Company is a Biotech Company as defined under Chapter 18A of the Listing Rules and is seeking a [REDACTED] under Chapter 18A of the Listing Rules. Rule 18A.03(3) of the Listing Rules requires that a Biotech Company must have been in operation in its current line

WAIVERS AND EXEMPTION

of business for at least two financial years prior to [REDACTED] under substantially the same management. Rule 18A.06 of the Listing Rules requires that a Biotech Company must comply with Rule 4.04 of the Listing Rules modified so that references to “three financial years” or “three years” in Rule 4.04 of the Listing Rules shall instead be references to “two financial years” or “two years,” as the case may be. Further, pursuant to Rule 8.06 of the Listing Rules, the latest financial period reported on by the reporting accountants for a new applicant must not have ended more than six months from the date of the [REDACTED] document.

In compliance with the abovementioned requirements under the Listing Rules, the Accountants’ Report set out in Appendix I to this Document is currently prepared to cover the two years ended December 31, 2023 and 2024. As such, we have applied to the SFC for a certificate of exemption from strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule regarding the inclusion of the Accountants’ Report covering the full three financial years immediately preceding the issue of this Document on the following grounds:

- (a) our Company is primarily engaged in R&D, application and commercialization of biotech products, and falls within the scope of Biotech Company as defined under Chapter 18A of the Listing Rules. Our Company will fulfill the additional conditions for [REDACTED] required under Chapter 18A of the Listing Rules;
- (b) the Accountants’ Report for the two years ended December 31, 2023 and 2024 has been disclosed in this Document and is set out in Appendix I in accordance with Rule 18A.06 of the Listing Rules;
- (c) given that our Company is only required to disclose its financial results for each of the two financial years ended December 31, 2023 and 2024 under Chapter 18A of the Listing Rules, strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule would be unnecessary and/or irrelevant for our Company. Substantially all of the other net income in 2022 came from net realized and unrealized gain on financial instruments carried at FVPL and government grants, which was immaterial and not the key business of the Company. Hence, our Directors consider that such additional information does not provide meaningful information to the [REDACTED] to make an informed assessment of the business, assets and liabilities, financial position, management and prospects of the Company;
- (d) notwithstanding that the financial results set out in the Document are only for the two financial years ended December 31, 2023 and 2024 in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this Document pursuant to the relevant requirements; and

WAIVERS AND EXEMPTION

- (e) the Accountants’ Report covering the two financial years ended December 31, 2023 and 2024 (as set out in Appendix I), together with other disclosures in the Document, have already provided adequate and reasonable up-to-date information in the circumstances for the potential [REDACTED] to make an informed assessment of the business, assets and liabilities, financial position, management and prospects and to form a view on the track record of our Company. Therefore, the exemption would not prejudice the interest of the [REDACTED].

The SFC [has granted] us a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting our Company from strict compliance with section 342(1)(b) in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule on the condition that particulars of the exemption are set out in this Document and that this Document will be issued on or before [REDACTED].

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality

Executive Directors

Dr. Michael Min XU	No. 7-138, No. 99 Qingcheng Road Suzhou Industrial Park Suzhou, Jiangsu Province, the PRC	American

Ms. Xiaojun WANG (王小軍)	Room 25H, No. 1 Lane 558, Xujiahui Road Shanghai, the PRC	Chinese

Non-executive Directors

Dr. Xiangjun ZHOU	29D, Building 10 of International Apartment Lanxi Valley International Apartment II Yan Shan Road China Merchants Street Shekou No. 16 Industrial Road 3 Nanshan District Shenzhen, Guangdong Province the PRC	American

Dr. Yuhong XU (徐宇虹)	Room 303, No. 304 Wulin Road Hangzhou, Zhejiang Province the PRC	Chinese

Ms. Ting ZHAI (翟婷)	Room 502, No. 38, Lane 1781 Tongchuan Road, Putuo District Shanghai, the PRC	Chinese

Mr. Hongkai LI (李宏凱)	No. 610, Jundong Building Sixth Avenue, Hedong District Tianjin, the PRC	Chinese

Independent non-executive Directors

Dr. Jiancun ZHANG	No. 30, 6 Street, Feng Cui Yuan Phoenix City Biguiyuan Zengcheng District Guangzhou, the PRC	American

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality

Independent non-executive Directors

Dr. Yangyang CHEN (陳秧秧)	Room 9D, No. 1, Lane 123 Yanping Road, Jing'an District Shanghai, the PRC	Chinese
Ms. Xinpeng FAN (范新鵬)	82 Greenfield Villa, Ngau Liu Sai Kung, New Territories Hong Kong	Chinese (Hong Kong)

SUPERVISORS

Name	Address	Nationality

Ms. Mengjiao WANG (王夢嬌)	Room 610, Building 47 Donghuan Xincun Pingjiang District Suzhou, Jiangsu Province the PRC	Chinese
Mr. Yongjun KONG (孔勇軍)	Room 705, Block 5, Unit 3 Longhu Tianjie Life Square Phase II Huqiu District Suzhou, Jiangsu Province the PRC	Chinese
Mr. Dong LI (李東)	Room 304, Building 10, Lane 2999 Gonghexin Road, Jing'an District Shanghai, the PRC	Chinese

See “Directors, Supervisors and Senior Management” for further details of our Directors and Supervisors.

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

Sole Sponsor

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]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Legal advisers to our Company

As to Hong Kong and United States laws:

Davis Polk & Wardwell

10/F, The Hong Kong Club Building
3A Chater Road
Central
Hong Kong

As to PRC laws:

JunHe LLP

20/F, China Resources Building
8 Jianguomenbei Avenue
Beijing 100005
P. R. China

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

As to Hong Kong and United States laws:

Paul Hastings

22/F, Bank of China Tower
1 Garden Road
Hong Kong

As to PRC laws:

Allbright Law Offices

9/11/12F, Shanghai Tower
No. 501, Yincheng Middle Road
Pudong New Area, Shanghai
200120 PRC

Reporting Accountants

KPMG

*Public Interest Entity Auditor registered in
accordance with the Accounting and
Financial Reporting Council Ordinance*
8th Floor, Prince’s Building
10 Chater Road
Central
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
China

Compliance Adviser

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Office No. 710
7/F Wing On House
71 Des Voeux Road Central
Central
Hong Kong

[REDACTED]

CORPORATE INFORMATION

**Registered Office, Headquarter and
Principal Place of Business in the PRC**

Room 606, Building 1
Haozhang Tower
Gongshu District
Hangzhou
Zhejiang Province
the PRC

Principal Place of Business in Hong Kong

46/F, Hopewell Centre
183 Queen’s Road East
Wanchai
Hong Kong

Company’s Website

<http://www.pegbio.com>
(the information contained on this website
does not form part of this Document)

Joint Company Secretaries

Mr. Yifeng HUANG (黃一峰)
Room 606, Building 1
Haozhang Tower
Gongshu District
Hangzhou
Zhejiang Province
the PRC

Ms. Yuen Mui CHAN (陳婉梅)
46/F, Hopewell Centre
183 Queen’s Road East
Wanchai
Hong Kong

Authorized Representatives

Dr. Michael Min XU
No. 7-138, No. 99 Qingcheng Road
Suzhou Industrial Park
Suzhou, Jiangsu Province, the PRC

Ms. Yuen Mui CHAN (陳婉梅)
46/F, Hopewell Centre
183 Queen’s Road East
Wanchai
Hong Kong

Audit Committee

Ms. Xinpeng FAN (范新鹏) (*chairperson*)
Dr. Xiangjun ZHOU
Dr. Yangyang CHEN (陳秧秧)

CORPORATE INFORMATION

Remuneration and Appraisal Committee	Dr. Jiancun ZHANG (<i>chairperson</i>) Ms. Xiaojun WANG (王小軍) Ms. Xinpeng FAN (范新鵬)
Nomination Committee	Dr. Jiancun ZHANG (<i>chairperson</i>) Dr. Michael Min XU Ms. Xinpeng FAN (范新鵬)
Strategy and Development Committee	Dr. Michael Min XU (<i>chairperson</i>) Dr. Xiangjun ZHOU Dr. Yuhong XU (徐宇虹)

[REDACTED]

Principal Bank	China Construction Bank Suzhou Industrial Park Sub-branch 1/F, East Tower, Juzhong Ginza No. 94 Nanshi Street Suzhou Industrial Park Suzhou, Jiangsu Province, the PRC

INDUSTRY OVERVIEW

Certain information and statistics set out in this section have been extracted from various official government publications, available sources from public market data providers and an Independent Third-Party source, China Insights Consultancy. The report prepared by China Insights Consultancy and cited in this document was [REDACTED] by us. We believe that the sources of this information are appropriate sources for such information and have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. The information from official government sources has not been independently verified by us, the Sole Sponsor, the [REDACTED], the [REDACTED], the [REDACTED] and the [REDACTED], the [REDACTED], any of their respective directors, employees, agents or advisers or any other person or party involved in the [REDACTED], and no representation is given as to its accuracy, fairness and completeness. For discussion of the risks relating to our industry, see “Risk Factors” in this Document.

OVERVIEW OF METABOLIC DISORDERS AND DIGESTIVE DISEASES

Introduction to Metabolic Disorders and Digestive Diseases

According to the World Health Organization, chronic diseases tend to be of long duration and are the result of a combination of genetic, physiological, environmental and behavioral factors. Metabolic disorders (such as diabetes) and some digestive diseases are among the major types of chronic diseases.

Metabolic disorders, also referred to as metabolic diseases, are conditions that disrupt the normal processing and distribution of macronutrients, including proteins, fats, and carbohydrates, within the body. Common manifestations of metabolic disorders encompass heightened blood pressure, elevated blood sugar levels, excessive accumulation of body fat, and irregular cholesterol or triglyceride levels. Digestive diseases involve physiological and morphological abnormalities within the gastrointestinal system. Critical organs impacted by these disorders include the liver, stomach, pancreas and gallbladder, among others.

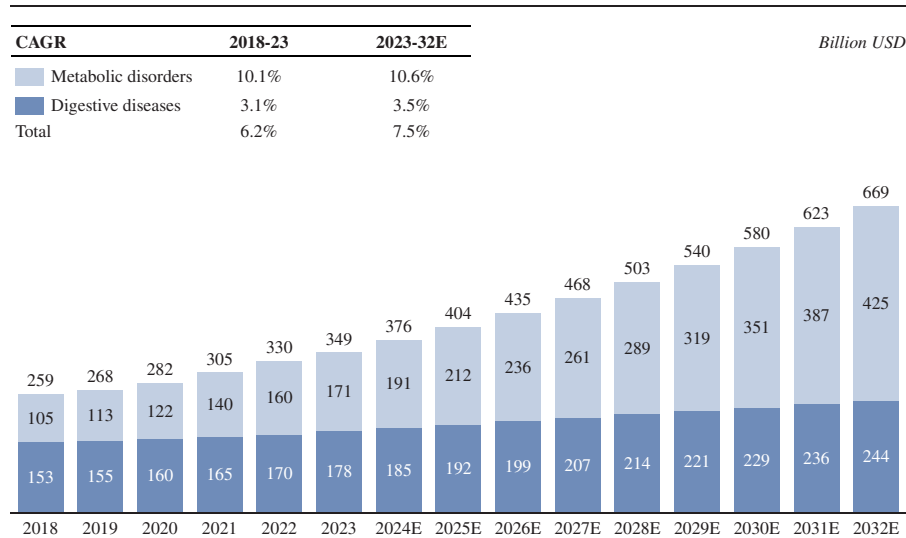
Metabolic disorders and digestive diseases are multifactorial conditions that result from the impaired functioning of several organs due to hormonal or enzymatic deficiencies. The interaction between these diseases can exacerbate the severity of the symptoms and the prognosis. Moreover, these diseases can cause various complications that may require specific treatment strategies. Effective treatment for metabolic disorders and digestive diseases requires a comprehensive approach and patients’ close adherence to the treatment plans.

Market Size of Major Metabolic Disorders and Digestive Diseases

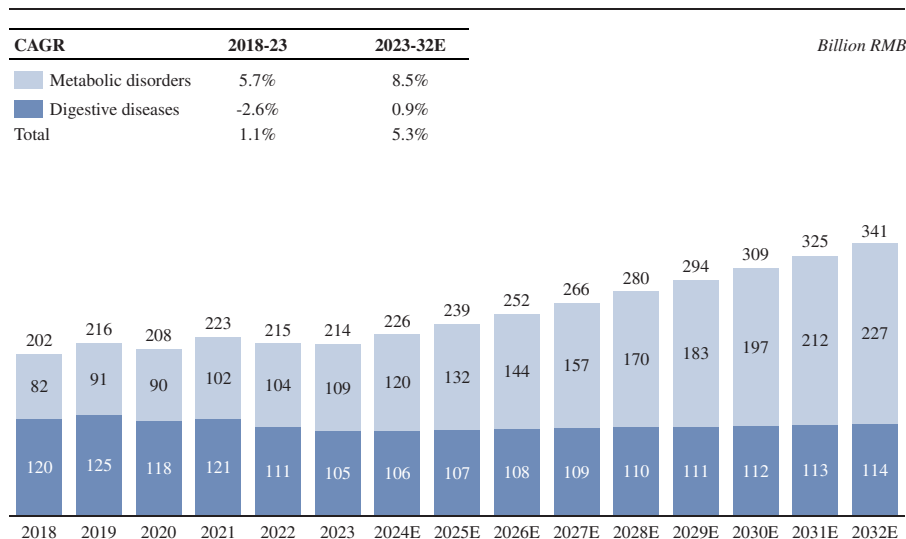
The following charts illustrate the historical and projected expansion of global and China markets of major metabolic disorders and digestive diseases.

INDUSTRY OVERVIEW

Global Market Size of Major Metabolic Disorders and Digestive Diseases, 2018-2032E



China Market Size of Major Metabolic Disorders and Digestive Diseases, 2018-2032E



Notes:

- (1) Major metabolic diseases include diabetes, hypertriglyceridemia, obesity, diabetic neuropathy, among others.
- (2) Major digestive diseases include NAFLD and other chronic liver diseases, gallbladder and biliary diseases, inflammatory bowel disease, pancreatitis, upper digestive system diseases, among others.

Source: Annual reports published by market players, Expert interview, Literature research, China Insights Consultancy

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Growth Drivers of the Metabolic Disorders and Digestive Diseases Treatment Market

The metabolic disorders and digestive disease market growth has primarily been driven by the following key factors:

- *Expansion of vulnerable population.* Metabolic disorders and digestive diseases may arise congenitally or due to various factors such as stress, fatigue, or dietary habits including alcohol abuse. The global aging trend contributes to a more vulnerable population, as the incidence of most metabolic disorders and digestive diseases tends to increase with age. In 2023, there were approximately 4,934 million diagnosed cases of metabolic disorders and digestive diseases worldwide, and it is anticipated that the patient population will reach 5,539 million by 2030.
- *Strengthened public awareness.* As the economy advances and living standards improve, there is a growing emphasis on healthcare management, leading to an anticipated increase in resources and funding dedicated to the healthcare sector. In this context, improvements to the government medical system and the widespread adoption of routine health examinations have resulted in and are expected to further contribute to a reduction in the oversight of diseases that were previously easily overlooked.
- *Improved understanding of diseases.* The advancement of scientific research in the field of metabolic disorders and digestive diseases has led to and will continue to result in a profound and comprehensive understanding of these conditions. This enhanced understanding forms a robust foundation for the development of new drugs. Databases specific to these diseases are under development for in-depth exploration. For instance, Asian and Caucasian populations are different in demographics, genetic predisposition, lifestyle factors, and healthcare practices. Databases that incorporate Asian and Caucasian cohorts and specific to these diseases could help with drug design that cater to these specific variations. Alongside databases, innovative technologies like drug design platforms and high-throughput drug screening platforms contribute to the realization of these databases. These technologies extract insightful information crucial for guiding drug design and development, streamlining the drug research and development process, and ultimately fostering market growth.

Future Trends of the Metabolic Disorders and Digestive Diseases Treatment Market

The global metabolic disorders and digestive diseases treatment market has demonstrated the following trends:

- *Treatments with long-term effects and better safety profile.* Metabolic disorders and digestive diseases are chronic diseases that often carry the risks of complications. Long-term treatment strategies focus on better safety profiles, ease of using, and higher patients' compliance. Treatments aiming to control symptoms and improve the patient's quality of life over the long term are gradually taking center stage. Patient's compliance to prescribed medications and lifestyle recommendations are the key to success of long-term treatments.

INDUSTRY OVERVIEW

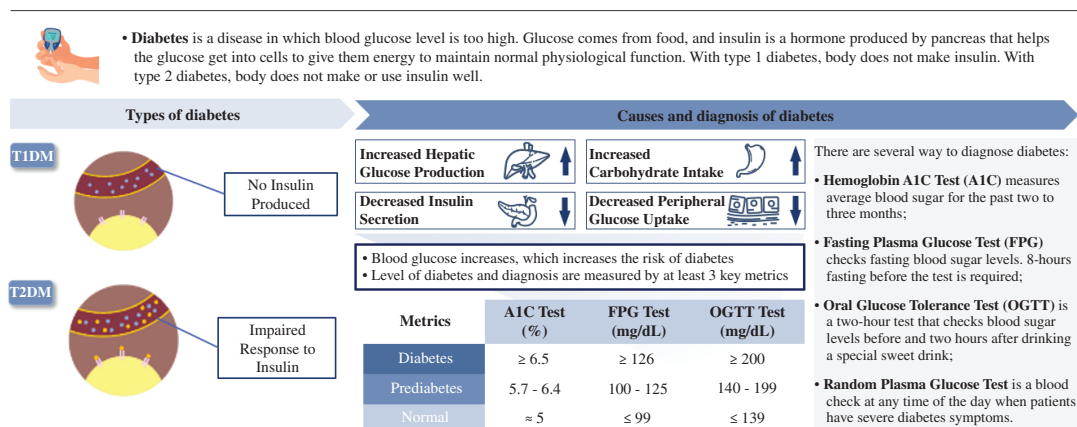
- *Wide recognition of treatment paradigms that could provide systematic metabolic and digestive benefits.* Clinical guidelines stress the vital role of effectively managing risk factors in reducing long-term complications. The “Healthy China Action” (2019-2030) proposes to advance the co-management of high blood pressure, high blood sugar and high blood lipids (三高共管) and standardize the management of such diseases. The specific plan is to achieve a standardized management rate of $\geq 70\%$ for hypertension and diabetes by 2030, and the annual blood lipid testing rate for residents aged 35 and over should be $\geq 35\%$.
- *Increasing market share of domestic products.* Through ongoing research and development efforts, specialized medications including GLP-1 receptor agonists, FXR agonists, DPP-4 inhibitors and SGLT-2 inhibitors have marked a milestone for meeting clinical needs within the realm of metabolic disorders and digestive diseases. Numerous domestic pharmaceutical companies have initiated clinical studies focused on the treatment of metabolic diseases, and recent approvals for certain domestic GLP-1 products signify a growing trend. It is anticipated that an increasing number of domestic products will capture market share in China to replace the imported products.

OVERVIEW OF T2DM DRUG MARKET

Introduction to T2DM

Diabetes is a chronic and metabolic disease in which the blood glucose, or blood sugar, levels are abnormally high. Glucose is derived from the food, and insulin is a hormone secreted by the pancreas that facilitates glucose intake to support cell functions. There are two main types of diabetes. Type 1 diabetes is a lifelong condition where the body’s immune system attacks and destroys the cells that produce insulin. In type 2 diabetes, also referred to as T2DM, the body does not produce enough insulin, or the body’s cells do not react to insulin properly. Consequently, T2DM causes excess sugar to circulate in the bloodstream.

The following chart sets forth the introduction of diabetes mellitus and T2DM.



Abbreviation: T1DM = type 1 diabetes mellitus

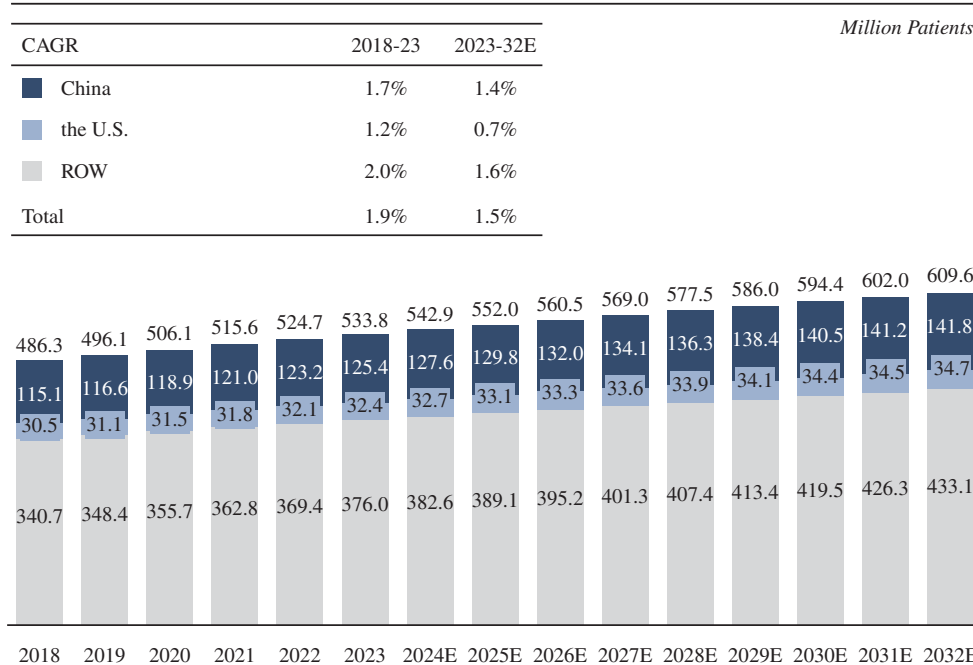
Source: Medscape, American Diabetes Association, China Insights Consultancy

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Prevalence of T2DM

The following chart sets forth the historical and projected prevalence of T2DM globally and in China from 2018 to 2032. According to the International Diabetes Federation, approximately 50% of the adults with T2DM are aware of their condition, being the addressable patient group for this indication.

Prevalence of T2DM, 2018-2032E



Abbreviation: ROW = rest of the world

Note: Data estimated based on (1) T2DM accounts for over 96% of diabetes prevalence globally and (2) countries and territories adopt their individual diagnostic criteria to report epidemiology for prevalence calibration globally, both diagnosed patients and undiagnosed patients are included

Source: WHO, IDF, World Bank, The Lancet, ADA, China Insights Consultancy

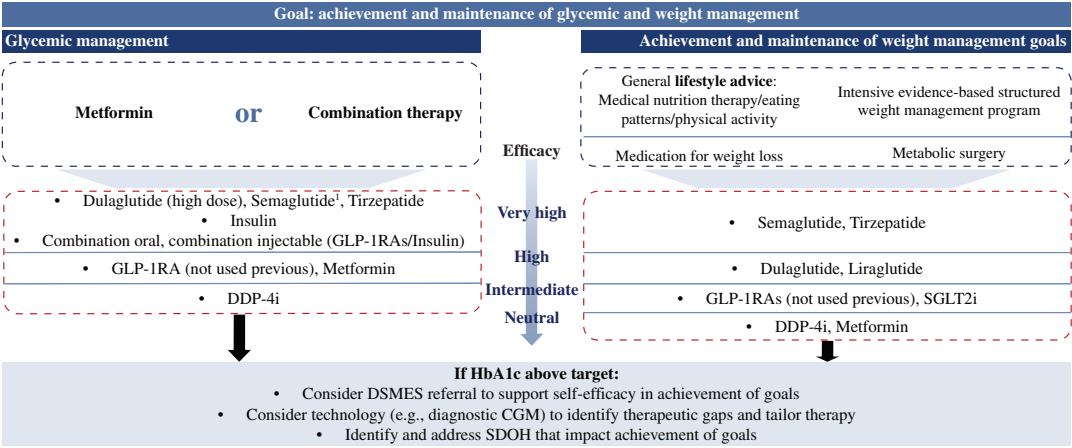
Current Treatment Regimen and Medical Needs

The treatment regimen of T2DM is mainly based on insulin therapy and diabetes medications. If adequate glycemia control cannot be achieved by insulin therapy, metformin is also often used. Other therapeutic options include glucagon-like peptide-1 (“GLP-1”) receptor agonists, thiazolidinediones (“TZDs”), oral sulfonylureas, dipeptidyl peptidase-4 (“DPP-4”) inhibitors, sodium-glucose co-transporter-2 (“SGLT-2”) inhibitors, as well as glucokinase activators (“GKAs”). Traditional Chinese medicines are also used for the treatment of T2DM and its related syndromes clinically. Weight-loss surgeries are sometimes adopted for more severe cases.

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The following chart sets forth the treatment regimen according to American Diabetes Association (“ADA”), which represents the global frontier of T2DM treatment:

Glucose-lowering Therapy in T2DM: General Recommendation from ADA



Abbreviations: CGM = continuous glucose monitoring; SDOH = social determinants of health

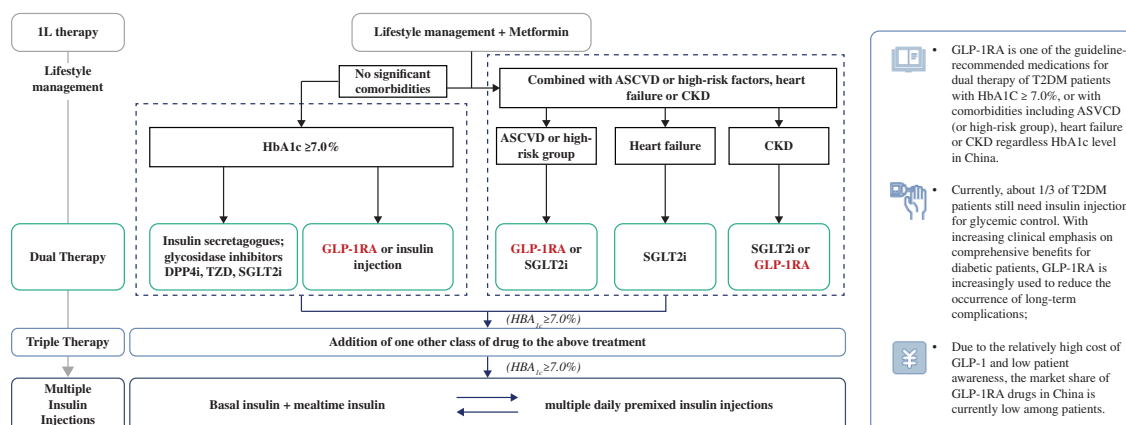
Note:

1. In January 2023, the FDA approved label update for Semaglutide, allowing its use as first-line option for adults with T2DM. This label update removes a previous limitation that stated the medication should not be used as initial therapy for treating patients with T2DM.

Source: ADA, China Insights Consultancy

INDUSTRY OVERVIEW

For the T2DM treatment in China, GLP-1 receptor agonists are one class of the guideline-recommended medications for dual therapy of T2DM patients with high HbA1c and comorbidities in China. In recent years, GLP-1 receptor agonists have been increasingly recommended for the treatment of T2DM as a result of their favored treatment outcomes demonstrated in various clinical studies and real-world applications. The following chart sets forth the treatment regimen according to Chinese Guidelines for the Prevention and Treatment of Type 2 Diabetes (2020 edition):



Abbreviations: HbA1c = glycated hemoglobin; ASCVD = atherosclerosis cardiovascular disease; CKD = chronic kidney disease

Source: Chinese Guidelines for the Prevention and Treatment of Type 2 Diabetes (2020 edition), China Insights Consultancy

China has a vast population base, with the highest number of T2DM patients globally and considerable market potential. However, the treatment of T2DM in China faces a range of challenges. The traditional treatment options often provide limit patient benefits due to their adverse effects. Considering the chronic nature of T2DM, there are higher requirements for medication accessibility, compliance, safety, and comprehensive benefits. The affordability, long-term treatment experience and overall effectiveness is crucial in T2DM management in China. Additionally, there is a more urgent need for clinical solutions in remote areas, with a higher emphasis on the affordability of treatments. GLP-1 receptor agonists have shown considerable potentials to combat such challenges, including good safety and efficacy profiles with fewer adverse effects and prolonged clinical benefits demonstrated in various clinical studies. Additional advantages of certain GLP-1 receptor agonist candidates such as PB-119 also include easy administration, increased patient compliance and better accessibility.

The following table sets forth the eight major classes of drugs commonly used for the treatment of T2DM and their corresponding characteristics. GLP-1 receptor agonists have exhibited extensive advantages over other classes of treatment options, which are often limited in overall clinical benefits due to their unsustainable efficacy, adverse effects and complex risk profiles.

INDUSTRY OVERVIEW

Major T2DM Drug Classes

Drug Class	Mechanism of Action	Blood glucose control	Hypoglycemia risk	Weight loss	CV effects		Renal effects DKD	Common adverse reaction	Benefits	Limitations
					MACE	HF				
GLP-1RA	Active GLP-1 receptor, increase insulin secretion, decrease glucagon secretion Sometimes combined with agonists targeting GCGR and/or GIPR	High to very high	×	High	Benefit	Neutral	Benefit on CVOT measured by Albuminuria	GI effects	Strong blood glucose control with weight loss and cardiovascular benefit	GI effects and costly
Metformin	Decrease in hepatic glucose production; increase in muscle insulin sensitivity by activating AMPK	High	×	Neutral	Potential benefit	Neutral	Neutral	GI effects	Low risk of hypoglycemia, affordable	Limited blood glucose control
TZDs	Bind PPAR-γ decrease insulin resistance and increase glucose utilization	High	×	Gain ¹	Potential benefit: pioglitazone	Increased risk ¹	Neutral	Edema	Increase HDL-C and decrease triglycerides	Increased risk of heart failure, dose-dependent adverse events and weight gain
Sulfonylureas	Stimulates beta cell insulin secretion	High	ψ ¹	Gain ¹	Neutral	Neutral	Neutral	Hypoglycemia	Affordable	Hypoglycemia and weight gain
DPP-4i	Prevent degradation of GLP-1	Intermediate	×	Neutral	Neutral	Neutral (potential risk: saxagliptin)	Neutral	N/A	Minimal risk of hypoglycemia	Modest blood glucose control
SGLT2i	Prevent glucose reabsorption and facilitate its excretion in urine by inhibiting SGLT-2	Intermediate to high	×	Intermediate	Benefits shown by selected SGLT2is	Benefits shown by selected SGLT2is	Benefits shown by selected SGLT2is	Urinary tract infection	Cardiorenal protective	Urinary tract infection
Insulin	Stimulate glycogen synthesis, increase glycolysis and glucose transport, inhibit glycogenolysis, gluconeogenesis, and glucagon secretion	High to very high	ψ ¹	Gain ¹	Neutral	Neutral	Neutral	Hypoglycemia	Effective blood glucose control	Require self-management, hypoglycemia
GKA	Acts as glucose sensor, triggering counter regulatory responses following a change in glucose levels to aid restoration of normoglycemia	High	×	Neutral	N/A	N/A	Neutral	N/A	Oral administration with good blood glucose control	Limited clinical evidence on MACE and HF

Abbreviations: CV = cardiovascular, MACE = major adverse cardiovascular events, HF = heart failure.

Note:

1. Represents unfavorable results

Source: American Diabetes Association, China Insights Consultancy

The following table sets forth the implications and corresponding challenges of existing drug modalities and marketed products to address the treatment regimen of T2DM.

	T2DM
Implications	- Existing drug modalities such as metformin, sulfonylureas, DPP-4 inhibitors, GLP-1 receptor agonists, SGLT2 inhibitors, and insulin offer various options for glycemic control. - These drugs help in managing blood glucose levels, reducing the risk of diabetic complications, and improving quality of life for patients with T2DM.
Challenges	Adherence: Complex dosing regimens and potential side effects may affect patient adherence to treatment. Hypoglycemia: Certain medications, such as sulfonylureas and insulin, can increase the risk of hypoglycemia, which poses a safety concern. Cost: Some newer medications, such as GLP-1 receptor agonists and SGLT2 inhibitors, may be expensive, limiting access for certain patient populations. Weight Gain: Certain medications, such as sulfonylureas and insulin, are associated with weight gain, which can exacerbate obesity in patients with T2DM.

Source: FDA, China Insights Consultancy

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T2DM is often influenced by both lifestyle factors and genetic factors. Certain ethnic groups and population with related family history are shown to exhibit elevated risk of developing T2DM. Specific genes including CALPN10 and TCF7L2 have also been identified to be associated with T2DM. Lifestyle factors including unbalanced diet may cause insulin resistance, and sedentary lifestyle also potentially increases the risk of developing T2DM. Lifestyle interventions for T2DM include both dietary control and regular exercise. Lifestyle interventions are beneficial in multiple manners, and may potentially decrease the risk of developing T2DM or delay the disease progression. However, they also require long-term adherence and higher self-management ability of patients, and it is usually difficult to achieve ideal glycemic control with lifestyle interventions alone. The following table sets forth the features of major prevention and maintenance methods for the treatment of T2DM.

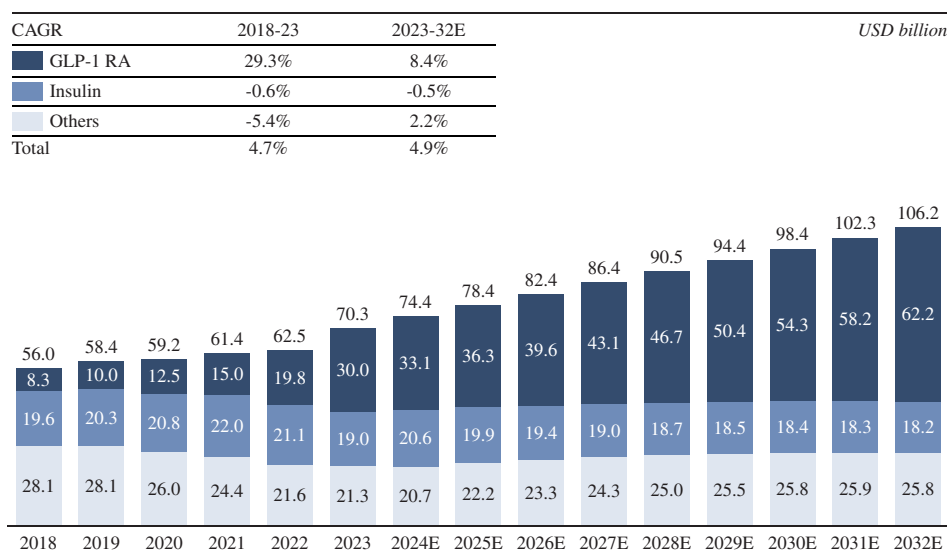
	Healthy diet	Regular exercise	Weight loss	Blood sugar monitoring
T2DM	A balanced diet rich in fruits, vegetables, whole grains, lean proteins, and healthy fats can help prevent and manage T2DM. Emphasizing low glycemic index foods and controlling portion sizes can aid in blood sugar regulation.	Engaging in regular physical activity helps improve insulin sensitivity, regulate blood glucose levels, and manage weight. Both aerobic exercise (e.g., brisk walking, swimming) and resistance training are recommended.	Achieving and maintaining a healthy weight is critical for preventing and managing T2DM. Even modest weight loss (5-10% of body weight) can lead to significant improvements in insulin sensitivity and glycemic control.	Regular monitoring of blood glucose levels, either through self-monitoring or continuous glucose monitoring (CGM), allows individuals with T2DM to track their response to treatment, make informed decisions about diet and exercise, and prevent complications.

Source: FDA, China Insights Consultancy

Market Size of T2DM Drug

In recent years, the development of GLP-1 receptor agonists has revolutionized the treatment of metabolic disorders and particularly T2DM, and such modality has been increasingly taking over the market share for the treatment of T2DM. The following chart sets forth the historical and projected global market size of T2DM drugs from 2018 to 2032, with breakdowns of GLP-1 receptor agonists, insulin products and other drugs, respectively.

Market Size of T2DM Drug Globally, 2018-2032E

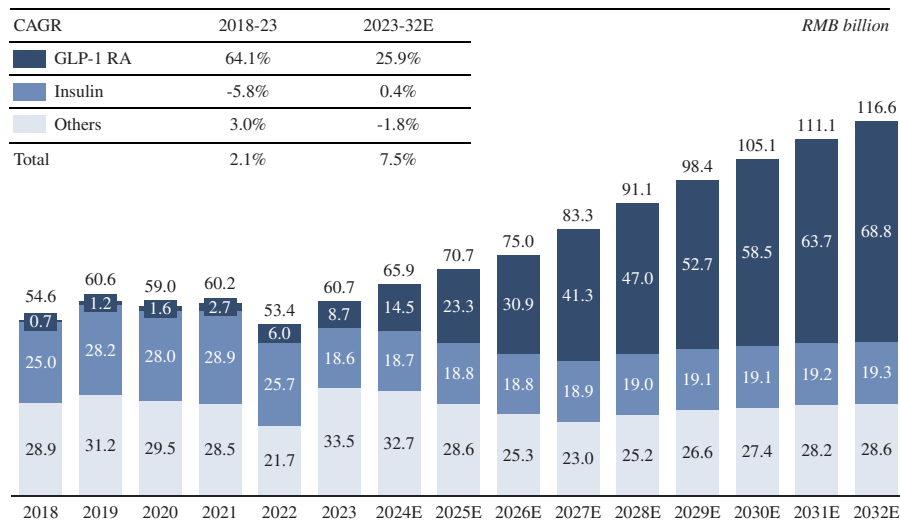


Source: WHO, FDA, IDF, China Insights Consultancy

INDUSTRY OVERVIEW

Penetration of GLP-1 receptor agonists lags behind in China due to its late entry and significant costs. However, given the comprehensive advantages demonstrated by GLP-1 receptor agonists in clinical trials, the Chinese market for GLP-1 receptor agonists is expected to experience an accelerated growth. The following chart sets forth the historical and projected China market size of T2DM drugs from 2018 to 2032, with breakdowns of GLP-1 receptor agonists, insulin products and other drugs, respectively. The drop in market size of T2DM drugs in China in 2022 was mainly due to the allocation of medical resources, patients’ decreased willingness to seek medical treatment, supply chain obstacles and economic impact at the peak of the COVID-19 outbreak in China, resulting in some patients unable to continue diabetes treatment. The growth in market size of GLP-1 receptor agonists for the treatment of T2DM in China during 2022 and 2032 are stimulated by three factors: (1) the diagnosis rate for T2DM in China is expected to rise from approximately 50% to 54%, (2) the treatment rate for T2DM in China is expected to rise from approximately 68% to 71%, and (3) the percentage of T2DM patients being treated with GLP-1 receptor agonists is estimated to rise from approximately 1% to 10%, from 2022 to 2032.

Market Size of T2DM Drug in China, 2018-2032E



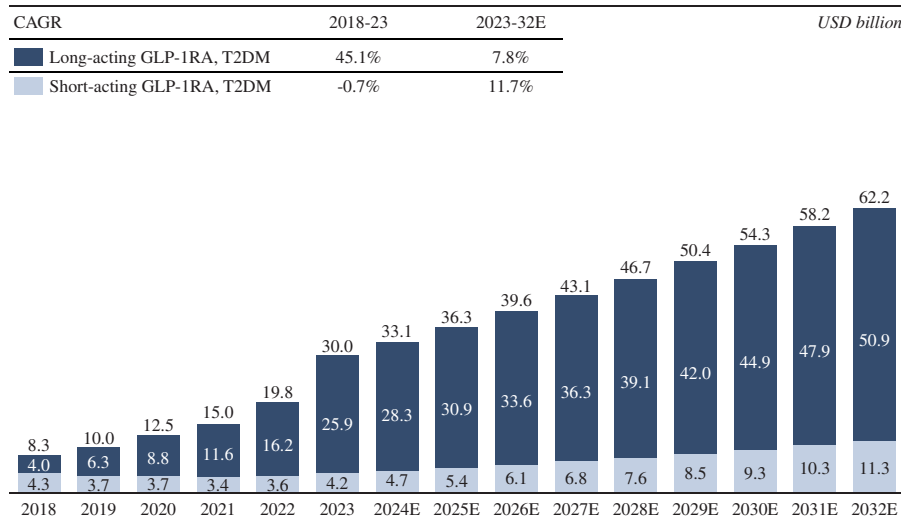
Source: NMPA, JAMA, IDF, periodic reports released by public companies, China Insights Consultancy

Market Size of T2DM Treatment with GLP-1 Receptor Agonists

The *in vivo* half-lives of the first synthetic GLP-1 receptor agonists were relatively short and therefore require dosing as frequent as one or twice daily. Subsequent modifications have been made to produce long-acting GLP-1 receptor agonists with longer *in vivo* half-lives, less frequent dosing and consequently higher compliance for chronic and metabolic disease patients where long-term treatments are often necessary, although subcutaneous short-acting GLP-1 receptor agonists tend to be more affordable. Recent development of short-acting GLP-1 receptor agonists shows potentially higher patient compliance compared to subcutaneous dosage if they are administered orally. The following chart sets forth the historical and projected global market size of T2DM treatment with GLP-1 receptor agonists from 2018 to 2032, with breakdowns of long-acting and short-acting GLP-1 receptor agonists, respectively.

INDUSTRY OVERVIEW

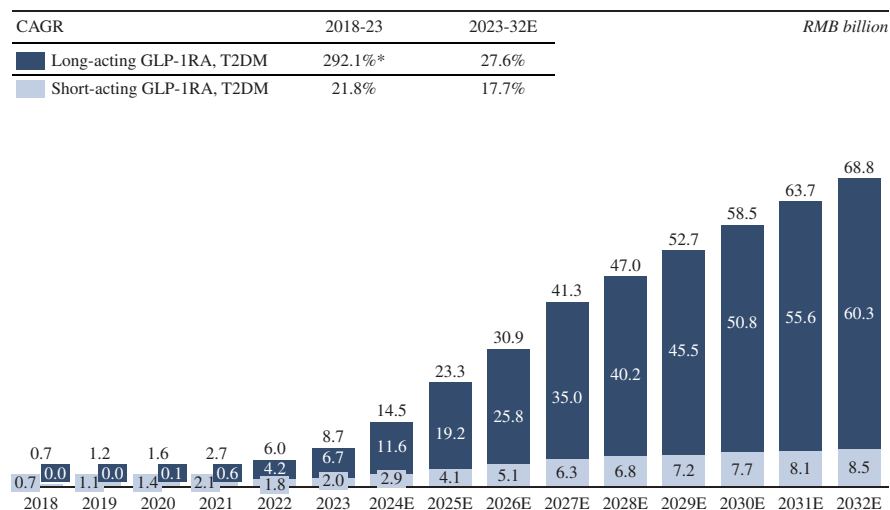
Market Size of T2DM Treatment with GLP-1 Receptor Agonists Globally, 2018-2032E



Source: FDA, ClinicalTrials.gov, periodic reports released by public companies, China Insights Consultancy

In China, with the development of an increasing number of product candidates, it is expected that more than 80% of the market share of GLP-1 receptor agonists for T2DM in China will be occupied by long-acting GLP-1 receptor agonists as of 2032. The following chart sets forth the historical and projected China market size of T2DM treatment with GLP-1 receptor agonists from 2018 to 2032, with breakdowns of long-acting and short-acting GLP-1 receptor agonists, respectively.

Market Size of T2DM Treatment with GLP-1 Receptor Agonists in China, 2018-2032E



* CAGR from 2019-2022

Source: China Insights Consultancy

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Competitive Landscape of T2DM Drug Market

According to the ADA guidelines, the glucose-lowering agents for T2DM include GLP-1 receptor agonists, metformin, DPP-4 inhibitors, SGLT-2 inhibitors, TZDs, insulinotropic agents, insulin and others. As of the Latest Practicable Date, there were over 300 products of metformin, over 50 products of insulin, over 30 products of SGLT-2 inhibitors, and over 40 products of DPP-4 inhibitors approved by the FDA for the treatment of T2DM in the United States. As of the Latest Practicable Date, there was one GLP-1/GIP dual receptor agonist, Tirzepatide, approved for the treatment of T2DM or obesity indications by each of the FDA and the NMPA. The following table sets forth the pipeline of all approved GLP-1 receptor agonists in the United States as of the Latest Practicable Date.

Pipeline of GLP-1 Receptor Agonists Approved in the United States

Drug Name	Brand Name	MoA	Efficacy Length	Indication		Administration	Company	Approval Date
				T2DM	Overweight/Obesity			
Exenatide	Byetta®	GLP-1R	Short-acting	√		s.c.	AstraZeneca	2005/04/28
Liraglutide	Victoza®	GLP-1R	Short-acting	√		s.c.	Novo Nordisk	2010/01/25
	Saxenda®	GLP-1R	Short-acting		√	s.c.		2014/12/23
Exenatide ER	Bydureon®	GLP-1R	Long-acting	√		s.c.	AstraZeneca	2012/01/27
Albiglutide	Tanzeum®	GLP-1R	Long-acting	√		s.c.	GlaxoSmithKline	2014/04/15
Dulaglutide	Trulicity®	GLP-1R	Long-acting	√		s.c.	Eli Lilly	2014/09/18
Lixisenatide	Adlyxin®	GLP-1R	Short-acting	√		s.c.	Sanofi	2016/07/27
Semaglutide	Ozempic®	GLP-1R	Long-acting	√		s.c.	Novo Nordisk	2017/12/05
	Rybelsus®	GLP-1R	Short-acting	√		p.o.		2019/09/20
	Wegovy®	GLP-1R	Long-acting		√	s.c.		2021/06/04

Abbreviations: p.o. = per os; s.c. = subcutaneous

Note: There is one GLP-1/GIP dual receptor agonist, Tirzepatide, that has been approved by the FDA for the treatment of T2DM or obesity indications in the United States, under the brand names Mounjaro and Zepbound, respectively.

Source: FDA, China Insights Consultancy

The companies with approved GLP-1 receptor agonist products listed above are mostly multinational pharmaceutical companies with ample financial resources, robust R&D capabilities and well-established in-house commercialization teams. The Company currently has relatively limited resources and operations in the United States. However, it plans to seek collaboration with a reputable local partner in the United States for the Phase III clinical development of PB-119. For more details, see “Business — Commercialization.”

As of the Latest Practicable Date, there were over 250 products of metformin, over 50 products of insulin, over 35 products of SGLT-2 inhibitors, and over 40 products of DPP-4 inhibitors approved by the NMPA for the treatment of T2DM in China. The following table sets forth the pipeline of all approved GLP-1 receptor agonists for the treatment of T2DM and/or overweight/obesity in China as of the Latest Practicable Date.

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The NRDL was updated in 2024 to include nine new drugs for the treatment of diabetes. Among these newly added diabetes drugs, there are no new GLP-1 drug products. Therefore, the implementation of the updated NRDL does not have a significant impact on the competitive landscape of the GLP-1-based drug products.

Pipeline of GLP-1 Receptor Agonists Approved for the Treatment of T2DM and/or Overweight/Obesity in China

Drug Name	Brand Name	MoA	Efficacy Length	Indication	Administration	NRDL status	NRDL price (RMB/unit)	Monthly Spending (RMB) ^a	Company	Approval Date
Supaglutide	怡诺轻/Diabegone	GLP-1R	Long-acting	T2DM	s.c.	N/A	N/A	N/A	Innogen	2025/1/26
Exenatide	/	GLP-1R	Short-acting	T2DM	s.c.	N/A	N/A	N/A	Hybio Pharmaceutical	2024/9/10
Liraglutide ¹	贝乐林	GLP-1R	Short-acting	T2DM	s.c.	No	N/A ²	N/A	Chia Tai Tianqing	2024/6/25
Semaglutide	诺和盈/Wegovy	GLP-1R	Long-acting	Overweight/Obesity	s.c.	No	N/A ²	N/A	Novo Nordisk	2024/6/25
Semaglutide	诺和忻/Rybelsus	GLP-1R	Short-acting	T2DM	p.o.	No	N/A ²	N/A	Novo Nordisk	2024/1/26
Liraglutide ¹	统博力	GLP-1R	Short-acting	T2DM	s.c.	Category B	268/(18mg:3ml)	~750	Tonghua Dongbao	2023/11/28
Beinaglutide	菲盟美	GLP-1R	Short-acting	Overweight/Obesity	s.c.	No	N/A ³	N/A	Shanghai Benemac	2023/7/28
Liraglutide ¹	利鲁平	GLP-1R	Short-acting	Overweight/Obesity	s.c.	No	N/A ³	N/A	Jiuyuan Gene	2023/7/4
Liraglutide ¹	利鲁平	GLP-1R	Short-acting	T2DM	s.c.	Category B	~300/(18mg:3ml)	~840	Jiuyuan Gene	2023/3/28
Exenatide ⁴	/	GLP-1R	Short-acting	T2DM	s.c.	Category B	407.83/(0.25mg:2.4ml)	~815	Qinghai Chenfei	2022/7/29
Beinaglutide	道生泰	GLP-1R	Short-acting	T2DM	s.c.	Category B	191/(4.2mg:2.1ml)	~764	Shanghai Benemac	2021/10/28
Semaglutide	诺和泰/Ozempic	GLP-1R	Long-acting	T2DM	s.c.	Category B	478.8/(2mg:1.5ml)	~957	Novo Nordisk	2021/4/27
Liraglutide	诺和力/Victoza	GLP-1R	Short-acting	T2DM	s.c.	Category B	339/(18mg:3ml)	~1,148	Novo Nordisk	2011/10/9
Polyethylene Glycol Loxenatide	孚来美	GLP-1R	Long-acting	T2DM	s.c.	Category B	187/(0.2mg:0.5ml)	~748	Hansoh	2019/5/5
Dulaglutide	度易达/Trulicity	GLP-1R	Long-acting	T2DM	s.c.	Category B	149/(1.5mg:0.5ml)	~596	Eli Lilly	2019/2/22
Exenatide Microspheres	百达扬/Bydureon	GLP-1R	Long-acting	T2DM	s.c.	Category B	496.25/(2 mg:0.65ml)	~1,985	AstraZeneca	2017/12/28
Lixisenatide	利时敏/Adlyxin	GLP-1R	Short-acting	T2DM	s.c.	Category B	157.65/(150µg)	~588	Sanofi	2017/9/29
Exenatide	百泌达/Byetta	GLP-1R	Short-acting	T2DM	s.c.	Category B	240/(5µg:1.2ml)	~815	AstraZeneca	2009/8/1

Notes:

1. Generic or biosimilar product
2. Marketed price not yet available
3. Not yet included in NRDL
4. Monthly spending estimated on recommended dosage indicated on drug label for 4 weeks
5. GLP-1 receptor agonists target GLP-1 receptors in the brain, cerebral blood vessels, pancreas, heart, gastrointestinal tract, adipose tissue, kidney and muscles, and consequently affect a variety of organs and physiological processes
6. There is one GLP-1/GIP dual receptor agonist, Tirzepatide, that has been approved by the NMPA for the treatment of T2DM or obesity indications in China

Source: NMPA, Chinese Journal of Modern Applied Pharmacy, National Reimbursement Drug List, NHSA, drug labels, China Insights Consultancy

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As of the Latest Practicable Date, there were two combination therapies of insulin and GLP-1 receptor agonist approved in China and the United States, both were approved for the treatment of T2DM. The following table sets forth the details of such therapies.

Pipeline of Insulin GLP-1 Receptor Agonist Combination Therapies Approved in China and the United States

Drug Name	Brand Name	MoA	Efficacy Length	Administration	Company	Approval Date FDA	Approval Date NMPA	NRDL status
iDegrLira	Xulophy/诺和盈	Insulin degludec/Liraglutide	Long-acting	s.c.	Novo Nordisk	2016/11/21	2021/10/28	Category B
iGlarLixi	Soliqua/赛益宁	Insulin glargine/Lixisenatide	Short-acting	s.c.	Sanofi	2016/11/21	2023/1/13	Category B

Source: FDA, NMPA, China Insights Consultancy

According to CIC, a network meta-analysis published on the British Medical Journal (volume 384, January 2024) studied the results of over 30 thousand participants with T2DM in more than 70 eligible clinical trials, and all 15 GLP-1 receptor agonists covered by the analysis effectively lowered HbA1c and fasting plasma glucose concentrations. Such GLP-1 receptor agonists were also shown with benefits for weight management for patients with T2DM. Another network meta-analysis published on Medicine (volume 102, July 2023) which studied the results of over six thousand participants with T2DM showed that GLP-1 receptor agonists were generally well-tolerated in the trials examined, with common adverse events (such as gastrointestinal disturbances) mostly of mild to moderate in severity, and were generally self-manageable.

The following tables set forth the comparisons of PB-119 with major approved GLP-1 receptor agonists as of the Latest Practicable Date. Such conclusions are based on parallel comparisons of PB-119 clinical trial results with results from the published clinical trials of these products rather than head-to-head comparisons.

Comparison between PB-119 and marketed long-acting GLP-1 products

Drug name (generic) ¹		PB-119	Semaglutide	Polyethylene Glycol Loxenatide	Dulaglutide	Exenatide-ER
Efficacy length		Long-acting	Long-acting	Long-acting	Long-acting	Long-acting
Dose frequency		Once a week	Once a week	Once a week	Once a week	Once a week
Half life		2~3 days	~7 days	4~5 days	~5 days	One-week sustained release
Dose titration		No	Yes	No	Yes	No
T2DM	Pricing in China	N/A	478.8 RMB (2mg:1.5ml)	187 RMB (0.2mg:0.5ml)	149 RMB (1.5mg:0.5ml)	496.25 RMB (2mg:0.65ml)
	Monthly spending ²	N/A	~957 RMB	~748 RMB	~596 RMB	~1,985 RMB
	NMPA approval date	N/A	诺和泰/Ozempic 2021/4/27	孚来美 2019/5/5	度易達/Trulicity 2019/2/22	百達揚/Bydureon 2017/12/28
Overweight/Obesity	Expected Pricing in China	N/A	N/A ⁴	NM ³	NM ³	NM ³
	NMPA approval date	N/A	诺和盈/Wegovy 2024/6/25	NM ³	NM ³	NM ³

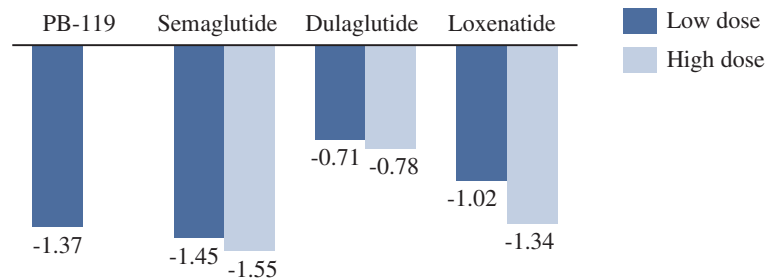
INDUSTRY OVERVIEW

Notes:

1. Other long-acting GLP-1 receptor agonists include albiglutide. Albiglutide is a GLP-1 receptor agonist used for the treatment of T2DM. It was originally developed by GlaxoSmithKline (GSK) and was approved by the FDA in 2014. By the end of 2017, GSK announced that it would cease all further research, development, manufacturing, and sales activities for albiglutide, effectively withdrawing it from the market
2. Monthly spending estimated on recommended dosage indicated on drug labels for 4 weeks
3. NM = Not Meaningful, no trials of overweight/obesity of underlying products registered at CDE
4. Not yet available

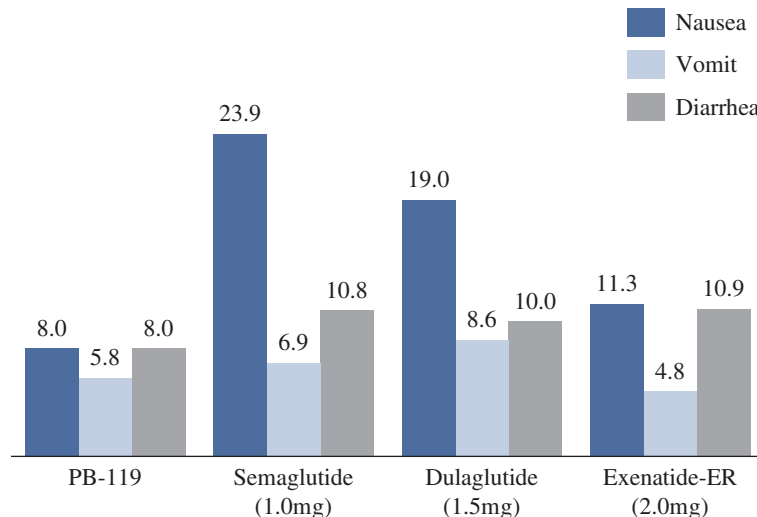
Source: ClinicalTrials.gov, China Insights Consultancy

Decrease in HbA1c as primary clinical endpoint (%)



Note: The time period of primary clinical endpoints of PB-119, Semaglutide, Dulaglutide and Loxenatide was 24 weeks, 30 weeks, 26 weeks and 24 weeks, respectively. The primary efficacy endpoints of placebo-controlled clinical trials for T2DM medications are usually evaluated at the end of a treatment period of approximately 24 to 30 weeks, and sometimes an extension period until 52 weeks is also included to gather additional information from the clinical trials.

Major GI disorders occurrence (%)



Note: This conclusion is based on parallel comparisons of PB-119 clinical trial results with results from these published clinical trials rather than head-to-head comparisons. Cross clinical trial comparison based on published clinical trials rather than head-to-head comparisons may involve risks and may not be representative of all the relevant clinical data.

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HbA1c measures the average blood sugar level over the past few months, and its level is adopted commonly as primary efficacy endpoint by clinical trials for T2DM medications including GLP-1 receptor agonists. For instance, the aforementioned clinical trial results illustrated that the marketed long-acting GLP-1 receptor agonists that are widely adopted by physicians and patients decreased the HbA1c level by 0.71% to 1.55% during the treatment period ranging from 24 to 30 weeks, while the low dose of PB-119 was shown to decrease the HbA1c level by 1.37% during the 24-week treatment period, which falls closer to the upper boundary within the comparative range. On the other hand, GI disorders, including nausea, vomit and diarrhea occurrences are the major adverse event metrics when evaluating the safety profile of GLP-1 receptor agonists in clinical trials. For instance, comparing the aforementioned clinical trial results, PB-119 also showed a favorable safety profile in terms of GI effects.

As of the Latest Practicable Date, there were more than 25 GLP-1 receptor agonist candidates undergoing clinical trials for the treatment of T2DM in the United States. In September 2023, the NMPA accepted the NDA of PB-119 for the treatment of T2DM in China, making it one of the earliest clinical-stage long-acting GLP-1 receptor agonists in China. As of the Latest Practicable Date, there were more than 25 GLP-1 receptor agonist candidates undergoing clinical trials for the treatment of T2DM in China, including 20 GLP-1 receptor agonist candidates with accepted NDAs or undergoing Phase III clinical trials, as of the same date. The following table sets forth the pipeline of such advanced-stage product candidates in China. GLP-1 receptor agonists could also be divided into peptide-based and small molecule GLP-1 receptor agonists. As compared to peptide-based GLP-1 receptor agonists, small molecule GLP-1 receptor agonists are generally short-acting products that are administered orally. Among the pipelines set forth below, Orforglipron, Noiglutide, HRS-7535 and rExenatide-4 are short-acting candidates while the other pipelines are long-acting candidates.

Pipeline of GLP-1 Receptor Agonists for T2DM with Accepted NDA or Undergoing Phase III Clinical Trial in China

Candidate	MoA	Company	Indications	Administration	Phase	First Posted Date ¹	Trial Number ²	Competent authority
PB-119	GLP-1R	PegBio	T2DM	s.c.	NDA	2023/9/26	CTR20201492	NMPA
Liraglutide biosimilar	GLP-1R	Chenan; Paijin	T2DM	s.c.	NDA	2024/12/3	CTR20210173	NMPA
Ecnoglutide	GLP-1R	Hangzhou Sciwind	T2DM	s.c.	NDA	2024/11/23	CTR20223156	NMPA
Semaglutide	GLP-1R	Qilu Pharmaceutical	T2DM	s.c.	NDA	2024/9/15	CTR20230841	NMPA
Semaglutide biosimilar	GLP-1R	Livzon Group	T2DM	s.c.	NDA	2024/6/16	CTR20222962	NMPA
CJC-1134-PC	GLP-1R	Hebei Changshan; Hbcsbio	T2DM	s.c.	NDA	2024/4/24	CTR20222496	NMPA
HDG1901	GLP-1R	Hangzhou Jiuyuan Gene Engineering	T2DM	s.c.	NDA	2024/4/3	CTR20232286	NMPA
Liraglutide biosimilar	GLP-1R	Zhuhai United	T2DM	s.c.	NDA	2023/8/22	CTR20200348	NMPA
GZR-18	GLP-1R	Ganlee	T2DM	s.c.	III	2024/12/26	CTR20244787	NMPA
Semaglutide	GLP-1R	Sinopep Allsino	T2DM	s.c.	III	2024/11/28	CTR20244501	NMPA
Noiglutide	GLP-1R	Jiangsu Hengrui	T2DM	s.c.	III	2024/10/15	CTR20243773	NMPA
HRS-7535	GLP-1R	Shandong Suncadia	T2DM	p.o.	III	2024/9/13	CTR20243398	NMPA
Semaglutide biosimilar	GLP-1R	Zhuhai United	T2DM	s.c.	III	2024/9/10	CTR20243310	NMPA
Semaglutide	GLP-1R	China Resources Double-Crane	T2DM	s.c.	III	2024/7/18	CTR20242569	NMPA
JY09	GLP-1R	Beijing Dongfang Biotech; Beijing Jingyitaixiang	T2DM	s.c.	III	2024/4/17	CTR20240355	NMPA
TG103	GLP-1R	CSPC Baike (Shandong) Biopharmaceutical	T2DM	s.c.	III	2024/2/26	CTR20240429	NMPA
Orforglipron	GLP-1R	Eli Lilly	T2DM	p.o.	III	2023/11/2	CTR20233528	NMPA
Recombinant GLP-1RA	GLP-1R	Beijing Lepu	T2DM	s.c.	III	2023/1/29	CTR20230029	NMPA
GMA102	GLP-1R	Hongyun Huaning	T2DM	s.c.	III	2022/10/11	CTR20222558	NMPA
rExenatide-4	GLP-1R	CSPC Zhongqi	T2DM	s.c.	III	2017/11/27	CTR20170495	NMPA

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Notes:

- denotes the date when CDE announces it receives the NDA for applicable pipelines
- denotes the Phase III trial number

Source: CDE, China Insights Consultancy

As of the Latest Practicable Date, there were 15 candidates undergoing Phase III clinical trials for the treatment of T2DM in the United States. The following table sets forth the pipeline of such candidates. Among the pipelines, the effective duration of CMG190303 is unknown, Orforglipron, Noiiiglutide, Insulin Degludec/Liraglutide and MSDC-0602K are short-acting candidates while the other pipelines are long-acting candidates.

Pipeline of Candidates for T2DM Undergoing Phase III Clinical Trial in the United States

Candidate	MoA	Company	Indications	Administration	Phase	First Posted Date	Trial Number	Competent authority
CagriSema	AMY3; GLP-1R	Novo Nordisk	T2DM	s.c.	III	2024/3/21	NCT06323174	FDA
CMG190303	SGLT2; HMGCR	Cmg Pharma	T2DM	N/A	III	2025/1/13	NCT06772168	FDA
GZR-18	GLP-1R	Ganlee	T2DM	s.c.	III	2025/1/15	NCT06777238	FDA
HGD1901	GLP-1R	Hangzhou Zhongmei Huadong	T2DM	s.c.	III	2024/12/10	NCT06739044	FDA
BGM-0504	GIPR; GLP-1R	BrightGene	T2DM	s.c.	III	2024/12/4	NCT06716203	FDA
HRS-7535	GLP1R	Shandong Suncadia	T2DM	p.o.	III	2024/11/4	NCT06672172	FDA
HRS-9531	GIPR; GLP-1R	Shandong Suncadia	T2DM	s.c.	III	2024/10/18	NCT06649344	FDA
Noiiiglutide	GLP1R	Jiangsu Hengrui	T2DM	s.c.	III	2024/10/21	NCT06649773	FDA
Insulin Degludec/ Liraglutide	INSR; GLP-1R	Tonghua Dongbao	T2DM	s.c.	III	2024/8/19	NCT06559722	FDA
IcoSema	INSR; GLP1R	Novo Nordisk	T2DM	s.c.	III	2024/2/21	NCT06269107	FDA
Retatrutide	GIPR; GLP-1R; GCGR	Eli Lilly	T2DM	s.c.	III	2024/2/15	NCT06260722	FDA
TG103	GLP-1R	CSPC Baike (Shandong) Biopharmaceutical	T2DM	s.c.	III	2024/2/14	NCT06258148	FDA
Survodutide	GLP-1R; GCGR	Boehringer Ingelheim	T2DM	s.c.	III	2023/10/4	NCT06066528	FDA
Orforglipron	GLP-1R	Eli Lilly	T2DM	p.o.	III	2023/8/24	NCT06010004	FDA
MSDC-0602K	MPC	Cirius Therapeutics Inc	T2DM	p.o.	III	2019/5/31	NCT03970031	FDA

Source: ClinicalTrials.gov, China Insights Consultancy

INDUSTRY OVERVIEW

As of the Latest Practicable Date, there were 14 candidates for the treatment of T2DM with accepted NDAs by the NMPA, and there were more than 35 candidates undergoing Phase III clinical trials in China, as of the same date. The following table sets forth the pipeline of NDA-accepted candidates for the treatment of T2DM in China. Among the pipelines, HEC-44616, Brenzavvy, HR20031, ORMD-0801, are short-acting candidates while the other pipelines are long-acting candidates.

Pipeline of Candidates for T2DM with Accepted NDA in China

Candidate	MoA	Company	Indications	Administration	Phase	First Posted Date ²	Competent authority
PB-119	GLP-1R	PegBio	T2DM	s.c.	NDA	2023/9/26	NMPA
IcoSema	INSR; GLP-1R	Novo Nordisk	T2DM	s.c.	NDA	2024/12/7	NMPA
Liraglutide biosimilar	GLP-1R	Chenan; Paijin	T2DM	s.c.	NDA	2024/12/3	NMPA
Ecnoglutide	GLP-1R	Hangzhou Sciwind	T2DM	s.c.	NDA	2024/11/23	NMPA
Semaglutide	GLP-1R	Qilu Pharmaceutical	T2DM	s.c.	NDA	2024/9/15	NMPA
IBI362	GCGR; GLP-1R	Innovent	T2DM	s.c.	NDA	2024/8/1	NMPA
Semaglutide ¹	GLP-1R	Livzon Group	T2DM	s.c.	NDA	2024/6/16	NMPA
CJC-1134-PC	GLP-1R	Hebei Changshan; Hbcsbio	T2DM	s.c.	NDA	2024/4/24	NMPA
HDG1901 ¹	GLP-1R	Hangzhou Jiuyuan Gene Engineering	T2DM	s.c.	NDA	2024/4/3	NMPA
HEC-44616	SGLT2	HEC Pharm	T2DM	p.o.	NDA	2024/1/11	NMPA
Brenzavvy	SGLT2	Newsocara Biopharma; Piramal Healthcare; TheracosBio	T2DM	p.o.	NDA	2024/1/4	NMPA
HR20031 ⁴	DPP-4; PRKAB-1; SGLT-2	Shengdi Medical	T2DM	p.o.	NDA	2023/11/11	NMPA
Liraglutide ¹	GLP-1R	Zhuhai United	T2DM	s.c.	NDA	2023/8/22	NMPA
ORMD-0801	INSR ³	Oramed Ltd	T2DM	p.o.	NDA	2023/4/25	NMPA

Notes:

1. Biosimilar or generic candidates
2. denotes the date when CDE announces it receives the NDA
3. INSR = insulin receptor
4. compound formulation of SGLT-2i, DPP-4i and metformin

Source: CDE, China Insights Consultancy

Growth drivers and Future Trends of T2DM Drug Market

The T2DM drug market growth has primarily been driven by the following key factors:

- *Development of long-acting GLP-1 receptor agonists.* In recent years, long-acting GLP-1 receptor agonists with longer *in vivo* half-lives and less frequent dosing requirements are being increasingly developed. Such favorable properties are expected to bring enhanced overall clinical benefits for T2DM patients that usually require long-term treatments. Both globally and in China, it is expected that more than 80% of the market share of GLP-1 receptor agonists for the treatment of T2DM will be occupied by long-acting GLP-1 receptor agonists as of 2032.

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- *Growing prevalence of T2DM.* The prevalence of patients with T2DM in China is growing due to various factors including unhealthy diet, sedentary lifestyle, lack of exercise, genetics and other disease complications such as obesity. Additionally, patients from rural regions in China face more challenges in terms of access to adequate healthcare with limited preventive diagnostics such as routine screenings and early detection programs, which lead to a lower control rate of blood glucose and increased burden of T2DM. Compared to urban residents, it is expected that the potential reduction in mortality and the improvement in quality-adjusted life years for rural residents from T2DM control and treatment will be greater. If 70% of diabetes patients achieve optimal control, the number of deaths before the age of 70 is expected to decrease by 7.1% over the next 10 years, leading to a direct reduction of 14.9% in healthcare costs. Outside China, the prevalence of T2DM also demonstrates a continued rise across all regions of the world. According to CIC, the prevalence of T2DM in the United States is expected to increase from 32.4 million in 2023 to 34.7 million in 2032. There are also concerning trends of rising prevalence and medical needs in lower-income countries according to the International Diabetes Federation, which are expected to be the major demographic drivers of the global T2DM market in the future.
- *Favorable policies towards chronic disease management.* The Healthy China Initiative (2019-2030) serves as a strategic blueprint for advancing public health in China and represents an innovative public policy initiative. Within this comprehensive framework, the Diabetes Prevention and Control Action stands out as one of the key measures among the actions targeting the prevention and control of chronic diseases outlined in the Healthy China Initiative (2019-2030). The Medium-to-Long Term Plan of China for the Prevention and Treatment of Chronic Diseases (2017-2025) also emphasizes the enhancement of health education to improve national health quality, the promotion of early diagnosis, and coordination between medical prevention and treatment to achieve comprehensive healthcare management.
- *Improved patient compliance and efficacy resilience.* T2DM is a major chronic disease that requires consistent medical attention and long-term or even lifetime disease management. A variety of drugs in T2DM treatment paradigm face challenges such as loss of efficacy over time that leads to lower disease control rate and suboptimal long-term patient adherence due to adverse effects or inconvenience of use. T2DM management paradigm awaits treatment options that could address these clinical needs and help achieve better clinical outcome. As innovative drugs are being developed, drugs that could simultaneously provide superior safety profile and long-lasting blood sugar control would improve patient compliance and efficacy resilience and drive substantial growth of the T2DM drug market.

INDUSTRY OVERVIEW

The T2DM drug market has demonstrated the following trends:

- *Increasing market share of GLP-1 receptor agonists.* In recent years, the development of GLP-1 receptor agonists has revolutionized the treatment of metabolic disorders and particularly T2DM, and such modality has been increasingly taking over the market share for the treatment of T2DM. It is expected that more than 60% of the market share for T2DM both in China and globally will be occupied by GLP-1 receptor agonists as of 2032, respectively.
- *Comprehensive benefits of T2DM management paradigm.* Clinical guidelines stress the vital role of effectively managing diabetes-related risk factors in reducing long-term complications. Integrating medications and lifestyle interventions are recommended to comprehensively address various risk factors such as cardiovascular health, obesity, hypertension, and high cholesterol. This approach optimizes metabolic control and yields the exemplified clinical outcomes. Medications that alone could bring a wide range of benefits would also be much favored by physicians and patients going forward.
- *Patient-centered strategy for the management of T2DM.* In contrast to the historical disproportional emphasis on the singular blood glucose indicator, HbA1c, there is now an increased focus on complications and weight management in the context of T2DM. Clinical guidelines for T2DM underscore comprehensive control objectives, emphasizing the necessity for more personalized treatment plans tailored to individual conditions. Consequently, patient-centered diagnostic and therapeutic strategies for T2DM are anticipated to emerge as a future trend.
- *Pancreatic islet function restoration and alleviation of T2DM.* Clinical healthcare objectives have evolved to prioritize enhancing the quality of life and achieving favorable prognoses for patients, with the goal of alleviating societal burdens and augmenting socioeconomic benefits. GLP-1 receptor agonists have demonstrated effectiveness in reducing blood glucose levels without elevating the risk of hypoglycemia. Moreover, these medications exhibit a protective impact on pancreatic β -cell function and contribute to a significant reduction in body weight. Consequently, GLP-1 receptor agonists are anticipated to emerge as the future trend in T2DM drug market.
- *Increasing patient accessibility of T2DM medications.* Considering the chronic nature of T2DM, medication accessibility is crucial for patients to receive stable treatments. The affordability, long-term treatment experience and overall effectiveness is especially vital in T2DM management in China. Going forward, treatment options available to the vast majority of T2DM patients are likely to occupy more market share and benefit from the huge market potential.

INDUSTRY OVERVIEW

Entry Barriers of T2DM Drug Market

The T2DM drug market has the following entry barriers:

- *Stringent regulatory requirements.* Meeting regulatory standards for safety, efficacy and quality presents a technical challenge necessitating thorough testing and documentation at every stage of T2DM drug development. China imposes specific clinical trial requirements, mandating companies intending to develop T2DM drugs to conduct trials demonstrating product safety and efficacy within the Chinese population.
- *Diversity of current T2DM drugs.* There are a number of drugs being used for the management of T2DM. Certain recommended medications may have already secured significant market share, posing challenges for new products attempting to establish themselves. Competition within the generic drug market is also intense. Newcomers must distinguish their products and demonstrate superior efficacy or safety to effectively compete.
- *Brand awareness.* The diabetes drug market in China is characterized by intense competition, with numerous competing domestic and international pharmaceutical companies. Successfully entering this market requires strong market positioning and effective brand promotion strategies to differentiate products and attract both patients and physicians.

OVERVIEW OF OBESITY DRUG MARKET

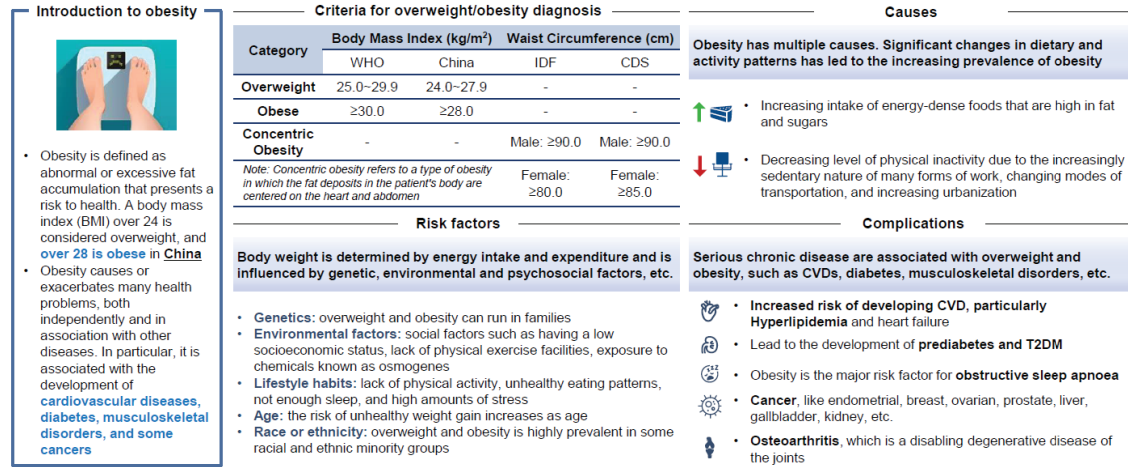
Introduction to Obesity

Obesity is a chronic health condition characterized by abnormal or excessive fat accumulation that poses comprehensive health concerns, such as cardiovascular diseases, T2DM, musculoskeletal disorders, and carcinogenesis. Body mass index (“**BMI**”) serves as a common measure of body fat based on height and weight. According to standards recommended by World Health Organization (“**WHO**”), BMI values exceeding 25 kg/m² indicate overweight, and those exceeding 30 kg/m² indicate obesity. In China, it is recommended that overweight is indicated by BMI values over 24 kg/m² and obesity is indicated by BMI values over 28 kg/m². Individuals exceeding the corresponding BMI levels are considered among the addressable patient group for this indication.

Obesity can lead to or exacerbate various health complications, either independently or in conjunction with other diseases. Specifically, obesity heightens the risk of CVDs, particularly heart failure and coronary heart disease, as well as osteoarthritis, a debilitating joint condition. Additionally, it is associated with prediabetes, T2DM and certain cancers.

INDUSTRY OVERVIEW

The following chart summarizes certain key information about obesity:



Source: WHO, National Institutes of Health, International Diabetes Federation, China Diabetes Society, China Insights Consultancy

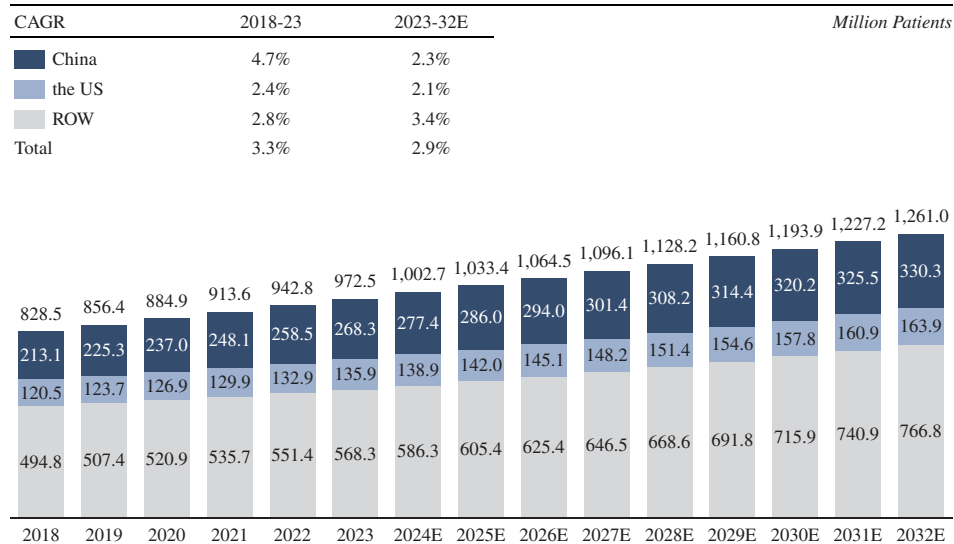
Prevalence of Obesity

Obesity has been a rising public health concern globally with relevant patient group expected to exceed one billion in size by the end of 2024. China has the largest obesity patient population in the world, and the number of obesity patients in China is expected to grow at a higher rate than that of more developed countries, such as the United States.

INDUSTRY OVERVIEW

The following chart sets forth the historical and projected prevalence of obesity globally and in China from 2018 to 2032.

Prevalence of Obesity, 2018-2032E



Source: World Obesity Atlas, WHO, China Insights Consultancy

Current Treatment Regimen and Medical Needs

Globally, the treatment regimen for obesity is generally consistent across international guidelines. The American Association of Clinical Endocrinology (“**AACE**”) and American College of Endocrinology (“**ACE**”) separately recommend a treatment framework that mainly consist of lifestyle intervention, maintenance medication, and surgical intervention, depending on the disease stage. Before the commercialization of GLP-1 receptor agonists, there were several traditional medications approved for the treatment of obesity. However, such medications are often limited in efficacy with potential severe adverse effects. The development of GLP-1 receptor agonists and the increasing number of such approved drugs has been shifting the standard of care for obesity patients globally and in China.

INDUSTRY OVERVIEW

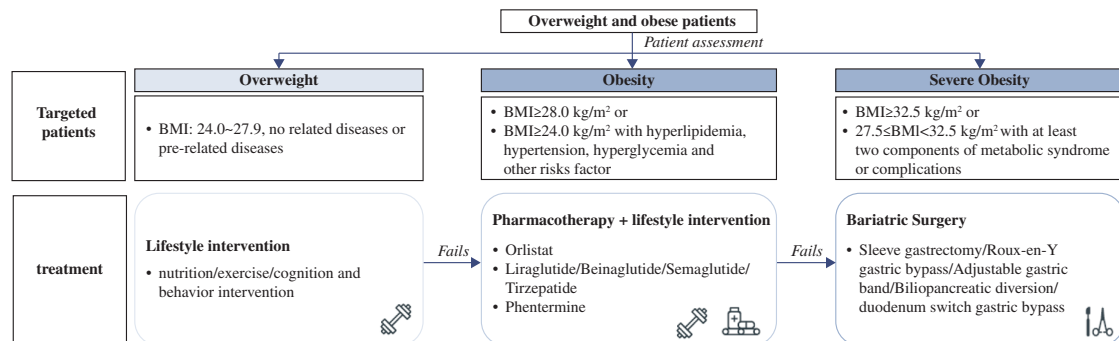
The following table sets forth the treatment regimen according to AACE/ACE treatment framework:

Diagnosis		Staging and treatment	
BMI, kg/m ² Anthropometric component	Clinical component	Disease stage	Suggested therapy (based on clinical judgement)
<25 <23 in patients of certain ethnicities; waist circumference below regional/ethnic cutoffs	Evaluate for presence or absence of adiposity- related complications and severity of complication	Normal weight (no obesity)	• Healthy lifestyle: Healthy meal plan/physical activity
25-29.9 23-24.9 in patients of certain ethnicities	• Metabolic syndrome • Prediabetes • Type 2 diabetes • Dyslipidemia • Hypertension • Cardiovascular disease • Nonalcoholic fatty liver disease • Polycystic ovary syndrome • Infertility (women) • Hypogonadism (men) • Obstructive sleep apnea • Asthma/reactive airway disease • Osteoarthritis • Urinary stress incontinence • Gastroesophageal reflux disease • Mental depression	Overweight stage 0 (no complications)	• Lifestyle therapy: Reduced-calorie healthy meal plan/ physical activity/behavioral interventions
≥30 ≥25 in patients of certain ethnicities		Obesity stage 0 (no complications)	• Lifestyle therapy: Reduced-calorie healthy meal plan/ physical activity/behavioral interventions • Anti-obesity medications: Consider if lifestyle therapy fails to prevent progressive weight gain (BMI≥27)
≥25 ≥23 in patients of certain ethnicities		Obesity stage 1 (1 or more mild to moderate complications)	• Lifestyle therapy: Reduced-calorie healthy meal plan/ physical activity/behavioral interventions • Anti-obesity medications: Consider if lifestyle therapy fails to achieve therapeutic target or imitate concurrently with lifestyle therapy (BMI≥27)
≥25 ≥23 in patients of certain ethnicities		Obesity stage 2 (at least 2 severe complications)	• Lifestyle therapy: Reduced-calorie healthy meal plan/ physical activity/behavioral interventions • Anti-obesity medications: Initiate concurrently with lifestyle therapy (BMI≥27); consider bariatric surgery (BMI≥35)

Source: AACE, ACE, China Insights Consultancy

In China, management of overweight and obesity primarily involves comprehensive lifestyle interventions, medications, and in severe cases, surgical treatments. However, there are only limited medications currently approved for the treatment of obesity, often with significant safety concerns for long-term usage and limited overall clinical benefits. Consequently, there are considerable medical needs for the treatment of obesity in China. The following chart demonstrates the current treatment options for obesity patients with different severities in China.

Treatment Options for Obesity in China



Source: Chinese Diabetes Society, Chinese Journal of Epidemiology, China Insights Consultancy

INDUSTRY OVERVIEW

GLP-1 receptor agonists have demonstrated significant efficacy in reducing body weight. Also importantly, approved GLP-1 receptor agonists are generally well tolerated and do not generally do not result in potentially severe side effects observed for other types of obesity treatment, such as dizziness, raised blood pressure or insomnia. Certain traditional treatment options for obesity also lead to complications such as unstable hormone levels and other metabolic disorders. The weight-controlling effect is often unsustainable as well and is prone to relapses. The following table summarizes the effects and limitations of traditional treatment options for obesity.

Drug	Mechanism of Action	Effect on weight	Adverse effects	Status	Comments
Medications for short-term weight management or selected medications used off-label to promote weight loss					
Phentermine	Sympathomimetic amine (appetite suppressant)	3.6 kg placebo-subtracted weight loss in studies ranging from 2-24 weeks	Insomnia, tremor, ↑ blood pressure and pulse rate, headache, palpitation, constipation	Currently approved drug for short-term weight management (≤ 12 weeks) in U.S., Korea and some countries, withdrawn 2000 in U.K.	Diffusion controlled release preparation is available
Diethylpropion	As above	3.0 kg placebo-subtracted weight loss in studies ranging from 6-52 weeks	As above	Currently approved drug for short-term weight management	
Zonisamide	Anti-convulsant agent	5.0% placebo-subtracted weight loss at 12 weeks	↑ Nervousness, sweating, tremors, gastrointestinal adverse effects, hypersomnia, fatigue, and insomnia	Used off-label	No enough clinical trials; should not exceed 400 mg/day
Topiramate	As above	6.5% placebo-subtracted weight loss at 24 weeks	Paresthesia, dizziness, altered taste, fatigue, memory impairment, somnolence, anorexia, and abdominal pain	Used off-label	Associated with teratogenicity; should not exceed 400 mg/day
Medication for long-term weight management					
Orlistat	Pancreatic lipase inhibitor	2.9 kg placebo-subtracted weight loss at 1 year	Abdominal pain, bloating, flatulence, oily stools, diarrhea, ↓ absorption of fat soluble vitamins	Only approved drug for long-term weight management	Available over-the-counter in several countries

Source: Kang JG, Park CY. *Anti-Obesity Drugs: A Review about Their Effects and Safety. Diabetes Metab J.* 2012;36(1):13-25., China Insights Consultancy

INDUSTRY OVERVIEW

The following table sets forth the implications and corresponding challenges of existing drug modalities and marketed products to address the treatment regimen of obesity.

	Obesity/Overweight
Implications	- Pharmacotherapy: Drugs such as orlistat, phentermine/topiramate, liraglutide, and bupropion/naltrexone can aid weight loss and improve metabolic parameters in obese individuals. - Multimodal Approaches: Combined with lifestyle modifications, pharmacotherapy can enhance weight loss outcomes and improve overall health.
Challenges	- Limited Efficacy: Weight loss medications may have modest efficacy, and long-term sustainability of weight loss is challenging. - Side Effects: Common side effects of weight loss drugs include gastrointestinal disturbances, insomnia, and increased heart rate, which may limit their tolerability. - Safety Concerns: Some weight loss medications have been associated with adverse effects such as cardiovascular events and psychiatric disorders. - Cost: Cost-effectiveness and insurance coverage for weight loss medications may be barriers to access for some patients.

Source: FDA, China Insights Consultancy

Obesity is often influenced by both lifestyle factors and genetic factors. Disruptions of certain genes such as LEPR, PMOC and AGRP, among others, could cause early-onset of obesity in humans. On the other hand, lack of physical exercise, unhealthy dietary habits, elevated stress level and usage of certain medication may all lead to the onset of obesity. Lifestyle intervention is often the first choice for many obese patients which includes dietary control, exercise and behavioral modifications. It has the advantage of being non-invasive with minimum side effects, and can improve metabolic health in the long term. However, it also requires a high degree of self-management by the patient, which often results in hindered effects. The following table sets forth the features of major prevention and maintenance methods for the treatment of obesity.

	Healthy diet	Regular exercise	Weight loss	Blood sugar monitoring
Obesity/overweight	Adopting a calorie-controlled diet that prioritizes nutrient-dense foods while limiting processed and high-calorie items can support weight loss. Strategies such as mindful eating, meal planning, and avoiding sugary beverages are also beneficial.	Exercise plays a key role in weight management by increasing energy expenditure, preserving lean muscle mass, and promoting fat loss. Consistent physical activity, including cardio workouts, strength training, and flexibility exercises, is essential.	Weight loss is a cornerstone of obesity management and can be achieved through a combination of dietary changes, physical activity, behavior modification, and, in some cases, pharmacotherapy or bariatric surgery.	While not directly related to weight management, blood sugar monitoring may be important for individuals with obesity or overweight who are at risk of developing T2DM. Monitoring fasting blood glucose or hemoglobin A1c levels can help identify early signs of impaired glucose metabolism.

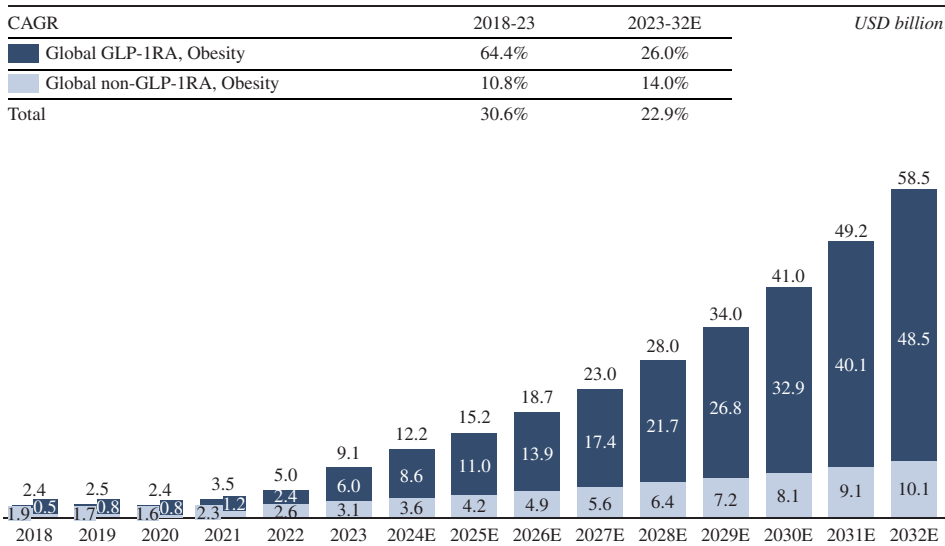
Source: FDA, China Insights Consultancy

INDUSTRY OVERVIEW

Market Size of Obesity Drug

With the continuous development of novel drugs and the increasing clinical demands, the global obesity drug market has witnessed significant expansion in the past years and is expected to grow at an expedited pace. The following chart sets forth the historical and projected global market size of obesity drugs from 2018 to 2032, with breakdowns of GLP-1 receptor agonists and other modalities, respectively.

Market Size of Obesity Drug Globally, 2018-2032E

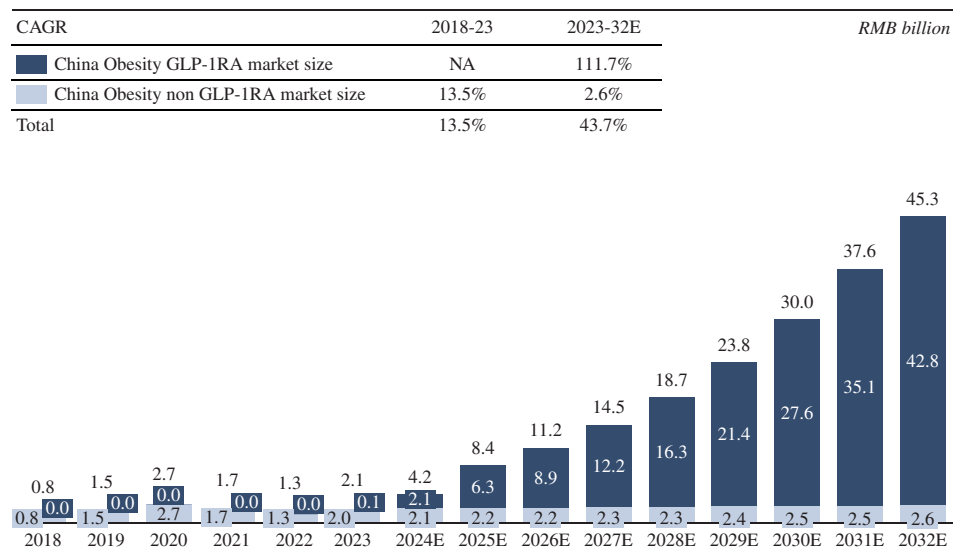


Source: FDA, periodic reports released by public companies, China Insights Consultancy

INDUSTRY OVERVIEW

The development of obesity drug market in China occurred relatively recent with significant potential in the coming years. The following chart sets forth the historical and projected China market size of obesity drugs from 2018 to 2032, with breakdowns of GLP-1 receptor agonists and other modalities, respectively. The market size is calculated by the number of eligible patients (estimated based on epidemiology of obesity) times percentage of obesity patients being treated with GLP-1 receptor agonists times the annual patient expenditure of such medications. The percentage of obesity patients being treated with GLP-1 receptor agonists is estimated to be 0.01% in China in 2023 as two GLP-1 receptor agonists were approved for the treatment of obesity in 2022, and is expected to rise to 0.57% as more GLP-1-based treatment options are expected to be approved by the NMPA over the next 10 years. The annual patient expenditure is expected to be approximately RMB15.0 thousand in 2023, and is expected to reach approximately RMB24.0 thousand in 2032.

Market Size of Obesity Drug in China, 2018-2032E



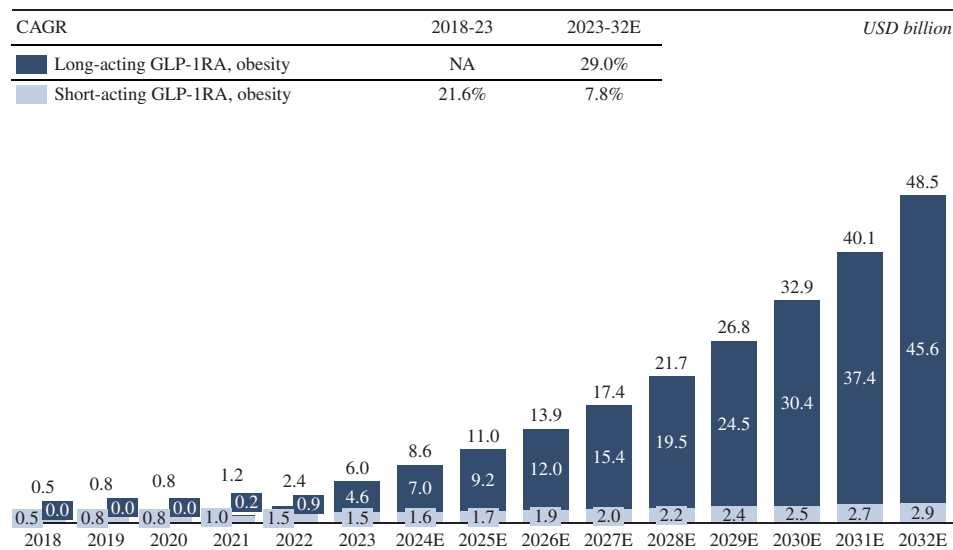
Source: NMPA, periodic reports released by public companies, China Insights Consultancy

INDUSTRY OVERVIEW

Market Size of Obesity Treatment with GLP-1 Receptor Agonists

In recent years, in addition to the significant efficacy observed in the treatment of metabolic disorders such as T2DM, GLP-1 receptor agonists have demonstrated encouraging weight reduction effects in overweight/obese patients. An increasing number of research endeavors have also been dedicating to the development of long-acting GLP-1 receptor agonists, whose longer half-lives *in vivo* reduce the need of frequent dosing, alleviate patient burdens, increase overall compliance and clinical benefits compared to those of short-acting GLP-1 receptor agonists, although subcutaneous short-acting GLP-1 receptor agonists may be more affordable. The following chart sets forth the historical and projected global market size of GLP-1 receptor agonists for the treatment of obesity from 2018 to 2032, with breakdowns of long-acting and short-acting GLP-1 receptor agonists, respectively.

Market Size of Obesity Treatment with GLP-1 Receptor Agonists Globally, 2018-2032E

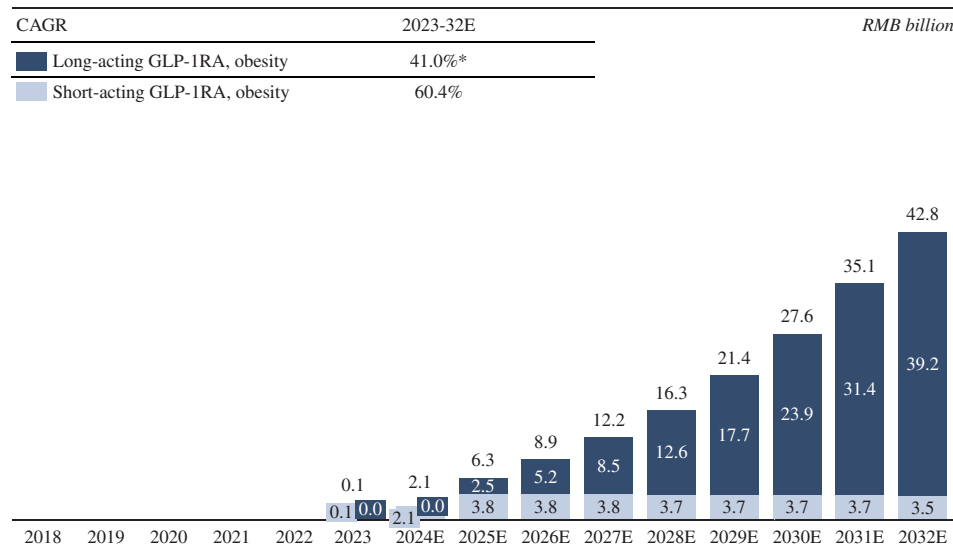


Source: FDA, ClinicalTrials.gov, periodic reports released by public companies, China Insights Consultancy

INDUSTRY OVERVIEW

It is also expected that long-acting GLP-1 receptor agonists will gradually dominate the overall GLP-1 receptor agonist market in China with considerable market potential. The following chart sets forth the historical and projected China market size of GLP-1 receptor agonists for the treatment of obesity from 2018 to 2032, with breakdowns of long-acting and short-acting GLP-1 receptor agonists, respectively.

Market Size of Obesity Treatment with GLP-1 Receptor Agonists in China, 2018-2032E



* CAGR from 2024-2032E

Source: NMPA, CDE, periodic reports released by public companies, China Insights Consultancy

Competitive Landscape of Obesity Drug Market

As of the Latest Practicable Date, there were seven drugs approved for the treatment of obesity in the United States, three of which were GLP-1 receptor agonists. The following table sets forth the approved drugs for the treatment of obesity in the United States.

Obesity Drugs Approved in the United States

Drug Name	MoA	Company	Approval	Indication	Administration	Dosage Frequency	Annual Cost	Pros	Cons
Orlistat	Lipase Inhibitor	Roche	04/1999	Obesity	p.o.	TID.	US\$1,095	- Oral formulation can increase compliance - Effective weight loss	- Has side-effects that affect quality of life, such as faecal incontinence - Lack of fat-soluble vitamins
Phentermine/Topiramate	NE/GABA	Vivus	07/2012	Overweight/obesity	p.o.	QD.	US\$1,615	- Good patient compliance - Effective weight loss	Bothersome side effect, such as dry mouth and a tingling sensation in hands
Naltrexone/Bupropion	Opioid antagonist	Orexigen	09/2014	Overweight/obesity	p.o.	BID.	US\$3,234	- Good patient compliance - Moderate weight loss	Carry FDA black box warning about suicidal thinking
Liraglutide	GLP-1	Novo Nordisk	12/2014	Overweight/obesity	s.c.	QD.	US\$3,276	- Simultaneously controls blood glucose - Effective weight loss	- Short-acting - Higher injection frequency - Increase the risk of GI adverse effect
Semaglutide	GLP-1	Novo Nordisk	06/2021	T2DM; Overweight/obesity	s.c.	QW.	US\$3,527	- Long acting - Simultaneously controls blood glucose - Marked weight loss	Increase the risk of GI adverse effect
Tirzepatide	GLP/GLP-1	Eli Lilly	11/2023	T2DM; Overweight/obesity	s.c.	QW.	US\$12,276	- Long acting - Simultaneously controls blood glucose - Significant weight loss	- Increase the risk of GI adverse effect - Withdraw drug lead to weight rebound
Setmelanotide	MC4R	Rhythm Pharmaceuticals	11/2020	Rare genetic diseases of obesity	s.c.	QD.	US\$390,559	Applicable to patients with specific types of rare obesity disorders	- Skin hyperpigmentation - Increase the risk of GI adverse effect - Depression and suicidal ideation

INDUSTRY OVERVIEW

Abbreviations: GABA = gamma aminobutyric acid; NE = norepinephrine; p.o. = per os; s.c. = subcutaneous; TID. = ter in die, three times a day; QD. = quaque die, once daily; BID. = bis in die, twice daily; QW. = quaque week, once weekly; GI = gastrointestinal

Source: The Lancet, FDA, China Insights Consultancy

As of the Latest Practicable Date, there were six drugs approved for the treatment of obesity in China, three of which were GLP-1 receptor agonists and two of these GLP-1 receptor agonists were in short-acting form. The following table sets forth the approved drugs for the treatment of obesity in China.

Obesity Drugs Approved in China

Drug Name	MoA	Company	Approval	Indication	Administration	Dosage Frequency	Unit Price	Annual Cost	NRDL	Pros	Cons
Orlistat¹	Lipase Inhibitor	Roche	03/2001	Obesity/overweight	p.o.	TID.	¥ 598 (0.12g*42)	¥ 15,548 ²	Not covered ³	• Oral intake is more convenient	• Has socially inconvenient side-effects, such as faecal incontinence
Liraglutide⁴	GLP-1	Hangzhou Zhongmei Huadong	07/2023	T2DM; Obesity/Overweight ⁵	s.c.	QD.	¥ 300 (18mg:3ml)	¥ 18,200 ³	Not covered ³	• Effective weight loss	• Short-acting • Higher injection frequency • expensive • Increase the risk of GI adverse effect
Beinaglutide	GLP-1	Shanghai Benemea	07/2023	Obesity/overweight ⁷	s.c.	TID.	¥ 216 (4.2mg:2.1ml)	¥ 11,232 ⁴	Not covered ³	• Modest weight loss	• Short-acting • Higher injection frequency • expensive
Mazindol	blocks dopamine & norepinephrine reuptake	Desano	07/2020	Simple obesity	p.o.	QD.	N/A	N/A	Not covered ³	• Direct suppression of appetite	• Rebound weight gain discontinuation of mazindol • significant side effects
Semaglutide	GLP-1	Novo Nordisk	06/2024	Obesity/overweight	s.c.	QW.	N/A	N/A	Not covered ³	• Long acting • Simultaneously controls blood glucose • Marked weight loss	• Increase the risk of GI adverse effect
Tirzepatide	GLP-1R; GIPR	Eli Lilly	07/2024	Obesity/overweight	s.c.	QW.	N/A	N/A	Not covered ³	• Long acting • Effective weight loss	• Expensive

Notes:

- The originator, orlistat, was developed by Roche and named xenical. However, due to a business adjustment by Roche, xenical began to gradually exit the Chinese market in 2008. In 2010, Zein Biotechnology launched a generic version of the orlistat capsule, and several branded generic products have been approved in the Chinese market since then. As of the Latest Practicable Date, there were over 20 generic orlistat products approved in China.
- 120mg TID dosage based on the Summary Review of Orlistat (NDA 020766), expected treatment duration is 52 weeks.
- 3.0mg daily dosage based on clinical data (NCT01272219), expected treatment duration is 52 weeks.
- 0.2mg TID dosage based on clinical data (CTR20190408), expected treatment duration is 52 weeks.
- Only T2DM indications are covered by medical insurance, obesity/overweight indications are not covered by medical insurance.
- Indications and usage on labeling: adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients with an initial BMI of 30 kg/m² or greater (obesity), or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, T2DM, or dyslipidemia).

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7. Indications and usage on labeling: Indicated for weight management in adult patients with a BMI $\geq 28\text{kg/m}^2$, or BMI $\geq 24\text{kg/m}^2$ and at least one weight associated metabolic disorders (e.g., hypertension, hypertension, dyslipidemia, fatty liver, obstructive sleep apnea syndrome).
8. Generic or biosimilar product.
9. There is one GLP-1/GIP dual receptor agonist, Tirzepatide, that has been approved by the NMPA for the treatment of T2DM or obesity indications in China.

Source: *Advances in Therapy, Chinese Medical Frontier Journal, Chinese Journal of Health Management, NMPA, China Insights Consultancy*

The following chart sets forth the comparisons of clinical trial results of approved GLP-1 based drugs for the treatment of obesity.

Comparisons of Clinical Trial Results of Approved GLP-1 based Drugs for the Treatment of Obesity

Products	MOA	Trial identity	Summary of clinical trials				Other safety profile
			Baseline profile ¹	Intervention	Treatment difference ² (%)	Adverse effects ³	
Liraglutide	GLP-1	SCALE	- Mean weight 106.2 kg - Mean BMI 38.3 kg/m²	3.0mg daily plus counseling on lifestyle modification for 56 weeks	5.4%	- Discontinuation rates⁴ 9.8% (4.3%) - Nausea 40.2% (14.7%) - Diarrhea 20.9% (9.3%) - Vomiting 16.3% (4.1%)	Black box warning of thyroid C-cell tumors
Semaglutide	GLP-1	STEP1	- Mean weight 105.4 kg - Mean BMI 37.8 kg/m²	2.4mg weekly plus lifestyle intervention for 68 weeks	12.4%	- Discontinuation rates 7.0% (3.1%) - Nausea 44.2% (17.4%) - Diarrhea 31.5% (15.9%) - Vomiting 24.8% (6.6%)	Black box warning of thyroid C-cell tumors
Tirzepatide	GLP-1/GIP	SURMO UNT-3 ⁵	- Mean weight 105.8 kg - Mean BMI 38.2 kg/m²	10mg weekly plus lifestyle intervention for 72 weeks	16.4%	- Discontinuation rates 7.1% (2.6%) - Nausea 33.3% (9.5%) - Diarrhea 21.2% (7.3%) - Vomiting 10.7% (1.7%)	Black box warning of thyroid C-cell tumors

Notes:

1. Trial subject profile in treatment group.
2. Treatment difference = mean percentage of weight loss in treatment group subtracted by mean percentage of weight loss in placebo group.
3. Adverse effect shown as percentage of adverse events in treatment group (percentage of adverse events in placebo group).
4. Data from Saxenda drug label, a cumulative parameter based on multiple clinical trials.
5. Trial with 3 treatment groups, 10mg group results shown in table.

Source: *New England Journal of Medicine, China Insights Consultancy*

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As of the Latest Practicable Date, there were over 150 clinical-stage pipeline candidates with various modalities for the treatment of obesity in the United States. As of the Latest Practicable Date, there were 10 GLP-1 receptor agonist candidates under clinical development for the treatment of obesity in the United States. The following table sets forth the pipeline of clinical-stage GLP-1 receptor agonist candidates for the treatment of obesity in the United States.

Pipeline of Clinical-stage GLP-1 Receptor Agonists for Obesity in the United States

Candidate	MoA	Company	Indications	Administration	Phase	First Posted Date	Trial Number	Competent Authority
Orforglipron	GLP-1R	Eli Lilly	T2DM/Obesity/Overweight/CVDs/CKDs	p.o.	III	2023/4/7	NCT05803421	FDA
			Obesity/Overweight/T2DM	p.o.	III	2023/3/24	NCT05872620	FDA
			Overweight/Obesity	p.o.	III	2023/3/22	NCT05869903	FDA
AZD5004	GLP-1R	AstraZeneca	Obesity/Overweight	p.o.	II	2024/10/8	NCT06579092	FDA
ROSE-010	GLP-1R	Rose Pharma	Obesity/Overweight	s.c.	II	2024/10/1	NCT06621017	FDA
RGT-075	GLP-1R	Regor	Obesity	p.o.	II	2024/2/26	NCT06277934	FDA
K-757	GLP-1R	Kallyope	Obesity	p.o.	II	2023/8/31	NCT06019559	FDA
S-309309	GLP-1R	Shionogi	Obesity	p.o.	II	2023/6/29	NCT05925114	FDA
Danuglipron	GLP-1R	Pfizer	Overweight/Obesity/T2DM	p.o.	II	2021/11/13	NCT04707313	FDA
GSBR-1290	GLP-1R	Gashernbrum Bio	Overweight/Obesity/T2DM	p.o.	I/II	2023/1/25	NCT05762471	FDA
CT-996	GLP-1R	Carmot	Obesity/Type 2 Diabetes	p.o.	I	2023/5/9	NCT05814107	FDA
XW014	GLP-1R	Sciwind	Obesity/Type 2 Diabetes/MASH	p.o.	I	2022/10/13	NCT05579314	FDA

Source: ClinicalTrials.gov, China Insights Consultancy

Additionally, there were other GLP-1-based pipeline candidates under clinical development for the treatment of obesity in the United States, such as maridebart cafraglutide, a novel antibody-peptide conjugate which functions as a GLP-1 receptor agonist and GIP receptor antagonist, undergoing Phase II clinical trial.

As of the Latest Practicable Date, there were over 50 clinical-stage pipeline candidates with various modalities for the treatment of obesity in China. As of the Latest Practicable Date, there were approximately 20 GLP-1 receptor agonist candidates under clinical development for the treatment of obesity in China. The following table sets forth the pipeline of clinical-stage GLP-1 receptor agonist candidates for the treatment of obesity in China.

Pipeline of Clinical-stage GLP-1 Receptor Agonists for Obesity in China

Candidate ¹	MoA	Company	Indications	Administration	Phase	First Posted Date	Trial Number	Competent authority
PB-119	GLP-1R	PegBio	Overweight/obesity	s.c.	I	2024/4/17	CTR20241107	NMPA
Semaglutide	GLP-1R	Jiangsu Thery	Obesity	s.c.	III	2024/12/23	CTR20244777	NMPA
GZR-18	GLP1R	Ganlee	Overweight/obesity	s.c.	III	2024/12/18	CTR20244647	NMPA
Semaglutide	GLP-1R	Jiangsu Sinopep	Obesity	s.c.	III	2024/12/12	CTR20244492	NMPA
VCT220	GLP-1R	Vincentage	Overweight/obesity	p.o.	III	2024/11/20	CTR20244365	NMPA
Semaglutide	GLP-1R	Chengdu Beite	Obesity	s.c.	III	2024/9/30	CTR20243408	NMPA
Semaglutide	GLP-1R	CSPC	Obesity	s.c.	III	2024/9/14	CTR20243491	NMPA
Orforglipron	GLP-1R	Eli Lilly	Overweight/obesity	p.o.	III	2023/8/11	CTR20232459	NMPA
Ecnoglutide	GLP-1R	Sciwind	Overweight/obesity	s.c.	III	2023/3/15	CTR20230745	NMPA
Semaglutide	GLP-1R	Novo Nordisk	Weight management	s.c.	III	2023/9/8	CTR20232812	NMPA
BPYT01	GLP-1R	Baiji Youtang	Overweight/obesity	s.c.	II	2024/8/13	CTR20242957	NMPA
HDM1002	GLP-1R	Hangzhou Zhongmei Huadong	Overweight/obesity	p.o.	II	2024/4/11	CTR20241151	NMPA
Supaglutide	GLP-1R	Innogen	Overweight/obesity	s.c.	II	2024/3/11	CTR20240801	NMPA
HRS-7535	GLP-1R	Shandong Shengdi	Obesity	p.o.	II	2024/2/18	CTR20240369	NMPA
GMA-105	GLP-1R	Hongyun Huaming	Overweight/obesity	s.c.	Ib/II	2022/6/27	CTR20221601	NMPA
MDR-001	GLP-1R	MindRank	Overweight/obesity	s.c.	II	2024/8/23	CTR20243057	NMPA
ZT002	GLP-1R	QL Biopharm	Overweight/obesity	s.c.	II	2024/7/12	CTR20242527	NMPA
ZT006	GLP-1R	QL Biopharm	Overweight	p.o.	I	2024/11/15	CTR20244313	NMPA
SAL-0112	GLP-1R	Salubris	Overweight/obesity	p.o.	I	2023/12/18	CTR20233948	NMPA

Note:

1. Biosimilars registered at CDE not included

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Source: CDE, China Insights Consultancy

As of the Latest Practicable Date, there were seven GLP-1/GCG dual receptor agonist candidates under clinical development for the treatment of obesity in the United States. The following table sets forth the pipeline of clinical-stage GLP-1/GCG dual receptor agonist candidates for the treatment of obesity in the United States.

Pipeline of Clinical-stage GLP-1/GCG Dual Receptor Agonists for Obesity in the United States

Candidate	MoA	Company	Indications	Administration	Phase	First Posted Date	Trial Number	Competent authority
IBI362 (Mazdutide)	GLP-1R/GCGR	Eli Lilly/Innovent	Diabetes Mellitus/T2DM/Obesity	s.c.	III	2023/12/28	NCT06184568	FDA
			Diabetes Mellitus/T2DM	s.c.	III	2022/11/7	NCT05606913	FDA
			Obesity/NASH	s.c.	III	2024/3/13	NCT06309992	FDA
Survodutide	GLP-1R/GCGR	Boehringer Ingelheim	Obesity	s.c.	III	2023/10/11	NCT06077864	FDA
			Obesity/T2DM	s.c.	III	2023/10/4	NCT06066528	FDA
			Obesity	s.c.	III	2023/10/4	NCT06066515	FDA
Pemvidutide	GLP-1R/GCGR	Altimmune	Obesity/Overweight	s.c.	II	2022/3/25	NCT05295875	FDA
Efinopegdutide	GLP-1R/GCGR	Merck Sharp & Dohme LLC	Obesity/T2DM	s.c.	II	2018/7/16	NCT03586830	FDA
			Obesity	s.c.	II	2018/4/3	NCT03486392	FDA
DA-1726	GLP-1R/GCGR	Neurobo	Obesity	s.c.	I	2024/2/9	NCT06252220	FDA
DD01	GLP-1R/GCGR	Neuraly	Overweight/Obesity/T2DM/MASLD	s.c.	I	2021/3/23	NCT04812262	FDA
			Overweight/Obesity	s.c.	I	2019/8/16	NCT04059367	FDA
NNC9204-1177	GLP-1R/GCGR	Novo Nordisk	Metabolism and Nutrition Disorder/Obesity	s.c.	I	2016/10/21	NCT02941042	FDA

Source: ClinicalTrials.gov, China Insights Consultancy

As of the Latest Practicable Date, there were three GLP-1/GCG dual receptor agonist candidates under clinical development for the treatment of obesity in China. The following table sets forth the pipeline of clinical-stage GLP-1/GCG dual receptor agonist candidates for the treatment of obesity in China.

Pipeline of Clinical-stage GLP-1/GCG Dual Receptor Agonists for Obesity in China

Candidate	MoA	Company	Phase	Indications	Administration	First Posted Date	Trial Number
PB-718	GLP-1/GCG	PegBio	I	Overweight/obesity	s.c.	2023/05/31	CTR20231655
Mazdutide	GLP-1/GCG	Innovent	NDA	Overweight/obesity	s.c.	2023/12/26 ¹	CTR20234187 ¹
Survodutide	GLP-1/GCG	Boehringer Ingelheim	III	Overweight/obesity	s.c.	2023/12/14	CTR20234044

Note:

1. Mazdutide's NDA was accepted by the CDE in February 2024, its First Post Date and Trial Number denote its earliest Phase III clinical trial registered at the CDE.

Source: CDE, China Insights Consultancy

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Growth drivers and Future Trends of Obesity Drug Market

The obesity drug market growth has primarily been driven by the following key factors:

- *Increasing number of overweight/obesity patients.* Urbanization and economic growth have shifted people’s dietary preferences. The contemporary lifestyle of unhealthy eating patterns and decreased physical activity has contributed to a growing incidence of obesity. Consequently, the prevalence of obesity is on the upward trajectory, accompanied by a rising demand for weight management solutions. This surge in demand has led to the continuous expansion of the drug market targeting overweight and obesity.
- *Increased public awareness leads to surging clinical needs.* There has been a surging public awareness of the adverse clinical outcomes of obesity over the years, and the public perception of obesity has shifted from purely aesthetic concerns to issues intricately connected to health. This shift has strengthened the community’s willingness to seek medical attention, subsequently improving treatment rates. This, in turn, propels the ongoing expansion of the market for weight management and obesity medications.
- *Widely recognized efficacy and safety of GLP-1 receptor agonists.* The escalating severity of the obesity issue has spurred the growth of the GLP-1 drug market, presenting a diverse array of GLP-1 medications for effective weight management and obesity treatment. Recently, there have been more dual- or triple-target obesity drugs undergoing clinical development, exhibiting significant development potential. A wealth of evidence from numerous clinical studies illustrates that weight loss can markedly reduce the risk of obesity-related complications and chronic diseases.

Entry Barriers of Obesity Drug Market

The obesity drug market has the following entry barriers:

- *Safety concerns and side effects.* The utilization of medication for weight loss remains a non-dominant approach. Safety considerations represent a paramount concern for individuals contemplating weight-loss interventions. Adverse perceptions and reports regarding the safety profiles of traditional obesity drugs can potentially hinder market acceptance.
- *Intense competition.* New obesity drugs face competition from both upcoming candidates and established products already present in the market. To succeed, the new products must demonstrate superior efficacy, reduced side effects, or other unique benefits, and establishing widespread brand recognition poses a challenge for new entrants.

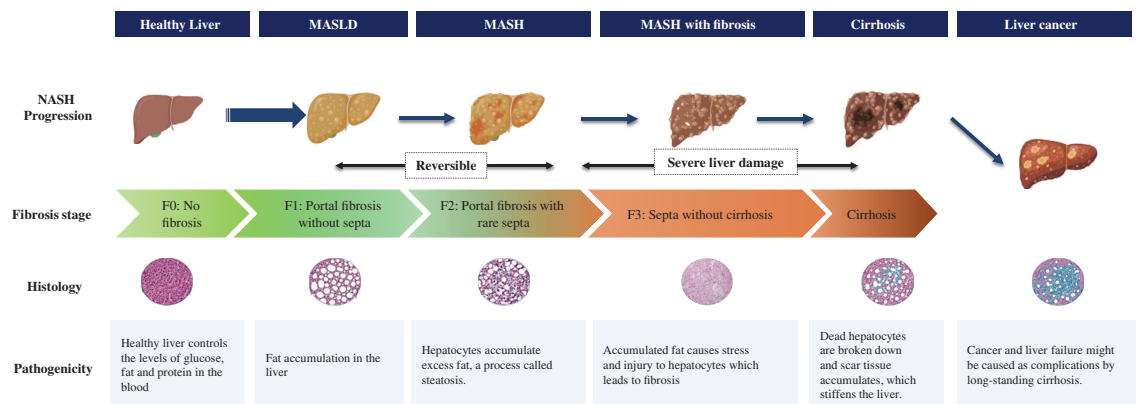
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OVERVIEW OF NASH DRUG MARKET

Introduction to NASH

Non-alcoholic steatohepatitis is liver inflammation and damage caused by excessive fat accumulation. It is the more severe form of non-alcoholic fatty liver disease (“**NAFLD**”), a term for a broad spectrum of liver conditions affecting people who consume little to no alcohol. NAFLD is characterized by fat deposition in the liver, and NASH is a necro-inflammatory process in which the liver cells are injured by fat accumulation. NASH can lead to liver scarring, which results in irreversible scarring (cirrhosis) and liver cancer if untreated. The risk factors of NASH include, among others, T2DM, insulin resistance, obesity, high blood cholesterol and triglycerides, with a combination of which often simultaneously present in NASH patients.

At EASL Congress 2023, the multinational liver societies leaders from La Asociación Latinoamericana para el Estudio del Hígado (ALEH), American Association for the Study of Liver Diseases (AASLD), and European Association for the Study of the Liver (EASL) as well as the co-chairs of the NAFLD Nomenclature Initiative announced that steatotic liver disease (SLD) was chosen as an overarching term to encompass the various aetiologies of steatosis. Nonalcoholic fatty liver disease (NAFLD) will now be metabolic dysfunction-associated steatotic liver disease (MASLD). Metabolic dysfunction-associated steatohepatitis (MASH) is the replacement term for nonalcoholic steatohepatitis (NASH). The following diagram illustrates the progression of NASH in different stages.



Source: ALF, NIHR, NIDDK, China Insights Consultancy

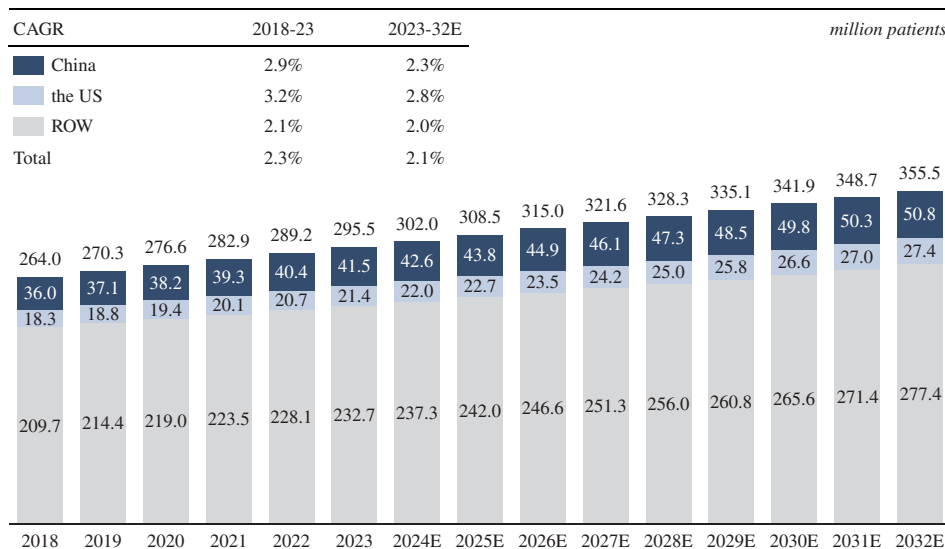
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Prevalence of NASH

The NASH patients represent a large group globally, resulted from a combination of genetic and environmental causes and various risk factors. NASH has also been a rising public health concern in China with the country’s rapid development in recent years and changes in people’s lifestyles.

The following charts set forth the historical and projected prevalence of NASH globally and in China, respectively, from 2018 to 2032. The growth of the NASH market in China might potentially be less pronounced than the global trend given the relatively lower level of obesity in China as compared to other countries. Given the first drug approved by the FDA for the treatment of NASH is indicated for NASH patients with F2~F3 Fibrosis without the need of liver biopsy, and liver fibrosis stage F2~F3/F1~F3 is often the key patient inclusion criteria for the majority of Phase II and Phase III clinical trials for the treatment of NASH, therefore patient stratification of fibrosis stage is the major parameter to estimate the addressable market of NASH treatment.

Prevalence of NASH, 2018-2032E



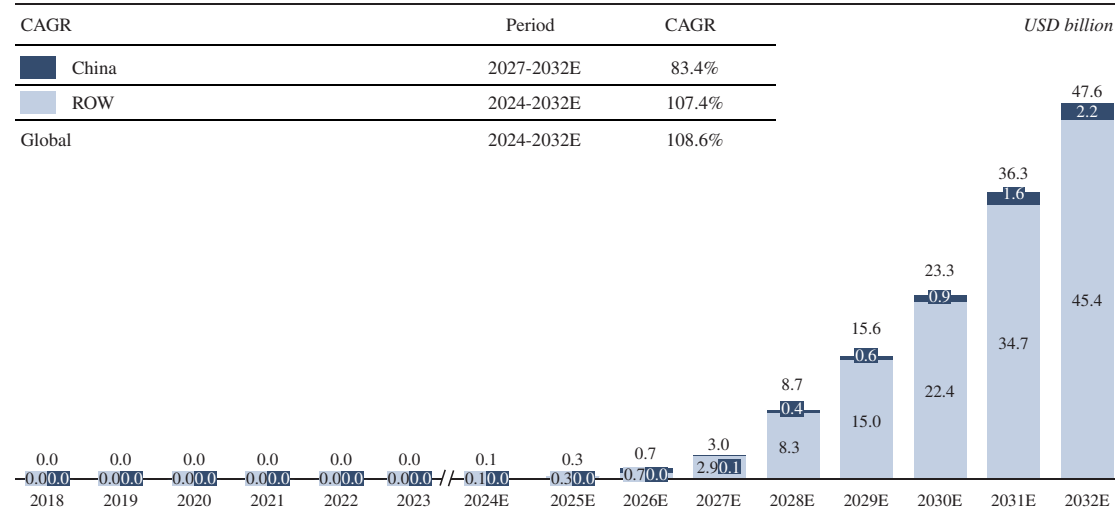
Source: World Obesity Atlas, WHO, China Insights Consultancy

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Market Size of NASH Drug

Despite the number of NASH patients reaching approximately 300 million globally, the first drug for the treatment of NASH was recently approved by the FDA in March 2024, and the global market size of NASH drug is expected to grow at an expedited pace in the following years. The following chart sets forth the projected global and China market size of NASH drug.

Market Size of NASH Drug Globally and in China, 2018-2032E



Notes: The market size of NASH is estimated as the average annual treatment expenditure of NASH drug multiplied by the number of treated patients. For the global market, the annual treatment price assumption is based on the first approved NASH drug Resmetirom, with an expected wholesale price of approximately US\$4.0 thousand for a pack of 30 tablets and an initial expected price of US\$47.4 thousand per year in 2024, and the price between 2024 and 2032 globally is expected to be within the range of US\$15.0 thousand to US\$30.0 thousand. The number of addressable patients is estimated as the number of NASH patients globally multiplied by the percentage of patients with advance stage (F2~F3) of fibrosis, which is expected to be within 35%~40% globally. The number of patients who adopt approved NASH-indicated drug is expected to be within 1,500~2,000 in 2024 globally, and the treatment rate at 2032 is expected to be around 1% out of the total addressable patients.

For the China market, the annual treatment price is expected to be US\$2,000~US\$2,400, the number of addressable patients is estimated as the number of NASH patients in China multiplied by the percentage of patients with advance stage (F2~F3) of fibrosis, which is expected to be within 25%~35% in China between 2027 and 2032. The first drug indicated for NASH is expected to be approved in 2027, when the patient treatment rate is expected to be 0.3% out of the total addressable patients, and is expected to be within 5%~6% in 2032.

Source: *Journal of Hepatology, FDA, ClinicalTrials.gov, China Insights Consultancy*

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Current Treatment Regimen

The global and China markets follow the same treatment regimen for NASH. The international and national guidelines recommend that management for NAFLD and NASH patients varies depending on their risk of clinical liver fibrosis. Due to its complex pathogenesis, medication for NASH is still currently underdeveloped. In both the United States and China, no evidence-based pharmacological therapy is approved, and currently treatment of NASH is primarily limited to adoption of a healthier lifestyle, such as body mass management, controlling diabetes, avoiding alcohol, exercising regularly, reducing the total cholesterol level, and taking supplement with vitamin E. In addition, while there is no specific medication that directly treats NASH, taking metformin and statins treats the related metabolic disorders such as insulin resistance and high cholesterol. In addition, the American Association for the Study of Liver Diseases confirms that vitamin E and pioglitazone (a drug used to treat diabetes) are the two best drug choices for biopsy-confirmed NASH, but the safety and efficacy of such methods remain unclear.

The following table sets forth the treatment regimen for NAFLD and NASH according to American Gastroenterological Association recommendations:

NAFLD/NASH Clinical Care Pathway multidisciplinary task force – Recommended management of patients with NAFLD/NASH			
Risk level	Low risk	Intermediate risk	High risk
Patient stratification	FIB-4 < 1.3 or LSM < 8 kPa or liver biopsy F0-F1	FIB – 4 1.3 – 2.67 and/or LSM 8 – 12 kPa and liver biopsy not available	FIB-4 > 2.67 or LSM >12 kPa or liver biopsy F2-F4
Lifestyle intervention	All patients require regular physical activity, healthy diet, and avoid excess alcohol intake		
Weight loss recommended if overweight or obese	May benefit	Greater need	Strong need
Pharmacotherapy for NASH	Not recommended	No pharmacological agent is FDA-approved so far for NASH treatment, patients with T2DM may benefit from some diabetes medications such as pioglitazone and some GLP-1 RAs; Vitamin E improves steatohepatitis in patients with NASH without diabetes, with less evidence in patients with T2DM	
		Not applicable	Pharmacotherapy for NASH cirrhosis is very limited and should be avoided
CVD risk reduction	Statins can be used safely in patients with steatohepatitis and liver fibrosis, but is to be avoided in decompensated cirrhosis		
Diabetes care	Standard of Care of diabetes	Medications with efficacy in NASH (pioglitazone, GLP-1 RAs) preferred	

- GLP-1RAs can improve insulin sensitivity, reduce hepatic glucose production, and promote weight loss. These metabolic effects may contribute to better management of NASH, as insulin resistance and obesity are common factors associated with the condition.
- GLP-1RAs have demonstrated anti-inflammatory effects, which can be beneficial in reducing liver inflammation, a key component of NASH pathology.
- Some studies suggest that GLP-1RAs may have anti-fibrotic effects, potentially helping to prevent or reduce liver fibrosis, a serious consequence of NASH.

Abbreviations: FIB-4 = fibrosis-4; LSM = liver stiffness measurement; CVD = cardiovascular disease

Source: *Gastroenterology, China Insights Consultancy*

GLP-1 receptor agonists exhibit promising treatment potential in the context of NAFLD. Research suggests that GLP-1 agonists may play a beneficial role in addressing the intricate interplay between insulin resistance, inflammation, and hepatic lipid accumulation associated with NAFLD. By targeting GLP-1 receptors, these agents not only contribute to glycemic control but also demonstrate potential in improving liver health. The anti-inflammatory and anti-fibrotic properties of GLP-1 receptor agonists are being investigated for their impact on reducing hepatic steatosis and preventing disease progression. As NAFLD is closely linked to metabolic dysfunction, the multifaceted effects of GLP-1 agonists make them a subject of interest in exploring comprehensive therapeutic strategies for this prevalent liver condition. The following table illustrates the recommendations of American Association for the Study of

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Liver Diseases practice guideline for the treatment of NASH, including GLP-1 receptor agonists, and none of such recommended medications was approved by the FDA for the treatment of NASH as of the Latest Practicable Date.

Medication ¹	Patient population	Liver clinical benefits	Non-liver related clinical benefits	Potential side effect
Vitamin E	NASH without T2DM or cirrhosis	- Improves steatosis - No proven benefit on fibrosis	/	- Hemorrhagic stroke - Potential risk of prostate cancer
Pioglitazone	NASH with or without T2DM	- Improves steatosis - Potential benefit on fibrosis	- Improves insulin sensitivity - Prevention of diabetes - CV risk reduction - Stroke prevention	- Weight gain - Risk of heart failure exacerbation - Bone loss
Liraglutide ²	NASH without cirrhosis	- Improves steatosis - Non proven impact on fibrosis	- Improves insulin sensitivity - Weight loss - CV risk reduction - May slow progression of renal disease	- Gastrointestinal - Gallstones (related to weight loss), Pancreatitis
Semaglutide ³	NASH without cirrhosis	- Improves steatosis - NASH resolution - May slow fibrosis progression	- Improves insulin sensitivity - Weight loss - Improves CV and renal outcomes - Stroke prevention	- Gastrointestinal - Gallstones (related to weight loss), Pancreatitis
Tirzepatide	T2DM or obesity with NAFLD	Reduces steatosis on imaging	- Improves in insulin sensitivity - Significant weight loss	- Gastrointestinal - Gallstones related to weight loss - Pancreatitis
SGLT2i	T2DM and NAFLD	Reduces steatosis on imaging	- May improve insulin sensitivity - Improves CV and renal outcomes - Benefit in heart failure - Modest weight loss	- Risk of genitourinary yeast infection - Volume depletion - Bone loss

Notes:

- Available data on semaglutide, pioglitazone, and vitamin E do not demonstrate an antifibrotic benefit, and none has been carefully studied in patients with cirrhosis. Metformin, ursodeoxycholic acid, dipeptidyl peptidase-4, statins, and silymarin are well studied in NASH and should not be used as a treatment for NASH as they do not offer a meaningful histological benefit.
- Study with small sample size and underpowered to determine key histological outcomes (fibrosis).
- Phase III clinical trial to determine efficacy currently ongoing.

Source: American Association for the Study of Liver Diseases, China Insights Consultancy

Research has shown that certain genetic factors are associated with NASH, such as a certain variation in the PNPLA3 gene which determines inter-individual and ethnicity-related differences in hepatic fat content independent of insulin resistance and serum lipid concentration. Non-genetic risk factors of NASH include obesity, insulin resistance, high levels of blood lipids, and other metabolic abnormalities. Lifestyle interventions and preventive methods may potentially alleviate the symptoms of NASH and/or delay the disease progression. The following table sets forth the features of major prevention and maintenance methods for the treatment of NASH.

	Healthy diet	Regular exercise	Weight loss	Blood sugar monitoring
NASH	Dietary modifications targeting weight loss and improved liver health are crucial for managing NASH. This may include reducing intake of refined carbohydrates, saturated fats, and added sugars while increasing consumption of fiber-rich foods and healthy fats.	Regular exercise can reduce liver fat accumulation, inflammation, and fibrosis associated with NASH. Incorporating both aerobic and resistance exercises into the routine can improve liver health and metabolic parameters.	Weight loss is the primary therapeutic target for NASH as it can improve liver histology and reduce the risk of disease progression. Lifestyle interventions aimed at sustained weight reduction are recommended as the first-line approach.	Monitoring blood glucose levels may indirectly benefit individuals with NASH by helping to control insulin resistance and prevent further liver damage. Tight glycemic control is important, especially in individuals with comorbid T2DM or insulin resistance.

Source: FDA, China Insights Consultancy

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Competitive Landscape of NASH Drug Market

As of the Latest Practicable Date, there was no GLP-1 receptor-targeted drug approved specifically for the treatment of NASH globally. On March 14, 2024, resmetirom, a thyroid hormone receptor β -selective agonist developed by Madrigal Pharmaceuticals Inc. with brand name Rezdiffra, became the first drug receiving marketing approval from the FDA for the treatment of NASH patients with moderate to advanced liver fibrosis, with mechanism of action designed by stimulating thyroid hormone receptor β in the liver to reduce intrahepatic triglycerides and decrease liver fat content. There were a number of product candidates under clinical development in the United States, nine of which were GLP-1 receptor-targeted, as of the Latest Practicable Date. The following table shows the details of GLP-1 receptor-targeted drug candidates under clinical development for the treatment of NASH in the United States.

Pipeline of Clinical-stage GLP-1 Receptor-Targeted NASH Drug Candidates in the United States

Candidate	MoA	Company	Indications	Administration	Phase	First Posted Date	Trial Number	Competent authority
PB-718	GLP-1R/GCGR	PegBio	NASH	s.c	I	2021/8/25	NCT05021666 ¹	FDA
Survodutide	GLP-1R/GCGR	Boehringer Ingelheim	NASH	s.c	III	2024/3/13	NCT06309992	FDA
Semaglutide	GLP-1R	Novo Nordisk	NASH	s.c	III	2021/3/30	NCT04822181	FDA
DD-01	GLP-1R/GCGR	Neuraly Inc	NAFLD	s.c	II	2024/5/13	NCT06410924	FDA
Pemvidutide	GLP-1R/GCGR	Altimune	NASH	s.c	II	2023/8/14	NCT05989711	FDA
Efinopegutide	GLP-1R/GCGR	Merck Sharp & Dohme LLC	MASH, NASLD	s.c	II	2023/5/26	NCT05877547	FDA
Efocipegutride (HM15211)	GLP-1R/GCGR/GIPR	Hanmi Pharmaceutical	NASH	s.c	II	2020/8/7	NCT04505436	FDA
AZD9550	GLP-1R/GCGR	AstraZeneca	NASLD	s.c	I/II	2023/11/30	NCT06151964	FDA
VK2735	GLP-1R/GIPR	Viking Therapeutics	NASLD	p.o.	I	2022/1/24	NCT05203237	FDA

Note:

1. Trial NCT05021666 is conducted on healthy participants.

Source: ClinicalTrials.gov, China Insights Consultancy

The following table shows the details of GLP-1 receptor-targeted drug candidates under clinical development for the treatment of NASH in China, as of the Latest Practicable Date.

Pipeline of Clinical-stage GLP-1 Receptor-Targeted NASH Drug Candidates in China

Candidate	MoA	Company	Indications	Administration	Phase	First Posted Date	Trial Number	Competent authority
Survodutide	GLP-1R/GCGR	Boehringer Ingelheim	NASH	s.c	III	2024/11/26	CTR20244843	NMPA
Semaglutide	GLP-1R	Novo Nordisk	NASH	s.c	III	2021/07/27	CTR20211818	NMPA
Efinopegutide	GLP-1R/GCGR	Merck & Co.	NASH	s.c	II	2023/10/19	CTR20233311	NMPA
HEC88473	GLP-1R/FGF21	GUANGDONG HEC TECHNOLOGY	NASH, T2DM, Obesity	s.c	II	2023/08/17	CTR20232481	NMPA
UBT251	GLP-1R/GCGR/GIPR	United Laboratories	T2DM, Overweight/Obesity, NASH	s.c	Ia	2023/09/20	CTR20232997	NMPA

Source: CDE, China Insights Consultancy

INDUSTRY OVERVIEW

Growth drivers and Future Trends of NASH Drug Market

The NASH drug market growth has primarily been driven by the following key factors:

- *Strengthened public awareness.* The surge in metabolic diseases prevalence including NASH has garnered heightened attention from the public, governments, medical institutions and social media, contributing to an enhanced awareness of NASH. Diverse channels are employed to educate physicians and NASH patients about disease diagnosis and pharmaceutical interventions. For instance, the National Health Commission of China initiated a specialized training program for metabolism physicians from regional medical and health services in 2022. This program aims to ensure accurate diagnoses of metabolic diseases, including NASH. Additionally, the establishment of more NASH care clinics in China enables physicians to offer comprehensive treatment, emphasizing rational medication use and lifestyle interventions.
- *Ongoing achievements in diagnosis.* Advancements in diagnostic techniques further propel the development of NASH market. Various diagnostic methods, such as physical examinations, imaging tests, and liver biopsy, are now available for NASH diagnosis. During physical examinations, doctors examine the liver and signs of insulin resistance or cirrhosis. Liver biopsy, while not routinely recommended for suspected NASH patients, can confirm the diagnosis and assess disease severity. In cases where advanced fibrosis or other indications of advanced liver disease are present, doctors may suggest liver biopsy to exclude other liver diseases and confirm a NASH diagnosis. The increasing use of physical examination, imaging tests, and liver biopsy for NASH diagnosis further boosts the demand for pharmaceutical interventions.
- *Expansion of susceptible population and patient group.* As a metabolic disease, NASH is linked to a variety of risk factors such as obesity, T2DM, abnormal lipid levels, aging, among others. The global escalating prevalence of metabolic disorders serves as a significant driving factor of the NASH incidence. Sedentary lifestyles, unhealthy dietary habits and obesity also contribute to the rising incidence of NASH.
- *Novel treatments to fulfil medical needs.* As of the Latest Practicable Date, there was no GLP-1 receptor-targeted drug approved for the treatment of NASH globally. Given the increasing prevalence of NASH, the economic burden associated with the disease is on the rise, resulting in a growing demand for new treatments capable of mitigating healthcare costs linked to the condition. As the public awareness increases and novel drugs for the treatment of NASH anticipated to be approved, NASH patients will rapidly adopt these newly approved drugs, thereby driving substantial growth of NASH drug market.

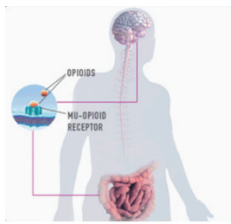
INDUSTRY OVERVIEW

OVERVIEW OF OIC DRUG MARKET

Introduction to OIC

Opioid-induced constipation (“**OIC**”) is a common and challenging side effect associated with the use of opioid medications for pain management. Opioid drugs, while effective in alleviating pain, can lead to a range of gastrointestinal issues, and constipation is one of the most prevalent complications. OIC occurs due to the interaction of opioid drugs with opioid receptors in the gastrointestinal tract, resulting in slowed bowel movement. This condition significantly impacts the quality of life for individuals using opioid drugs for pain relief, and often leads to discomfort, abdominal pain and adverse effects in overall well-being. It is crucial to recognize the unique mechanism that leads to OIC, as traditional laxatives may not effectively address the underlying complications.

The following chart summarizes certain key information about OIC:

 - Opioids represent a mainstay for treatment chronic cancer- and noncancer-related pain Opioid-Induced Constipation (OIC) is the most common gastrointestinal adverse associated with opioid pharmacotherapy and negatively affects pain management, quality of life and daily functioning - The development of OIC is quite common even at low dosages of opioids and does not spontaneously decrease over time due to opioids tolerance					
Pathophysiology of OIC  - Opioids exert analgesic effects via activation of central μ-opioid receptors μ-opioid receptors also ubiquitously distributed in the GI tract - Activation of μ-opioid receptors located in GI tract results in decrease bowel tone and contractility and increase colonic fluid absorption and anal sphincter tone while reducing rectal sensation - Leads to harder stools, which can be difficult to pass	Diagnosis of OIC <u>Diagnosis made according to the Rome criteria</u> - New or worsening symptoms must include 2+ of the following - Loose stools rarely present without the use of laxatives <table><tr><td>More than 1/4 of defecations</td><td> ✓ Straining ✓ Lumpy or hard stools ✓ Sensation of incomplete evacuation ✓ Sensation of anorectal obstruction/blockage ✓ Manual maneuvers to facilitate </td></tr><tr><td>Less than 3 times/week</td><td> ✓ Spontaneous bowel movements </td></tr></table>	More than 1/4 of defecations	✓ Straining ✓ Lumpy or hard stools ✓ Sensation of incomplete evacuation ✓ Sensation of anorectal obstruction/blockage ✓ Manual maneuvers to facilitate	Less than 3 times/week	✓ Spontaneous bowel movements
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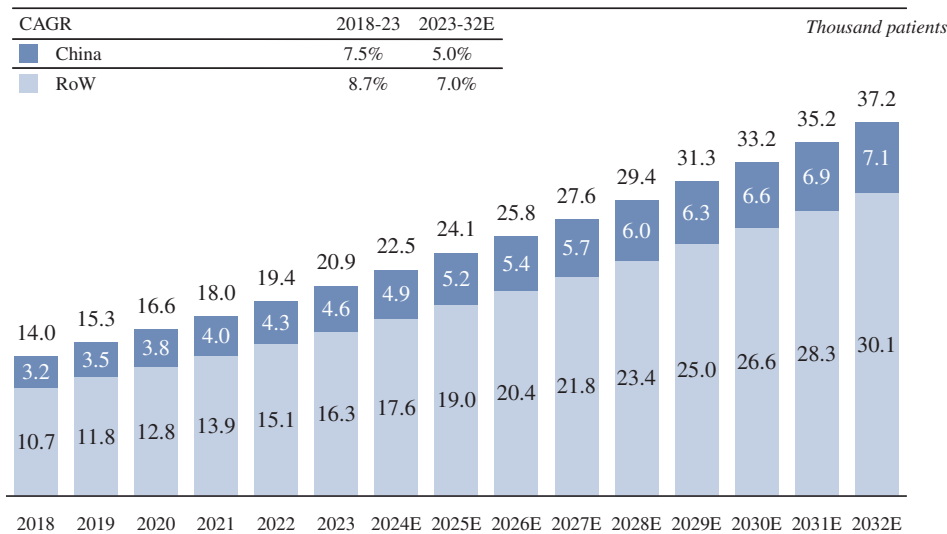
Source: Alkermes, UpToDate, China Insights Consultancy

INDUSTRY OVERVIEW

Prevalence of OIC

The development of OIC is common among patients using even low dosages of opioid drugs. The symptoms of OIC do not spontaneously decrease over time. Consequently, the OIC patient group is growing steadily with the rapid increase of cancer incidents and other severe pain indications. The following chart sets forth the historical and projected prevalence of OIC globally and in China from 2018 to 2032.

Prevalence of OIC, 2018-2032E



Source: WHO, Pain Manag., J Anaesthesiol Clin Pharmacol., China Insights Consultancy

Current Treatment Regimen

For patients with OIC, laxatives are usually given as first-line treatment option. However, laxatives could only partially alleviate the symptoms for some of the OIC patients with limited clinical benefits. As a result, opioid receptor antagonists are being developed as potentially more effective treatment options. The following table demonstrates the current treatment options for OIC patients globally and in China as well as their corresponding features.

Treatment Options for OIC

	First-line	Second-line			Other therapies	
Classification	• conventional laxatives	• Peripherally acting μ -opioid receptor antagonists (PAMORAs)	• CLCN2	• 5-HT	• Lifestyle therapy	• Traditional Chinese Medicine
Representative Drugs	• lactulose • PEG	• Naloxegol • Naldemedine • Methylnaltrexone	• Lubiprostone	• Prucalopride		
Efficacy	• Effectiveness is often limited • Time to action is unpredictable	• Proven efficacy superior to placebo • Alleviates constipation without compromising the analgesic effects	• Proven efficacy superior to placebo	• Leading to increased colonic motility and accelerated transit	• Increase fiber intake/increase fluid intake/increase physical activity • Efficacy is limited esp for cancer pts	• Effective in treating OIC, but lack of double-blinded multicenter clinical studies with large sample size
AE	• GI side effects such as nausea, vomiting, diarrhea, and abdominal pain	• flatulence and diarrhea	• nausea and diarrhea	• abdominal pain and nausea		
Guideline recommendation status	• AGA • Chinese guideline	• AGA • Chinese guideline	• Chinese guideline		• AGA • Chinese guideline	• Chinese guideline

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Abbreviations: CLCN2 = chloride voltage-gated channel 2; 5-HT = 5-hydroxytryptamine

Source: Chinese Journal of Digestion, American Gastroenterological Association, China Insights Consultancy

Competitive Landscape of OIC Drug Market

As of the Latest Practicable Date, there were four drug products approved by the FDA for the treatment of OIC, being three peripherally acting μ -opioid receptor antagonists (“PAMORAs”) and one CLCN2 activator, respectively. The following table sets forth the approved drugs for OIC in the United States.

Approved OIC Drugs in the United States

MoA	Generic Name	Brand Name	Company	Administration	Approved Indication	First Approval Date	2022 global sales (Mn USD)
PAMORA	Naloxegol	Movantik	RedHill Biopharma	p.o.	chronic non-cancer pain OIC	2014/09/16	~180
	Methylnaltrexone	Relistor	Salix Pharmaceuticals	p.o.	OIC in adult patients with chronic non-cancer pain	2016/07/19	~250
				s.c.	OIC in adult patients with chronic non-cancer pain, OIC in adults with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient	2008/04/25	
	Naldemedine	Symproic	Shionogi	p.o.	chronic non-cancer pain OIC	2017/03	~60
CLCN2	Lubiprostone	Amitiza	Mallinckrodt Pharmaceuticals	p.o.	Chronic idiopathic constipation OIC in people with chronic, non-cancer pain, or in patients with long-lasting pain caused by a previous cancer or its treatment, irritable bowel syndrome with constipation in women	2006/01/31	~190

Abbreviations: PAMORA = peripherally acting μ -opioid receptor antagonist

Source: FDA, China Insights Consultancy

As of the Latest Practicable Date, there were two drugs approved by the NMPA for the treatment of OIC in China, which are both opioid receptor antagonists.

Approved OIC Drug in China

MoA	Generic Name	Brand Name	Company	Administration	Approved Indication	First Approval Date
Opioid antagonist & opioid analgesic	Prolonged-release oxycodone/naloxone	米美欣	Luye Pharma	p.o.	For adults with severe pain that requires opioid analgesics to adequately control. The addition of the opioid receptor antagonist naloxone alleviates the symptoms of opioid-induced constipation by blocking the effect of oxycodone on the intestinal opioid receptors	2024/6/28
Opioid antagonist & opioid analgesic	Prolonged-release oxycodone/naloxone	奥施瑞定	Mundipharma	p.o.	For adults with severe pain that requires opioid analgesics to adequately control. The addition of the opioid receptor antagonist naloxone alleviates the symptoms of opioid-induced constipation by blocking the effect of oxycodone on the intestinal opioid receptors	2022/11/22

Source: NMPA, China Insights Consultancy

INDUSTRY OVERVIEW

As of the Latest Practicable Date, there were three clinical-stage drug candidates for the treatment of OIC in the United States, as shown in the following table.

Pipeline of Clinical-stage OIC Drug Candidates in the United States

MoA	Drug Name	Company	Administration	Indication	Phase	First posted date	Trial number
PAMORA	Naloxegol	Trihealth	Oral	Constipation Constipation Drug Induced	II/III	2017/10/20	NCT03316859
	Naldemedine	Shionogi	Oral	Pediatric Participants Receiving Opioids	I/II	2022/10/20	NCT05588323
N/A	BGP345A	BioGaia Pharma	Oral	Opioid-Induced Constipation	II	2021/11/24	NCT05133076

Source: ClinicalTrials.gov, China Insights Consultancy

As of the Latest Practicable Date, there were 10 clinical-stage drug candidates for the treatment of OIC in China, being seven PAMORAs, two opioid receptor antagonists and one CLCN2 activator, respectively. PB-1902 was the first and one of the only two domestically developed clinical-stage oral μ -opioid receptor antagonist drug candidates for the treatment of OIC in China, as of the same date. The following table sets forth the pipeline of OIC drug candidates under clinical development in China.

Pipeline of Clinical-stage OIC Drug Candidates in China

Candidate	MoA	Company	Indications	Administration	Phase	First Posted Date	Trial Number	Competent authority
PB-1902	PAMORA	PegBio ¹	OIC	p.o.	I	2021/10/21	CTR20212557	NMPA
					I	2021/4/2	CTR20210655	NMPA
Methylnaltrexone Bromide	PAMORA	Yichang Renfu Pharmaceutical	OIC	p.o	BE ²	2024/5/6	CTR20241542	NMPA
	PAMORA	Shenyang Eliving Pharmaceutical Technology	OIC	s.c.	I	2018/7/2	CTR20180953	NMPA
	PAMORA	Beijing Collab Pharma	OIC	s.c.	III	2015/6/18	CTR20150393	NMPA
	PAMORA	Furuikangzheng	OIC	s.c.	II	2015/7/6	CTR20150290	NMPA
	PAMORA	Institute of Toxicology, Academy of Military Medical Sciences, PLA., Beijing Molike Technology	OIC	s.c.	III	2018/10/18	CTR20181837	NMPA
Naldemedine	PAMORA	Shionogi	OIC	p.o.	III	2022/3/22	CTR20220673	NMPA
Prolonged-release oxycodone/naloxone	Opioid antagonist & opioid analgesic	Luye Pharma	OIC	p.o.	NDA	2021/7/23	CTR20211699	NMPA
Lubiprostone	CLCN2	Langxite	OIC in adult patients with chronic non cancer pain	p.o.	BE ²	2018/12/20	CTR20182238	NMPA
Naloxone Hydrochloride/ Oxycodone Hydrochloride Hydrate	Opioid receptors antagonist & opioid receptors agonist	Jiangsu Nhwa	OIC	p.o.	BE ²	2024/7/18	CTR20242606	NMPA

Note:

- Registered by Shanghai Hanmai, a subsidiary of PegBio
- Bioequivalence trial

Source: CDE, China Insights Consultancy

INDUSTRY OVERVIEW

Growth drivers and Future Trends of OIC Drug Market

The OIC drug market growth has primarily been driven by the following key factors:

- *Increased clinical demand.* The escalating global trend of aging has resulted in an increasing demand for pain management in conditions such as cancer and other chronic pain. Consequently, there has been a rise in the use of opioid drugs among such patients. However, these patients face a significant challenge of managing pain while dealing with severe constipation induced by opioid analgesics. This dilemma has led to a growing market demand for medications that specifically address OIC.
- *Inadequate traditional treatments and development of targeted drugs.* In China, the primary first-line treatment for OIC involves lifestyle modifications and the use of conventional laxatives such as lactulose and PEG. Despite the available methods, many patients do not experience improvement in constipation symptoms. Emerging OIC medications including PAMORAs have significant market potential for their efficacy in the overall management of OIC patients.
- *PAMORAs as the research focus.* Non-selective opioid receptor antagonists, such as naloxone, have demonstrated efficacy in alleviating the symptoms of OIC. However, their clinical application is constrained by the concurrent attenuation of opioid analgesic effects. Consequently, there is a heightened focus on the research and development of medications for OIC that fall under the category of PAMORAs. These agents aim to mitigate intestinal dysfunction caused by opioids without compromising their analgesic efficacy.

OVERVIEW OF CONGENITAL HYPERINSULINEMIA DRUG MARKET

Introduction to Congenital Hyperinsulinemia

Congenital hyperinsulinemia is a rare hereditary endocrine disease whose patients experience constant hypoglycemia induced by hyperinsulinemia. Congenital hyperinsulinemia is caused by dysfunction of pancreatic β cells, leading to sustained insulin release and inappropriate reduction of blood sugar levels, resulting in hypoglycemia. Congenital hyperinsulinemia is the most common cause of severe and persistent hypoglycemia in newborns and infants, with severe implications for the central nervous system and even mortality. It requires prompt and aggressive treatment to prevent neurological sequelae. If remain untreated, congenital hyperinsulinemia can lead to permanent brain damage, resulting in conditions such as epilepsy and cerebral palsy. In China, congenital hyperinsulinemia was included in the “Rare Disease Catalog of China First Edition” in 2018.

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Incidence of Congenital Hyperinsulinemia Globally

As a rare disease, the patient group of congenital hyperinsulinemia is relatively small. The incidence of congenital hyperinsulinemia globally grew from 2.8 thousand in 2018 to 3.4 thousand in 2023 with a CAGR of 4.2%. The incidence of congenital hyperinsulinemia globally is expected to further grow to 4.9 thousand in 2032 with a CAGR of 4.0% from 2023 to 2032.

Current Treatment Regimen

As of the Latest Practicable Date, there was no drug approved specifically for the treatment of congenital hyperinsulinemia globally. The current treatment options of congenital hyperinsulinemia include diazoxide, octreotide, glucagon and sirolimus. While diazoxide treatment tends to exhibit efficacy initially, rapidly occurred tolerance issues and adverse reactions include elevated liver enzymes and asymptomatic gallbladder disorders often limit its long-term use. Therefore, as the treatment duration extends, the need for continuous alternation of new drugs or alternative treatment approaches persists.

The following chart demonstrates the current treatment regimen for congenital hyperinsulinemia globally and in China.

Treatment Options for Congenital Hyperinsulinemia

Treatment pathway for CHI					
	First-line	Second-line		Other therapies	
Classification	• Non-diuretic benzothiadiazine derivative	• Somatostatin analog	• Glucoregulatory peptide hormone	• Surgical treatment	• Nutritional auxiliary therapy
Representative Drugs	• Diazoxide	• Octreotide • Lanreotide	• Glucagon		
Efficacy	• Suboptimal for patients with CHI caused by the most common K_{ATP} ion channel mutations (ABCC8/KCNJ11)	• Employed where the efficacy of diazoxide is suboptimal • Prone to developing drug resistance	• Rapidly elevates blood glucose • Used for emergency rather than long-term use	• Surgery is recommended for patients with ineffective single-drug and multi-drug combination therapy and for patients with focal lesions or insulinoma • Risk of reoperation	• For children with pathogenic variants in GLUD1 and HADH genes, dietary intervention is recommended
AE	• Fluid retention • Electrolyte disturbances • Gastrointestinal discomfort	• More severe hypoglycemia	• High blood glucose and low blood potassium levels • Nausea • Vomiting • Polymorphic erythema		
Guideline recommendation status	• AAP • Chinese guideline ¹	• Chinese guideline		• Chinese guideline	

Abbreviations: CHI = congenital hyperinsulinemia; AE = adverse event

Source: Expert consensus (2022), China Insights Consultancy

INDUSTRY OVERVIEW

Competitive Landscape of Congenital Hyperinsulinemia Drug Market

As of the Latest Practicable Date, there was no drug approved specifically for the treatment of congenital hyperinsulinemia globally. There were six clinical-stage drug candidates for the treatment of congenital hyperinsulinemia globally, as of the same date. The following table sets forth the pipeline of congenital hyperinsulinemia drug candidates under clinical development.

Pipeline of Clinical-stage Congenital Hyperinsulinemia Drugs Globally and in China

MoA	Drug Name	Company	Indication	Phase	First Posted Date	Trial Number	Competent Authority
GCGR	PB-722	PegBio	CHI	IND approval	2023/02/27	–	NMPA
	Dasiglucagon	Zealand Pharma	CHI	NDA ¹	2018/12/17 ²	NCT04172441 ²	FDA
	HM15136	Hanmi Pharm	CHI	II	2021/02/01	NCT04732416	FDA
	CSI-glucagon	Xeris Pharmaceuticals	CHI	II	2016/10/18	NCT02937558	FDA
INSR	RZ358	Rezolute; XOMA	CHI	III	2024/01/17	NCT06208215	FDA
GLP-1R	Exendin-(9-39)	Diva De Leon	CHI	I/II	2007/12/12	NCT00571324	FDA

Abbreviations: GCGR = glucagon receptor, INSR = insulin receptor.

Notes:

1. Zealand Pharma has submitted NDA to FDA regarding Dasiglucagon in June 2023. In January 2024, the FDA issued a complete response letter related to deficiencies identified at a third-party manufacturing facility. In October 2024, the FDA issued a complete response letter regarding the timing of a re-inspection.
2. The first posted date and trial number represents the Phase II/III trial of Dasiglucagon registered at ClinicalTrials.gov.

Source: CDE, Zealand Pharma, ClinicalTrials.gov, China Insights Consultancy

Growth drivers and Entry Barriers of Congenital Hyperinsulinemia Drug Market

The congenital hyperinsulinemia drug market growth has primarily been driven by the following key factors:

- *Medical advancements.* Enhanced diagnostic tools, including genetic testing and advanced imaging techniques, facilitate early and precise identification of patients with congenital hyperinsulinemia. Continued advancements in medical research hold the potential to deepen our understanding of its pathophysiology, paving the way for the development of novel therapeutic approaches and medications for more effective treatment of congenital hyperinsulinemia.
- *Favorable policy environment.* Regulatory authorities such as the NMPA in China emphasize the acceleration of the review and approval process for drugs targeting rare diseases, demonstrating a full commitment to safeguarding the health rights and interests of patients with rare diseases. Currently, there are no approved targeted drugs for congenital hyperinsulinemia, and there are relevant policies to encourage and support the research and development of pharmaceuticals dedicated to addressing rare diseases such as congenital hyperinsulinemia.

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REPORT [REDACTED] BY CHINA INSIGHTS CONSULTANCY

In connection with the [REDACTED], we [REDACTED] China Insights Consultancy, an Independent Third Party, to prepare a report on global and China’s markets regarding metabolic disorders and digestive diseases. Except as otherwise noted, all data and forecasts in this section come from the China Insights Consultancy Report. We have agreed to pay a total of RMB400,000 in fees for the preparation of the China Insights Consultancy Report. China Insights Consultancy is a market research and consulting company that provides market research on a variety of industries including healthcare. In preparing the report, China Insights Consultancy collected and reviewed publicly available data such as government-derived information, annual reports and industry association statistics, as well as market data collected by conducting interviews with key industry experts and leading industry participants. China Insights Consultancy has exercised due care in collecting and reviewing the information so collected.

REGULATORY OVERVIEW

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

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

Drug Regulatory Regime

Major Regulatory Authorities

The regulatory system for the pharmaceutical industry in the PRC consists of the Standing Committee of the National People’s Congress (the “NPCSC”), the State Council and several ministries and agencies under its authority, including, among others, the National Medical Products Administration (the “NMPA”, formerly known as China Food and Drug Administration (the “CFDA”)), the National Health Commission (the “NHC”, formerly known as the National Health and Family Planning Commission), and the National Healthcare Security Administration.

The NMPA, which inherits the drug supervision function from its predecessor the CFDA, is the primary drug regulator in China. It is the regulatory authority responsible for the registration and supervision of drugs under the supervision of the State Administration for Market Regulation (formerly known as the State Administration for Industry and Commerce, which is responsible for supervising and administering the market in the PRC), including the stages of non-clinical research, clinical trials, marketing approval, production and distribution.

The NHC, China’s chief healthcare regulator, is primarily responsible for drafting national health policies, regulating public health, medical services and the health contingency response system, coordinating the healthcare reforms, and overseeing the operation of medical institutions and the practice of medical personnel.

The National Healthcare Security Administration, a new authority established in May 2018 pursuant to the Institutional Reform Program of the State Council (《國務院機構改革方案》), is responsible for drafting and implementing policies, plans and standards relating to medical insurance, maternity insurance and medical assistance; administering the healthcare funds; formulating a uniform medical insurance catalogue and payment standards on drugs, medical consumables and healthcare services; and formulating and administering the bidding and tendering policies for drugs and medical consumables.

Laws and Regulations Related to Drugs

Drug Administration Laws and Regulations

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”) promulgated by the NPCSC on September 20, 1984 and amended on February 28, 2001, December 28, 2013, April 24, 2015 and August 26, 2019 and the Implementing Rules for the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) (the “**Implementing Rules for the Drug Administration Law**”)

REGULATORY OVERVIEW

promulgated by State Council on August 4, 2002 and amended on February 6, 2016, March 2, 2019 and December 6, 2024, respectively, have laid down the legal framework for the administration of pharmaceutical products, including the research, development, manufacturing and business operation of new drugs, which regulate the administration of pharmaceutical manufacturing enterprises, pharmaceutical trading enterprises, and medicinal preparations of medical institutions and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products.

Pharmaceutical Research of Chemically Synthesized Peptide Drugs

On February 17, 2023, CDE issued the Technical Guiding Principles on Pharmaceutical Research of Chemically Synthesized Peptide Drugs (Trial) (《化學合成多肽藥物藥學研究技術指導原則(試行)》) (the “**Technical Guiding Principles**”), which provided the general technical requirements on the pharmaceutical research of chemically synthesized peptide drugs on the basis of the analysis on the particular problems arising from the pharmaceutical research of synthesized peptide drugs, and taking into consideration the practical experience in the research and assessment of peptide drugs both domestic and overseas. Our Directors confirmed that we have adopted the technical guidelines and satisfied the technical requirements as stipulated in the Technical Guiding Principles in the research and development of our drug candidates, and have complied with and will continue to constantly ensure our compliance with the Technical Guiding Principles.

Non-clinical Research and Animal Testing

The State Administration for Market Regulation requires preclinical data to support registration applications for imported and domestic drugs. According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) issued by the State Administration for Market Regulation on January 22, 2020 and effective from July 1, 2020, the non-clinical safety evaluation studies for drugs should comply with the Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) (the “**GLP**”). The CFDA implemented the latest GLP from September 1, 2017 to improve the quality of non-clinical laboratory studies.

According to the Administrative Measures for the Certification of Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》) issued by the NMPA on January 19, 2023 and effective from July 1, 2023, the institutions intending to carry out non-clinical safety evaluation studies in China for the purpose of drug registration applications shall apply for the certification of GLP. The NMPA is responsible for the administration of the certification of GLP in China, and the drug regulatory authorities at the provincial level are responsible for the daily supervision and management on institutions of non-clinical safety evaluation studies within their administrative regions. The NMPA will approve and issue GLP certificates to the applicants that meet the GLP requirements, and the GLP certificates are valid for 5 years. Any entity without such certification must engage a qualified third party to conduct non-clinical studies regulated under relevant laws and regulations.

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According to the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) issued by the State Scientific and Technological Commission on November 14, 1988 and last amended by the State Council on March 1, 2017, the Administrative Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) jointly issued by the State Scientific and Technological Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997 and the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) issued by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001 and effective from January 1, 2002, using and breeding experimental animals shall be subject to some rules and performing experimentation on animals requires a Certificate for Use of Experimental Animals. Any entity without such certification must engage a qualified third party to conduct such non-clinical studies regulated under relevant laws and regulations.

Clinical Trial Approval

According to the Drug Administration Law, the Implementing Rules for the Drug Administration Law and the Administrative Measures for Drug Registration, clinical trials should be conducted when applying for registration of a new drug. The Center for Drug Evaluation, an agency under the NMPA, is responsible for the application for clinical trials of new drugs. After the approval of an application for investigational new drug (“**IND application**”), the applicant shall register the information about the clinical trial protocol on the Drug Clinical Trial Registration and Information Disclosure Platform before the implementation of the clinical trial of the drug.

According to the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) issued by the CFDA on September 6, 2013, all applicants who have obtained clinical trial approvals from the NMPA and are conducting clinical trials in China, shall complete clinical trial registration and publish trial information through the Drug Clinical Trial Public Information Platform. The applicant shall complete the trial pre-registration within one month after obtaining the approval of IND application, in order to obtain the unique registration number of the trial, and complete the registration of subsequent information before the enrollment of the first subject. If the first submission is not completed within one year after obtaining the approval of IND application, the applicant shall submit an explanation; and if the first submission is not completed within three years, the approval of IND application will be revoked by itself.

The CFDA issued the Announcement on Certain Policies Pertaining to the Review and Approval of Drug Registration (《關於藥品註冊審評審批若干政策的公告》) on November 11, 2015, according to which, the drug approval process was further simplified by implementing a one-time approval for INDs of new drugs, and no longer adopting declarations, reviews or approvals at different phases. The Announcement on Adjustment of the Procedures for Review and Approval of Drug Clinical Trials (《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, stipulates that, applicants could proceed with their drug clinical trials in accordance with the submitted protocols if they have not received any objection or query from the Center for Drug Evaluation under NMPA (“**CDE**”) within 60 business days after the IND application has been accepted and the relevant application fees have been paid.

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On February 9, 2025, the CDE issued the Guidelines for Acceptance and Review of Applications for Registration of Chemical Drugs (Trial) (《化學藥品註冊受理審查指南(試行)》) which became effective on March 10, 2025 and prevailed its previous version, providing implementation details on IND applications for chemical drugs.

Communication with CDE at Clinical Trial Phases

According to the Administrative Measures for Drug Registration, based on the characteristics of the drug and the purpose of the study, clinical trials of drugs are divided into phase I clinical trials, phase II clinical trials, phase III clinical trials, phase IV clinical trials and bioequivalence trials, and the content of the study includes clinical pharmacological studies, exploratory clinical trials, confirmatory clinical trials and post-marketing studies. Clinical trials shall be conducted in accordance with the provisions of the Good Clinical Practice (《藥物臨床試驗質量管理規範》), including the preparation of clinical trials, clinical trial protocols, responsibilities of sponsors and investigators, and protection of subjects.

According to the Announcement on Adjustment of the Procedures for Review and Approval of Drug Clinical Trials, where the approval has been granted for clinical trial of a new drug, upon the completion of Phase I and Phase II clinical trials and prior to the commencement of Phase III clinical trial, the applicant shall submit an application for communication meetings to the CDE to discuss with the CDE the key technical issues, including the design of Phase III clinical trial protocol.

According to the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》) issued by the CDE on December 10, 2020, during the research and development periods and in the registration applications of innovative new drugs, the applicant may propose to hold communication meetings with the CDE. The mode of communication may be face-to-face meeting, video conference, teleconference or written response. The communication meetings can be classified into three types. Type I meetings are held to resolve major safety issues in clinical trials and major technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development periods of drugs, including pre-IND application meetings, meetings upon the completion of Phase II clinical trials and before the commencement of Phase III clinical trials, meetings before submitting a marketing application for a new drug and meetings for risk assessment and control. Type III meetings refer to meetings not classified as Type I and II.

International Multi-Centre Clinical Trials

According to the International Multi-Center Clinical Trial Guidelines (Trial) (《國際多中心藥物臨床試驗指南(試行)》), which was issued by the CFDA on January 30, 2015 and became effective on March 1, 2015, the sponsor may conduct clinical trials simultaneously at multiple centres in multiple regions in accordance with the same clinical trial protocol, and may also conduct regional clinical trials simultaneously at multiple centres in different countries within a region in accordance with the same clinical trial protocol. If the applicants

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plan to use the data derived from international multi-centre clinical trials for approval of drug registration in China, such international multi-center clinical trials shall comply with the provisions concerning clinical trials in the Administrative Measures for Drug Registration. When planning and implementing international multi-centre clinical trials in China, the sponsor shall comply with the Drug Administration Law, the Implementing Rules for the Drug Administration Law and the Administrative Measures for Drug Registration and other related laws and regulations, implement the Good Clinical Practice (GCP) in China, make reference to universal international principles such as ICH-GCP, and meet the legal and regulatory requirements of the corresponding countries.

NMPA issued the Technical Guiding Principles for the Acceptance of Overseas Clinical Trial Data of Drugs (《接受藥品境外臨床試驗數據的技術指導原則》) on July 6, 2018, according to which, for drugs applied for registration within the PRC, overseas clinical trial data submitted by the applicant may be accepted as the information for clinical evaluation.

New Drug Registration Application

According to the Administrative Measures for Drug Registration, drug registration shall be subject to classified registration administration in terms of traditional Chinese medicines, chemical drugs and biological products, etc. Among them, chemical drug registration shall be categorized by innovative new chemical drugs, improved new chemical drugs, generic chemical drugs, etc.

According to the Reform Plan for Registration Category of Chemical Drugs (《化學藥品註冊分類改革工作方案》) issued by the CFDA on March 4, 2016, the registration classification of the chemical drugs is adjusted to five categories: (I) Category 1 refers to innovative new chemical drugs that have not been marketed anywhere in the world. Category 1 drugs shall contain new compounds with clear structure and pharmacological effects and clinical value; (II) Category 2 refers to improved new chemical drugs that are not marketed anywhere in the world. Category 2 drugs, which should have obvious clinical advantages, shall be optimized in terms of their structure, dosage form, formulation technology, route of administration and indications on the basis of known active ingredients; (III) Category 3 refers to chemical drugs that are imitated by domestic applicants to original drugs that have been marketed abroad but not domestically. Category 3 drugs should have equivalent quality and efficacy as the original drugs, which refer to the first drugs approved for marketing at home and abroad and with complete and sufficient safety and effectiveness data as the basis for marketing; (IV) Category 4 refers to chemical drugs that are imitated by domestic applicants to original drugs that have been marketed domestically. Category 4 drugs should have equivalent quality and efficacy as the original drugs; and (V) Category 5 refers to chemical drugs that have been marketed abroad and applied to be marketed domestically. For drugs of Category 1 and Category 2, the application shall be filed according to the procedures for new drugs, drugs of Category 3 and Category 4 shall be filed according to the procedures for generic drugs, and drugs of Category 5 shall be filed according to the procedures for imported drugs.

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According to The Chemical Drug Registration Classification and Application Data Requirements (《化學藥品註冊分類及申報資料要求》) which was promulgated by the NMPA on June 29, 2020, and took effect on July 1, 2020 (for the chemical drug registration classification part), chemical drug registration shall be categorized by innovative new chemical drugs, improved new chemical drugs, generic chemical drugs, and chemical drugs marketed abroad but not domestically. The Chemical Drug Registration Classification and Application Data Requirements reaffirmed the principles of the classification set forth by the Reform Plan for Registration Category of Chemical Drugs, made further adjustments to the subclassifications of chemical drugs under Category 2 and Category 5, and made further explanations on the quality and efficacy requirements for generic chemical drugs of Category 3 and Category 4. It also provided requirements for registration administration and application materials for various chemical drugs as well.

According to the Administrative Measures for Drug Registration, an applicant shall upon completion of pharmacy, pharmacology and toxicology and clinical trial studies of drugs, etc. to support registration of drug marketing, determination of quality standards, verification of commercial scale manufacturing process, and preparation to undergo examination and inspection for drug registration, submit a new drug application (the “NDA”), which shall be evaluated by the NMPA in accordance with applicable laws and regulations. The applicant must obtain approval of an NDA before the drugs can be manufactured and sold in China. During the drug clinical trials, for drugs which fall under the following circumstances, an application for conditional approval may be submitted: (I) for drugs used for the treatment of severe and life-threatening diseases that cannot be treated in an effective manner and those the clinical trial data of which already show their efficacy and their clinical value is predictable; (II) for drugs urgently needed for public health and those the clinical trial data of which already show their efficacy and their clinical value is predictable; and (III) for vaccines that are urgently needed for major public health emergencies or other vaccines deemed by the NHC to be urgently needed, whose benefits outweigh their risks according to the evaluation.

According to the Provisions on the Administration of Special Examination and Approval of Registration of New Drugs (《新藥註冊特殊審批管理規定》) promulgated by the CFDA on January 7, 2009, the CFDA may conduct special examination and approval for new drugs registration applications when (I) the effective constituent of a drug extracted from plants, animals, minerals, etc., as well as the preparations thereof, have never been marketed in China, and the material medicines and the preparations thereof are newly discovered; (II) the chemical raw materials for medicines as well as the preparations thereof and the biological products have not been approved for marketing, either in China or abroad; (III) new drugs with distinctive clinical treatment advantages for diseases such as AIDS, malignant tumor or other rare diseases; or (IV) new drugs for diseases that currently lack effective treatment. Under the circumstances set out in (I) and (II), drug registration applicants (the “**applicants**”) may make special approval applications in submitting applications for clinical trials of new drugs; under the circumstances set out in (III) and (IV), the applicants may make special approval applications only in applying for production. The CFDA shall, according to the applicants’ applications, offer priority processing to applications that verifiably fulfil the listed exceptional circumstances, in addition to an enhanced interaction with the applicants.

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The Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment promulgated by the State Council on August 9, 2015 (《國務院關於改革藥品醫療器械審評審批制度的意見》) established a framework for reforming the evaluation and approval system for drugs, medical devices and equipment, and indicated enhancing the standard of approval for drug registration and accelerating the evaluation and approval process for innovative new drugs as well as improving the approval of drug clinical trials.

The Announcement on Certain Policies Pertaining to the Review and Approval of Drug Registration issued by the CFDA provided fast-track clinical trial approvals and drug registration pathways for the following NDAs: (I) registration of innovative new drugs treating HIV, malignant tumors (cancers), severe infectious diseases and rare diseases; (II) registration of pediatric drugs; (III) registration of geriatric drugs and drugs treating diseases specially or commonly contracted by the senior population; (IV) registration of drugs listed in national major science and technology projects or national key research and development plans; (V) registration of innovative new drugs using advanced technology or innovative treatments, or having distinctive clinical benefits; (VI) registration of foreign innovative new drugs to be manufactured locally in China; (VII) concurrent applications for new drug clinical trials which are already approved in the United States or the European Union or concurrent drug registration applications for drugs which have applied to the competent drug approval authorities for marketing authorization and passed such authorities’ onsite inspections in the United States or European Union and are manufactured using the same production line in China; and (VIII) clinical trial applications for drugs with urgent clinical need and patent expiry within three years, and manufacturing authorization applications for drugs with urgent clinical need and patent expiry within one year.

On October 8, 2017, the General Office of Chinese Communist Party’s Central Committee and the General Office of the State Council jointly issued the Opinions on Deepening the Reform of the Review and Approval System to Encourage the Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》), seeking to streamline the clinical trial process and shorten the timeline. It provided expedited review and approval for marketing of new drugs and medical devices in urgent clinical need, and drugs and medical devices for rare diseases.

In addition, on May 17, 2018, the NMPA and the NHC jointly promulgated the Circular on Issues Concerning Optimizing Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》), which further simplified and accelerated the drug review and approval process.

According to the Evaluation Procedures for Breakthrough Therapeutic Drugs (Trial) (《突破性治療藥物審評工作程序(試行)》) issued by the NMPA on July 7, 2020, during clinical trials, the applicants may apply for the breakthrough therapy drug procedure during the phase I and II clinical trials and normally no later than the commencement of phase III clinical trials for innovative new drugs or improved new drugs that are used to prevent and treat diseases that are severely life-threatening or severely affecting the quality of life and have no effective prevention and treatment or have sufficient evidence showing they have obvious clinical advantages compared with existing treatments.

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According to the Evaluation and Approval Procedures for Conditionally Approval of Marketing Application of Drugs (Trial) (《藥品附條件批准上市申請審評審批工作程序(試行)》) issued by the NMPA on July 7, 2020, during clinical trials, the applicants may file conditional approval applications to the CDE for drugs that fall under the circumstances and conditions set forth by the Clinical Technical Guideline for Conditional Marketing Approval of Drugs.

According to the Prioritized Evaluation and Approval Procedures for Drug Marketing Authorization (Trial) (《藥品上市許可優先審評審批工作程序(試行)》) issued by the NMPA on July 7, 2020, at the time of the drug marketing authorization, drugs that have the obvious clinical value may apply for application of procedures for prioritized review and approval, including (I) clinically and urgently needed but insufficient drugs, innovative new drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases; (II) new pharmaceutical product types, dosage form and specifications of pediatric drugs which comply with pediatric physiological characteristics; (III) vaccines and innovative vaccines urgently needed for prevention and control of diseases; (IV) drugs included in the procedures for ground-breaking therapeutic drugs; (V) drugs which comply with conditional approval criteria; and (VI) other circumstances of prioritized review and approval stipulated by the NMPA.

In addition, the Guidelines for Acceptance and Review of Applications for Registration of Chemical Drugs (Trial) recently issued by the CDE provide implementation details on NDAs for chemical drugs.

Marketing Authorization Holder System

According to the Drug Administration Law, the State implements the drug marketing authorization holder system for drug administration. “Drug marketing authorization holder” means an enterprise, a drug development institute, or the like that has obtained the drug registration certificate. The drug marketing authorization holder shall be responsible for the safety, effectiveness, and quality controllability of drugs during the whole process of the development, production, distribution, and use of the drugs, as legally required. The drug marketing authorization holder shall also be responsible for non-clinical research, clinical trials, production and distribution, post-marketing research, adverse reaction monitoring, reporting and processing of drugs. The legal representative or the key person-in-charge of the drug marketing authorization holder shall be fully responsible for the drug quality. The drug marketing authorization holder may engage in drug manufacturing on its own or may entrust a drug manufacturing enterprise that satisfies the required conditions to manufacture, and it may sell the drugs for which it has obtained a drug registration certificate on its own or entrust a drug distribution enterprise that satisfies the required conditions to sell. The drug marketing authorization holder shall establish a drug quality assurance system and assign special personnel to independently take charge of drug quality control. The drug marketing authorization holder shall periodically review the quality management system of the entrusted drug manufacturing enterprise and drug distribution enterprise, and supervise their continuous quality assurance and control capabilities. The drug marketing authorization holder, the drug manufacturing enterprise, the drug distribution enterprise and the medical institution shall establish and implement a drug traceability system, provide traceability information pursuant to the provisions and ensure the traceability of drugs.

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Pharmacovigilance

According to the Good Pharmacovigilance Practices (《藥物警戒質量管理規範》), which was issued by the NMPA on May 7, 2021 and became effective on December 1, 2021, the drug marketing authorization holder and the drug registration applicant who has been approved to conduct drug clinical trials shall establish a pharmacovigilance system, through the effective operation and maintenance of which, they can monitor, identify, evaluate and control the adverse drug reactions and other drug-related harmful reactions. The drug marketing authorization holder shall formulate pharmacovigilance quality objectives, establish a quality assurance system, and conduct quality management of the pharmacovigilance system and activities, so as to continuously improve the operation efficiency of the pharmacovigilance system and ensure that pharmacovigilance activities continue to comply with the requirements of relevant laws and regulations. The legal representative or the key person-in-charge of the drug marketing authorization holder is fully responsible for the pharmacovigilance activities. The drug marketing authorization holder shall complete information registration in the National Adverse Drug Reaction Monitoring System within 30 days after obtaining the first drug approval document.

Sampling and Collecting Human Genetic Resources Filing

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》) issued by the Ministry of Science and Technology (MOST) on July 2, 2015 and the Circular on Implementing the Administrative Licensing for the Sampling, Collecting, Trading, Exporting of Human Genetic Resources, or Taking Such Resources out of PRC (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) issued by the MOST on August 24, 2015, the sampling, collecting or research activities of human genetic resources with the participation of a foreign-invested sponsor fall within the scope of international cooperation, and the Chinese collaborating party shall apply for approval of the China Human Genetic Resources Management Office through the online system. 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》) which took effect on December 1, 2017, simplifying the approval of sampling and collecting human genetic resources for the purpose of listing a drug in the PRC.

According to the Regulations of the PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》), which was promulgated by the State Council on May 28, 2019, became effective on July 1, 2019 and was amended on March 10, 2024, for the purpose of obtaining marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China's human genetic resources at clinical institutions, if not involving the export of human genetic resource materials. However, the two parties shall file the type, quantity and usage of the human genetic resource to be used with the administrative department of health under the State Council before clinical trials. The Implementing Rules of the Regulation on the

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Administration of 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 became effective on July 1, 2023, further provides specific requirements on the collection, preservation, utilization and external provision of China’s human genetic resources.

The PRC Biosecurity Law (《中華人民共和國生物安全法》) (the “**Biosecurity Law**”), which was promulgated by NPCSC on October 17, 2020, became effective on April 15, 2021 and was amended on April 26, 2024, establishes a comprehensive legislative framework for the pre-existing regulations in such areas as epidemic control of infectious diseases for humans, animals and plants; research, development, and application of biology technology; biosecurity management of pathogenic microbial laboratories; security management of human genetic resources and biological resources; countermeasures for microbial resistance; and prevention of bioterrorism and defending threats of biological weapons. According to the Biosecurity Law, the research and development activities of high-risk and medium-risk biotechnology shall be carried out by a legal person organization established within the territory of the PRC in accordance with the law, upon obtaining the approval or record-filing; the establishment of a pathogenic microorganism laboratory shall be subject to approval or record-filing requirements in accordance with the law; (I) collecting human genetic resources of important genetic families or specific areas in the PRC, or collecting human genetic resources of which the types and quantities are subject to provisions of the competent department of health under the State Council, (II) preserving China’s human genetic resources, (III) using China’s human genetic resources to carry out international scientific research cooperation, or (IV) transporting, mailing, and carrying China’s human genetic resource materials out of the country shall subject to approval of the competent department of health.

Administrative Protection and Monitoring Period for New Drugs

According to the Implementing Rules for the Drug Administration Law, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of up to five years for new drugs approved to be manufactured, to continually monitor the safety of those new drugs. During the monitoring period of a new drug, the NMPA will not approve any other enterprise’s application to manufacture or import a similar new drug.

Drug Manufacturing License

According to the Drug Administration Law and the Implementing Rules for the Drug Administration Law, when engaging in pharmaceutical manufacturing activities, an enterprise must obtain a drug manufacturing license (藥品生產許可證) granted by the drug regulatory authority of the people’s government of the province, autonomous region, or municipality directly under the central government at the place where the enterprise is located. No pharmaceutical products shall be produced without a drug manufacturing license. The drug regulatory authority of the people’s government of the province, autonomous region, or municipality directly under the central government shall organize acceptance inspection for an enterprise subject to the following conditions, and issue a drug manufacturing license if the acceptance inspection is passed: (I) It shall be staffed with legally certified pharmaceutical

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technical personnel, engineering technical personnel, as well as corresponding skilled workers; (II) It shall have factory premises, facilities and a sanitary environment suitable for the drugs produced; (III) It shall have institutions and personnel capable of managing and inspecting the quality of the drugs produced, as well as necessary instruments and equipment; and (IV) It shall have rules and regulations to ensure the quality of drugs. Each Drug Manufacturing License is valid for five years. If an enterprise holding the drug manufacturing license needs to continue the manufacturing of drugs upon the expiration of the license, the enterprise should apply for renewal in compliance with the regulation of the drug regulatory authority under the State Council six months prior to the expiration of the license.

GMP

The Good Manufacturing Practices (GMP) was first promulgated by the Ministry of Health on March 17, 1988 and subsequently amended on December 28, 1992. After the establishment of the NMPA, the GMP was amended on June 18, 1999 and became effective on August 1, 1999. The GMP, which was amended by the Ministry of Health on January 17, 2011 and became effective on March 1, 2011, sets the basic standards for the manufacture of pharmaceuticals, covering issues such as the production plant and facilities, the qualification of the personnel at the management level, documentation, material packaging and labeling, inspection, production management, sales and return of products and customer complaints.

On August 2, 2011, the CFDA promulgated the Notice on Issuing the Administrative Rules Governing the Certification of Good Manufacturing Practice for Drugs (《關於印發藥品生產質量管理規範認證管理辦法的通知》), according to which, a new pharmaceutical manufacturer, or a pharmaceutical manufacturer that extends its manufacturing scope or establishes a new workshop shall apply for GMP certification for drugs in compliance with the Implementing Rules for the Drug Administration Law. For any pharmaceutical manufacturer holding GMP certification for drugs, the certificate shall be renewed no later than six months before the expiry of its valid term. On December 30, 2015, the CFDA issued the Notice on Matters concerning the Implementation of Good Manufacturing Practice (《關於切實做好實施藥品生產質量管理規範有關工作的通知》), which provided that drug manufacturers failing to obtain the GMP certificates will not be issued with the drug manufacturing license.

On November 29, 2019, the NMPA promulgated the Circular 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》), which confirmed that since December 1, 2019, the GMP certifications have been cancelled, applications for GMP certifications are no longer accepted, and GMP certificates are no longer issued. However, according to the Drug Administration Law, when engaging in drug manufacturing activities, a manufacturer shall comply with the GMP and establish a sound GMP system, so as to ensure that the entire process of drug manufacturing always meets the statutory requirements.

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The Administrative Measures for the Inspection of Pharmaceuticals (Trial) (《藥品檢查管理辦法(試行)》) was promulgated by the NMPA on May 24, 2021 and amended on July 19, 2023, and the Certification Measures for Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》) was repealed simultaneously. The Administrative Measures for the Inspection of Pharmaceuticals (Trial) stipulated that if a drug manufacturer applies for a drug manufacturing license for the first time, it will be subject to on-site inspection under relevant contents of the GMP; if a drug manufacturer applies for re-issuance of drug manufacturing license, relevant authorities shall conduct examination pursuant to risk management principle, taking into account the enterprise’s compliance with pharmaceutical administration laws and regulations, operation status of GMP and quality system, and may conduct GMP compliance inspection where necessary.

Entrusted Manufacturing of Drugs

According to the Administrative Measures on Supervision of Pharmaceutical Manufacturing (《藥品生產監督管理辦法》), which was promulgated by the State Administration for Market Regulation on December 11, 2002 and last amended on January 22, 2020, and whose latest amendment took effect on July 1, 2020, a drug marketing authorization holder can entrust a qualified drug manufacturer to manufacture drugs, but it shall evaluate the entrusted party’s quality assurance capabilities and risk management capabilities. And the drug marketing authorization holder shall follow the Guidelines for the Quality Agreements of Entrusted Manufacturing of Drugs (《藥品委託生產質量協議指南》) formulated by the NMPA to sign the quality agreement and the entrustment agreement with the entrusted party and to supervise the entrusted party to fulfill the obligations agreed upon in the agreement. The entrusted party shall not re-entrust a third party to manufacture the drugs for which it has accepted the manufacturing entrustment. A drug marketing authorization holder shall establish a drug quality assurance system which shall be independently managed by professionals for the quality control of drugs. A drug marketing authorization holder shall regularly examine the quality management system of drug producers and drug trading companies entrusted by it to ensure that they remain capable in quality assurance and control. The legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the quality of drugs, while the legal representative and the key person-in-charge of a drug manufacturer shall be fully responsible for the manufacturing activities of its own. The drug marketing authorization holder and drug manufacturers shall establish and implement a drug traceability system, assign traceability labels to sales packaging of their drugs in accordance with regulations, implement drug traceability through information-based means, record and keep drug traceability data in a timely manner, and provide traceability information to the drug traceability collaborative service platform.

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Other Relevant Regulations in China’s Pharmaceutical Industry

Coverage of the National Medical Insurance System

On 14 December 1998, the State Council issued the Decision of the State Council on the Establishment of a Basic Medical Insurance System for Urban Workers (《國務院關於建立城鎮職工基本醫療保險制度的決定》), which for the first time implemented the national medical insurance system, requiring all urban employers and their employees to participate in basic medical insurance, with the basic medical insurance premiums to be borne by both the employer and the employee. The State Council issued the Guiding Opinions of the State Council on the Launching of Pilot Basic Medical Insurance for Urban Residents (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》) on 10 July 2007, which further expanded the coverage of the basic medical insurance system, according to which urban non-employed residents within the scope of the pilot scheme could voluntarily participate in basic medical insurance for urban residents. In addition, the State Council issued 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》) on 3 January 2016, which called for the integration of the two systems of basic medical insurance for urban residents and new type rural cooperative medical care, and the establishment of a unified basic medical insurance system for urban and rural residents, i.e., to cover all urban and rural residents other than rural migrant workers and flexibly employed persons participating in basic medical insurance for urban workers in accordance with the law. Participants in medical insurance are reimbursed for all or part of the cost of medicines on the national medical insurance catalogue.

According to the Circular on the Printing and Issuance of the Interim Measures for the Administration of the Scope of Medicines Used in Basic Medical Insurance for Urban Workers (《關於印發城鎮職工基本醫療保險用藥範圍管理暫行辦法的通知》), jointly issued by the Ministry of Labour and Social Security and the Ministry of Finance of the People’s Republic of China (the “MOF”) and other departments on 12 May 1999, the scope of medicines used in basic medical insurance is administered through the formulation of a Basic Medical Insurance Drug Catalogue. Drugs included in the Basic Medical Insurance Drug Catalogue shall be those that are clinically necessary, safe and effective, reasonably priced, convenient to use, and that the market can guarantee their availability, and shall meet one of the following conditions: (I) drugs included in the Pharmacopoeia of the People’s Republic of China, (II) drugs in compliance with the standards issued by the National Medical Products Administration, and (III) drugs formally imported with the approval of the National Medical Products Administration. The medicines listed in the Basic Medical Insurance Drug Catalogue include western medicines, proprietary Chinese medicines and Chinese medicine decoction pieces, and are divided into “Class A Catalogue” and “Class B Catalogue”. The “Class A Catalogue” is uniformly set by the State and cannot be adjusted by localities. The “Class B Catalogue” is formulated by the State, and provinces, autonomous regions and municipalities directly under the Central Government may make appropriate adjustments in accordance with the local economic level, medical needs and medication habits, and the sum of the number of varieties to be increased or decreased shall not exceed 15% of the total number of medicines in the “Class B Catalogue” formulated by the State. Expenses incurred by basic medical insurance participants for the use of drugs in the “Class A Catalogue” shall be paid in accordance with

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the provisions of basic medical insurance. Expenses incurred for the use of medicines in the “Class B Catalogue” are paid by the participants at a certain percentage of their own expense, and then paid in accordance with the provisions of basic medical insurance. The specific percentage of out-of-pocket payment shall be set by the region subject to overall planning and reported to the labour security administrative department of the province, autonomous region or municipality directly under the Central Government for record. The National Basic Medical Insurance Drug Catalogue is adjusted in principle every two years, and is adjusted accordingly in each province, autonomous region and municipality directly under the Central Government.

According to the Interim Measures for the Administration of the Use of Drugs Covered by Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) issued by the National Healthcare Security Administration on 30 July 2020 and effective from 1 September 2020, the scope of the use of drugs covered by basic medical insurance is administered through the formulation of the Basic Medical Insurance Drug Catalogue. The costs of medicines in line with the Basic Medical Insurance Drug Catalogue are paid by the basic medical insurance fund in accordance with national regulations. Drugs included in the national Basic Medical Insurance Drug Catalogue should be chemical drugs, biological products, proprietary Chinese medicines (ethnomedicines), and Chinese medicine decoction pieces prepared in accordance with national standards, which have been approved by the national drug regulatory authorities and have obtained drug registration certificates, and which meet the basic conditions of being clinically necessary, safe and effective, and reasonably priced. The State Council’s administrative department for medical insurance has established a sound dynamic adjustment mechanism, and in principle adjusts the Basic Medical Insurance Drug Catalogue once a year. On the premise of meeting clinical needs, medical insurance designated medical institutions shall give priority to equipping and using drugs in the Basic Medical Insurance Drug Catalogue.

According to the Interim Measures for the Administration of the Use of Drugs Covered by Basic Medical Insurance, expenses incurred by insured persons for the use of medicines in the Basic Medical Insurance Drug Catalogue can be paid by the basic medical insurance fund if they meet the following conditions: (I) they are for the purpose of the diagnosis or treatment of diseases; (II) the diagnosis and treatment are in line with the condition of the disease, and are in line with the legal indications for the medicines as well as the limited scope of payment by the medical insurance; (III) they are provided by the designated medical institutions in compliance with the regulations, except for emergency and rescue medicines; (IV) the cost of medicines paid for by the pooled fund should be based on a doctor’s prescription or hospitalization order; and (V) they are reviewed by pharmacists or licensed pharmacists in accordance with the stipulated procedures. Western medicines and proprietary Chinese medicines in the Basic Medical Insurance Drug Catalogue are divided into “Class A drugs” and “Class B drugs”. The use of “Class A drugs” is paid for by the insured according to the payment standards and sharing methods stipulated by the basic medical insurance; the use of “Class B drugs” is paid for according to the payment standards stipulated by the basic medical insurance, with a certain percentage paid out of pocket by the insured first, and then paid for according to the sharing methods stipulated by the basic medical insurance. The proportion of out-of-pocket payments for “Class B drugs” is determined by the medical insurance administrative departments in provinces or regions subject to overall planning.

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National Basic Drug Catalogue

Pursuant to the Circular on the Printing and Issuance of the Measures for the Administration of the National Basic Drug Catalogue (《關於印發國家基本藥物目錄管理辦法的通知》) issued on 13 February 2015, the Opinions of the General Office of the State Council on Improving the National Basic Drug System (《國務院辦公廳關於完善國家基本藥物制度的意見》) issued on 13 September 2018 and the National Basic Drug Catalogue (2018) issued by the NHC on 30 September 2018 and effective from 1 November 2018 (the “**National Basic Drug Catalogue**”), primary healthcare institutions operated by the government (mainly including county hospitals, county hospitals of traditional Chinese medicine, township health centres and community outpatient clinics) shall be equipped with and use the drugs listed in the National Basic Drug Catalogue. Drugs in the National Basic Drugs Catalogue must be procured through a centralized bidding process and are subject to price control by the National Development and Reform Commission (the “**NDRC**”). Therapeutic drugs in the National Basic Drug Catalogue are included in the medical insurance catalogue and the full cost of purchasing such drugs is reimbursed.

Centralized Purchasing of Drugs

According to the Guiding Opinions on the Reform of the Urban Medical and Health Care System (《關於城鎮醫藥衛生體制改革的指導意見》), jointly issued by the Economic Restructuring Office of the State Council and other departments on 16 February 2000, and the Opinions on the Implementation of the Classification and Management of Urban Medical Institutions (《關於城鎮醫療機構分類管理的實施意見》), jointly issued by the Ministry of Health and other departments on 18 July 2000 and effective from 1 September 2000, medical institutions are classified into two categories for management: non-profit and for-profit. Non-profit medical institutions are those that are set up and operated for the benefit of the public and not for profit; for-profit medical institutions are those whose proceeds from medical services can be used for the financial return of investors. The Government does not operate for-profit medical institutions. The Guiding Opinions on the Reform of the Urban Medical and Health Care System proposes a pilot centralized bidding and purchasing exercise for medicines, requiring that centralized bidding and purchasing must adhere to the principles of openness and fair competition.

According to the Several Provisions on the Pilot Work of the Centralized Bidding and Purchasing of Drugs for Medical Institutions (《醫療機構藥品集中招標採購試點工作若干規定》), which was jointly issued by the Ministry of Health and other departments on 7 July 2000, and the Circular on Further Improving the Work of Centralized Bidding and Purchasing of Drugs for Medical Institutions (《關於進一步做好醫療機構藥品集中招標採購工作的通知》), which was jointly issued by the Ministry of Health and other departments on 23 July 2001, non-profit medical institutions run by the people’s governments at county level and above are required to carry out centralized bidding and purchasing of drugs. Drugs included in the drug catalogue of basic medical insurance for urban workers (or publicly-funded medical care) and those with relatively high clinical usage in medical institutions are, in principle, subject to centralized bidding and procurement.

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According to the Opinions on Further Regulating the Centralized Purchasing of Drugs for Medical Institutions (《關於進一步規範醫療機構藥品集中採購工作的意見》), jointly issued by the Ministry of Health and other departments on 17 January 2009, the centralized purchasing of drugs for medical institutions is to be implemented on a provincial (regional and municipal) basis. Non-profit medical institutions under the people’s governments at county level and above, state-owned enterprises (including state-controlled enterprises), etc., must all participate in the centralized purchasing of drugs; other medical institutions are encouraged to participate in the centralized purchasing of drugs. The centralized purchasing of drugs should give full consideration to the characteristics of the clinical demand for drugs at all levels and in all types of medical institutions, and the centralized purchasing cycle should be once a year in principle. Provinces (autonomous regions and municipalities) are required to formulate a catalogue of drugs for centralized purchasing. Drugs included in the National Basic Drug Catalogue are implemented in accordance with the provisions of the national basic drugs system. A few varieties of drugs under special management by the State, such as Class II psychotropic drugs, toxic drugs for medical use and radiopharmaceuticals, as well as Chinese herbal drugs and Chinese medicine decoction pieces, may not be included in the catalogue for the centralized purchasing of drugs, and narcotic drugs and Class I psychotropic drugs are not included in the catalogue for the centralized purchasing of drugs. In addition to the above drugs, all other drugs used by medical institutions must, in principle, be included in the centralized purchasing catalogue.

According to the Code of Practice for the Centralized Purchasing of Drugs for Medical Institutions (《醫療機構藥品集中採購工作規範》) jointly issued by the Ministry of Health and other departments on 7 July 2010, medical institutions must procure drugs through the non-profit platform for the centralized purchasing of drugs established by the government.

According to the Guiding Opinions of the General Office of the State Council on Improving the Centralized Purchasing of Drugs for Public Hospitals (《國務院辦公廳關於完善公立醫院藥品集中採購工作的指導意見》) issued by the General Office of the State Council on 9 February 2015, the centralized purchasing of drugs is carried out in a categorized manner: (I) for basic drugs and generic drugs with high clinical usage, high purchasing amounts and produced by multiple enterprises, the advantages of centralized bulk purchasing at the provincial level are brought into play, and the provincial drug purchasing agencies adopt the two-envelope system of public bidding and purchasing. Hospitals, as the main purchasing body, purchase drugs at the winning price; (II) for some patented drugs and exclusively produced drugs, an open and transparent price negotiation mechanism with multi-party participation shall be established, and the negotiation results are announced on the national comprehensive management information platform for the supply security of drugs, with hospitals purchasing drugs in accordance with the negotiation results; (III) for generic medicines for women and children, emergency (rescue) medicines, basic infusion solutions, medicines with small clinical dosages (the specific scope of the above medicines is determined by the provinces, autonomous regions and municipalities) and commonly-used, low-priced medicines, centralized online bidding is implemented, and hospitals directly procure them; (IV) for drugs that are clinically necessary, in small dosages, and in short supply in the market, they shall be produced by the national bidding system and procured through bargaining; (V) for

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narcotic drugs, psychotropic drugs, free drugs for the prevention and treatment of infectious and parasitic diseases, vaccines of national immunization plan, family planning drugs and Chinese medicine decoction pieces, they shall be procured in accordance with the current state regulations.

According to the Several Opinions of the General Office of the State Council on the Further Reform and Improvement of the Policies on the Production, Circulation and Use of Drugs (《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》), issued by the General Office of the State Council on 24 January 2017, cross-regional and specialist hospitals are encouraged to conduct joint purchases; in areas where the reform of the payment method of health insurance is comprehensively implemented or where the payment standard for drugs under health insurance has already been formulated, public hospitals are allowed to jointly carry out volume- and budget-based procurement on the provincial centralized drug procurement platform (the provincial public resources trading platform).

The Pilot Program for Conducting the Centralized Purchasing and Use of Drugs Organized by the State (《國家組織藥品集中採購和使用試點方案》) issued by the General Office of the State Council on 1 January 2019 selected 11 cities, namely Beijing, Tianjin, Shanghai, Chongqing and Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi'an, to carry out the pilot programme on the centralized purchasing and use of state-organized drugs. The National Healthcare Security Administration and other departments issued the Implementing Opinions on Expanding the Pilot Program for Conducting the Centralized Procurement and Use of Drugs Organized by the State to Wider Areas (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》) on 25 September 2019 to expand the regional scope of the pilot program for conducting the centralized purchasing and use of drugs organized by the State to wider areas, and to promote the volume-based purchasing model of the pilot program for conducting the centralized purchasing and use of drugs organized by the State on a nationwide scale.

The Opinions of the General Office of the State Council on Promoting the Normalization and Institutionalization of the Centralized Volume-based Purchasing of Drugs (《國務院辦公廳關於推動藥品集中帶量採購工作常態化制度化開展的意見》), issued by the General Office of the State Council on 22 January 2021, requires the promotion of the normalization and institutionalization of the centralized volume-based purchasing of drugs. All public medical institutions (including military medical institutions, hereinafter the same) should participate in the centralized volume-based purchasing of drugs, and medical insurance designated social medical institutions and designated pharmacies should refer to the requirements for the management of designated agreements for implementation; in accordance with the principles of preserving the basic and clinical aspects of health care, the focus will be on including in the scope of procurement those medicines in the basic health insurance drug catalogue that have a large dosage and a high procurement amount, and gradually covering all types of domestically marketed medicines that are clinically necessary and of reliable quality, so as to ensure that they are procured to the fullest extent possible.

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Drug price administration

According to the Opinions on Promoting the Drug Price Reform (《推進藥品價格改革的意見》) jointly issued by the NDRC and other departments on May 4, 2015, starting from June 1, 2015, the original government-set prices of drugs were abolished, except for narcotic drugs and Class I psychotropic drugs. Narcotic drugs and Class I psychotropic drugs are still temporarily managed by the NDRC through the implementation of maximum factory prices and maximum retail prices. With the exception of narcotic drugs and Class I psychotropic drugs, the government pricing of drugs was abolished and the drug procurement mechanism was improved, giving full play to the role of medical insurance in controlling fees, and therefore the actual transaction prices of drugs were formed mainly by market competition. In particular, (I) for drugs paid for by the medical insurance fund, the medical insurance department, in conjunction with the relevant departments, shall formulate rules on the procedures, bases and methods for formulating payment standards for drugs, and explore the establishment of a mechanism to guide the formation of reasonable prices for drugs; (II) for patented drugs and exclusively produced drugs, to establish an open and transparent negotiation mechanism with multi-party participation to form prices; (III) for blood products not in the medical insurance catalogue, preventive immunization drugs uniformly procured by the State, and national free HIV antiretroviral therapy drugs and contraceptives, to form prices through bidding and procurement or negotiation; (IV) narcotic drugs and Class I psychotropic drugs are still temporarily subject to maximum factory prices and maximum retail prices; (V) other drugs are priced independently by producers and operators on the basis of production and operation costs and market supply and demand.

Two-invoice system

According to the 2016 Key Tasks for Deepening the Reform of the Pharmaceutical and Healthcare System (《深化醫藥衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council on April 21, 2016, in order to optimize the order of drug purchasing and marketing and compress the distribution chain, the pilot provinces of the comprehensive healthcare reform are to implement the “two-invoice system” throughout the provinces, and the pilot cities of the comprehensive reform of public hospitals are to be actively encouraged to implement the “two-invoice system.”

According to the Implementing Opinions on Launching the “Two-invoice System” in Drug Procurement for 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)》) jointly issued by the Office of the State Council Leading Group for Deepening the Reform of the Pharmaceutical and Healthcare System and other departments on 26 December, 2016, the “two-invoice system” refers to the fact that a drug manufacturer issues an invoice to the distribution enterprise once, and the distribution enterprise issues an invoice to the healthcare institution once. The wholly-owned or controlling commercial companies (limited to one commercial company nationwide) and the domestic general agents of overseas drugs (limited to one domestic general agent nationwide) set up by a pharmaceutical manufacturer or a group-type enterprise integrating science, industry and trade, which only sells drugs of their own enterprise (group), can be regarded as

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manufacturing enterprises. The appropriation of drugs within a pharmaceutical distribution group-type enterprise to a wholly-owned (holding) subsidiary or between wholly-owned (holding) subsidiaries may not be regarded as a single invoice, but is allowed to be invoiced at most once. The “two-invoice system” is gradually implemented in the procurement of drugs for public medical institutions, and other medical institutions are encouraged to implement the “two-invoice system” in the procurement of drugs. Pilot provinces (autonomous regions and municipalities) for the comprehensive medical reform and pilot cities for the public hospital reform should take the lead in implementing the “two-invoice system”, and other regions are encouraged to implement the “two-invoice system”, with a view to achieving its full-scale implementation throughout the country by 2018.

Other significant PRC regulations affecting our business activities in the PRC

Laws and regulations relating to Company Law and foreign investment

The formation, operation and management of enterprises in the PRC are governed by the Company Law of the People’s Republic of China (《中華人民共和國公司法》) (the “**Company Law**”), which was promulgated by the Standing Committee of the NPC (NPCSC) on December 29, 1993, effective on July 1, 1994, and subsequently amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013, October 26, 2018 and December 29, 2023, respectively. Under the Company Law, companies are categorized into two types, i.e. limited liability companies and companies limited by shares. The Company Law also applies to foreign-invested limited liability companies and companies limited by shares. Under the Company Law, if there are other provisions in the laws relating to foreign investment, such provisions shall prevail.

The latest amendment made by the NPCSC on December 29, 2023 mainly included the improvement of a company’s establishment and exit system, the optimization of a company’s organization, the improvement of a company’s capital system, the reinforcement of the responsibilities of controlling shareholders and management personnel, and the enhancement of a company’s social responsibility, etc. This amendment became effective from July 1, 2024.

On March 15, 2019, the National People’s Congress (the “**NPC**”) promulgated the Law of the People’s Republic of China on Foreign Investment (《中華人民共和國外商投資法》) (the “**FIL**”). The FIL took effect on January 1, 2020 and the Law of the People’s Republic of China on Chinese-Foreign Equity Joint Ventures (《中華人民共和國中外合資經營企業法》), the Law of the People’s Republic of China on Foreign-Funded Enterprises (《中華人民共和國外資企業法》) and the Law of the People’s Republic of China on Cooperative Joint Ventures (《中華人民共和國合作經營企業法》) were simultaneously repealed. Since then, the FIL has become the fundamental law regulating foreign-invested enterprises wholly or partially invested by foreign investors. In accordance with the FIL and the Regulations for the Implementation of the Foreign Investment Law of the People’s Republic of China (《中華人民共和國外商投資法實施條例》) promulgated by the State Council on December 26, 2019, which came into effect on January 1, 2020, foreign investment refers to the investment activities carried out directly or indirectly in the PRC by foreign natural persons, enterprises

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or other organizations (hereinafter referred to as “**foreign investors**”), including the following circumstances: (I) foreign investors alone or jointly with other investors establish foreign-invested enterprises within the territory of the PRC; (II) foreign investors acquire shares, equity, property shares or other similar interests in enterprises within the territory of the PRC; (III) foreign investors alone or jointly with other investors invest in new construction projects within the territory of the PRC; (IV) other forms of investment prescribed by the laws, administrative regulations or the State Council. The provisions of the Company Law, the Law of the People’s Republic of China on Partnerships and other laws shall apply to the form of organization of a foreign-invested enterprise, its organizational structure and the rules governing its activities.

The PRC implements a pre-access national treatment plus negative list management system for foreign investment, which means that foreign investors and their investments are given treatment no less favourable than that accorded to domestic investors and their investments at the stage of investment access; the so-called negative list refers to the special access management measures that the State has stipulated to be applied to foreign investment in specific areas, and the State grants national treatment to foreign investment that is not on the negative list.

The Catalogue of Industries Encouraging Foreign Investment (2022 Version) (《鼓勵外商投資產業目錄(2022年版)》) issued by the NDRC and the Ministry of Commerce on October 26, 2022 (effective January 1, 2023), and the Special Administrative Measures for Foreign Investment Entry (Negative List) (2024 Version) (《外商投資准入特別管理措施(負面清單)(2024年版)》) issued by the NDRC and the Ministry of Commerce on September 6, 2024 (the “**Negative List**”), which became effective on November 1, 2024, together constitute the Catalogue of Industries Encouraging Foreign Investment and the Special Administrative Measures for Foreign Investment Access to Industries Restricted or Prohibited for Foreign Investment, of which the Negative List has uniformly listed the special administrative measures in respect of foreign investment access, such as shareholding requirements and senior management requirements. Fields outside the Negative List are managed in accordance with the principle of consistency between domestic and foreign investments. Domestic enterprises engaging in businesses in the areas of investment prohibited by the Negative List that issue shares abroad and list them for trading shall be subject to the examination and consent of the relevant competent state authorities. Foreign investors shall not participate in the operation and management of the enterprise, and the proportion of their shareholding shall be implemented with reference to the relevant provisions on the management of domestic securities investment by foreign investors.

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The Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》) were issued by the Ministry of Commerce and the State Administration for Market Supervision and Administration on December 30, 2019 and came into effect on January 1, 2020. According to the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》), foreign investors carrying out investment activities directly or indirectly in the PRC shall report investment information to the competent commerce department by the foreign investor or foreign-invested enterprise in accordance with the Measures. When submitting annual reports, foreign-invested enterprises shall report basic information about the enterprise, information about investors and their de facto controllers, information about the enterprise’s operation and assets and liabilities, and information about obtaining relevant industry licenses if special administrative measures for foreign investment access are involved.

Laws and regulations relating to intellectual property

Patent

In accordance with the Patent Law of the People’s Republic of China (《中華人民共和國專利法》) (the “**Patent Law**”) promulgated by the NPCSC on March 12, 1984, as amended on September 4, 1992, August 25, 2000, December 27, 2008, October 17, 2020, and with the latest amendment effective on June 1, 2021, and the Rules for the Implementation of the Patent Law of the People’s Republic of China (《中華人民共和國專利法實施細則》) promulgated by the State Council on June 15, 2001, as last amended on December 11, 2023, and as last amended and effective on January 20, 2024, inventions are defined as inventions, utility models and exterior designs. Inventions and utility models for which patents are granted shall possess novelty, inventiveness and utility. The Patent Office under China National Intellectual Property Administration is responsible for uniformly accepting, examining and approving patent applications. The term of a patent right for an invention is twenty years, the term of a patent right for a utility model is ten years, and the term of a patent right for an exterior design is fifteen years, all calculated from the date of application.

In accordance with the Patent Law and the Rules for the Implementation of the Patent Law of the People’s Republic of China (《中華人民共和國專利法實施細則》), in order to compensate for the time taken for the review and approval of the introduction of new drugs to the market, the patent administration department of the State Council shall, at the request of the patentee, grant compensation for the term of the patent right for patents relating to new drugs that have been granted marketing authorization in the PRC. The compensation period shall not exceed five years, and the total effective patent right period after the new drug is approved for marketing shall not exceed fourteen years. During the period of patent term compensation for a patent for invention related to a new drug, the scope of protection of the patent is limited to the new drug and its approved indications related to the technical program; within the scope of protection, the patentee enjoys the same rights and undertakes the same obligations as before the patent term compensation.

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The NMPA and China National Intellectual Property Administration jointly issued the Measures for the Implementation of the Mechanism for the Early Resolution of Drug Patent Disputes (for Trial Implementation) (《藥品專利糾紛早期解決機制實施辦法(試行)》) on July 4, 2021, to establish a mechanism for the early resolution of drug patent disputes; the holder of a marketing authorization for a drug shall, within 30 days after obtaining the certificate of registration for the drug, register the relevant patent information of the drug on the platform for the registration of patent information of marketed drugs in the PRC. When an applicant for a chemical generic drug applies for a marketing authorization for the drug, it shall make a declaration for each relevant pharmaceutical patent of the drug to be copied in comparison with the patent information that has been made public on the PRC’s patent information registration platform for marketed drugs. If the patentee or the interested party has any objection to the patent declaration, he/she may, within 45 days from the date when the application for marketing authorization of the drug is publicized by a state drug evaluation agency, file a lawsuit to the people’s court or request for an administrative ruling from the patent administrative department under the State Council as to whether the relevant technical solution of the drug applying for marketing falls within the scope of the protection of the relevant patent right.

Trademark

Pursuant to the Trademark Law of the People’s Republic of China (《中華人民共和國商標法》) promulgated by the NPCSC on August 23, 1982, as subsequently amended on February 22, 1993, October 27, 2001 and August 30, 2013, respectively, and last amended on April 23, 2019 and last amended and effective on November 1, 2019, and the Regulations for the Implementation of the Trademark Law of the People’s Republic of China (《中華人民共和國商標法實施條例》) promulgated by the State Council on August 3, 2002, effective on September 15, 2002, as amended on April 29, 2014 and last amended and effective on May 1, 2014, the validity period of a registered trademark is ten years from the date of approval of registration. If the registered trademark expires and needs to be used continuously, the trademark registrant shall, within twelve months prior to the expiration date, go through the renewal procedures in accordance with the provisions of the law; if it fails to do so within this period, it may be given a grace period of six months. Each renewal of registration is valid for ten years, calculated from the day after the expiration of the previous validity of the trademark. Failure to apply for renewal procedures at the end of the period will lead to cancellation of the registered trademark.

Copyright

The Copyright Law of the People’s Republic of China (《中華人民共和國著作權法》), promulgated by the NPCSC on September 7, 1990 and last amended on November 11, 2020, with the latest amendment taking effect on June 1, 2021, and the Regulations for the Implementation of the Copyright Law of the People’s Republic of China (《中華人民共和國著作權法實施條例》), promulgated by the State Council on August 2, 2002 and last amended on January 30, 2013, with the latest amendment taking effect on March 1, 2013, provide for the legal protection of copyrights, as well as the categorization of works, and the acquisition of copyrights and the protection of copyrights and their related rights.

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Domain name

The Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) issued by the Ministry of Industry and Information Technology (“MIIT”) on August 24, 2017, which took effect on November 1, 2017, and the Rules for the Implementation of the Registration of National Top-Level Domain Names (《國家頂級域名註冊實施細則》) issued by China Internet Network Information Center (CNNIC) on June 18, 2019, provide legal protection for domain names. The MIIT is the regulatory body responsible for the administration of Internet domain names in the PRC, and CNNIC is responsible for the registration and administration of national top-level domain names. Domain name registration is handled through domain name registration service organizations established in accordance with relevant regulations. Upon successful registration, the applicant shall become the domain name holder.

Trade secrets

In accordance with the Anti-Unfair Competition Law of the People’s Republic of China (《中華人民共和國反不正當競爭法》) promulgated by the NPCSC on September 2, 1993 and amended on November 4, 2017 and April 23, 2019, respectively, and the Supreme People’s Court’s Provisions on Several Issues Concerning the Application of Law to the Trial of Civil Cases Involving Infringement of Trade Secrets (《最高人民法院關於審理侵犯商業秘密民事案件適用法律若干問題的規定》), which were issued by the Supreme People’s Court on September 10, 2020 and have come into effect on September 12, 2020, “trade secret” refers to the technical information, business information and other commercial information that is not known to the public, has commercial value, and is likely to create commercial interests or profits for the lawful owner or holder of the same and has been subject to the corresponding confidentiality measures taken by the owner. Pursuant to the Anti-Unfair Competition Law of the People’s Republic of China (《中華人民共和國反不正當競爭法》), operators shall not commit the following acts of infringing upon the commercial secrets of others: (I) acquiring the commercial secrets of the right holder by theft, bribery, fraud, coercion, electronic intrusion or other improper means; (II) disclosing, using or permitting other people to use the commercial secrets of the right holder acquired by the means mentioned in the preceding paragraph; (III) violating the obligation of confidentiality or the requirements on keeping commercial secrets of the right holder, disclose, use or allow others to use the trade secrets in their possession; (IV) abetting, inducing, helping others to violate the obligation of confidentiality or violation of the requirements of the right holder to keep trade secrets, to obtain, disclose, use or allow others to use the right holder’s trade secrets. If the third party knows or should know the above violations, but still obtains, uses or allows others to use the trade secrets, it is regarded as the infringement of trade secrets. The person whose trade secret has been infringed may request administrative corrective measures, and the supervisory authority shall order the cessation of the illegal behavior and impose a fine on the infringer.

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Laws and regulations relating to foreign exchange

The principal law regulating foreign currency exchange in the PRC is 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**”). The Foreign Exchange Administration Regulations were promulgated by the State Council on January 29, 1996 and came into effect on April 1, 1996, and were amended on January 14, 1997 and August 5, 2008, respectively. Under the Foreign Exchange Administration Regulations, the State does not impose restrictions on international payments in foreign currencies and foreign currency transfers under the current account. Foreign currency transactions under the capital account are still subject to restrictions and the approval or registration procedures of the General Administration of Foreign Exchange of the People’s Republic of China (the “SAFE”) or its local branches and other relevant Chinese government agencies.

In accordance with the Regulations for the Administration of Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》) issued by the People’s Bank of China on June 20, 1996 and effective on July 1, 1996, foreign-invested enterprises may purchase, sell or repatriate foreign currency at banks authorized to conduct foreign exchange business only after they have provided valid business certification documents and, in the case of capital account transactions, have obtained the approval of the SAFE or its local branch.

The SAFE issued the Circular of the State Administration of Foreign Exchange on the Reform of the Management of Foreign Exchange Capital Fund Settlement of Foreign-invested Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) on March 30, 2015 (hereinafter referred to as “**SAFE Circular No. 19**”), which came into effect on June 1, 2015, and was amended on December 30, 2019 and March 23, 2023, respectively. Pursuant to SAFE Circular 19, foreign exchange capital funds in the capital account of a foreign-invested enterprise for which the foreign exchange bureau has confirmed the rights and interests of the monetary contribution (or for which the bank has registered the monetary contribution) may be settled at the bank in accordance with the actual operational needs of the enterprise. At the same time, the use of such RMB amounts shall still be subject to the restrictions set out in SAFE Circular No. 19, such as not to be used directly or indirectly for expenditures outside the scope of business of the enterprise or prohibited by national laws and regulations; not to be used directly or indirectly for investment in securities unless otherwise provided by laws and regulations; not to be used directly or indirectly for the release of entrusted loans in RMB (except for those permitted by the scope of business), repayment of inter-enterprise loans (including advances to a third party) and repayment of bank loans in RMB that have been re-lent to a third party; except for foreign-invested real estate enterprises, they shall not be used to pay for expenses related to the purchase of real estate not for self-use.

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Pursuant to the Circular of the State Administration of Foreign Exchange on Reforming and Standardizing the Management Policy of Capital Account Settlement (《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》) (“**SAFE Circular No. 16**”) issued by the SAFE on June 9, 2016, and amended on December 4, 2023, if there is any inconsistency between the previous circular (e.g., SAFE Circular No. 19) and SAFE Circular No. 16, SAFE Circular No. 16 shall prevail. SAFE Circular No. 16 will standardize the settlement of foreign exchange for all domestic institutions. In addition, the use of foreign exchange earnings from capital items by domestic institutions shall comply with the principles of truthfulness and self-consumption within the scope of business operation. SAFE Circular No. 16 reiterates that the foreign exchange income from capital items of domestic institutions and the RMB funds derived from their foreign exchange settlement may be used for expenditures under the current account within the scope of their own operations, as well as for expenditures under the capital account as permitted by laws and regulations. The use of RMB funds derived from foreign exchange earnings from capital items and their settlement by domestic institutions shall comply with the following provisions: (I) they shall not be used directly or indirectly for expenditures outside the scope of business of the enterprise or prohibited by national laws and regulations; (II) unless otherwise expressly provided, they shall not be used directly or indirectly for investment in securities or other investment and wealth management (except for wealth management products and structured deposits with risk ratings not higher than Level 2); (III) they shall not be used for the release of loans to non-affiliated enterprises except for cases expressly permitted by the scope of business; (IV) they shall not be used for the purchase of residential properties not for self-use (except for enterprises engaging in real estate development and real estate leasing).

Based on the Circular of the State Administration of Foreign Exchange on Optimizing 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》) issued by the SAFE on April 10, 2020, the SAFE will push forward the reform of facilitating the payment of income under capital accounts on a nationwide basis. Provided that the use of funds is genuine, compliant and in line with the existing regulations for the management of the use of income under capital accounts, eligible enterprises will be allowed to use the income under capital accounts such as capital funds, foreign debt and income from overseas [REDACTED] for domestic payments without having to provide materials proving authenticity to the banks on a case-by-case basis beforehand.

Distribution of dividends

Pursuant to the provisions of the Company Law, when a company distributes its after-tax profit for the year, ten percent of the profit should be set aside as its statutory surplus reserve fund. The company may no longer do so if its cumulative statutory surplus reserve accounts for more than fifty percent of its registered capital. If the company’s statutory surplus reserve is insufficient to make up for the losses of previous years, the company shall use the current year’s profit to make up for the losses before the set-aside of the statutory surplus reserve. After the company has set aside a part of its after-tax profit as its statutory surplus reserve, it may also set aside a part of its after-tax profit as its discretionary reserve. Distributions can be made to shareholders only after the remaining after-tax profit have made up for losses and the surplus reserve has been set aside.

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On January 26, 2017, the SAFE issued the Circular on Further Promoting the Reform of Foreign Exchange Management and Improving the Examination of Authenticity and Compliance (《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》), which stipulates that when banks handle profit remittance business exceeding US\$50,000 equivalent (excluding) for domestic institutions, they shall audit, in accordance with the principle of authentic transaction, the board of directors’ resolution on profit distribution (or the partners’ resolution on profit distribution), the original tax filing form, and the audited financial statements, and the amount of the current remittance and the date of remittance on the original tax filing form shall be affixed with an endorsement. The domestic organization shall make up for the losses of previous years in accordance with the law before remitting the profits.

Regulations for EIT and VAT

EIT

Pursuant to the Enterprise Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法》) (the “**EIT Law**”), which was promulgated by the NPCSC on March 16, 2007, became effective on January 1, 2008, and was last amended on December 29, 2018, enterprises are classified into resident enterprises and non-resident enterprises; the income tax rate for resident enterprises is 25% and the income tax rate for non-resident enterprises is 20%. Pursuant to the EIT Law and the Regulations for the Implementation of the Enterprise Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法實施條例》) (the “**Regulations for the Implementation of the EIT Law**”), which were issued by the State Council on December 6, 2007 and became effective on January 1, 2008, and were most recently amended on April 23, 2019, a resident enterprise shall pay EIT on its income derived from sources within and outside the PRC. If a non-resident enterprise has offices or establishments in the PRC, it shall pay EIT on the income derived from sources within the PRC and the income derived from sources outside the PRC that has real connection with the said offices or establishments. If a non-resident enterprise does not have offices or establishments in the PRC, or if it has offices or establishments but the income it derives has not actual connection to its offices or establishments, it shall pay EIT on the income derived from sources within the PRC, but at a reduced rate of 10 per cent.

In accordance with the EIT Law and the Regulations for the Implementation of the EIT Law, dividends, bonuses and other equity investment income between qualified resident enterprises are tax-exempt income.

VAT

Pursuant to the Provisional Regulations of the People’s Republic of China on Value-added Tax (《中華人民共和國增值稅暫行條例》) issued by the State Council on December 13, 1993 and amended on November 10, 2008, February 6, 2016 and November 19, 2017, respectively, and the Rules for the Implementation of the Provisional Regulations of the People’s Republic of China on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》) issued by the Ministry of Finance on December 25, 1993, last amended on October 28, 2011 and latest

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amended and effective on November 1, 2011, units and individuals selling goods or processing, repair and fitting-out services, selling services, intangible assets, immovable property and importing goods within the territory of the PRC shall be subject to VAT; depending on the taxable acts of the general taxpayers, the applicable VAT rates are 17%, 11%, 6% and 0%, respectively. The Notice of the Ministry of Finance and the State Administration of Taxation on the Adjustment of the Value-added Tax Rate (《財政部、稅務總局關於調整增值稅稅率的通知》), which was jointly issued by the Ministry of Finance and the State Administration of Taxation on April 4, 2018 and became effective from May 1, 2018, adjusted the VAT rates for relevant taxable acts of general taxpayers originally subject to the tax rates of 17% and 11% to 16% and 10%, respectively. The Announcement of the Ministry of Finance, the State Administration of Taxation and the General Administration of Customs on the Relevant Policies on Deepening the Value-added Tax Reform (《財政部、稅務總局、海關總署關於深化增值稅改革有關政策的公告》), which was jointly issued by the Ministry of Finance and other departments on March 20, 2019 and became effective from April 1, 2019, has further adjusted the VAT rates for taxable acts related to general taxpayers originally subject to the tax rates of 16% and 10% to 13% and 9%, respectively.

On December 25, 2024, the NPCSC promulgated the Value-added Tax Law of the PRC (《中華人民共和國增值稅法》), which will come into effect on January 1, 2026, and as of the Latest Practicable Date, it has not come into effect.

Taxation on Dividends

Individual Investors

According to the Individual Income Tax Law of the People’s Republic of China (《中華人民共和國個人所得稅法》) (hereinafter referred to as the “**Individual Income Tax Law**”) promulgated by NPCSC on September 10, 1980, as last amended on August 31, 2018 and the latest amendment effective on January 1, 2019, and the Regulations on the Implementation of the Individual Income Tax Law of the People’s Republic of China (《中華人民共和國個人所得稅法實施條例》) promulgated by the State Council on January 28, 1994, as last revised on December 18, 2018 and the latest revision effective on January 1, 2019 (hereinafter referred to as the “**Implementation Regulations of the Individual Income Tax Law**”), individual investors shall pay individual income tax at a rate of 20% on dividend income received from enterprises within China (regardless of whether the place of payment is within China), which shall be withheld and paid by enterprises in China, except for the income exempted from tax stipulated in international conventions and agreements signed by the PRC government, as well as other tax-free income and tax reductions stipulated by the State Council.

According to the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) signed on August 21, 2006 (hereinafter referred to as the “**Arrangement**”), the PRC government may impose penalties on Chinese companies in accordance with PRC laws. Dividends paid by Hong Kong residents are taxed, but the tax

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imposed (if the beneficial owner of the dividend is not a company that directly holds at least 25% equity interest in the company paying the dividend) should not exceed 10% of the total amount of the dividend. However, according to the Fifth Protocol to the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》第五議定書) (hereinafter referred to as the “Fifth Protocol to the Arrangement”) that came into effect on December 6, 2019, notwithstanding the other provisions of the Arrangement, if it is reasonably ascertained, having regard to all relevant facts and circumstances, that one of the main purposes of any arrangement or transaction directly or indirectly inducing a benefit under the Arrangement is to obtain the concessions, the concessions shall not be granted in respect of the relevant proceeds unless it can be established that the grant of the benefit in such circumstances is in accordance with the purpose and objective of the relevant provisions of the Arrangement.

In addition, according to the Notice on the Issues concerning the Application of the Dividend Clauses of Tax Agreements (《關於執行稅收協定股息條款有關問題的通知》) issued by the State Administration of Taxation on February 20, 2009, when a Chinese resident company pays dividends to a Hong Kong resident, and the Hong Kong resident (or dividend recipient) is the beneficial owner of the dividend, then the dividend so received can enjoy the treatments provided under the tax agreements. Accordingly, the income tax payable by the Hong Kong resident in China is calculated according to the tax rate stipulated in the agreements. If the tax rate stipulated in the agreements are higher than the tax rate stipulated in the domestic tax laws of the PRC, the taxpayer can still pay tax determined under domestic tax laws of the PRC. If a taxpayer needs to enjoy the agreed treatments specified in the preceding paragraph, the following conditions shall be met at the same time: (I) the taxpayers who can enjoy the agreed treatments should be Hong Kong residents; (II) the taxpayers who can enjoy the agreed treatments should be the beneficial owners of the relevant dividends person; (III) dividends eligible for the agreed treatments should be dividends, bonuses and other equity investment income determined in accordance with domestic tax laws of the PRC; and (IV) other conditions stipulated by the State Administration of Taxation. Transactions or arrangements whose main purpose is to obtain preferential tax status should not constitute a reason for implementing agreed treatments. If a taxpayer improperly enjoys agreed tax treatments due to such transactions or arrangements, the competent tax authorities may make adjustments.

Corporate Investors

According to the Enterprise Income Tax Law (《企業所得稅法》) and the Regulation on the Implementation of the Enterprise Income Tax Law (《企業所得稅法實施條例》), non-resident enterprises shall pay enterprise income tax on their income derived from China (including dividends, bonuses and other equity investment income paid by Chinese enterprises). However, if a non-resident enterprise has not established an office or establishment in China, or if it has established an office or establishment but the income obtained has no actual connection with the office or establishment, it shall be levied enterprise income tax at a reduced rate of 10%. The above-mentioned income tax payable by non-resident

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enterprises shall be withheld at source, and the income payer shall be the withholding agent. The tax shall be withheld by the withholding agent from the amount paid or payment due at the time of payment or due for payment. The State Administration of Taxation issued the Circular on Issues Relating to the Withholding of Enterprise Income Tax by PRC Resident Enterprises on Dividends Paid to Overseas Non-Resident Enterprise Shareholders of H Shares (《關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》) issued by the State Administration of Taxation on November 6, 2008. When Chinese resident enterprises distribute dividends to H-share holders which are overseas non-resident enterprises for 2008 and subsequent years, enterprise income tax will be withheld and paid at a uniform rate of 10%.

Under the arrangement, the PRC government can tax dividends paid by Chinese companies to Hong Kong residents in accordance with PRC laws. However, if the beneficial owner of the dividends is a Hong Kong resident, the tax levied shall not exceed: (I) 5% of the total amount of the dividends if the beneficial owner is a company that directly owns at least 25% of the equity of the company paying the dividends, or (II) in other cases, 10% of the total dividend amount. According to the Fifth Protocol to the Arrangement, notwithstanding the provisions of other terms of this Arrangement, if, after taking into account all relevant facts and circumstances, it can be reasonably determined that one of the main purposes of any arrangement or transaction that directly or indirectly brings about the benefits of this Arrangement is to obtain the benefits, the benefits shall not be granted in connection with the relevant income, unless it can be confirmed that the benefits under such circumstances is consistent with the purposes and objectives of the relevant provisions of this Arrangement.

In addition, according to the Notice on Issues Concerning the Application of Dividend Clauses of Tax Agreements (《關於執行稅收協定股息條款有關問題的通知》), if a Chinese resident company pays dividends to a Hong Kong resident, and the Hong Kong resident (or dividend recipient) is the beneficial owner of the dividend, then the Hong Kong resident shall obtain the dividend. This dividend can enjoy agreed treatments, that is, the income tax payable by Hong Kong residents in China will be calculated according to the tax rate stipulated in the agreements. If the tax rate stipulated in the agreement is higher than the tax rate stipulated in domestic tax laws of the PRC, the taxpayer can still pay tax determined under domestic tax laws of the PRC. If a taxpayer needs to enjoy the agreed treatments stipulated in the preceding paragraph, the following conditions must be met at the same time: (I) the taxpayer who can enjoy the agreed treatments should be a Hong Kong resident, (II) the taxpayer who can enjoy the agreed treatments should be the beneficial owner of the relevant dividends (III) dividends eligible for agreed treatments shall be dividends, bonuses and other equity investment income determined in accordance with domestic tax laws of the PRC, and (IV) other conditions stipulated by the State Administration of Taxation. According to the dividend provisions of relevant tax agreements, if a Hong Kong resident directly owns more than a certain proportion of the equity of a Chinese resident company that pays dividends, the dividends obtained by the Hong Kong resident may be taxed at the rate specified in the tax agreements. If a Hong Kong resident needs to enjoy the benefits of this tax treaty, the following conditions must be met at the same time: (I) according to the provisions of the tax agreements, the Hong Kong resident receiving dividends should be a company; (II) all the ownership rights and interests of Chinese

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resident companies directly owned by the Hong Kong resident and the proportion of shares with voting rights shall comply with the prescribed proportion; (III) at any time within 12 consecutive months before receiving dividends, the proportion of equity directly owned by the Hong Kong resident in the Chinese resident company shall comply with the proportion stipulated in the tax agreements. Transactions or arrangements with the main purpose of obtaining preferential tax status should not constitute a reason for implementing agreed treatments. If a taxpayer improperly enjoys tax agreed treatments due to such transactions or arrangements, the competent tax authorities have the right to make adjustments.

Tax Agreements

Non-Chinese resident investors who live in countries that have signed double taxation agreements with China or who live in Hong Kong or the Macau Special Administrative Region can enjoy preferential tax rates on dividends from Chinese companies. China has entered into double taxation avoidance arrangements with Hong Kong and the Macao Special Administrative Region respectively, and has entered into double taxation avoidance agreements with several other countries, including but not limited to Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the U.S. Non-Chinese resident enterprises that have obtained preferential tax rates under relevant tax agreements or arrangements may apply to the Chinese tax authorities for a refund of the difference between the withholding tax and the tax calculated based on the preferential tax rates stipulated in the relevant tax agreements or arrangements. The application is subject to approval by the Chinese tax authorities.

Taxes Related to Share Transfers

Individual Investor

According to the Individual Income Tax Law and the Implementation Regulations of the Individual Income Tax Law, income from the transfer of property (including income from the transfer of securities, equity, and partnership property shares among individuals) is subject to individual income tax at a rate of 20%. According to the Circular of Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) jointly issued by the Ministry of Finance and the State Administration of Taxation on March 30, 1998 (Cai Shui Zi [1998] No. 61), starting from January 1, 1997, individual income tax will continue to be exempted on the income obtained by individuals from transferring shares of [REDACTED] companies.

Corporate Investors

According to the Enterprise Income Tax Law (《企業所得稅法》) and the Regulation on the Implementation of the Enterprise Income Tax Law (《企業所得稅法實施條例》), non-resident enterprises shall pay enterprise income tax on their income derived from China (including income from the transfer of equity investments in Chinese enterprises). For a non-resident enterprise having no office or establishment in China, or if an office or

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establishment has been established in China but the income obtained has no actual connection with the office or establishment, the enterprise income tax shall be levied at a reduced rate of 10%. The above-mentioned income tax payable by non-resident enterprises shall be withheld at source, and the income payer shall be the withholding agent. The tax shall be withheld by the withholding agent from the amount paid or due for payment at the time it is paid or due for payment.

Product Liability

According to the Civil Code of the People's Republic of China (《中華人民共和國民法典》) promulgated by the National People's Congress on May 28, 2020 and effective on January 1, 2021, if a patient suffers damage due to a defect in a drug, the patient may claim compensation from the marketing authorization holder and manufacturer of the drug, or from a medical institution. If the patient requests compensation from the medical institution, the medical institution shall have the right to recover from the responsible marketing authorization holder and manufacturer after compensation.

Labor, Social Insurance and Housing Provident Fund

The Labor Law of the People's Republic of China (《中華人民共和國勞動法》) promulgated by the NPCSC on July 5, 1994 and last amended on December 29, 2018 and the Labor Contract Law of the People's Republic of China (《中華人民共和國勞動合同法》), promulgated on June 29, 2007, effective on January 1, 2008, last amended on December 28, 2012 and effective on July 1, 2013 stipulate the relationship between employers and employees, and specifies the terms and conditions of employment contracts.

According to the Social Insurance Law of the People's Republic of China (《中華人民共和國社會保險法》) promulgated by the NPCSC on October 28, 2010, effective on July 1, 2011, and last revised on December 29, 2018, and the Interim Regulation on the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) promulgated by the State Council on January 22, 1999 and revised on March 24, 2019, as well as the Regulation on the Administration of Housing Provident Fund (《住房公積金管理條例》) promulgated by the State Council on April 3, 1994 and revised on March 24, 2002 and March 24, 2019, employers shall pay social insurance premiums such as basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance, and maternity insurance for their employees, as well as contribute to housing provident funds.

Precursor Chemicals

According to the Regulation on the Administration of Precursor Chemicals (《易製毒化學品管理條例》) promulgated by the State Council on August 26, 2005, effective on November 1, 2005, and revised on July 29, 2014, February 6, 2016 and September 18, 2018, the State regulates the production, operation, purchase, transportation, import and export of precursor chemicals. Units that purchase Category II and Category III precursor chemicals shall report the types and quantities of required precursor chemicals to the public security organs of the local people's governments at the county level for filing before purchasing.

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Explosive Precursors

According to the Measures for the Public Security Management of Explosives Precursors (《易製爆危險化學品治安管理办法》) issued by the Ministry of Public Security on July 6, 2019 and effective on August 10, 2019, enterprises which have obtained permits for safe production of hazardous chemicals, permits for the safe use of hazardous chemicals and permits for business operation of hazardous chemicals in accordance with the law shall purchase explosive precursor hazardous chemicals with the corresponding licenses. Other entities that purchase explosive precursors shall submit the following materials to the selling unit: (I) photocopies of legal certificates of the entity such as industrial and commercial license (《工商營業執照》), and legal person certificate for a public institution (《事業單位法人證書》), as well as a photocopy of the identity certificate of the responsible person; and (II) instructions on how to legally use explosives precursors, including such contents as specific usage, types, and quantity of explosives precursors. A buyer of explosives precursors shall, within five days after purchasing, shall report the information about the types, quantity and flowing direction of explosives precursors purchased to the local county-level public security organ for filing.

Regulations on Information Security and Data Privacy

Data security and data export

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

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

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According to the Measures for Standard Contract for Outbound Transfer of Personal Information (《个人信息出境标准合同办法》) issued by the Cyberspace Administration of China on February 22, 2023 and effective from June 1, 2023, to provide personal information to an overseas recipient through the conclusion of the standard contract, a personal information processor shall meet all of the following circumstances: (I) it is not a critical information infrastructure operator; (II) it has processed the personal information of less than one million individuals; (III) it has cumulatively provided the personal information of less than 100,000 individuals to overseas recipients since January 1 of the previous year; and (IV) it has cumulatively provided the sensitive personal information of less than 10,000 individuals since January 1 of the previous year. In addition, the Measures for Standard Contract for Outbound Transfer of Personal Information require that all Outbound Transfers of personal information that have been carried out before June 1, 2023 and do not comply with the provisions of the Measures for Standard Contract for Outbound Transfer of Personal Information be rectified within 6 months.

On March 22, 2024, the CAC promulgated the Regulations on Improving and Regulating the Cross-Border Transfer of Data (《促进和规范数据跨境流动规定》) (the “**Regulations on Cross-Border Transfer of Data**”), which provided implementation rules on the security assessment of outbound data transfer, the standard contract for outbound transfer of personal information, the certification of personal information protection and other systems governing the outbound transfer of data. Pursuant to the Regulations on Cross-Border Transfer of Data, except as otherwise provided, (I) a data processor that provides data overseas under any of the following circumstances shall apply to the national cyberspace administration for the security assessment of the outbound data transfer through local provincial cyberspace administration: (A) a critical information infrastructure operator provides personal information or important data abroad, (B) a data processor other than critical information infrastructure operator provides important data abroad, or has provided personal information (excluding sensitive personal information) of over 1,000,000 people or sensitive personal information of over 10,000 people abroad cumulatively since January 1 of the year; and (II) a data processor other than critical information infrastructure operator that has provided personal information (excluding sensitive personal information) of over 100,000 people and less than 1,000,000 people, or sensitive personal information of less than 10,000 people abroad cumulatively since January 1 of the year shall enter into a standard contract for outbound transfer of personal information with the receiver overseas or pass the certification of personal information protection in accordance with laws and regulations.

Personal information protection

According to the Civil Code (《民法典》), personal information of natural persons is protected by law. If any organization or individual needs to obtain other people’s personal information, they should obtain it in accordance with the law and ensure the security of the information. They must not illegally collect, use, process, or transmit other people’s personal information, and must not illegally buy, sell, provide, or disclose the information. The Personal Information Protection Law of the People’s Republic of China (《中华人民共和国个人信息保

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護法》) promulgated by the NPCSC on August 20, 2021 and implemented on November 1, 2021, further emphasizes the obligations and responsibilities of processors for the protection of personal information, and requests higher level of protective measures on the processing of sensitive personal information.

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

On September 24, 2024, the State Council issued the Regulation on the Administration of Cyber Data Security (《網路數據安全管理條例》) (the “**Cyber Data Security Regulation**”), which shall be effective from January 1, 2025. The Cyber Data Security Regulation stipulated certain requirements on network data processing activities, the security and protection of network data, and the reasonable and effective use of network data, and further shed light on the protection of personal information, security of important data, management of cross-border security of network data and obligations of network platform service providers. As of the Latest Practicable Date, the Cyber Data Security Regulation has not yet come into effect.

NHC released the Administrative Measures on the Standards, Security and Service of National Health and Medical Big Data (Trial) (《國家健康醫療大數據標準、安全和服務管理辦法(試行)》) on July 12, 2018 (hereinafter referred to as the “**Health and Medical Big Data Measures**”). The Health and Medical Big Data Measures stipulate the guidelines and principles for standard management, security management and service management of health and medical big data. According to the Health and Medical Big Data Measures, medical and health institutions at all levels and related enterprises and institutions should adopt data classification, important data backup, encryption authentication and other measures to ensure the security of health and medical big data. Health and medical big data should be used in accordance with laws and regulations. Data-related information should provide secure information query and copy channels to ensure privacy protection and data security; data access and use permissions of users at different levels should be strictly regulated to ensure that data is used within the scope of authorization. No unit or individual may use or publish health and medical big data without authorization or beyond the scope of authorization, and it is prohibited to obtain data through illegal means. When various types of medical and health institutions at all levels and related service institutions disclose health and medical big data to the public, they must abide by relevant national regulations and must not disclose state secrets, business secrets and personal data, and must not infringe on national interests, public interests and legitimate rights and interests of citizens, legal persons and other organizations.

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Regulations on Overseas [REDACTED]

According to the Trial Measures for the Administration of Overseas Issuance and Listing of Securities by Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》) issued by the China Securities Regulatory Commission (the “CSRC”) on February 17, 2023 and effective from March 31, 2023 (hereinafter referred to as the “**Management Trial Measures**”), where domestic enterprises seek overseas securities issuance and [REDACTED], the issuer shall file with the CSRC in accordance with the Management Trial Measures. If an issuer procures an overseas [REDACTED] or [REDACTED], it shall file with the CSRC within 3 working days after submitting [REDACTED] documents for overseas securities issuance and [REDACTED]. If the filing materials are complete and comply with regulations, the CSRC will complete the filing within 20 working days from the date of receipt of the filing materials and publicize the filing information through its website.

According to the Management Trial Measures, overseas securities [REDACTED] and [REDACTED] is not allowed if one of the following circumstances exists: (I) financing through [REDACTED] is explicitly prohibited by laws, administrative regulations or relevant national regulations; (II) the overseas [REDACTED] and [REDACTED] may endanger national security as determined by the relevant competent department under the State Council after examination according to the law; (III) a domestic enterprise or its controlling shareholder or actual controller has committed a criminal crime of corruption, bribery, embezzlement, misappropriation of property or disrupting the order of the socialist market economy in the last three years; (IV) a domestic enterprise is under formal investigation according to the law for being suspected of any crime or major violation of laws and regulations, but no clear conclusions have been made; or (V) there is a major dispute over ownership of the equity held by the controlling shareholder or a shareholder controlled by the controlling shareholder or the actual controller.

Overseas [REDACTED] Confidentiality and Archives Administration

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

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with the power of examination and approval according to the law, and report to the administrative department of confidentiality at the same level for filing. A domestic enterprise that, either directly or through its overseas [REDACTED] entity, publicly discloses or provides to relevant securities companies, securities service institutions, overseas regulators, and other entities and individuals, other documents and materials whose divulgence will have adverse impact on national security or public interest, shall strictly undergo the relevant procedures in accordance with the relevant regulations of the state.

Regulations on the Full Circulation of H Shares

According to the Management Trial Measures, for a domestic company undertaking direct [REDACTED] and [REDACTED] of securities overseas, shareholders of its domestic unlisted shares applying to convert such shares into shares to be [REDACTED] and [REDACTED] on an overseas [REDACTED] venue shall conform to relevant regulations promulgated by the CSRC and authorize the domestic company to file with the CSRC on their behalf.

According to the Guidelines for H-share Companies to Apply for Full Circulation of Domestic Unlisted Shares (《H股公司境內未上市股份申請“全流通”業務指引》) issued by the CSRC on November 14, 2019 and revised on August 10, 2023, “full circulation” means [REDACTED] and [REDACTED] of domestic unlisted shares of H-share companies (including unlisted domestic shares held by domestic shareholders before overseas [REDACTED], unlisted domestic shares additionally issued after overseas [REDACTED], and unlisted shares held by foreign shareholders) on the Hong Kong Stock Exchange. Shareholders of domestic unlisted shares may, under the premise of complying with the relevant laws and regulations and the requirements of the policies on management of state-owned assets, foreign investment, and industry regulation, among others, determine the amount and proportion of shares whose circulation is applied for on their own through consultation, and entrust H-share companies with undergoing the recordation formalities with the CSRC. A domestic unlisted company limited by shares may undergo the recordation formalities with the CSRC in respect of “full circulation” while applying for overseas [REDACTED] and [REDACTED]. A shareholder of domestic unlisted shares shall, according to the relevant business rules of China Securities Depository and Clearing Corporation Limited (the “CSDC”), handle registration of transfer of shares, undergo the formalities of registration of shares, and quotation and [REDACTED] of shares, among others, according to the relevant provisions of the Hong Kong market, and conduct information disclosure according to the law and regulations. H-share companies should submit relevant status reports to the CSRC within 15 days after the shares involved in the application are transferred to the CSDC.

On December 31, 2019, the CSDC and Shenzhen Stock Exchange jointly issued the Implementation Rules for H-Share Full Circulation Business (《H股“全流通”業務實施細則》), which are applicable to cross-border transfer registration, depository and holding, details maintenance, transaction entrustment and instruction transmission, settlement, clearing participant management, nominee holder services and other related operations involved in H-Share Full Circulation Business.

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On September 20, 2024, the CSDC issued the H-Share Full Circulation Business Guide for CSDC Shenzhen Branch (《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》), which are applicable to the H-Share Full Circulation Business which includes activities such as preparation, account arrangement, cross-border transfer registration and overseas centralized depository, initial records and records of changes of onshore shareholding details, corporate actions, clearing and settlement, and risk management measures. On the same day, China Securities Depository and Clearing (Hong Kong) Co., Ltd. amended the H-Share Full Circulation Business Guide of China Securities Depository and Clearing (Hong Kong) Limited (《中國證券登記結算(香港)有限公司H股“全流通”業務指南》), which apply to businesses including share custody and depository, nominee services, settlement arrangements and risk management measures involved in the H-Share Full Circulation Business.

LAWS AND REGULATIONS IN THE UNITED STATES

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

U.S. Government Regulation of Drug and Biological Products

In the United States, the Food and Drug Administration (“**FDA**”) regulates drugs under the Food, Drug, and Cosmetic Act (“**FDCA**”) and its implementing regulations, and the FDA regulates biologics under the FDCA and the Public Health Service Act (the “**PHSA**”) and their respective implementing regulations. Both drugs and biologics also are subject to other federal, state, and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals to manufacture or market drugs and biologics in the United States and the subsequent compliance with appropriate federal, state, local, and non-U.S. applicable statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative proceedings administrative actions, government prosecution, judicial sanctions or any combination of them in the United States. These actions and sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any administrative proceeding on action or any judicial enforcement action could have a material adverse effect on our business, financial condition and results of operations as well as the market’s acceptance of our products and our reputation. Outside the United States, drugs and biologics are regulated under other statutory and regulatory systems with which we would need to comply if we were to manufacture or market drugs or biologics outside the United States, and failure to comply there could also subject us to administrative actions, government prosecution or judicial sanctions (or any combination of them).

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Once a product candidate is identified for development, it enters preclinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Preclinical testing is conducted in accordance with FDA’s Good Laboratory Practice regulations. A sponsor of an Investigational New Drug application (“**IND**”) must submit the results of the preclinical tests (such as animal tests), manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance. Although information a sponsor submits in an IND is confidential information, general clinical trial information such as the number of patients involved and the type of adverse events studied can be made public information and can be available for public review through publication on government websites such as www.clinicaltrials.gov.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice (“**GCPs**”) and human subject protection regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board (“**IRB**”), often under the auspices of a university and sometimes a private, independent organization, must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB’s requirements or human subject research regulations or if the product has been associated with unexpected serious harm to subjects and the IRB believes patients are at risk.

Clinical trials generally are conducted in three sequential phases, known as Phase I, Phase II and Phase III, and may overlap.

- Phase I clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.
- Phase II clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetics and pharmacodynamics information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

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- Phase III clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA before marketing approval is received. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor’s initial receipt of the information. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with FDA’s current Good Manufacturing Practices (“cGMP”).

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of a New Drug Application (“NDA”). Unless deferred or waived, NDAs, or supplements, must contain data adequate to assess the safety and efficacy of the product at the proposed commercial dosing regimen and administration for the claimed indications in all relevant populations, including any pediatric subpopulations. The submission of an NDA is subject to the payment of a user fee and an annual prescription drug product program fee to the FDA although in certain circumstances the FDA may waive the annual prescription drug product program fee if the drug qualifies for orphan drug designation.

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

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

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

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologic candidates intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the United States. The first applicant to receive FDA approval for the disease or indication for which it has orphan drug designation is entitled to a seven-year exclusive marketing period. During the exclusivity period, the FDA may not approve any other applications to market the same product for the same disease or condition except in limited circumstances. The impacts on the clinical development and registration of drugs receiving Orphan Drug designation are: the sponsors may be provided with (1) a tax credit of 50 percent of the cost of conducting human clinical trials, and (2) federal research grants for clinical testing of new therapies to treat and/or diagnose rare diseases; (3) eligibility for seven-year marketing exclusivity and (4) a waiver of NDA PDUFA fees. The approval of an orphan drug designation request does not alter the standard regulatory requirements and processes for obtaining marketing approval. Sponsors must establish safety and efficacy of a compound to treat a rare disease through adequate and well-controlled studies.

FDA may revoke orphan-drug designation for any drug if the agency finds that:

- The request for designation contained an untrue statement of material fact; or
- The request for designation omitted required or material information; or
- FDA subsequently finds that the drug in fact had not been eligible for orphan-drug designation at the time of submission of the request.

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For an approved drug, revocation of orphan-drug designation also suspends or withdraws the sponsor’s exclusive marketing rights for the drug but not the approval of the drug’s marketing application.

Where a drug has been designated as an orphan drug because the prevalence of a disease or condition (or, in the case of vaccines, diagnostic drugs, or preventive drugs, the target population) is under 200,000 in the United States at the time of designation, its designation will not be revoked on the ground that the prevalence of the disease or condition (or the target population) becomes more than 200,000 persons.

If FDA revokes an orphan-drug designation, FDA will publicize that the drug is no longer designated in accordance with 21 CFR 316.28. The sponsor may request the designation to be rescinded/withdrawn. The impact of revocation is that the sponsor will lose all the benefits of Orphan Drug designation.

Post-Marketing Requirements

Following approval of a new product, the manufacturer of the approved product is subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse events (“**AEs**”) experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as “**off-label use**”) and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies such as the Department of Justice actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities as well as potential tort liability. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy (“**REMS**”), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA/BLA must submit a proposed REMS. The FDA will not approve the NDA/BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

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FDA regulations require that products be manufactured in specific approved facilities according to approved manufacturing processes and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. The manufacturer is ultimately responsible for its products and the manufacturing practices of its contract manufacturers, therefore the manufacturer must take responsibility for the failure for the contract manufacturers to manufacture according to cGMPs.

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

Once an approval is granted, if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug reaches the market, the FDA may take enforcement actions such as issuing Warning Letters or Untitled Letters, ordering removal of the product from the market until deficiencies are remedied, withdrawing the approval of the product, or imposing civil and criminal penalties. Corrective action in response to these enforcement activities could delay drug distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences which could arise from such regulatory violations include, among other things:

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

REGULATORY OVERVIEW

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of NDA/BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product’s testing phase, which is the time between IND and BLA submission, and all of the review phase, which is the time between NDA/BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which a BLA has not been submitted.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OVERVIEW

Our history can be traced back to July 10, 2001, when Pan-Asia, the holding company of our Group prior to September 2020, was incorporated in the BVI. Our Company was established on May 13, 2008 as a limited liability company under the PRC Company Law with the name “派格生物醫藥(蘇州)有限公司” and a wholly-owned subsidiary of Pan-Asia. On December 30, 2020, our Company was converted into a joint stock company with limited liability, and was renamed as PegBio Co., Ltd. (派格生物醫藥(蘇州)股份有限公司) (further renamed as PegBio Co., Ltd. (派格生物醫藥(杭州)股份有限公司) on February 6, 2025). We are a biotechnology company focused on the in-house discovery and development of innovative therapies for chronic diseases with a particular emphasis on metabolic disorders, and have been managed by Dr. Michael Min XU, our founder, chairman of the Board and executive Director, who has extensive research and managerial experience in the pharmaceutical industry across the PRC and the United States, since our inception. Our achievements have been enabled under the leadership of Dr. Michael Min XU, who is the principal inventor behind our key patents and is responsible for the overall strategic planning, business direction and operational management of our Group. For details of Dr. Michael Min XU’s biographical background, relevant industry experience and contributions to the research and development of our product pipelines, see “Directors, Supervisors and Senior Management” and “Business — Overview.”

KEY MILESTONES

The following table summarizes the key business development milestones since our inception:

Year	Milestone
2010	We filed the patent applications of novel exendin variant and conjugate thereof in connection with PB-119, our Core Product, in multiple jurisdictions in April 2010, which represents the first significant progress we achieved in connection with our research and development of PB-119.
	We established Suzhou Pharmaceutical Polyethylene Glycol Engineering Technology Research Center (蘇州市藥用聚乙二醇工程技術研究中心).
2012	We launched a R&D project of PB-718, our key product, with government support for “Major National Science and Technology Projects for New Drug Development” (“重大新藥創製”科技重大專項) under the National 12th Five-Year Plan.
2013	The NMPA issued IND approval for Phase I clinical trial for PB-119, our Core Product, in September 2013.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Milestone
2015	We were named as one of “Top 50 of China’s Most Valuable Investment Enterprises.” We initiated Phase I clinical trial of PB-119, our Core Product, in the United States.
2016	We launched a R&D project of PB-119, our Core Product, with government support for “Major National Science and Technology Projects for New Drug Development” (“重大新藥創製”科技重大專項) under the National 13th Five-Year Plan. We completed Phase I clinical trial of PB-119, our Core Product, in the United States.
2017	The NMPA issued IND approval for Phase II and Phase III clinical trials for PB-119, our Core Product, in September 2017.
2018	We were recognized as a Seed Unicorn Enterprise (獨角獸培育企業) by Suzhou Industrial Park Administrative Committee (蘇州工業園區管理委員會). We initiated Phase II clinical trial of PB-119, our Core Product, in the United States.
2019	We were named among “VB100 Future Healthcare Companies — Top 100 China Innovative Pharma & Biotech Companies” (2019未來醫療100強 — 中國創新醫藥榜TOP100) by VCBeat (動脈網). We completed Phase II clinical trial of PB-119, our Core Product, in the United States.
2020	We initiated the Phase I clinical trial of PB-718 in the United States. PB-119, our Core Product, obtained the approval of the Phase III clinical trial from NMPA, and the trial was initiated in China.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Milestone
2021	We initiated a Phase I, randomized, double-blind, placebo-controlled, single ascending dose clinical study of PB-1902 in China and completed the trial. We obtained the IND approval of PB-119, our Core Product, for the treatment of obesity. We initiated a Phase I, randomized, double-blind, placebo-controlled, multiple ascending dose clinical study of PB-1902 (the “PB1902-M-02-Ia-02 Trial”) in China.
2022	We completed the PB1902-M-02-Ia-02 Trial in China. We completed the Phase I clinical trial of PB-718 in the United States. We completed the Phase III clinical trial PB119-301 of PB-119, our Core Product, in China.
2023	Our new drug application (“NDA”) for PB-119, our Core Product, in China for T2DM was accepted by the NMPA. We initiated the Phase Ib/IIa clinical trial of PB-718 in China.
2025	We relocated our headquarter to Hangzhou and were renamed as PegBio Co., Ltd. (派格生物醫藥(杭州)股份有限公司)

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OUR SUBSIDIARIES

We conducted all our material operations, including but not limited to the research and development of PB-119, our Core Product, and other pipeline products such as PB-718, through our Company during the Track Record Period and up to the Latest Practicable Date. Set forth below are details for each of subsidiaries as of the Latest Practicable Date.

Name of Subsidiary	Place of Incorporation	Registered Capital	Date of Incorporation	Principal Business Activities ⁽³⁾
Shanghai Hanmai ⁽¹⁾ . . .	PRC	RMB5,000,000	June 26, 2017	Research and development of PB-1902
Shanghai Maiji ⁽¹⁾	PRC	RMB5,000,000	June 26, 2017	Research and development of GLP-2 (a peptide hormone that is involved in intestinal functions and metabolism)
PegBio Suzhou ⁽²⁾ . . .	PRC	RMB1,000,000	January 21, 2025	Biotechnology research and development, medical research and technical services

Notes:

- (1) Each of Shanghai Hanmai and Shanghai Maiji was established in the PRC on June 26, 2017 with a registered capital of RMB5,000,000. During the Track Record Period, each of them contributed less than 6% of our Group’s total assets.

During the Track Record Period and as of the Latest Practicable Date, each of Shanghai Hanmai and Shanghai Maiji was owned (i) as to approximately 64.77% by our Company, (ii) as to approximately 11.38% by Ms. Mei HE, who is also the general manager of Shanghai Hanmai and Shanghai Maiji, (iii) as to approximately 15.38%, 3.85%, 0.77% and 0.77% by Beijing Agile Way Consulting Co., Ltd. (北京敏捷之道諮詢有限公司) (the “Beijing Agile”), Ms. Yu ZHANG (張鈺), Ms. Ying KUANG (匡鶯) and Mr. Jiangmin SHAN (單江閩), also our Shareholders, and (iv) as to approximately 1.54% and 1.54%, by Mr. Wei JIANG (江蔚) and Shanghai Zheyi Investment Management Co., Ltd. (上海柘懿投資管理有限公司), being Independent Third Parties.

- (2) PegBio Suzhou was established in the PRC on January 21, 2025 with a registered capital of RMB1,000,000.

As of the Latest Practicable Date, PegBio Suzhou was owned as to 100% by the Company.

- (3) Save as mentioned in the table above, the research and development of our products, including but not limited to PB-119 and PB-718, are conducted by our Company.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Our Non-wholly-owned Subsidiaries

As at the Latest Practicable Date, each of Shanghai Hanmai and Shanghai Maiji had a registered capital of RMB5,000,000 contributed by its shareholders on a pro-rated basis and such registered capital had primarily funded their operations and R&D activities during the Track Record Period.

Shanghai Hanmai primarily engages in the research and development of PB-1902, and Shanghai Maiji primarily engages in the research and development of GLP-2. The Company’s equity investment in these two non-wholly-owned subsidiaries diversified the Company’s pipeline and reduced the Company’s reliance on its then existing pipeline products. Investments from minority shareholders in these two subsidiaries supported their R&D development, especially during the initial stage of their operations which had been capital intensive.

Going forward, we will continue to leverage our majority shareholding stake to control the operations and direct the R&D activities of Shanghai Hanmai and Shanghai Maiji after the [REDACTED]. Minority shareholders in these two subsidiaries are expected to maintain an inactive and non-control role in view of their shareholding. To the extent Shanghai Hanmai and Shanghai Maiji have additional capital needs in the future, the Board will (i) firstly assess the development prospects of PB-1902 or GLP-2 against the capital required, and (ii) assess the availability of various financing options, including bank loans, and/or investment from existing shareholders or new investors. Where the Board is of the view that additional equity investment in the research and development in PB-1902 or GLP-2 is commercially justifiable and represents good use of our Group’s capital, the Board may, subject to agreement with the shareholders and obtaining the necessary corporate approvals of Shanghai Hanmai and Shanghai Maiji, commercially increase its investment in Shanghai Hanmai and Shanghai Maiji proportionally or disproportionately.

Shanghai Hanmai and Shanghai Maiji contributed less than 6% of our Group’s total assets during the Track Record Period. As of the Latest Practicable Date, they were not involved in the research and development, and were not expected to be involved in the future commercialization, of the Group’s Core Product (PB-119) and key product (PB-718). As such, the operations of Shanghai Hanmai and Shanghai Maiji do not make material contribution to our Group and are not expected to be material to the Group’s operations in the near term. As such, whether or not the Company continues investing in Shanghai Hanmai and Shanghai Maiji is not expected to have material adverse impact on the business, operations and financial performance of the Group and any continued or further investment in Shanghai Hanmai and Shanghai Maiji will be determined primarily based on the clinical results and prospects of PB-1902 and GLP-2, as applicable.

MAJOR ACQUISITIONS, DISPOSALS AND MERGERS

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

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

CORPORATE DEVELOPMENT AND MAJOR SHAREHOLDING CHANGES

(1) Establishment and Shareholding Changes of Pan-Asia and Xinfeng Biotech

On July 10, 2001, Pan-Asia, the holding company of our Group prior to September 2020, was incorporated in the BVI as a company with limited liability. Upon incorporation, Pan-Asia had an authorized share capital of US\$50,000 divided into 50,000 shares of a par value of US\$1 each, held as to 50% by Dr. Michael Min XU and 50% by Mr. Junlian HUANG (黃駿廉), an Independent Third Party and an early business partner of Dr. Michael Min XU. During the period from its establishment up to March 2008, Pan-Asia underwent a series of initial shareholding changes, upon the completion of which Pan-Asia was held (i) as to approximately 67.86% by Dr. Michael Min XU and 12.34% by Dr. Xiangjun ZHOU, both being our Directors and members of the Single Largest Group of Shareholders, and (ii) as to approximately 12.96% by Jung-Hsi LIU (劉容西) and 6.85% by Asia Private, both being our [REDACTED] Investors. Mr. Junlian HUANG (黃駿廉) disposed of his interests in Pan-Asia on terms that were determined based on arm’s length negotiation with Pan-Asia (including but not limited to Pan-Asia’s payment of RMB100,000 to Mr. Junlian HUANG (黃駿廉)) taking into account the contribution by Mr. Junlian HUANG (黃駿廉) to the Group, pursuant to a share repurchase agreement dated January 16, 2008 between Pan-Asia and him, and had not remained as a shareholder after the incorporation of the Company in 2008, in connection with which there is no disagreement or dispute. The shareholders of Pan-Asia during the aforesaid period, other than Mr. Junlian HUANG (黃駿廉), subsequently became, and remained as of the Latest Practicable Date, the Shareholders of the Company either directly or indirectly through investment vehicles. Pan-Asia was established for shareholding purpose only, and had no substantial business operations since its inception.

On September 17, 2001, Xinfeng Biotech was established as a limited liability company in the PRC with a registered capital of US\$200,000 and as a wholly-owned subsidiary of Pan-Asia. Xinfeng Biotech was primarily engaged in providing PEGylation services to pharmaceutical companies, and was subsequently transferred to the Company, as detailed in “— (2) Establishment of our Company, our Offshore [REDACTED] Investments and Intra-group Transfer of Xinfeng Biotech” below. Other than the Company and Xinfeng Biotech, Pan-Asia had no subsidiaries or affiliates up to its de-registration in May 2023.

(2) Establishment of our Company, our Offshore [REDACTED] Investments and Intra-group Transfer of Xinfeng Biotech

On May 13, 2008, our Company was established as a limited liability company in the PRC with an initial registered capital of US\$500,000 and wholly owned by Pan-Asia. During the period from May 2008 to December 2019, we went through a series of financings through [REDACTED] Investments in Pan-Asia as detailed in “— [REDACTED] Investments” below. During the period from January 2009 to July 2020, our Company went through a series of capital increases and its registered capital increased by US\$38,623,431 to US\$39,123,431, and the additional registered capital of our Company was fully subscribed by Pan-Asia at a consideration of US\$38,623,431 with cash.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Pursuant to an equity transfer agreement between Pan-Asia and the Company dated January 9, 2020, Xinfeng Biotech was acquired as a wholly-owned subsidiary by the Company from Pan-Asia for nil consideration. In order to further focus our resources and efforts on the research and development of our drug candidates and to streamline our corporate structure, we de-registered Xinfeng Biotech on December 23, 2021, and no longer provide PEGylation services to pharmaceutical companies, which contributed no revenue to our Group in the years 2020 and 2021.

(3) Equity Transfers in September 2020

In preparation of the Company’s plan to apply for a listing of the Shares in the PRC, the shareholding in Pan-Asia was flipped down to the level of the Company in September 2020. Pan-Asia had complied with the relevant laws and regulations in all material respects since its inception and up to its voluntary winding-up and de-registration in May 2023.

After the aforesaid equity transfers in September 2020, the shareholding structure of our Company was as follows:

Name of Shareholder	Registered Share Capital Subscribed	Corresponding Equity Interest in our Company
	(US\$)	
Dr. Michael Min XU	13,944,765	35.64%
Mingly China Growth Fund, L.P. (“ Mingly ”)	5,262,845	13.45%
True Wing Limited (“ True Wing ”)	2,337,977	5.98%
Nice Credit Limited (“ Nice Credit ”)	2,195,803	5.61%
TSL HK	1,923,895	4.92%
SIP Surgent BioVenture Capital Investment Partnership (Limited Partnership) (蘇州工業園 區新建元生物創業投資企業(有限合夥)) (“ SIP BioVC ”)	1,712,393	4.38%
Kaifeng Venture Capital Co., Ltd. (凱風創業投資 有限公司) (“ Kaifeng VC ”)	1,472,645	3.76%
Share Link Capital Co., Ltd. (“ Share Link ”)	1,472,645	3.76%
Dr. Xiangjun ZHOU	1,100,268	2.81%
Chelmsford International Limited (“ Chelmsford ”)	1,079,924	2.76%
Ms. Lin BAI (白林)	1,028,477	2.63%
Dr. Yuhong XU (徐宇虹)	1,028,477	2.63%
Hongkong Tigermed Co., Limited (香港泰格醫藥 科技有限公司) (“ Tigermed HK ”)	641,350	1.64%
Beijing Agile	641,311	1.64%
Asia Private	570,811	1.46%

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Name of Shareholder	Registered Share Capital Subscribed	Corresponding Equity Interest in our Company
	(US\$)	
SIP Sungen Venture Capital Investment Partnership II (Limited Partnership) (蘇州工業 園區新建元二期創業投資企業(有限合夥)) (“SIP VC II”)	483,409	1.24%
Qianhai Equity Investment Fund (Limited Partnership) (前海股權投資基金(有限合夥)) (“Qianhai FoF”)	483,409	1.24%
Shihezi Xinyue Equity Investment Enterprise (Limited Partnership) (石河子市鑫悅股權投資合 夥企業(有限合夥)) (“Shihezi Xinyue”)	483,409	1.24%
Suzhou KF Pegbio Venture Capital Partnership (Limited Partnership) (蘇州凱風派格創業投資合 夥企業(有限合夥)) (“KF Pegbio”)	362,557	0.93%
YuanBio Venture Capital L.P. (“YuanBio”)	362,557	0.93%
Nanjing Kaiyuan Growth Capital Investment Partnership (Limited Partnership) (南京凱元成 長創業投資合夥企業(有限合夥)) (“Nanjing Kaiyuan”)	285,405	0.73%
Connected Triumph Limited (“CTL”)	128,247	0.33%
Suzhou Jinmao Enterprise Management Consulting Co., Ltd. (蘇州錦茂企業管理諮詢有限公司) (“Suzhou Jinmao”)	120,852	0.31%
Total	39,123,431	100%

(4) Equity Transfer to the Equity Incentive Platform in October 2020, Conversion into a Joint Stock Company with Limited Liability in December 2020, and Onshore [REDACTED] Investments

In October 2020, Dr. Michael Min XU transferred US\$4,405,612 of the registered capital of our Company reserved for employee incentive purpose to Shanghai Sujie, our Equity Incentive Platform, at a consideration of US\$3,427, which equaled the subscription price previously paid by Dr. Michael Min XU for the corresponding shares in Pan-Asia calculated based on the par value.

On December 30, 2020, our Company was converted into a joint stock company with limited liability and renamed as PegBio Co., Ltd. (派格生物醫藥(蘇州)股份有限公司) (further renamed as PegBio Co., Ltd. (派格生物醫藥(杭州)股份有限公司) on February 6, 2025), with a registered capital of RMB354,509,625 divided into 354,509,625 Shares with a nominal value of RMB1.00 each, which were subscribed by all the then Shareholders in proportion to their respective equity interests in our Company before the conversion. The conversion was completed on December 30, 2020 when our Company obtained a new business license issued by Administration for Market Regulation of Jiangsu Province (江蘇省市場監督管理局).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Subsequent to the stock conversion, the Company and its then existing Shareholders completed a series of [REDACTED] Investments. For details, see “— [REDACTED] Investments” below. On June 26, 2023, the registered capital of our Company increased from RMB354,509,625 to RMB366,672,032. As at the Latest Practicable Date, the registered capital of our Company was RMB366,672,032, as detailed in “— Capitalization” below.

As advised by our PRC Legal Adviser, the Company had complied with the then effective and applicable PRC laws and regulations in respect of the Company’s equity transfers as described in this section in all material aspects.

PREVIOUS LISTING ATTEMPT

In August 2021, we submitted an application for listing (the “**A Share Listing**”) of our shares on the Shanghai Stock Exchange Science and Technology Innovation Board to the CSRC. The Shanghai Stock Exchange issued two rounds of comments while reviewing our application for the A Share Listing, to which we provided response. In April 2022, we voluntarily withdrew the application for the A Share Listing based on our latest corporate strategy so as to focus on the R&D of our products.

In December 2022, we entered into a tutoring agreement (the “**Tutoring Agreement**”) with China International Capital Corporation Limited (中國國際金融股份有限公司) in connection with an A Share Listing and made a preliminary filing (上市輔導備案) (the “**Preliminary Filing**”) with the Jiangsu Regulatory Bureau of CSRC (中國證券監督管理委員會江蘇監管局). To further expand our global business and considering that the Stock Exchange would provide us with an international platform to access foreign capital and attract diverse overseas investors, the Company voluntarily decided in the second half of 2023 to pursue a [REDACTED] in Hong Kong. Considering the overall development plan of the Company and its focus to the [REDACTED] for the [REDACTED], the Company and China International Capital Corporation Limited entered into a termination agreement to the Tutoring Agreement on April 19, 2024 with immediate effect, and made relevant filing with Jiangsu Regulatory Bureau of CSRC to voluntarily withdraw the Preliminary Filing, which was announced on April 28, 2024.

Our Directors confirmed, and the Sole Sponsor, who was not a sponsor of or otherwise involved in the A Share Listing, concurred based on its due diligence work, that (i) all major comments raised by the Shanghai Stock Exchange for the A Share Listing have been resolved or addressed in all material respects; (ii) there are no material disagreements or unresolved disputes between the Company and the relevant professional parties involved in the application for the A Share Listing or the Preliminary Filing; (iii) there is no other matter relating to the attempts for A Share Listing and the Preliminary Filing that would affect the Company’s suitability for [REDACTED] on the Stock Exchange or that are relevant to the [REDACTED] and are necessary to be disclosed in this Document for the [REDACTED] to form an informed assessment of our Company; and (iv) during the period of preparation for A Share Listing, the Group did not encounter any disagreements with the CSRC.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

We may conduct an offering and listing of A shares at an appropriate time after the [REDACTED]. As of the Latest Practicable Date, we had not determined the size or the listing venue of the potential A share offering. Save as the aforesaid application for A Share Listing submitted in August 2021, we have not submitted any application to any recognized stock exchange in the PRC for approval of A share listing as of the Latest Practicable Date. There is no assurance that we will conduct an A share offering in the future.

CONCERT PARTY AGREEMENT

Dr. Michael Min XU (our founder, chairman of the Board, executive Director and general manager), Dr. Xiangjun ZHOU (our non-executive Director) and Dr. Yuhong XU (徐宇虹) (our non-executive Director) shared the same values and goals, as well as the belief in our prospects, which constantly strengthened as we grew. On April 2, 2021, to document their acting in concert arrangement in preparation for the Company’s [REDACTED] plans and to enhance their influence and control at general meetings of the Company to promote stability over the direction, management, operation and development of the Group, Dr. Michael Min XU, Dr. Xiangjun ZHOU, Dr. Yuhong XU (徐宇虹) and Shanghai Sujie, our Equity Incentive Platform, (collectively, the “**Concert Parties**”) entered into a concert party agreement (the “**Concert Party Agreement**”), pursuant to which they (i) acknowledged and confirmed their relationship of acting in concert as shareholders when exercising the voting rights of the Company and Pan-Asia (as the case may be) since they became shareholders of these companies, and (ii) agreed to continue such acting in concert relationship so long as they hold any Shares, unless termination is agreed among all parties to the agreement. Shanghai Sujie’s general partner, namely Ms. Xiaojun WANG (王小軍), plays an administrative role, and has been designated by the Company, upon which Dr. Michael Min XU exercises significant influence.

As of the Latest Practicable Date, the Concert Parties held approximately 27.37% of our total issued share capital, comprising approximately 15.84% held by Dr. Michael Min XU, approximately 1.86% held by Dr. Yuhong XU (徐宇虹), approximately 1.71% held by Dr. Xiangjun ZHOU and approximately 7.96% held by Shanghai Sujie respectively. Immediately following the completion of the [REDACTED], the Concert Parties will hold approximately [REDACTED]% of our total issued share capital, comprising approximately [REDACTED]% held by Dr. Michael Min XU, approximately [REDACTED]% held by Dr. Yuhong XU (徐宇虹), approximately [REDACTED]% held by Dr. Xiangjun ZHOU and approximately [REDACTED]% held by Shanghai Sujie respectively.

REASONS FOR THE [REDACTED]

Our Company is seeking a [REDACTED] of its H Shares on the Stock Exchange in order to provide further capital for the development and expansion of our Company’s business, to strengthen our Company’s working capital and to further raise our business profile and global presence. For further details of our future plans, see “Future Plans and Use of [REDACTED].”

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

EQUITY INCENTIVE PLATFORM

In recognition of the contributions of our employees and to incentivize them to further promote our development, we established Shanghai Sujie Business Management Consulting Partnership (Limited Partnership) (上海蘇頔企業管理諮詢合夥企業(有限合夥)) as our Equity Incentive Platform in the PRC on August 28, 2020, and adopted the [REDACTED] Equity Incentive Scheme in March 2021, as amended from time to time.

Ms. Xiaojun WANG (王小軍), as the sole general partner of Shanghai Sujie, is responsible for the management of Shanghai Sujie and exercising the voting rights attaching to the Shares held by Shanghai Sujie, in accordance with the partnership agreement entered into among the general and limited partners of Shanghai Sujie.

As of the Latest Practicable Date, Ms. Xiaojun WANG (王小軍) held approximately 3.11% partnership interests in Shanghai Sujie, with the remaining interests being held by 20 limited partners of Shanghai Sujie, namely (i) Dr. Michael Min XU (our executive Director and general manager, holding approximately 93.10% interests of Shanghai Sujie), Ms. Mengjiao WANG (王夢嬌) (our Supervisor, holding approximately 0.06% interests of Shanghai Sujie), Mr. Yifeng HUANG (黃一峰) (secretary of the Board and our joint company secretary, holding approximately 0.41% interests of Shanghai Sujie), and (ii) the other 17 current employees who are not the Directors, Supervisors, senior management or connected persons of our Company (holding approximately 3.33% interests of Shanghai Sujie in aggregate, with their respective interests less than 1.1%). For further details of the [REDACTED] Equity Incentive Scheme, see “Statutory and General Information — [REDACTED] Equity Incentive Plan” in Appendix IV.

As of the Latest Practicable Date, Shanghai Sujie owned approximately 7.96% of our issued Shares. All awards under the [REDACTED] Equity Incentive Scheme were granted to specified participants as of the Latest Practicable Date, and the [REDACTED] Equity Incentive Scheme does not involve the grant of new Shares or awards by the Company after the [REDACTED].

[REDACTED] INVESTMENTS

Overview

We underwent the following rounds of [REDACTED] investments, details of which are set forth below.

(1) Series A1 Financing

On May 15, 2008, Mingly entered into a share purchase agreement with Pan-Asia, the Company, Xinfeng Biotech and the then shareholders of Pan-Asia, pursuant to which Mingly agreed to subscribe for 2,500,000 Series A preferred shares of Pan-Asia at a consideration of US\$1,200,000 (the “**Series A1 Financing**”). The consideration of Series A1 Financing was determined based on arm’s length negotiation amongst parties after taking into consideration of the R&D status and prospects of our products including the commencement of research and development of PB-119, our Core Product, by the Group, which was fully paid up in cash on March 14, 2008.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(2) Series A2 Financing

On May 15, 2008, Pan-Asia granted a warrant to Mingly, pursuant to which, Mingly was entitled to purchase, at any time after the date thereof and on or before December 31, 2012, up to 1,250,000 Series A preferred shares of Pan-Asia, at an exercise price per share equal to US\$0.48 per share, which was determined based on arm’s length negotiation amongst parties after taking into consideration of the subscription price of Series A1 Financing conducted in parallel.

On April 6, 2011, Mingly exercised such warrant to purchase 1,250,000 Series A preferred shares of Pan-Asia, at a total exercise price of US\$600,000 (the “**Series A2 Financing**”, together with Series A1 Financing, the “**Series A Financing**”).

(3) Series B Financing

On June 20, 2011, Pan-Asia, the Company, Xinfeng Biotech and the then shareholders of Pan-Asia entered into share purchase agreements with True Wing, Hua Yuan International Limited (華圓管理諮詢(香港)有限公司) (“**Hua Yuan**”), Share Link and Mingly respectively, pursuant to which, True Wing, Hua Yuan, Share Link and Mingly agreed to subscribe for 1,374,570, 1,145,475, 1,145,475 and 343,643 Series B preferred shares of Pan-Asia respectively, at considerations of US\$1,200,000, US\$1,000,000, US\$1,000,000 and US\$300,000 respectively (the “**Series B Financing**”). The considerations of Series B Financing were determined based on arm’s length negotiation amongst parties after taking into consideration of the R&D status and prospects of our products including that the Group obtained patents in relation to PB-119, our Core Product, which were fully paid up in cash on September 27, 2011.

(4) Series C Financing

On June 10, 2014, Pan-Asia, the Company, Xinfeng Biotech and the then shareholders of Pan-Asia entered into a share purchase agreement with LC Fund VI, L.P. (“**LC Fund VI**”), LC Parallel Fund, SIP BioVC, True Wing and Nanjing Kaiyuan, pursuant to which, LC Fund VI, LC Parallel Fund, SIP BioVC, True Wing and Nanjing Kaiyuan agreed to subscribe for 1,278,693, 53,279, 1,331,972, 443,991 and 221,995 Series C preferred shares of Pan-Asia respectively, at considerations of US\$2,880,000, US\$120,000, US\$3,000,000, US\$1,000,000 and US\$500,000 respectively (the “**Series C Financing**”). The considerations of Series C Financing were determined based on arm’s length negotiation amongst parties after taking into consideration of the R&D status and prospects of our products including that we filed an IND application to the NMPA and obtained the approval in September 2013 to conduct a Phase I clinical trial of PB-119, our Core Product, in China, which were fully paid up in cash on September 30, 2014.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(5) *Series D Financing*

On August 30, 2015, Pan-Asia, the Company, Xinfeng Biotech and the then shareholders of Pan-Asia entered into a share purchase agreement with LC Fund VI, LC Parallel Fund, SIP VC II, Co-win Healthcare Fund I, L.P. (“**Co-win Healthcare**”), Suzhou Industrial Park Zhongyi Mingyuan Venture Capital Investment Center (Limited Partnership) (蘇州工業園區中億明源創業投資中心(有限合夥)) (“**Zhongyi Mingyuan**”), Shihezi Xinyue, Wuhu Zhongchuang Venture Capital Investment Fund (Limited Partnership) (蕪湖眾創創業股權投資基金(有限合夥)) (“**Wuhu Zhongchuang**”) and Jing Shing (HK) Limited (香港錦城有限公司) (“**Jing Shing**”) (the “**Series D Share Purchase Agreement**”), pursuant to which, LC Fund VI, LC Parallel Fund, SIP VC II, Co-win Healthcare, Zhongyi Mingyuan, Shihezi Xinyue, Wuhu Zhongchuang and Jing Shing agreed to subscribe for 356,377, 19,639, 376,015, 282,011, 376,015, 376,015, 282,011 and 94,004 Series D preferred shares of Pan-Asia respectively, at considerations of US\$1,895,544, US\$104,456, US\$2,000,000, US\$1,500,000, US\$2,000,000, US\$2,000,000, US\$1,500,000 and US\$500,000 respectively (the “**Series D Financing**”).

On June 8, 2017, (i) Zhongyi Mingyuan transferred 376,015 unpaid Series D preferred shares of Pan-Asia it held to Epoch Vantage Limited (“**Epoch**”) at nil consideration, and Epoch agreed to pay the consideration for such shares under the Series D Share Purchase Agreement; (ii) Wuhu Zhongchuang transferred 282,011 unpaid Series D preferred shares of Pan-Asia it held to Yuansheng Bioventure Inc. (“**Yuansheng**”) at nil consideration, and Yuansheng agreed to pay the consideration for such shares under the Series D Share Purchase Agreement. To the best knowledge of our Directors, there were no disagreements or disputes in connection with the aforesaid subscription or transfer of Series D preferred shares of Pan-Asia by Zhongyi Mingyuan and Wuhu Zhongchuang.

The considerations of Series D Financing were determined based on arm’s length negotiation amongst parties after taking into consideration of the R&D status and prospects of our products including the completion of Phase Ia and Ib registrational clinical trial for PB-119, our Core Product, in China, and commencement of Phase Ic of such trial, which were fully paid up in cash on August 4, 2017.

(6) *Series E Financing*

On June 29, 2017, Pan-Asia, the Company, Xinfeng Biotech and the then shareholders of Pan-Asia entered into a share purchase agreement with TSL HK, pursuant to which, TSL HK agreed to subscribe for 1,110,366 Series E preferred shares of Pan-Asia at a consideration of US\$20,000,000 (the “**TSL HK Initial Investment Agreement**”). Subsequently, the relevant parties agreed to adjust the number of Series E preferred shares of Pan-Asia to be purchased by TSL HK into 832,774, and to adjust the total consideration to be paid therefor into US\$15,000,000 (the “**TSL HK Series E Investment**”).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

In 2018, Pan-Asia, the Company, Xinfeng Biotech and the then shareholders of Pan-Asia entered into share purchase agreements with Hidaca Limited (“**Hidaca**”) and CTL respectively, pursuant to which Hidaca and CTL agreed to subscribe for 277,591 and 55,518 Series E preferred shares of Pan-Asia respectively, at considerations of US\$5,000,000 and US\$1,000,000 respectively (together with TSL HK Series E Investment, the “**Series E Financing**”).

Pursuant to the shareholders resolutions of Pan-Asia dated January 20, 2020, Pan-Asia issued 663,699, 221,233 and 44,246 Series E preferred shares of Pan-Asia, at considerations of US\$663.699, US\$221.233 and US\$44.246, equal to the par value of the shares issued to TSL HK, Hidaca and CTL, as compensations from Pan-Asia to each of TSL HK, Hidaca and CTL considering the valuation adjustment of Pan-Asia immediately prior to the Series E-1 Financing (as defined below).

The considerations of Series E Financing were determined based on arm’s length negotiation amongst parties after taking into consideration of the R&D status and prospects of our products including our contemplated initiation of Phase II registrational clinical trial for PB-119, our Core Product, in China, which were fully paid up in cash on August 1, 2018.

(7) Series E-1 Financing

On September 14, 2019, Pan-Asia, the Company, Xinfeng Biotech and the then shareholders of Pan-Asia entered into a share purchase agreement with Tigermed HK, pursuant to which Tigermed HK agreed to subscribe for 498,882 Series E-1 preferred shares of Pan-Asia at a consideration of US\$5,000,000 (the “**Series E-1 Financing (Offshore)**”).

On November 21, 2019, the Company, Dr. Michael Min XU and Pan-Asia entered into capital increase agreements with Pingtan Puxin Yingke Ruiyuan Venture Capital Partnership (Limited Partnership) (平潭浦信盈科睿遠創業投資合夥企業(有限合夥)) (“**Pingtan Puxin**”) and Pingtan Yingke Shengxin Venture Capital Partnership (Limited Partnership) (平潭盈科盛鑫創業投資合夥企業(有限合夥)) (“**Pingtan Yingke**”), pursuant to which Pingtan Puxin and Pingtan Yingke agreed to subscribe for US\$365,364 and US\$1,278,772 of the registered capital of the Company respectively, at considerations of RMB20,000,000 and RMB70,000,000 respectively. On October 15, 2020, the Company entered into a capital increase agreement with Suzhou Yipu II Equity Investment Partnership (Limited Partnership) (蘇州翼樸二號股權投資合夥企業(有限合夥)) (“**Suzhou Yipu**”), pursuant to which Suzhou Yipu agreed to subscribe for US\$730,730 of the registered capital of the Company at consideration of RMB40,000,000 (collectively, the “**Series E-1 Financing (Onshore)**”).

The considerations of Series E-1 Financing (Offshore) and Series E-1 Financing (Onshore) were determined based on arm’s length negotiation amongst parties after taking into consideration of the prospects in the research and development of our products and the then market conditions of biotech industry, which were fully paid up in cash on December 23, 2019 and November 10, 2020 respectively.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(8) Series F Financing

On November 21, 2020, the following investment agreements (the “Series F Financing”) were entered into.

- (a) The Company and its then Shareholders entered into a capital increase agreement with the parties as detailed below:

Name of Subscriber	Registered Capital Subscribed	Consideration
	(RMB)	(RMB)
Wuhan Taiming Venture Capital Partnership (Limited Partnership) (武漢泰明創業投資 合夥企業(有限合夥)) (formally known as Xi'an Taiming Venture Capital Partnership (Limited Partnership) (西安泰明創業投資 合夥企業(有限合夥)) (“ Wuhan Taiming ”).	2,035,657	20,000,000
Hangzhou Tigermed Equity Investment Partnership (Limited Partnership) (杭州泰 格股權投資合夥企業(有限合夥)) (“ Hangzhou Tigermed ”)	5,089,142	50,000,000
Shanghai Yaocui Investment Center (Limited Partnership) (上海曜萃投資中心(有限合 夥)) (“ Shanghai Yaocui ”)	12,213,941	120,000,000
Zibo Yingke Jiyun Venture Capital Partnership (Limited Partnership) (淄博盈 科吉運創業投資合夥企業(有限合夥)) (“ Zibo Yingke ”)	4,071,314	40,000,000
Pingtian Puxin	2,035,657	20,000,000
Pingtian Yuanbo Kangjian Phase I Venture Capital Partnership (Limited Partnership) (平潭苑博康健一期創業投資合夥企業(有限 合夥)) (“ Pingtian Yuanbo ”)	1,017,828	10,000,000
YuanBio	712,480	7,000,000
Kaifeng VC	3,053,485	30,000,000
Qianhai FoF	5,089,142	50,000,000
SIP Sungent Venture Capital Investment Partnership III (Limited Partnership) (蘇州 工業園區新建元三期創業投資企業) (“ SIP VC III ”)	2,646,354	26,000,000
Zhongyuan Qianhai Equity Investment Fund (Limited Partnership) (中原前海股權投資 基金(有限合夥)) (“ Zhongyuan Qianhai ”) .	3,562,399	35,000,000

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Name of Subscriber	Registered Capital Subscribed	Consideration
	(RMB)	(RMB)
Huaxin Securities Investment Co., Ltd. (華鑫證券投資有限公司) (“ Huaxin Investment ”)	2,035,657	20,000,000
Suzhou Industrial Park Zhongxin Hengxiang Investment Center (Limited Partnership) (蘇州工業園區中鑫恆祥投資中心(有限合夥)) (“ Zhongxin Hengxiang ”)	1,526,743	15,000,000
Suzhou Industrial Park Zhongxin Huiyuan Investment Center (Limited Partnership) (蘇州工業園區中鑫惠遠投資中心(有限合夥)) (“ Zhongxin Huiyuan ”)	11,705,026	115,000,000
Suzhou Industrial Park Investment Fund L.P. (蘇州工業園區產業投資基金(有限合夥)) (“ SIP Investment Fund ”)	5,089,142	50,000,000
Suzhou Lanhu Zhuopu Venture Investment Partnership (Limited Partnership) (蘇州嵐湖卓璞創業投資合夥企業(有限合夥)) (“ Suzhou Lanhu ”)	1,017,828	10,000,000
Agricultural Bank II Wuxi Equity Investment Center (Limited Partnership) (農銀二號無錫股權投資中心(有限合夥)) (“ Agricultural Bank II ”)	3,053,485	30,000,000
Wuxi Guolian Guokang Health Industry Investment Center (Limited Partnership) (無錫國聯國康健康產業投資中心(有限合夥)) (“ Wuxi Guolian ”)	3,053,485	30,000,000
Huzhou Qiyuan Zhixin Equity Investment Partnership (Limited Partnership) (湖州啟緣致欣股權投資合夥企業(有限合夥)) (“ Huzhou Qiyuan ”)	3,562,399	35,000,000
Suzhou Ruihua Investment Partnership (Limited Partnership) (蘇州瑞華投資合夥企業(有限合夥)) (“ Suzhou Ruihua ”)	2,035,657	20,000,000
CCB Sci-Tech (Suzhou) Investment and Loan Linkage Equity Investment Fund (Limited Partnership) (建銀科創(蘇州)投貸聯動股權投資基金(有限合夥)) (“ CCB Sci-Tech ”)	2,035,657	20,000,000
China-Singapore Suzhou Industrial Park Industrial Investment Co., Ltd. (中新蘇州工業園區產業投資有限公司) (“ China-Singapore Industrial Investment ”)	3,053,485	30,000,000
Total	79,695,963	783,000,000

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(b) A series of equity transfer agreements were entered into as detailed below:

<u>Name of Transferor</u>	<u>Name of Transferee</u>	<u>Registered Capital Transferred</u>	<u>Consideration</u>
		(RMB)	(RMB)
Nanjing Kaiyuan . .	Huzhou Qiyuan	1,890,034	18,569,283
Dr. Michael	Beijing Lehe Century Technology	1,017,828	10,000,000
Min XU	Co., Ltd. (北京樂和世紀科技有 限公司) (“ Beijing Lehe ”)		
Dr. Michael	Mr. Gang LU (陸剛)	508,914	5,000,000
Min XU			
Dr. Michael	Shanghai Tongyuan Enterprise	508,914	5,000,000
Min XU	Consulting Management Center (Limited Partnership) (上海通 元企業諮詢管理中心(有限合 夥)) (“ Shanghai Tongyuan ”)		
Dr. Michael	Xi’an Jingsong Business	1,526,743	15,000,000
Min XU	Information Consulting Partnership (Limited Partnership) (西安景宋商務信 息諮詢合夥企業(有限合夥)) (“ Xi’an Jingsong ”)		
Dr. Michael	Suzhou Yuankang Dingxiang	1,526,743	15,000,000
Min XU	Investment Management Partnership (Limited Partnership) (蘇州遠康鼎祥投 資管理合夥企業(有限合夥)) (“ Suzhou Yuankang ”)		
Dr. Xiangjun	Beijing Lehe	1,017,828	10,000,000
ZHOU			

The considerations of Series F Financing were determined based on arm’s length negotiation amongst parties after taking into consideration of the R&D status and prospects of our products including the commencement of Phase III registrational clinical trial for PB-119, our Core Product, in China, which were fully paid up in cash on March 1, 2021.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(9) Series F+ Financing

On June 24, 2023, the Company and its then Shareholders entered into a capital increase agreement (the “**Series F+ Financing**”) with parties as detailed below:

Name of Subscriber	Shares Subscribed	Consideration (RMB)
Hangzhou Tigermed.	4,544,995	50,000,000
Hangzhou Taiyu Phase IV Venture Capital Partnership (Limited Partnership) (杭州泰譽四 期創業投資合夥企業(有限合夥)) (“ Hangzhou Taiyu ”)	1,817,998	20,000,000
Mr. Jian CHEN (陳儉).	1,817,998	20,000,000
Mr. Hongfu XIE (謝紅付)	727,199	8,000,000
Mr. Tao XIE (謝濤)	181,800	2,000,000
Ms. Liping LIU (劉麗萍).	354,509	3,900,000
Mr. Anquan PENG (彭安全)	363,600	4,000,000
Mr. Xiao WANG (王嘯).	90,900	1,000,000
Mr. Sumin SHAN (單蘇閩)	45,450	500,000
Ms. Yu ZHANG (張鈺)	181,800	2,000,000
Mr. Sujian SHAN (單蘇建)	109,080	1,200,000
Ms. Ying KUANG (匡鶯)	45,450	500,000
Mr. Jiangmin SHAN (單江閩)	63,630	700,000
Beijing Wuyouen Enterprise Management Consulting Partnership (Limited Partnership) (北京烏尤恩企業管理諮詢合夥企業(有限合夥)) (now known as Zhoushan Wuyouen Enterprise Management Consulting Partnership (Limited Partnership) (舟山烏尤恩企業管理諮詢合夥企業 (有限合夥)) (“ Wuyouen ”)	1,817,998	20,000,000
Total	12,162,407	133,800,000

The considerations of Series F+ Financing were determined based on arm’s length negotiation amongst parties after taking into consideration of the R&D status and prospects of our products including the completion of Phase III registrational clinical trial for PB-119, our Core Product, in China, which were fully paid up in cash on June 29, 2023.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Principal Terms of the [REDACTED] Investments

The following table summarizes the principal terms of the [REDACTED] Investments:

Round ⁽¹⁾	Date of Investment Agreement	Date of Settlement of Consideration (last payment)	Total Funds Raised	Post-money Valuation (approximation)	Cost per Share ⁽²⁾	Discount to the H Share [REDACTED] ⁽³⁾
<i>Financings through investments in Pan-Asia</i>						
Series A1	May 15, 2008	March 14, 2008	US\$1,200,000	US\$4 million ⁽⁴⁾	US\$0.06	[REDACTED]%
Series A2	May 15, 2008	August 31, 2010	US\$600,000	US\$5 million ⁽⁴⁾	US\$0.06	[REDACTED]%
Series B	June 20, 2011	September 27, 2011	US\$3,500,000	US\$12 million ⁽⁴⁾⁽⁵⁾	US\$0.10	[REDACTED]%
Series C	June 10, 2014	September 30, 2014	US\$7,500,000	US\$40 million ⁽⁵⁾⁽⁶⁾	US\$0.26	[REDACTED]%
Series D	August 30, 2015	August 4, 2017	US\$11,500,000	US\$117 million ⁽⁶⁾⁽⁷⁾	US\$0.62	[REDACTED]%
Series E	June 29, 2017 and 2018	August 1, 2018	US\$21,000,000	US\$432 million ⁽⁷⁾⁽⁸⁾	US\$1.18	[REDACTED]%
Series E-1 (Offshore)	September 14, 2019	December 23, 2019	US\$5,000,000	US\$255 million ⁽⁸⁾	US\$1.18	[REDACTED]%
<i>Financings through investments in our Company</i>						
Series E-1 (Onshore)	November 21, 2019 and October 15, 2020	November 10, 2020	RMB130,000,000	RMB2.3 billion ⁽⁹⁾	RMB8.27 ⁽¹¹⁾	[REDACTED]%
Series F	November 21, 2020	March 1, 2021	RMB783,000,000	RMB3.5 billion ⁽⁹⁾⁽¹⁰⁾	RMB9.82 ⁽¹¹⁾	[REDACTED]%
Series F+	June 24, 2023	June 29, 2023	RMB133,800,000	RMB4.0 billion ⁽¹⁰⁾⁽¹²⁾	RMB11.00 ⁽¹¹⁾	[REDACTED]%

Basis of determination of the consideration

The considerations for each round of [REDACTED] Investments were determined based on arm’s length negotiation amongst the respective [REDACTED] Investors and our Group after taking into consideration of the timing of the investments, the status of our business operations, financial performance of our Group, and the prospects of our business.

Lock-up period

Pursuant to the PRC Company Law, Shares issued by our Company prior to the [REDACTED] (including those held by the [REDACTED] Investors) will be subject to a lock-up period of one year from the [REDACTED].

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Use of proceeds from the

[REDACTED] Investments

We utilized the proceeds from the [REDACTED] Investments for the principal business of our Group, including but not limited to research and development of our products, the growth and expansion of our business and general working capital purposes. As of the Latest Practicable Date, we have utilized 89.76% of the proceeds from the [REDACTED] Investments.

Strategic benefits to our Group

brought by the [REDACTED]

Investors

At the time of the [REDACTED] Investment, we believed that our Group could benefit from the additional funds raised from the [REDACTED] Investments as well as their knowledge and experience. In addition, with the introduction of the [REDACTED] Investors, the management team of our Group has become increasingly experienced in corporate governance enhancement and shareholder communications.

Notes:

- (1) For avoidance of doubt, the information of Series A1, A2, B, C, D, E and E-1 (Offshore) financings presented in this table reflects the details of the financings of Pan-Asia, the then ultimate holding company of our Group. For the details on the [REDACTED] Investors, see “— Information about our [REDACTED] Investors” below.
- (2) The cost per Share is calculated based on the amount of investment made by the relevant [REDACTED] Investors and the number of Shares of the Company held by them corresponding to the investment. The cost per Share of Series E Financing has reflected the valuation adjustment as detailed in “— [REDACTED] Investments — Overview — (6) Series E Financing” above.
- (3) The discount to the H Share [REDACTED] is calculated based on the assumption that the [REDACTED] is HK\$[REDACTED] per H Share.
- (4) The post-money valuation increased during the period between the Series A Investments and the Series B Investments as the Group obtained patents in relation to PB-119, our Core Product.
- (5) The post-money valuation increased during the period between the Series B Investments and the Series C Investments as we filed an IND application to the NMPA and obtained the approval in September 2013 to conduct a Phase I clinical trial of PB-119, our Core Product, in China.
- (6) The post-money valuation increased during the period between the Series C Investments and the Series D investments as we successfully completed Phase Ia and Ib registrational clinical trial for PB-119, our Core Product, in China, and started Phase Ic of such trial.
- (7) The post-money valuation increased during the period between the Series D Investments and the Series E Investments as we planned to initiate Phase II registrational clinical trial for PB-119, our Core Product, in China.
- (8) The post-money valuation decreased during the period between the Series E Investments and the Series E-1 Investment (Offshore) due to the then sluggish market conditions of biotech industry.
- (9) The post-money valuation increased during the period between the Series E-1 Investments (Onshore) and the Series F Investments as we started Phase III registrational clinical trial for PB-119, our Core Product, in China.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- (10) The post-money valuation increased during the period between the Series F Investments and the Series F+ Investments as we successfully completed Phase III registrational clinical trial for PB-119, our Core Product, in China.
- (11) On November 11, 2020, the currency of the registered capital of the Company was changed from US\$41,498,297 to RMB274,813,662.
- (12) As at the Latest Practicable Date, market capitalization of the Company upon the completion of the [REDACTED] is expected to be approximately HK\$[REDACTED] (based on the [REDACTED] of HK\$[REDACTED]), which represents an increase of approximately [REDACTED]% as compared with the post-money valuation immediately after the Series F+ Investments, taking into account: (i) the development of our pipeline products since the Series F+ Investments, including but not limited to the acceptance of NDA for PB-119, our Core Product, in China for T2DM by the NMPA in September 2023, a Phase Ib/IIa clinical trial of PB-119 for the treatment of obesity in China being initiated, for which we received the NMPA approval in April 2024, and the initiation and progress of a Phase Ib/IIa clinical trial of PB-718 in China since July 2023; (ii) the potential business development of the Company; (iii) the increased liquidity of the Shares subsequent to the [REDACTED]; and (iv) the current market conditions.

Special Rights of the [REDACTED] Investors

The [REDACTED] Investors were granted certain special rights including, but not limited to redemption right, valuation adjustment, and veto rights on certain important corporate matters. All special rights were terminated on the date of the Company’s conversion into a joint stock company.

PRC Legal Adviser’s Confirmation

As advised by our PRC Legal Adviser, our Company has obtained all necessary approvals from and made all necessary registration or filings with the relevant local branch of SAMR in respect of the [REDACTED] Investments in material aspects set out above.

Compliance with the [REDACTED] Investment Guidance

On the basis that (i) the consideration for the [REDACTED] Investments was settled more than 28 clear days before the first filing of the [REDACTED] by our Company with the Stock Exchange, and (ii) the termination of special rights granted to the [REDACTED] Investors as disclosed in “— Special Rights of the [REDACTED] Investors” above, the Sole Sponsor confirms that the [REDACTED] Investments are in compliance with the [REDACTED] Investment Guidance in Chapter 4.2 of the Guide for New Listing Applicants.

Information about our [REDACTED] Investors

YuanBio Venture Capital, which made meaningful investment to us and will hold approximately [REDACTED]% of our total issued share capital upon the completion of the [REDACTED], is our Sophisticated Investor. To the best knowledge of our Directors, save as disclosed below, each of our [REDACTED] Investors and their respective ultimate beneficial owner (where applicable) is an Independent Third Party. Set out below are details of our principal [REDACTED] Investors as of the Latest Practicable Date.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

YuanBio Venture Capital

SIP BioVC is a limited partnership established in the PRC, whose general partner is SIP Yuansheng Bioventure Capital Management Co., Ltd. (蘇州工業園區元生創業投資管理有限公司) (“**SIP Yuansheng**”), mainly focused on early and growth stage life science and healthcare investment. Its portfolio includes companies across new drug, medtech, medical devices, diagnosis and healthcare services sectors. SIP BioVC has 29 limited partners, among which SIP Sungent Holding Group Co., Ltd. (蘇州新建元控股集團有限公司) holds approximately 43.88% partnership interests therein and each of other limited partners holds less than 20% partnership interests therein. The SIP Yuansheng is owned as to approximately 51% by Suzhou Yuanxiang Enterprise Consulting Partnership (Limited Partnership) (蘇州元響企業諮詢合夥企業(有限合夥)) (“**Suzhou Yuanxiang**”), 35% by SIP Sungent Holding Group Co., Ltd. (蘇州新建元控股集團有限公司), and 14% by Suzhou Industrial Park Bio-industry Development Co., Ltd. (蘇州工業園區生物產業發展有限公司). Suzhou Yuanxiang is controlled by its general partner, Suzhou Industrial Park Zhinuo Business Information Consulting Co., Ltd. (蘇州工業園區智諾商務信息諮詢有限公司), which is in turn controlled by Mr. Jie CHEN (陳傑).

SIP VC II is a limited partnership established in the PRC and is managed by its general partner, Suzhou YuanBio Private Equity Fund Management Partnership Enterprise (Limited Partnership) (蘇州元生私募基金管理合夥企業(有限合夥)) (“**YuanBio Management**”) (formerly known as Suzhou Industrial Park YuanFu Venture Capital Management Partnership Enterprise (Limited Partnership) (蘇州工業園區元福創業投資管理企業(有限合夥))) which is ultimately controlled by Mr. Jie CHEN (陳傑). As of the Latest Practicable Date, SIP VC II had 32 limited partners, with the two largest limited partners each holding approximately 14.71% partnership interests.

SIP VC III is a limited partnership established in the PRC and is managed by its general partner, YuanBio Management. As of the Latest Practicable Date, SIP VC III had 49 limited partners, none of which holds more than 10% partnership interests.

YuanBio is a limited partnership established in the Cayman Islands, which is mainly focused on early and growth stage life science and healthcare investments. YuanBio is owned as to approximately (i) 4.76% by its general partner, Yuansheng Capital L.P., and (ii) 95.24% by its 25 limited partners, each holding less than 10% of the partnership interests therein. The ultimate beneficial owner of YuanBio is Mr. Jie CHEN (陳傑).

SIP BioVC, SIP VC II, SIP VC III and YuanBio are investment funds established by YuanBio Venture Capital (元生創投) which focuses on early and growth stage life science and healthcare investments. YuanBio Venture Capital had total assets under management of over RMB10 billion, and has invested over RMB4 billion in healthcare industry with investment portfolio comprising various companies across biotech, medical devices, in vitro diagnostic and healthcare services sectors, including Suzhou Nanomicro Technology Company Limited (蘇州納微科技股份有限公司) (a company listed on the Shanghai Stock Exchange; stock code: 688690) and Shenzhen YHLO Biotech Co., Ltd. (深圳市亞輝龍生物科技股份有限公司) (a company listed on the Shanghai Stock Exchange; stock code: 688575).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

YuanBio Venture Capital is a Sophisticated Investor and has made meaningful investment in our Company at least six months before the [REDACTED]. To the best knowledge of our Directors, each of SIP BioVC, SIP Yuansheng, SIP Sungen Holding Group Co., Ltd. (蘇州新建元控股集團有限公司), Suzhou Yuanxiang, Suzhou Industrial Park Bio-industry Development Co., Ltd. (蘇州工業園區生物產業發展有限公司), Suzhou Industrial Park Zhinuo Business Information Consulting Co., Ltd. (蘇州工業園區智諾商務信息諮詢有限公司), SIP VC II, SIP VC III, YuanBio Management, YuanBio, Yuansheng Capital L.P. and Mr. Jie CHEN (陳傑) is an Independent Third Party.

Mingly

Mingly is a limited partnership incorporated in Cayman Islands, and is mainly engaged in investments in early stage technology companies and investment management. The general partner of Mingly is Mingly China Growth Partners, L.P. The limited partners of Mingly include Up Focus Limited, Medley Partners (offshore) L.P., SinoBase International Trading Ltd, Wise-Win Technology Limited, Kingsbridge Global Holdings Ltd. and Henry Gaw, and none of them have control over Mingly. The fund management team of Mingly has total assets under management of over HK\$1 billion and invested in biotech companies such as RemeGen Co., Ltd. (榮昌生物製藥(煙台)股份有限公司) (a company listed on the Shanghai Stock Exchange (stock code: 688331) and the Hong Kong Stock Exchange (stock code: 9995)). To the best knowledge of our Directors, each of Mingly, Mingly China Growth Partners, L.P., Up Focus Limited, Medley Partners (offshore) L.P., SinoBase International Trading Ltd, Wise-Win Technology Limited, Kingsbridge Global Holdings Ltd. and Henry Gaw is an Independent Third Party.

Tigermed

Hangzhou Tigermed is a limited partnership established in the PRC, which primarily focuses on investment management. Hangzhou Tigermed is owned as to approximately 99.99% by its sole limited partner, Hangzhou Tigermed Consulting Co., Ltd. (杭州泰格醫藥科技股份有限公司) (the “**Tigermed Consulting**”), a company dual-listed on the Shenzhen Stock Exchange (stock code: 300347) and the Hong Kong Stock Exchange (stock code: 3347), and approximately 0.01% by its sole general partner, Shanghai Tigermed Technology Co., Ltd. (上海泰格醫藥科技有限公司), a company wholly owned by Tigermed Consulting.

Tigermed HK is a limited liability company incorporated in Hong Kong with a main focus on investment holding and clinical trial operation, which is wholly owned by Tigermed Consulting.

Hangzhou Taiyu is a limited partnership established in the PRC, which primarily focuses on investment management. Hangzhou Taiyu is owned as to approximately (i) 1.14% by its general partner, Hangzhou Taiyu Investment Consulting Co., Ltd. (杭州泰煜投資諮詢有限公司), which is controlled by Tigermed Consulting, and (ii) 98.86% by its 7 limited partners, each holding less than 30% partnership interests therein.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

To the best knowledge of our Directors, each of Hangzhou Tigermed, Shanghai Tigermed Technology Co., Ltd. (上海泰格醫藥科技有限公司), Tigermed HK, Hangzhou Taiyu, Hangzhou Taiyu Investment Consulting Co., Ltd. (杭州泰煜投資諮詢有限公司) and Tigermed Consulting is an Independent Third Party.

Yingke PE

Pingtan Yingke is a limited partnership established in the PRC, which is mainly focused on equity investment. The general partner of Pingtan Yingke is Yingke Innovation Asset Management Co., Ltd. (盈科創新資產管理有限公司) (“**Yingke Innovation**”) (whose shareholders include Mr. Mingfei QIAN (錢明飛), being its largest shareholder holding approximately 39.365% equity interests therein, and 15 other shareholders, each holding less than 11% equity interests therein). Pingtan Yingke has 49 limited partners, among which Pingtan Yingke Shengmei Venture Capital Partnership (Limited Partnership) (平潭盈科盛美創業投資合夥企業(有限合夥)) (controlled by Yingke Innovation) holds approximately 60% partnership interests therein and each of other limited partners holds less than 20% partnership interests therein.

Zibo Yingke is a limited partnership established in the PRC, which primarily focuses on equity investment. The general partner of Zibo Yingke is Yingke Innovation. Zibo Yingke has 10 limited partners, among which Zibo Finance Holding Group Co., Ltd. (淄博市財金控股集團有限公司), which is wholly owned by Zibo Finance Bureau (淄博市財政局), holds approximately 24.5% partnership interests therein and each of other limited partners holds less than 20% partnership interests therein.

To the best knowledge of our Directors, each of Pingtan Yingke, Zibo Yingke, Yingke Innovation, Pingtan Yingke Shengmei Venture Capital Partnership (Limited Partnership) (平潭盈科盛美創業投資合夥企業(有限合夥)), Zibo Finance Holding Group Co., Ltd. (淄博市財金控股集團有限公司), Zibo Finance Bureau (淄博市財政局) and Mr. Mingfei QIAN (錢明飛) is an Independent Third Party.

Qianhai

Qianhai FoF is a limited partnership established in Shenzhen Qianhai Shenzhen-Hong Kong Cooperation Zone, the PRC, with a current fund management scale of RMB28.5 billion. It started investing in the biopharmaceutical sector since December 2015. It has approximately RMB24 billion of assets under management, of which 48 portfolio companies are in the biopharmaceutical sector including, among others, Akeso, Inc. (a company listed on the Hong Kong Stock Exchange, stock code: 9926), Ascletis Pharma Inc. (a company listed on the Hong Kong Stock Exchange, stock code: 1672) and Shenzhen Lifetronic Technology Co., Ltd. (深圳普門科技股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 688389). It is managed by Qianhai Ark Asset Management Co., Ltd. (前海方舟資產管理有限公司) (“**Qianhai Ark**”) as its general partner and a company which is ultimately controlled by Mr. Haitao JIN (靳海濤), which manages several investment platforms and focuses on the strategic emerging industries. Qianhai FoF has 49 limited partners and each of its six largest limited partners holds approximately 5.26% interest in the partnership.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Zhongyuan Qianhai is a limited partnership established in Zhengdong New District of Zhengzhou in the Henan Province in the PRC whose general partner is Qianhai Ark (Zhengzhou) Venture Capital Management Enterprise (Limited Partnership) (前海方舟(鄭州)創業投資管理企業(有限合夥)), a limited partnership which is ultimately controlled by Mr. Haitao JIN (靳海濤), which manages several investment platforms, covering three of the PRC’s most active economic zones, namely the Greater Bay Area, Yangtze River Delta and Yellow and Bohai Sea Rim. Zhongyuan Qianhai has 20 limited partners and its largest limited partner holds approximately 17.73% interest in the partnership. It started investing in the biopharmaceutical sector in December 2019 and has approximately RMB5.14 billion of assets under management, of which 18 portfolio companies are in the biopharmaceutical sector, including, among others, Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術股份有限公司) (a company listed on the Hong Kong Stock Exchange, stock code: 6955), Shanghai Bio-heart Biological Technology Co., Ltd. (上海百心安生物技術股份有限公司) (a company listed on the Hong Kong Stock Exchange, stock code: 2185), Guangzhou Huayinkang Medical Group Co., Ltd. (廣州華銀康醫療集團股份有限公司) (formerly known as Guangzhou Huayin Health Medical Group Co., Ltd. (廣州華銀健康科技有限公司)) and Shanghai Bluepha Microbial Technology Co., Ltd. (上海藍晶微生物科技有限公司) (formerly known as Beijing Bluepha Microbial Technology Co., Ltd. (北京藍晶微生物科技有限公司)).

To the best knowledge of our Directors, each of Qianhai FoF, Qianhai Ark, Zhongyuan Qianhai, Qianhai Ark (Zhengzhou) Venture Capital Management Enterprise (Limited Partnership) (前海方舟(鄭州)創業投資管理企業(有限合夥)) and Mr. Haitao JIN (靳海濤) is an Independent Third Party.

Beijing Agile

Beijing Agile is a limited company established in the PRC, which primarily focuses on equity investment and is controlled by Mr. Jian CHEN (陳儉), who is also one of our direct Shareholders. Beijing Agile is a substantial shareholder of each of Shanghai Maiji and Shanghai Hanmai, being our subsidiaries.

True Wing

True Wing is a limited company incorporated in the British Virgin Islands, which is mainly focused on equity investment. True Wing is wholly owned by Cheer Elite Holdings Limited, which is wholly owned by Right Lane Limited, and is in turn wholly owned by Legend Holdings Corporation, a company listed on the Hong Kong Stock Exchange (stock code: 3396). To the best knowledge of our Directors, each of True Wing, Cheer Elite Holdings Limited, Right Lane Limited and Legend Holdings Corporation is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Nice Credit

Nice Credit is a limited company incorporated in Hong Kong, which is mainly focused on equity investment. Nice Credit is wholly owned by LC Healthcare Continued Fund I, L.P., of which the general partner is LC Healthcare Continued Fund GP Limited. LC Healthcare Continued Fund GP Limited is wholly owned by LC Fund GP Limited, which is in turn wholly owned by Union Season Holdings Limited (“**Union Season**”). Union Season is wholly owned by Legend Capital Co., Ltd. (君聯資本管理股份有限公司), which is ultimately and jointly controlled by Mr. Linan ZHU, Mr. Hao CHEN (陳浩), Mr. Nengguang WANG and Mr. Jiaqing LI. To the best knowledge of our Directors, each of Nice Credit, LC Healthcare Continued Fund I, L.P., LC Healthcare Continued Fund GP Limited, LC Fund GP Limited, Union Season, Mr. Linan ZHU, Mr. Hao CHEN (陳浩), Mr. Nengguang WANG and Mr. Jiaqing LI is an Independent Third Party.

Kaifeng VC

Kaifeng VC is a limited company established in the PRC, and is mainly engaged in equity investments. Kaifeng VC is wholly owned by China-Singapore Suzhou Industrial Park Ventures Co., Ltd. (中新蘇州工業園區創業投資有限公司), which is in turn wholly owned by Suzhou Oriza Holdings Corporation (蘇州元禾控股股份有限公司). To the best knowledge of our Directors, each of Kaifeng VC, China-Singapore Suzhou Industrial Park Ventures Co., Ltd. (中新蘇州工業園區創業投資有限公司) and Suzhou Oriza Holdings Corporation (蘇州元禾控股股份有限公司) is an Independent Third Party.

TSL HK

TSL HK is a company established in Hong Kong, whose business is investment holding and is a wholly-owned subsidiary of Tasly Pharmaceutical Group Co., Ltd. (天士力醫藥集團股份有限公司) (“**TSL Pharmaceutical**”), a company listed on the Shanghai Stock Exchange (stock code: 600535). TSL Pharmaceutical has always been promoting the integrative development of traditional Chinese medicine (TCM) and modern medicine. TSL Pharmaceutical continuously focuses on the three disease fields of cardio-cerebro-vascular diseases, digestive and metabolic diseases and tumors, which have the largest market share and the fastest development in China. It is committed to providing drug R&D that is urgently needed for clinical use and even addresses the unmet needs in China’s clinical market. By leveraging the coordinated development advantages of modern TCM, biological medicine and chemical medicine, it carries out the strategic layout of innovative drugs and continues to maintain its leading position in the industry and the development momentum of R&D and innovation. To the best knowledge of our Directors, each of TSL HK and TSL Pharmaceutical is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shanghai Yaocui

Shanghai Yaocui is a limited partnership established in the PRC, and is mainly engaged in equity investments. Shanghai Yaocui is owned as to approximately 99.78% by its sole limited partner, Shanghai Chaocui Investment Center (Limited Partnership) (上海超萃投資中心(有限合夥)) (“**Shanghai Chaocui**”), and as to approximately 0.22% by its sole general partner, Shanghai Yunfeng Xinchuang Equity Investment Management Center (Limited Partnership) (上海雲鋒新創股權投資管理中心(有限合夥)) (“**Yunfeng Xinchuang**”). The general partner of Shanghai Chaocui is Yunfeng Xinchuang, of which the general partner is Shanghai Yunfeng Xinchuang Enterprise Management Co., Ltd. (上海雲鋒新創企業管理有限公司), which is ultimately controlled by Mr. Xuedong YU (虞學東). To the best knowledge of our Directors, each of Shanghai Yaocui, Shanghai Chaocui, Yunfeng Xinchuang, Shanghai Yunfeng Xinchuang Enterprise Management Co., Ltd. (上海雲鋒新創企業管理有限公司) and Mr. Xuedong YU (虞學東) is an Independent Third Party.

Zhongxin Huiyuan

Zhongxin Huiyuan is a limited partnership established in the PRC, which is mainly focused on equity investment. The general partner of Zhongxin Huiyuan is Suzhou Industrial Park Zhongxin Dayi Investment Management Partnership (Limited Partnership) (蘇州工業園區中鑫大一投資管理合夥企業(有限合夥)) (“**Zhongxin Dayi**”). Zhongxin Huiyuan has 17 limited partners, among which Suzhou Huyanglin Zhiyuan Investment Center (Limited Partnership) (蘇州胡楊林智源投資中心(有限合夥)) holds approximately 22.61% partnership interests therein and each of other limited partners holds less than 20% partnership interests therein. Zhongxin Dayi is controlled by its general partner, Suzhou Industrial Park Haijia Enterprise Management Consulting Partnership (Limited Partnership) (蘇州工業園區海嘉企業管理諮詢合夥企業(有限合夥)), which is in turn controlled by its general partner, Guangdong Haisel Medical Technology Co., Ltd. (廣東海思爾醫療科技有限公司), a company controlled by Mr. Zhi LI (李直). To the best knowledge of our Directors, each of Zhongxin Huiyuan, Zhongxin Dayi, Suzhou Huyanglin Zhiyuan Investment Center (Limited Partnership) (蘇州胡楊林智源投資中心(有限合夥)), Suzhou Industrial Park Haijia Enterprise Management Consulting Partnership (Limited Partnership) (蘇州工業園區海嘉企業管理諮詢合夥企業(有限合夥)), Guangdong Haisel Medical Technology Co., Ltd. (廣東海思爾醫療科技有限公司) and Mr. Zhi LI (李直) is an Independent Third Party.

Share Link

Share Link is a limited company incorporated in the British Virgin Islands, which is mainly focused on equity investment. Share Link is wholly owned by Nanjing Sharelink Venture Capital Co., Ltd. (南京協立創業投資有限公司), which is in turn wholly owned by Jiangsu Spruce Capital Management Co., Ltd. (江蘇雲杉資本管理有限公司) (“**Jiangsu Spruce**”). Jiangsu Spruce is wholly owned by Jiangsu Communications Holding Company Limited (江蘇交通控股有限公司), which is in turn wholly owned by Jiangsu Provincial People’s Government (江蘇省人民政府). To the best knowledge of our Directors, each of Share Link, Nanjing Sharelink Venture Capital Co., Ltd. (南京協立創業投資有限公司), Jiangsu Spruce, Jiangsu Communications Holding Company Limited (江蘇交通控股有限公司) and Jiangsu Provincial People’s Government (江蘇省人民政府) is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Chelmsford

Chelmsford is a limited company incorporated in the British Virgin Islands, which is wholly owned by Jung-Hsi LIU (劉容西). Jung-Hsi LIU (劉容西) is an experienced investor. To the best knowledge of our Directors, each of Chelmsford and Jung-Hsi LIU (劉容西) is an Independent Third Party.

Huzhou Qiyuan

Huzhou Qiyuan is a limited partnership established in the PRC, which is mainly focused on equity investment. The general partner of Huzhou Qiyuan is Shanghai Yicun Private Equity Fund Management Co., Ltd. (上海一村私募基金管理有限公司), which is controlled by V Capital Co., Ltd. (一村資本有限公司). Huzhou Qiyuan has 7 limited partners, among which Xi'an Chuyang Financial Consulting Partnership (Limited Partnership) (西安楚陽財務諮詢合夥企業(有限合夥)) holds approximately 31.56% partnership interests therein, Xinyu Xuanhao Changsheng One Enterprise Management Partnership (Limited Partnership) (新余暄昊常勝壹號企業管理合夥企業(有限合夥)) holds approximately 21.41% partnership interests therein, and each of other limited partners holds less than 20% partnership interests therein. V Capital Co., Ltd. has 6 shareholders, among which Wuxi Guolian Industrial Investment Private Equity Fund Management Co., Ltd. (無錫國聯產業投資私募基金管理有限公司) (“**Guolian PE**”) holds approximately 41.92% equity interests therein, Jiangxi Huaxicun Co., Ltd. (江西華西村股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 000936), holds approximately 40.92% equity interests therein, and each of other shareholders holds less than 20% equity interests therein. Guolian PE is controlled by Wuxi Innovation Investment Group Co., Ltd. (無錫市創新投資集團有限公司), which is controlled by Wuxi Guofa Capital Operation Co., Ltd. (無錫市國發資本運營有限公司), a wholly-owned subsidiary of State-owned Assets Supervision and Administration Commission of Wuxi Municipal People's Government (無錫市人民政府國有資產監督管理委員會). To the best knowledge of our Directors, each of Huzhou Qiyuan, Shanghai Yicun Private Equity Fund Management Co., Ltd. (上海一村私募基金管理有限公司), V Capital Co., Ltd. (一村資本有限公司), Xi'an Chuyang Financial Consulting Partnership (Limited Partnership) (西安楚陽財務諮詢合夥企業(有限合夥)), Xinyu Xuanhao Changsheng One Enterprise Management Partnership (Limited Partnership) (新余暄昊常勝壹號企業管理合夥企業(有限合夥)), Guolian PE, Jiangxi Huaxicun Co., Ltd. (江西華西村股份有限公司), Wuxi Innovation Investment Group Co., Ltd. (無錫市創新投資集團有限公司), Wuxi Guofa Capital Operation Co., Ltd. (無錫市國發資本運營有限公司) and State-owned Assets Supervision and Administration Commission of Wuxi Municipal People's Government (無錫市人民政府國有資產監督管理委員會) is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

SIP Investment Fund

SIP Investment Fund is an industrial investment fund with a fund size of approximately RMB10 billion managed by Suzhou Harvest Capital Co., Ltd. (蘇州園豐資本管理有限公司) (“**Harvest Capital**”). Harvest Capital is a wholly-owned subsidiary of China-Singapore Suzhou Industrial Park Investment Management Co., Ltd. (中新蘇州工業園區投資管理有限公司). SIP Investment Fund focuses on investing healthcare, nano-materials, and artificial intelligence industries. To the best knowledge of our Directors, each of SIP Investment Fund, Harvest Capital and China-Singapore Suzhou Industrial Park Investment Management Co., Ltd. (中新蘇州工業園區投資管理有限公司) is an Independent Third Party.

Suzhou Yipu

Suzhou Yipu is a limited partnership established in the PRC, which primarily focuses on equity investment. The general partner of Suzhou Yipu is Suzhou Yipu No. 2 Chuangzhe Management Consulting Partnership (Limited Partnership) (蘇州翼樸二號創喆管理諮詢合夥企業(有限合夥)) (the “**Yipu Chuangzhe**”). Suzhou Yipu has 17 limited partners, each of which holds no more than 20% partnership interests therein. The general partner of Yipu Chuangzhe is Suzhou Yipu Equity Investment Fund Management Co., Ltd. (蘇州翼樸股權投資基金管理有限公司), a wholly-owned subsidiary of Suzhou Private Capital Investment Holding Co., Ltd. (蘇州民營資本投資控股有限公司) (the “**Suzhou Private Capital**”). Suzhou Private Capital has 21 shareholders, none of which holds more than 20% equity interests therein. To the best knowledge of our Directors, each of Suzhou Yipu, Yipu Chuangzhe, Suzhou Yipu Equity Investment Fund Management Co., Ltd. (蘇州翼樸股權投資基金管理有限公司) and Suzhou Private Capital is an Independent Third Party.

Pingtian Puxin

Pingtian Puxin is a limited partnership established in the PRC, mainly engaged in equity investment. The general partners of Pingtian Puxin are Shanghai Puyao Xinye Investment Management Co., Ltd. (上海浦耀信晔投資管理有限公司) (“**Shanghai Puyao**”) and Yingke Innovation, which hold 0.50% and 5% partnership equity, respectively. The limited partners of Pingtian Puxin are Shanghai International Trust Co., Ltd. (上海國際信託有限公司) and Shangxin Asset Management Co., Ltd. (上信資產管理有限公司) (“**Shangxin Asset**”), which hold 84.50% and 10.00% partnership equity, respectively. Shanghai Puyao and Shangxin Asset are wholly owned by Shanghai International Trust Co., Ltd. (上海國際信託有限公司), which is controlled by Shanghai Pudong Development Bank Co., Ltd. (上海浦東發展銀行股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 600000). To the best knowledge of our Directors, each of Pingtian Puxin, Shanghai Puyao, Yingke Innovation, Shanghai International Trust Co., Ltd. (上海國際信託有限公司), Shangxin Asset and Shanghai Pudong Development Bank Co., Ltd. (上海浦東發展銀行股份有限公司) is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Asia Private

Asia Private is a limited company incorporated in Japan, which is mainly focused on equity investment. Asia Private is wholly owned by West Wood Capital, which is controlled by Mr. Takashi NISHIKI. To the best knowledge of our Directors, each of Asia Private, West Wood Capital and Mr. Takashi NISHIKI is an Independent Third Party.

Shihezi Xinyue

Shihezi Xinyue is a limited partnership established in the PRC, which is mainly focused on equity investment. Shihezi Xinyue is owned as to 99% by its general partner, Linlu YE (葉琳璐), and 1% by its limited partner, Yishan ZHU (朱益善). To the best knowledge of our Directors, each of Shihezi Xinyue, Linlu YE (葉琳璐) and Yishan ZHU (朱益善) is an Independent Third Party.

China-Singapore Industrial Investment

China-Singapore Industrial Investment is a limited liability company established in the PRC, which is mainly focused on equity investment with investment portfolio across biotech and innovative sectors. China-Singapore Industrial Investment is wholly owned by China-Singapore Suzhou Industrial Park Development Group Co., Ltd. (中新蘇州工業園區開發集團股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 601512). To the best knowledge of our Directors, each of China-Singapore Industrial Investment and China-Singapore Suzhou Industrial Park Development Group Co., Ltd. (中新蘇州工業園區開發集團股份有限公司) is an Independent Third Party.

Agricultural Bank II

Agricultural Bank II is a limited partnership established in the PRC, which is mainly focused on equity investment. The general partner of Agricultural Bank II is ABC Qihang (Suzhou) Private Equity Fund Management Co., Ltd. (農銀企航(蘇州)私募基金管理有限公司), which is controlled by ABC Wuxi Investment Consulting Co., Ltd. (農銀無錫投資諮詢有限公司), a wholly-owned subsidiary of ABC International (China) Investment Co., Ltd. (農銀國際(中國)投資有限公司) (“**ABC China**”). ABC China is wholly owned by ABC International Holdings Limited, and is in turn wholly owned by Agricultural Bank of China Limited (中國農業銀行股份有限公司), a company listed on the Hong Kong Stock Exchange (stock code: 1288) and the Shanghai Stock Exchange (stock code: 601288). Agricultural Bank II has 12 limited partners, among which the largest limited partner holds approximately 26.14% partnership interests therein and each of the remaining limited partner holds less than 20% partnership interests therein. To the best knowledge of our Directors, each of Agricultural Bank II, ABC Qihang (Suzhou) Private Equity Fund Management Co., Ltd. (農銀企航(蘇州)私募基金管理有限公司), ABC Wuxi Investment Consulting Co., Ltd. (農銀無錫投資諮詢有限公司), ABC China, ABC International Holdings Limited and Agricultural Bank of China Limited (中國農業銀行股份有限公司) is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Wuxi Guolian

Wuxi Guolian is a limited partnership established in the PRC, which is mainly focused on equity investment. Wuxi Guolian is owned as to (i) 0.50% by its general partner, Guolian PE, and (ii) 99.50% by its 3 limited partners, among which the largest limited partner, Wuxi Guolian Financial Investment Group Co., Ltd. (無錫國聯金融投資集團有限公司), holds 49.50% partnership interests therein, and each of the remaining two limited partners holds 25% partnership interests therein. Guolian PE is controlled by Wuxi Innovation Investment Group Co., Ltd. (無錫市創新投資集團有限公司), which is controlled by Wuxi Guofa Capital Operation Co., Ltd. (無錫市國發資本運營有限公司), a wholly-owned subsidiary of State-owned Assets Supervision and Administration Commission of Wuxi Municipal People’s Government (無錫市人民政府國有資產監督管理委員會). To the best knowledge of our Directors, each of Wuxi Guolian, Guolian PE, Wuxi Guolian Financial Investment Group Co., Ltd. (無錫國聯金融投資集團有限公司), Wuxi Innovation Investment Group Co., Ltd. (無錫市創新投資集團有限公司), Wuxi Guofa Capital Operation Co., Ltd. (無錫市國發資本運營有限公司) and State-owned Assets Supervision and Administration Commission of Wuxi Municipal People’s Government (無錫市人民政府國有資產監督管理委員會) is an Independent Third Party.

KF Pegbio

KF Pegbio is a limited partnership established in the PRC, which is mainly focused on equity investment. The general partner of KF Pegbio is Ningbo Free Trade Zone Kai Feng Venture Capital Management Co., Ltd. (寧波保稅區凱風創業投資管理有限公司), of which the largest shareholder is Guibin ZHAO (趙貴賓), holding 36.50% equity interests therein. KF Pegbio has 6 limited partners, among which Lingya CAI (蔡玲雅) holds approximately 39.18% partnership interests therein and each of the remaining limited partners holds less than 30% partnership interests therein. To the best knowledge of our Directors, each of KF Pegbio, Ningbo Free Trade Zone Kai Feng Venture Capital Management Co., Ltd. (寧波保稅區凱風創業投資管理有限公司), Guibin ZHAO (趙貴賓) and Lingya CAI (蔡玲雅) is an Independent Third Party.

Wuhan Taiming

Wuhan Taiming is a limited partnership established in the PRC, which is mainly focused on equity investment in biomedical sector. The general partner of Wuhan Taiming is Ningbo Zeyi Investment Management Partnership (Limited Partnership) (寧波澤亦投資管理合夥企業(有限合夥)), which is controlled by its general partner, Ningbo Xianghong Business Consulting Co., Ltd. (寧波湘泓商務諮詢有限公司), of which Junjun LIU (劉軍軍) is the largest shareholder holding 40% equity interests therein. To the best knowledge of our Directors, each of Wuhan Taiming, Ningbo Zeyi Investment Management Partnership (Limited Partnership) (寧波澤亦投資管理合夥企業(有限合夥)), Ningbo Xianghong Business Consulting Co., Ltd. (寧波湘泓商務諮詢有限公司) and Junjun LIU (劉軍軍) is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Suzhou Ruihua

Suzhou Ruihua is a limited partnership established in the PRC, which is mainly focused on equity investment, with investment portfolio including, among others, Mabwell (Shanghai) Bioscience Co., Ltd. (邁威(上海)生物科技股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 688062). The general partner of Suzhou Ruihua is Jiangsu Ruihua Venture Capital Management Co., Ltd. (江蘇瑞華創業投資管理有限公司), which is owned as to 49% by Tibet Ruihua Capital Management Co., Ltd. (西藏瑞華資本管理有限公司) (“**Tibet Ruihua**”) and 51% by other 6 shareholders, each holding less than 30% equity interests therein. Suzhou Ruihua has 5 limited partners, among which (i) Tibet Ruihua holds 40% partnership interests therein, (ii) National Center for Science and Technology Venture Development (國家科技風險開發事業中心) holds 30% partnership interests therein, and (iii) each of the remaining three limited partners holds no more than 10% partnership interests therein. To the best knowledge of our Directors, each of Suzhou Ruihua, Jiangsu Ruihua Venture Capital Management Co., Ltd. (江蘇瑞華創業投資管理有限公司), Tibet Ruihua and National Center for Science and Technology Venture Development (國家科技風險開發事業中心) is an Independent Third Party.

CCB Sci-Tech

CCB Sci-Tech is a limited partnership established in the PRC, which is mainly focused on equity investment across TMT, new energy high-end manufacturing and biotech sectors with investment portfolio including, among others, iMotion Automotive Technology (Suzhou) Co., Ltd. (知行汽車科技(蘇州)股份有限公司), a company listed on the Hong Kong Stock Exchange (stock code: 1274). The general partner of CCB Sci-Tech is Tianjin CCB International Golden Harvest Equity Investment Management Co., Ltd. (天津建銀國際金禾股權投資管理有限公司), which is wholly owned by CCB International Capital Management (Tianjin) Co., Ltd. (建銀國際資本管理(天津)有限公司) (“**CCB Tianjin**”). CCB Tianjin is wholly owned by CCB International (China) Co., Ltd. (建銀國際(中國)有限公司), a wholly-owned subsidiary of CCB International (Holdings) Limited (建銀國際(控股)有限公司), and is ultimately wholly owned by China Construction Bank Corporation (中國建設銀行股份有限公司), a company incorporated in the PRC and listed on the Hong Kong Stock Exchange (stock code: 0939) and the Shanghai Stock Exchange (stock code: 601939). To the best knowledge of our Directors, each of CCB Sci-Tech, Tianjin CCB International Golden Harvest Equity Investment Management Co., Ltd. (天津建銀國際金禾股權投資管理有限公司), CCB Tianjin, CCB International (China) Co., Ltd. (建銀國際(中國)有限公司), CCB International (Holdings) Limited (建銀國際(控股)有限公司) and China Construction Bank Corporation (中國建設銀行股份有限公司) is an Independent Third Party.

Huaxin Investment

Huaxin Investment is a limited liability company established in the PRC, which is mainly focused on equity investment. Huaxin Investment is wholly owned by Huaxin Securities Co. Ltd. (華鑫證券有限責任公司), a wholly-owned subsidiary of Shanghai Huaxin Co. Ltd. (上海華鑫股份有限公司) (“**Shanghai Huaxin**”). The controlling shareholder of Shanghai Huaxin is

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shanghai Yidian (Group) Co. Ltd. (上海儀電(集團)有限公司), which is wholly owned by State-owned Assets Supervision and Administration Commission of Shanghai Municipal People’s Government (上海市國有資產監督管理委員會). To the best knowledge of our Directors, each of Huaxin Investment, Huaxin Securities Co. Ltd. (華鑫證券有限責任公司), Shanghai Huaxin, Shanghai Yidian (Group) Co. Ltd. (上海儀電(集團)有限公司) and State-owned Assets Supervision and Administration Commission of Shanghai Municipal People’s Government (上海市國有資產監督管理委員會) is an Independent Third Party.

Beijing Lehe

Beijing Lehe is a limited liability company established in the PRC, which is mainly focused on equity investment. Beijing Lehe is owned as to 99% by Xiaomeng DONG (董小蒙) and 1% by Shaowei WANG (王少偉). To the best knowledge of our Directors, each of Beijing Lehe, Xiaomeng DONG (董小蒙) and Shaowei WANG (王少偉) is an Independent Third Party.

Wuyouen

Wuyouen is a limited partnership established in the PRC, which is mainly focused on equity investment. Wuyouen is owned as to approximately 0.01% by its general partner, Xiaoxiao SONG (宋瀟瀟), and approximately 99.99% by its limited partner, Naihua ZHU (朱乃華). To the best knowledge of our Directors, each of Wuyouen, Xiaoxiao SONG (宋瀟瀟) and Naihua ZHU (朱乃華) is an Independent Third Party.

Xi’an Jingsong

Xi’an Jingsong is a limited partnership established in the PRC, which is mainly focused on equity investment. Xi’an Jingsong is owned as to approximately (i) 53.33% by Huachang WEI (魏華昌), its general partner, and (ii) 46.67% by 5 limited partners, among which the largest limited partner, Yixuan ZHAO (趙益軒), holds 25% partnership interests therein. To the best knowledge of our Directors, each of Xi’an Jingsong, Huachang WEI (魏華昌) and Yixuan ZHAO (趙益軒) is an Independent Third Party.

Zhongxin Hengxiang

Zhongxin Hengxiang is a limited partnership established in the PRC, which is mainly focused on equity investment across healthcare, intelligent manufacturing, new energy sectors with investment portfolio including, among others, CanSino Biologics Inc. (康希諾生物股份有限公司), a company listed on the Hong Kong Stock Exchange (stock code: 6185) and the Shanghai Stock Exchange (stock code: 688185), and CareRay Digital Medical Technology Co., Ltd. (江蘇康眾數字醫療科技股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 688607). The general partner of Zhongxin Hengxiang is Suzhou Zhongxin Innovation Private Equity Fund Management Co., Ltd. (蘇州中鑫創新私募基金管理有限公司), which is owned as to (i) 40% by Qiang XU (許強), (ii) 40% by Suzhou Chinese Consortium Holdings Co., Ltd. (蘇州中方財團控股股份有限公司) (“**Suzhou CCH**”), (iii) 10% by Suzhou Zhongxin Zhidao Venture Capital Partnership (Limited Partnership) (蘇州中鑫致道創業投資合夥企業(有

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限合夥)), and (iv) 10% by other 2 shareholders thereof. Zhongxin Hengxiang has 7 limited partners, among which the largest limited partner holds approximately 28.57% partnership interests therein. To the best knowledge of our Directors, each of Zhongxin Hengxiang, Suzhou Zhongxin Innovation Private Equity Fund Management Co., Ltd. (蘇州中鑫創新私募基金管理有限公司), Qiang XU (許強), Suzhou CCH and Suzhou Zhongxin Zhidao Venture Capital Partnership (Limited Partnership) (蘇州中鑫致道創業投資合夥企業(有限合夥)) is an Independent Third Party.

Suzhou Yuankang

Suzhou Yuankang is a limited partnership established in the PRC, which is mainly focused on equity investment in healthcare sector with investment portfolio including, among others, Sipai Health Technology Co., Ltd. (思派健康科技有限公司), a company listed on the Hong Kong Stock Exchange (stock code: 0314). The general partners of Suzhou Yuankang are Shengding Private Equity Investment Fund Management Co., Ltd. (盛鼎私募基金管理有限責任公司) (“**Shengding PE**”) and Hangzhou Shengding Jikang Enterprise Management Co., Ltd. (杭州盛鼎濟康企業管理有限公司) (“**Shengding Jikang**”), a wholly-owned subsidiary of Shengding PE. Shengding PE is controlled by Dajia Investment Holding Co., Ltd. (大家投資控股有限責任公司), which is wholly owned by Dajia Life Insurance Co., Ltd. (大家人壽保險股份有限公司) (“**Dajia Life Insurance**”). Dajia Life Insurance is controlled by China Insurance Guarantee Fund Co., Ltd. (中國保險保障基金有限責任公司), a company wholly-owned by Ministry of Finance of the People’s Republic of China (中華人民共和國財政部). To the best knowledge of our Directors, each of Suzhou Yuankang, Shengding PE, Shengding Jikang, Dajia Investment Holding Co., Ltd. (大家投資控股有限責任公司), Dajia Life Insurance, China Insurance Guarantee Fund Co., Ltd. (中國保險保障基金有限責任公司) and Ministry of Finance of the People’s Republic of China (中華人民共和國財政部) is an Independent Third Party.

Pingtian Yuanbo

Pingtian Yuanbo is a limited partnership established in the PRC, which is mainly focused on equity investment. The general partner of Pingtian Yuanbo is Zhejiang Yuanbo Investment Management Co., Ltd. (浙江苑博投資管理有限公司), which is controlled by Xiaolong ZHOU (周小龍). Pingtian Yuanbo has 23 limited partners, each holding less than 10% partnership interests therein. To the best knowledge of our Directors, each of Pingtian Yuanbo, Zhejiang Yuanbo Investment Management Co., Ltd. (浙江苑博投資管理有限公司) and Xiaolong ZHOU (周小龍) is an Independent Third Party.

Suzhou Lanhu

Suzhou Lanhu is a limited partnership established in the PRC, which is mainly focused on equity investment. The general partners of Suzhou Lanhu are Suzhou Lanhu Venture Capital Management Partnership (Limited Partnership) (蘇州嵐湖創業投資管理合夥企業(有限合夥)) (“**Lanhu VC**”) and Suzhou Zhuopu Investment Fund Management Co., Ltd. (蘇州卓璞投資基金管理有限公司) (“**Zhuopu Investment**”). Lanhu VC is controlled by its general partner,

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Suzhou Lanhu Equity Investment Fund Management Co., Ltd. (蘇州嵐湖股權投資基金管理有限公司), a company controlled by Weimin TONG (童為民). Zhuopu Investment is wholly owned by Suzhou Asset Management Co., Ltd. (蘇州資產管理有限公司) (“**Suzhou AM**”), which is owned by 19 shareholders, each holding less than 30% equity interests therein. Suzhou Lanhu has 7 limited partners, among which the largest limited partner, Suzhou AM, holds approximately 41.59% partnership interests therein. To the best knowledge of our Directors, each of Suzhou Lanhu, Lanhu VC, Zhuopu Investment, Suzhou Lanhu Equity Investment Fund Management Co., Ltd. (蘇州嵐湖股權投資基金管理有限公司), Weimin TONG (童為民) and Suzhou AM is an Independent Third Party.

CTL

CTL is a company incorporated in the BVI, which is mainly focused on equity investment. CTL is owned as to approximately 66.67% by Ran LIN (林然), and approximately 33.33% by Xu ZHENG (鄭旭). To the best knowledge of our Directors, each of CTL, Ran LIN (林然) and Xu ZHENG (鄭旭) is an Independent Third Party.

Suzhou Jinmao

Suzhou Jinmao is a limited company established in the PRC, which is mainly focused on equity investment, and wholly owned by Xiaojun YAN (嚴曉君). To the best knowledge of our Directors, each of Suzhou Jinmao and Xiaojun YAN (嚴曉君) is an Independent Third Party.

Shanghai Tongyuan

Shanghai Tongyuan is a limited partnership established in the PRC, which is mainly focused on equity investment. Shanghai Tongyuan is owned as to (i) 10% by its general partner, Peijie XI (奚佩潔), and (ii) 90% by its 5 limited partners, among which the largest limited partner, Chen CHEN (陳晨), holds 32% partnership interests therein. To the best knowledge of our Directors, each of Shanghai Tongyuan, Peijie XI (奚佩潔) and Chen CHEN (陳晨) is an Independent Third Party.

Individual [REDACTED] Investors

Save as disclosed above, our other [REDACTED] Investors are individuals, among whom (i) Mr. Jian CHEN (陳儉) is a substantial shareholder (through Beijing Agile) of Shanghai Hanmai and Shanghai Maiji, each a subsidiary of the Company, (ii) Ms. Yu ZHANG (張鈺) is a minority shareholder and supervisor of Shanghai Hanmai and Shanghai Maiji, (iii) Ms. Ying KUANG (匡鶯) and Mr. Jiangmin SHAN (單江閩) are minority shareholders of Shanghai Hanmai and Shanghai Maiji, and (iv) Ms. Lin BAI (白林), Mr. Hongfu XIE (謝紅付), Mr. Gang LU (陸剛), Mr. Anquan PENG (彭安全), Ms. Liping LIU (劉麗萍), Mr. Tao XIE (謝濤), Mr. Sujian SHAN (單蘇建), Mr. Xiao WANG (王嘯) and Mr. Sumin SHAN (單蘇閩) are Independent Third Parties. See “— Our Subsidiaries” above and “— Public Float” below for further details.

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CAPITALIZATION

Our Company has applied for H-share full circulation to convert certain Unlisted Shares into H Shares after the [REDACTED]. The conversion of Unlisted Shares into H Shares will involve an aggregate of [REDACTED] Unlisted Shares, representing approximately [REDACTED]% of total issued share capital of the Company as of the Latest Practicable Date. The table below is a summary of the capitalization of our Company as of the Latest Practicable Date immediately prior to and upon completion of the [REDACTED] and the conversion of Unlisted Shares into H Shares:

Shareholders	As of the Latest Practicable Date		Immediately upon Completion of the [REDACTED]		
	Number of Unlisted Shares Held	Ownership Percentage (approximation)	Number of Unlisted Shares Held	Number of H Shares Held	Ownership Percentage (approximation)
Concerted Parties⁽¹⁾					
Dr. Michael Min XU ⁽¹⁾ . . .	58,081,874	15.84%	[REDACTED]	[REDACTED]	[REDACTED]%
Shanghai Sujie ⁽¹⁾	29,175,230	7.96%	[REDACTED]	[REDACTED]	[REDACTED]%
Dr. Yuhong XU (徐宇虹) ⁽¹⁾ .	6,810,871	1.86%	[REDACTED]	[REDACTED]	[REDACTED]%
Dr. Xiangjun ZHOU ⁽¹⁾	6,268,463	1.71%	[REDACTED]	[REDACTED]	[REDACTED]%
Sub-total	100,336,438	27.37%	[REDACTED]	[REDACTED]	[REDACTED]%
Mingly⁽²⁾					
Mingly	34,852,074	9.50%	[REDACTED]	[REDACTED]	[REDACTED]%
YuanBio Venture Capital⁽³⁾					
SIP BioVC	11,339,959	3.09%	[REDACTED]	[REDACTED]	[REDACTED]%
SIP VC II.	3,201,273	0.87%	[REDACTED]	[REDACTED]	[REDACTED]%
YuanBio	3,113,437	0.85%	[REDACTED]	[REDACTED]	[REDACTED]%
SIP VC III	2,646,354	0.72%	[REDACTED]	[REDACTED]	[REDACTED]%
Sub-total	20,301,023	5.53%	[REDACTED]	[REDACTED]	[REDACTED]%
Tigermed⁽⁴⁾					
Hangzhou Tigermed	9,634,137	2.63%	[REDACTED]	[REDACTED]	[REDACTED]%
Tigermed HK	4,247,204	1.16%	[REDACTED]	[REDACTED]	[REDACTED]%
Hangzhou Taiyu	1,817,998	0.50%	[REDACTED]	[REDACTED]	[REDACTED]%
Sub-total	15,699,339	4.29%	[REDACTED]	[REDACTED]	[REDACTED]%
Yingke PE⁽⁵⁾					
Pingtian Yingke	8,468,396	2.31%	[REDACTED]	[REDACTED]	[REDACTED]%
Zibo Yingke	4,071,314	1.11%	[REDACTED]	[REDACTED]	[REDACTED]%
Sub-total	12,539,710	3.42%	[REDACTED]	[REDACTED]	[REDACTED]%
Qianhai⁽⁶⁾					
Qianhai FoF	8,290,415	2.26%	[REDACTED]	[REDACTED]	[REDACTED]%
Zhongyuan Qianhai	3,562,399	0.97%	[REDACTED]	[REDACTED]	[REDACTED]%
Sub-total	11,852,814	3.23%	[REDACTED]	[REDACTED]	[REDACTED]%
Mr. Jian CHEN (陳儉) and his controlled entity⁽⁷⁾					
Beijing Agile	4,246,946	1.16%	[REDACTED]	[REDACTED]	[REDACTED]%
Mr. Jian CHEN (陳儉)	1,817,998	0.50%	[REDACTED]	[REDACTED]	[REDACTED]%
Sub-total	6,064,944	1.66%	[REDACTED]	[REDACTED]	[REDACTED]%

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Shareholders	As of the Latest Practicable Date		Immediately upon Completion of the [REDACTED]		
	Number of Unlisted Shares Held	Ownership Percentage (approximation)	Number of Unlisted Shares Held	Number of H Shares Held	Ownership Percentage (approximation)
<i>Other [REDACTED] Investors⁽⁸⁾</i>					
True Wing	15,482,756	4.22%	[REDACTED]	[REDACTED]	[REDACTED]%
Nice Credit.	14,541,239	3.97%	[REDACTED]	[REDACTED]	[REDACTED]%
Kaifeng VC	12,805,764	3.49%	[REDACTED]	[REDACTED]	[REDACTED]%
TSL HK	12,740,586	3.47%	[REDACTED]	[REDACTED]	[REDACTED]%
Shanghai Yaocui	12,213,941	3.33%	[REDACTED]	[REDACTED]	[REDACTED]%
Zhongxin Huiyuan	11,705,026	3.19%	[REDACTED]	[REDACTED]	[REDACTED]%
Share Link	9,752,279	2.66%	[REDACTED]	[REDACTED]	[REDACTED]%
Chelmsford.	7,151,567	1.95%	[REDACTED]	[REDACTED]	[REDACTED]%
Ms. Lin BAI (白林)	6,810,871	1.86%	[REDACTED]	[REDACTED]	[REDACTED]%
Huzhou Qiyuan	5,452,433	1.49%	[REDACTED]	[REDACTED]	[REDACTED]%
SIP Investment Fund.	5,089,142	1.39%	[REDACTED]	[REDACTED]	[REDACTED]%
Suzhou Yipu	4,839,104	1.32%	[REDACTED]	[REDACTED]	[REDACTED]%
Pingtang Puxin	4,455,203	1.22%	[REDACTED]	[REDACTED]	[REDACTED]%
Asia Private	3,780,075	1.03%	[REDACTED]	[REDACTED]	[REDACTED]%
Shihezi Xinyue	3,201,273	0.87%	[REDACTED]	[REDACTED]	[REDACTED]%
China-Singapore Industrial Investment.	3,053,485	0.83%	[REDACTED]	[REDACTED]	[REDACTED]%
Agricultural Bank II	3,053,485	0.83%	[REDACTED]	[REDACTED]	[REDACTED]%
Wuxi Guolian	3,053,485	0.83%	[REDACTED]	[REDACTED]	[REDACTED]%
KF Pegbio	2,400,957	0.65%	[REDACTED]	[REDACTED]	[REDACTED]%
Wuhan Taiming	2,035,657	0.56%	[REDACTED]	[REDACTED]	[REDACTED]%
Suzhou Ruihua	2,035,657	0.56%	[REDACTED]	[REDACTED]	[REDACTED]%
CCB Sci-Tech	2,035,657	0.56%	[REDACTED]	[REDACTED]	[REDACTED]%
Huaxin Investment	2,035,657	0.56%	[REDACTED]	[REDACTED]	[REDACTED]%
Beijing Lehe	2,035,656	0.56%	[REDACTED]	[REDACTED]	[REDACTED]%
Wuyouen	1,817,998	0.50%	[REDACTED]	[REDACTED]	[REDACTED]%
Xi'an Jingsong	1,526,743	0.42%	[REDACTED]	[REDACTED]	[REDACTED]%
Zhongxin Hengxiang.	1,526,743	0.42%	[REDACTED]	[REDACTED]	[REDACTED]%
Suzhou Yuankang.	1,526,743	0.42%	[REDACTED]	[REDACTED]	[REDACTED]%
Pingtang Yuanbo	1,017,828	0.28%	[REDACTED]	[REDACTED]	[REDACTED]%
Suzhou Lanhu	1,017,828	0.28%	[REDACTED]	[REDACTED]	[REDACTED]%
CTL	849,289	0.23%	[REDACTED]	[REDACTED]	[REDACTED]%
Suzhou Jinmao	800,317	0.22%	[REDACTED]	[REDACTED]	[REDACTED]%
Mr. Hongfu XIE (謝紅付)	727,199	0.20%	[REDACTED]	[REDACTED]	[REDACTED]%
Shanghai Tongyuan.	508,914	0.14%	[REDACTED]	[REDACTED]	[REDACTED]%
Mr. Gang LU (陸剛)	508,914	0.14%	[REDACTED]	[REDACTED]	[REDACTED]%
Mr. Anquan PENG (彭安全)	363,600	0.10%	[REDACTED]	[REDACTED]	[REDACTED]%
Ms. Liping LIU (劉麗萍)	354,509	0.10%	[REDACTED]	[REDACTED]	[REDACTED]%
Mr. Tao XIE (謝濤)	181,800	0.05%	[REDACTED]	[REDACTED]	[REDACTED]%
Ms. Yu ZHANG (張鈺)	181,800	0.05%	[REDACTED]	[REDACTED]	[REDACTED]%
Mr. Sujian SHAN (單蘇建)	109,080	0.03%	[REDACTED]	[REDACTED]	[REDACTED]%
Mr. Xiao WANG (王嘯)	90,900	0.02%	[REDACTED]	[REDACTED]	[REDACTED]%
Mr. Jiangmin SHAN (單江閩)	63,630	0.02%	[REDACTED]	[REDACTED]	[REDACTED]%

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	As of the Latest Practicable Date		Immediately upon Completion of the [REDACTED]		
	Number of Unlisted Shares Held	Ownership Percentage (approximation)	Number of Unlisted Shares Held	Number of H Shares Held	Ownership Percentage (approximation)
Shareholders					
Mr. Sumin SHAN (單蘇閩)	45,450	0.01%	[REDACTED]	[REDACTED]	[REDACTED]%
Ms. Ying KUANG (匡鶯)	45,450	0.01%	[REDACTED]	[REDACTED]	[REDACTED]%
[REDACTED] taking part in the [REDACTED]	—	—	—	[REDACTED]	[REDACTED]%
Sub-total	165,025,690	45.00%	[REDACTED]	[REDACTED]	[REDACTED]%
Total	366,672,032	100.00%	[REDACTED]	[REDACTED]	100.00%

Notes:

- (1) Dr. Michael Min XU, Shanghai Sujie, Dr. Yuhong XU (徐宇虹) and Dr. Xiangjun ZHOU are acting-in-concert parties. See “— Concert Party Agreement” above for details.
- (2) See “— [REDACTED] Investments — Information about our [REDACTED] Investors — Mingly” above for details.
- (3) See “— [REDACTED] Investments — Information about our [REDACTED] Investors — YuanBio Venture Capital” above for details.
- (4) See “— [REDACTED] Investments — Information about our [REDACTED] Investors — Tigermed” above for details.
- (5) See “— [REDACTED] Investments — Information about our [REDACTED] Investors — Yingke PE” above for details.
- (6) See “— [REDACTED] Investments — Information about our [REDACTED] Investors — Qianhai” above for details.
- (7) See “— [REDACTED] Investments — Information about our [REDACTED] Investors — Beijing Agile” above for details.
- (8) See “— [REDACTED] Investments — Information about our [REDACTED] Investors” above for details of these [REDACTED] Investors.

PUBLIC FLOAT

Following the conversion of the Unlisted Shares into H Shares and upon completion of the [REDACTED]:

- (a) a total of [REDACTED] Shares held by our core connected persons, including (i) Dr. Michael Min XU, Dr. Yuhong XU (徐宇虹) and Dr. Xiangjun ZHOU (our Directors and members of the Single Largest Group of Shareholders), (ii) Shanghai Sujie (a close associate of Ms. Xiaojun WANG (王小軍), our executive Director, and a member of the Single Largest Group of Shareholders), (iii) Beijing Agile (a substantial shareholder of Shanghai Hanmai and Shanghai Maiji) and Mr. Jian CHEN (陳儉) (who controls Beijing Agile and thus a substantial shareholder of Shanghai Hanmai and Shanghai Maiji), and (iv) Ms. Yu ZHANG (張鈺) (a supervisor of Shanghai Hanmai and Shanghai Maiji), will not be counted towards the public float, representing [REDACTED]% of our share capital in aggregate;

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- (b) a total of [REDACTED] Unlisted Shares held by Mingly, Shanghai Yaocui, Zhongxin Huiyuan, Pingtan Yingke, Huzhou Qiyuan, SIP Investment Fund, Zibo Yingke, Wuxi Guolian, Wuhan Taiming, Zhongxin Hengxiang, Suzhou Jinmao, Ms. Liping LIU (劉麗萍), Mr. Sujian SHAN (單蘇建), Mr. Xiao WANG (王嘯), Mr. Jiangmin SHAN (單江閩), Mr. Sumin SHAN (單蘇閩) and Ms. Ying KUANG (匡鶯) will not be converted into H Shares and [REDACTED] on the Stock Exchange, and therefore will not be counted as part of the public float, representing [REDACTED]% of our share capital in aggregate;
- (c) a total of [REDACTED] Unlisted Shares held by Mingly, True Wing, Nice Credit, Kaifeng VC, TSL HK, Shanghai Yaocui, Zhongxin Huiyuan, SIP BioVC, Share Link, Hangzhou Tigermed, Qianhai FoF, Chelmsford, Ms. Lin BAI (白林), Suzhou Yipu, Pingtan Puxin, Tigermed HK, Asia Private, Zhongyuan Qianhai, SIP VC II, Shihezi Xinyue, YuanBio, China-Singapore Industrial Investment, Agricultural Bank II, Wuxi Guolian, SIP VC III, KF PegBio, Wuhan Taiming, Huaxin Investment, Suzhou Ruihua, CCB Sci-Tech, Beijing Lehe, Hangzhou Taiyu, Wuyouen, Suzhou Yuankang, Xi'an Jingsong, Pingtan Yuanbo, Suzhou Lanhu, CTL, Suzhou Jinmao, Mr. Hongfu XIE (謝紅付), Shanghai Tongyuan, Mr. Gang LU (陸剛), Mr. Anquan PENG (彭安全), Ms. Liping LIU (劉麗萍), Mr. Tao XIE (謝濤), Mr. Sujian SHAN (單蘇建), Mr. Xiao WANG (王嘯), Mr. Jiangmin SHAN (單江閩), Mr. Sumin SHAN (單蘇閩), and Ms. Ying KUANG (匡鶯) (the “**Current Unlisted Shareholders**”) will be converted into H Shares and [REDACTED] on the Stock Exchange, and therefore will be counted as part of the public float, representing [REDACTED]% of our share capital in aggregate. None of the Current Unlisted Shareholders is accustomed to take instructions from any core connected persons in relation to the acquisition, disposal, voting or other disposition of their Shares and none of their acquisition of the Shares were financed directly or indirectly by our core connected person; and
- (d) a total of [REDACTED] H Shares issued pursuant to the [REDACTED] will be counted as part of the public float, representing [REDACTED]% of our share capital in aggregate.

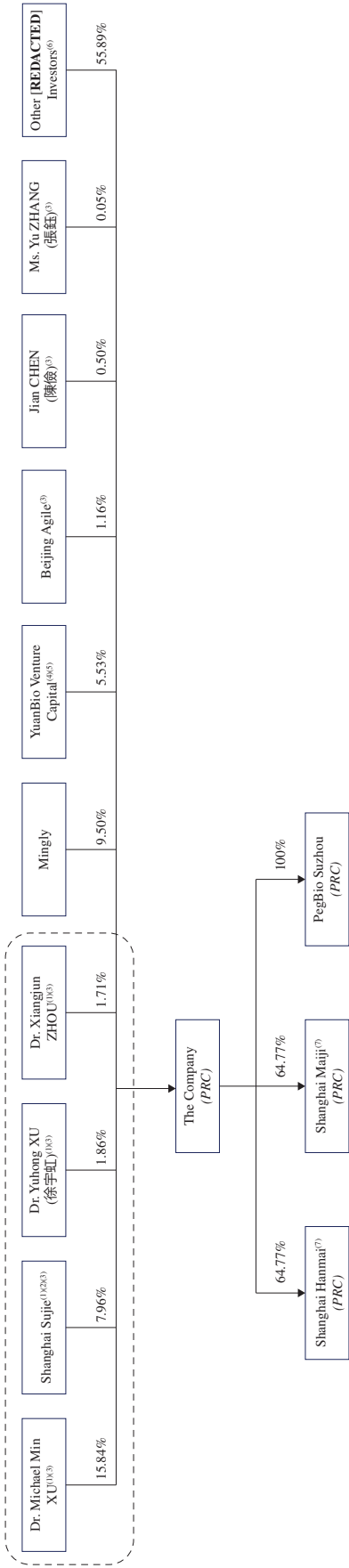
Based on the above, it is expected that immediately following completion of the [REDACTED], a total of [REDACTED] Shares, representing [REDACTED]% of our total share capital upon the completion of the [REDACTED] will be counted as part of the public float. As a result, over 25% of our Company’s total issued Shares will be held by the public upon completion of the [REDACTED] as required under Rule 8.08(1)(a) of the Listing Rules. In addition, the market capitalization of the portion of the total number of the Company’s issued Shares held by the public pursuant to the requirements under Rule 18A.07 of the Listing Rules would be over HK\$375 million at the time of the [REDACTED].

Immediately following the completion of the [REDACTED], a total of [REDACTED] Shares, representing [REDACTED]% of our total share capital upon the completion of the [REDACTED], will be subject to a lock-up period. For details, see “— [REDACTED] Investments — Principal Terms of the [REDACTED] Investments” above.

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CORPORATE STRUCTURE IMMEDIATELY BEFORE COMPLETION OF THE [REDACTED]

The chart below sets out the shareholding structure of our Group immediately before completion of the [REDACTED]:



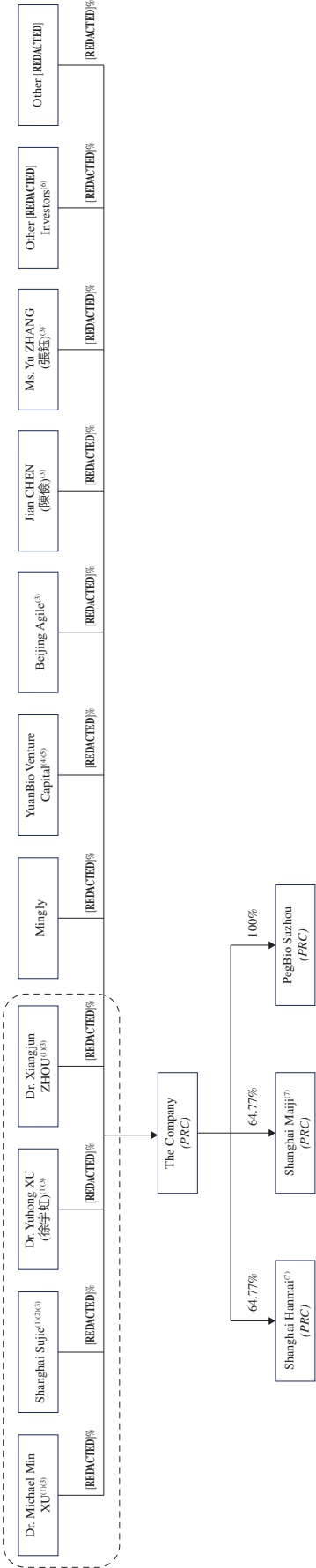
Notes:

- (1) Dr. Michael Min XU, Shanghai Sujie, Dr. Yuhong XU (徐宇虹) and Dr. Xiangjun ZHOU are acting-in-concert parties. See “— Concert Party Agreement” above for details.
- (2) Shanghai Sujie is our Equity Incentive Platform, of which the sole general partner is Ms. Xiaojun WANG (王小军). See “— Equity Incentive Platform” above for details.
- (3) Dr. Michael Min XU, Shanghai Sujie, Dr. Yuhong XU (徐宇虹), Dr. Xiangjun ZHOU, Beijing Agile, Jian CHEN (陈健) and Ms. Yu ZHANG (张钰) are our core connected persons under the Listing Rules. See “— Public Float” above for details.
- (4) YuanBio Venture Capital is our Sophisticated Investor. See “— [REDACTED] Investments — Information about our [REDACTED] Investors” above for details.
- (5) YuanBio Venture Capital represents SIP BioVC, SIP VC II, SIP VC III and YuanBio. See “— [REDACTED] Investments — Information about our [REDACTED] Investors — YuanBio Venture Capital” above for details.
- (6) Other [REDACTED] Investors include 50 Shareholders, each holding less than 5% equity interests in our Company immediately before completion of the [REDACTED]. See “— [REDACTED] Investments” and “— Capitalization” above for details.
- (7) Each of Shanghai Hammai and Shanghai Maiji has seven minority shareholders. See “— Our Subsidiaries” above for details.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

CORPORATE STRUCTURE IMMEDIATELY FOLLOWING COMPLETION OF THE [REDACTED]

The chart below sets out the shareholding structure of our Group immediately following completion of the [REDACTED]:



Notes: For notes (1) to (7), please see “— Corporate Structure Immediately Before Completion of the [REDACTED]” above. For the Unlisted Shares and H Shares held by each of the Shareholders, please see “— Capitalization” above.

BUSINESS

OVERVIEW

We aspire to bring effective treatment options to global patients with chronic diseases. We focus on leveraging accumulated industry experience and established R&D capabilities for the discovery and development of differentiated therapeutics. We have cultivated a diverse pipeline of six product candidates to capture the market potential in prevalent chronic and metabolic diseases, including type 2 diabetes mellitus (“**T2DM**”), obesity, non-alcoholic steatohepatitis (“**NASH**”), opioid-induced constipation (“**OIC**”) and congenital hyperinsulinemia. Our Core Product PB-119 is one of the earliest domestically developed long-acting GLP-1 receptor agonists in China, according to CIC. It has demonstrated multiple benefits in glycemic control, cardiovascular health, and a good efficacy profile in weight management across several clinical trials. The new drug application (“**NDA**”) for PB-119 in China for T2DM was accepted by the NMPA in September 2023, marking a key milestone for its upcoming commercialization.

We strategically focus on chronic diseases with a particular emphasis on metabolic disorders, as they feature a significant and growing market opportunity and considerable medical needs. Chronic and metabolic diseases, encompassing a spectrum of conditions such as diabetes, obesity and NASH, are increasingly prevalent worldwide driven by changing lifestyles and aging populations. According to CIC, metabolic diseases are among the fastest growing diseases worldwide with a global prevalence of 2,522 million in 2023, which is expected to increase to 2,991 million by 2032, representing a CAGR of 1.9%. Metabolic diseases are also among the most common diseases in China with a prevalence of 545 million in 2023, which is expected to increase to 646 million by 2032, representing a CAGR of 1.9%.

Despite the increased prevalence of chronic and metabolic diseases and efforts to address them, there remains significant medical needs. Patients with chronic and metabolic diseases typically require prolonged medical interventions that provide comprehensive benefits across various disease complications. Successful treatments for these conditions lie in delivering all-encompassing benefits, robust clinical effectiveness and safety, unparalleled affordability, and significant patient compliance. Despite the availability of various treatments for T2DM and obesity, there lacks available treatment options that offer promising long-term outcomes, minimize side effects, with satisfying affordability and patient compliance. NASH, a less recognized but increasingly concerning condition, often correlates with obesity and T2DM, yet it still lacks specific, targeted treatments. Current treatment paradigms for these chronic and metabolic diseases often involve complex treatment regimens consisting of either multiple interventions administered simultaneously that are costly and inconvenient, or therapies providing more comprehensive benefits but are expensive and demand significant medical resources. This treatment landscape underscores the need for not only more effective and holistic treatment options that bring comprehensive benefits at the same time, but also improved accessibility and patient compliance.

Our pipeline of product candidates is precisely designed to fulfill these needs. Our product pipeline primarily centers around the GLP-1 receptor and aims to deliver safe, effective, accessible, convenient, and multi-functional therapies for patients with chronic and metabolic diseases.

BUSINESS

The following chart summarizes the development status of our drug candidates as of the Latest Practicable Date. We strategically prioritize our resources for the clinical development and/or commercialization of certain pipeline candidates, including our Core Product PB-119 and key product PB-718.

Drug candidates	MoA/Target	Development origin	Indications	Preclinical	Phase I	Phase II	Phase III	Rights	Commercialization region	NDA date	Current status/Future milestones
PB-119 ¹ ★	Long-acting GLP-1 receptor agonist	In-house	T2DM (Monotherapy) first-line	China (NMPA)				Global 	China	Submitted and accepted in September 2023 ²	Expected to be approved for marketing in China in 1H 2025
			T2DM (+Metformin) first-line	China (NMPA)					China		
			Overweight or obesity first-line	U.S. (FDA)					U.S.		Phase I and II clinical trials completed in July 2016 and July 2019, respectively, in the United States. Phase III clinical trial plan is to be finalized ³
			T2DM (Cardiovascular benefits)	China (NMPA)					China		Phase Ib/Ila clinical trial is being initiated in China, participant enrollment completed in June 2024
			T2DM (+ Basal insulin) first-line	China (NMPA)					China		IND approved by the NMPA in August 2021 and Phase III clinical trial to be initiated in 2026 in China ³
PB-718 ⁴ ☆	Long-acting GLP-1/GCG dual receptor agonist	In-house	T2DM (+SGLT-2 inhibitor) first-line	China (NMPA)				Global 	China		To prepare IND and commence a Phase III clinical trial in China in 2026
			Overweight or obesity	China (NMPA)					China		To prepare IND and commence a Phase III clinical trial in China in 2026
			NASH	U.S. (FDA/EU (EMA))					U.S., EU		Completed participant follow-up for a Phase Ib/Ila clinical trial in China and Phase Ib clinical trial is expected to commence in China following a communication with the NMPA to be conducted in 2025
PB-1902 ⁵	Opioid receptor antagonist	In-house	NASH	China (NMPA)/U.S. (FDA)					China, U.S.		Phase III MRCT trial is expected to commence following a communication with the FDA and the EMA to be completed in 2026
PB-722 ⁶	GCG receptor agonist	In-house	OIC	China (NMPA)					China		Phase I clinical trial completed in May 2022 in the United States, and IND for a Phase II clinical trial in China is expected to be submitted in 2H 2025
PB-2301	GLP-1/GIP dual receptor agonist	In-house	Congenital hyperinsulinemia	China (NMPA)					China		Phase I clinical trials completed in January 2022 in China, and Phase II clinical trial is expected to commence in China in 2025
PB-2309	GLP-1/GIP/GCG triple receptor agonist	In-house	T2DM/Overweight or obesity/NASH	China (NMPA)					China		IND approved by the NMPA in May 2023 and Phase I clinical trial to be initiated in China in 2026
			T2DM/Overweight or obesity/NASH						China		IND submission in China expected in 2026
									China		IND submission in China expected in 2025

★ Core Product ☆ Key Product  Metabolic diseases  Digestive disease

BUSINESS

Abbreviations: MoA = mechanism of action; GCG = glucagon; GIP = glucose-dependent insulinotropic polypeptide; OIC = opioid-induced constipation; IND = investigational new drug; U.S. = the United States

Notes:

1. Both T2DM (monotherapy) and T2DM (+metformin) are expected to be the lead indications of PB-119. The other indications are expansions of indications. PB-119 is primarily designed for the first-line treatment of T2DM and obesity. In recent years, GLP-1 receptor agonists have been increasingly recommended for the treatment of T2DM and obesity as a result of their favored treatment outcomes demonstrated in various clinical studies and real-world applications. For additional information, see “Industry Overview — Overview of T2DM drug market — Current treatment regimen and medical needs” and “Industry Overview — Overview of obesity drug market — Current treatment regimen and medical needs.”
2. We also completed two clinical trials in the United States, namely a Phase I clinical trial to evaluate the safety, tolerability, PK and PD of PB-119 in T2DM patients, as well as a Phase II clinical trial to evaluate efficacy and safety of PB-119 in T2DM patients not well-controlled by metformin monotherapy. We intend to finalize the clinical development plan in the United States and conduct Phase III clinical trials of PB-119 for the treatment of T2DM. For additional information, see “— Core Product — Core Product PB-119, a near-commercialized, long-acting GLP-1 receptor agonist.”
3. Based on the existing good clinical efficacy and safety data of PB-119 from our completed clinical trials, we plan to further test its multiple beneficial effects in potentially reducing the risk of cardiovascular events through a Phase III cardiovascular outcome clinical trial (PB119-305). We filed IND application with the NMPA for PB119-305 in June 2021 as we did not need to conduct such Phase I or II clinical trials since the clinical trial methods including the patient population and the dosage of PB-119 would be same as our completed Phase III clinical trials. In August 2021, we received the IND approval from the NMPA for this clinical trial.
4. We irrevocably granted to TSL HK the right of first refusal of exclusive commercialization rights of PB-718 in Mainland China.
5. The Phase I clinical trial of PB-1902 was registered by Shanghai Hanmai, a subsidiary of us.
6. PB-722 has been granted the Orphan Drug Designation by the FDA.
7. We submitted one NDA of PB-119 for the treatment of T2DM (containing relevant clinical trial results of PB-119 as a monotherapy or in combination with metformin) in July 2023 which was accepted by the NMPA in September 2023.

Our Core Product, PB-119, is a self-developed, near-commercialized, long-acting GLP-1 receptor agonist primarily designed for the first-line treatment of T2DM and obesity. The prevalence of T2DM is increasing worldwide, posing a significant medical, social and economic burden and medical needs. In the last decade, GLP-1 receptor agonists have been recommended as the first-line treatment for T2DM, with clear evidenced benefits of improved glucose control, weight loss, and cardiovascular protection. We have conducted a series of clinical trials to assess the safety and efficacy of PB-119. These trials have revealed its broad-ranging benefits, good safety profile, rapid and sustained effectiveness, and potentially a high level of patient compliance. With our PEGylation technology, we extended the half-life of PB-119 to enable a weekly dosing regimen. PB-119 also does not require titration given its good tolerability and effectiveness at relatively low dosage levels, resulting in enhanced administration convenience and improved patient compliance.

BUSINESS

We successfully completed two Phase III registrational clinical trials in China for PB-119 by early 2023. The clinical results regarding both monotherapy and combination therapy for T2DM have underpinned our NDA for PB-119 in China, which was accepted by the NMPA in September 2023, making it one of the earliest clinical-stage long-acting GLP-1 receptor agonists in China, according to CIC. We expect to receive the NDA approval and commercially launch PB-119 for the treatment of T2DM in China in 2025. We also completed a Phase II clinical trial of PB-119 for the treatment of T2DM in the United States, paving the way for expanding the territory of PB-119 beyond China. In addition to T2DM and obesity, we expect to explore therapeutic potentials for combination therapies and further indication expansions for PB-119.

PB-718 is a novel long-acting GLP-1/GCG dual receptor agonist primarily designed for the treatment of obesity and NASH. Through dual activation of both GLP-1 receptor and glucagon (“GCG”) receptor, PB-718 is designed to achieve a synergistic effect that surpasses the efficacy of either receptor agonist alone, characterized by significant weight loss and reduced appetite. Our preliminary study results showed that PB-718 decreased lipid accumulation in the liver, thereby preventing hepatic inflammation and subsequent liver fibrosis. We also applied PEGylation to extend the half-life of PB-718, thereby reducing the dosing frequency to just once a week, which we believe could similarly enhance the patient compliance and convenience of administration for obesity and NASH patients. We have completed a Phase I clinical trial of PB-718 in the United States, which demonstrated its safety profile in healthy participants. We have also completed the participant follow-up for a Phase Ib/IIa clinical trial of PB-718 in China for the treatment of obesity.

We are also developing other dual and triple receptor agonists to bring advanced, effective and affordable treatment options to patients with chronic and metabolic diseases. These include our preclinical-stage drug candidates PB-2301 and PB-2309. We believe that PB-2301 and PB-2309 have the potential to become a promising GLP-1/GIP dual receptor agonist and GLP-1/GIP/GCG triple receptor agonist, respectively.

The breadth of our pipeline portfolio and our capabilities extend beyond GLP-1 receptor agonists. In particular, we are developing PB-1902, an oral, selective opioid receptor antagonist under clinical development in China for OIC. It is designed to effectively alleviate opioid-induced bowel dysfunction without diminishing the central pain-relieving effects of opioids, rendering PB-1902 a potentially optimal treatment option for OIC. PB-1902 has been assessed in a Phase I clinical trial in China. In addition, we are developing PB-722, a GCG receptor agonist, for the treatment of congenital hyperinsulinemia. PB-722 has been granted the Orphan Drug Designation by the FDA and has demonstrated its safety in several animal models and its efficacy in raising and maintaining blood glucose levels in a hypoglycemic animal model.

BUSINESS

We have developed our pipeline leveraging our proprietary Highly Effective Target Screening & Molecule Modifier Platform (HECTOR[®]), a core technology platform supporting our research and development. HECTOR[®] encompasses a metabolic disease data collection, a drug molecular design platform, and a compound screening platform. Through the metabolic disease data collection, we integrate vast publicly available information and our research team’s in-depth understanding of target mechanisms, as well as their rich practical know-how in the rational design of drug molecules with ideal properties. The drug molecular design platform features our polyethylene glycol (“PEG”) technology that enables innovation and brings multiple benefits, including prolonged half-lives of compounds, enhanced long-acting efficacy, improved compound stability, reduced immunogenicity and lowered research costs. It underpins our pursuit of precise structural design and modification of drug molecules to enhance key physicochemical properties and achieve significant differentiation as compared to existing therapeutic options. Additionally, we leverage the efficient compound screening platform to adeptly identify promising lead compounds based on a range of critical parameters, setting a solid foundation for our future drug development.

We are crafting targeted marketing strategies to set the stage for our upcoming product commercialization. Our efforts are geared towards fostering commercialization partnerships with domestic and international companies, thereby achieving a fast market penetration and maximizing commercial opportunities. Leveraging the existing sales network of our partners, we expect to commence commercialization of our drug products effectively and efficiently. We are also deeply engaged in a range of academic forums within the industry, aiming to strengthen our dialogue with leading experts. By consulting with these key industry figures, we seek to garner insightful feedback on the clinical needs in the relevant therapeutic areas. These initiatives are integral to our thorough and strategic preparations for the successful market debut of PB-119 and beyond.

Our path to date has been guided by an experienced management team comprised of seasoned industry veterans. Our achievements have been enabled under the leadership of our founder, Dr. Michael Min XU. A distinguished alumnus of Columbia University and Xiangya School of Medicine at Central South University, Dr. XU brings a wealth of over 30 years’ industry experience in clinical medicine, scientific research and corporate management. He is not only the principal inventor behind our key patents but also serves as a project review expert for the State Administration of Foreign Experts Affairs. His illustrious career is marked by numerous accolades, including the prestigious “Jiangsu Province High-level Innovative and Entrepreneurial Talent” award and inclusion in the National High-Level Talents Special Support Program (國家高層次人才特殊支持計劃). Our core R&D team members possess relevant expertise with skills spanning across the entire spectrum of the new drug development lifecycle, including drug molecular design, process and formulation development, preclinical pharmacology and efficacy, drug metabolism, safety assessment, and the intricacies of clinical trial design, management, and regulatory submissions, thereby synergistically and swiftly propelling our R&D endeavors forward.

BUSINESS

STRENGTHS

A leading player in the chronic and metabolic disease market with a competitive and balanced drug portfolio

We have developed a leading, differentiated and balanced drug portfolio primarily targeting significant medical needs in the chronic and metabolic disease market, including T2DM, obesity and NASH. According to CIC, the global market size of T2DM and obesity treatment was US\$70.3 billion and US\$9.1 billion in 2023, respectively, and is anticipated to reach US\$106.2 billion and US\$58.5 billion in 2032, with CAGRs of 4.9% and 22.9%, respectively. The NASH treatment market is also witnessing growth in line with the rising occurrence of T2DM and obesity, yet there are still limited treatment options available.

Our product portfolio addresses both evidence-based targets that ensure certainty and novel targets or disease mechanisms that bring considerable market potential and future growth to us. Our drug candidates also span all stages of development from preclinical stage to near-commercialization stage, thereby demonstrating a healthy balance of development prospect.

We deploy GLP-1 receptor agonists to realize the market potential. We have built a proprietary and distinguished pipeline primarily centering around the GLP-1 receptor for T2DM, obesity and NASH. GLP-1 receptor agonists are based on validated mechanism of action and represent the trend of metabolic disorders treatment, demonstrating significant potential in treating diabetes and obesity. According to CIC, the global market size of GLP-1 receptor agonists is expected to reach US\$110.6 billion by 2032. In 2022, GLP-1 receptor agonists accounted for more than 44% of the T2DM drug market in the United States, while they only accounted for approximately 10% in China’s T2DM drug market, underscoring the market potential in China.

- ***Our Core Product PB-119*** is a near-commercialized product with demonstrated druggability, safety and efficacy profiles. In China, the NMPA accepted the NDA of PB-119 for the treatment of T2DM in September 2023. We anticipate to receive the NDA approval and commercially launch PB-119 for the treatment of T2DM in China in 2025, making it one of the earliest domestically developed long-acting GLP-1 receptor agonists which potentially brings a substantial impact on the landscape of diabetes treatment in the China market. We believe this track record of developing PB-119 showcases our capability in the research and development of innovative therapeutics. Moreover, we are actively exploring its therapeutic potential as a part of combination therapies and for expansion of indications including obesity. We believe that encouraging features of PB-119, coupled with our differentiated marketing strategy, would position us to capture the significant market opportunity in China in the T2DM and obesity treatment market.

BUSINESS

- ***Our key product PB-718*** is a dual receptor agonist that activates both the GLP-1 receptor and the glucagon receptor and embodies the industry evolution from single-target agonists. Dual activation of these receptors could create a synergistic effect that is superior to the impact of either receptor agonist acting in isolation. The innovative design of PB-718 demonstrates our research and development capabilities and validates our balanced portfolio. We believe PB-718 is a promising candidate in our pipeline for the treatment of obesity and NASH. It is an advanced GLP-1-based product candidate besides our Core Product PB-119 and a dual receptor agonist, therefore, we identify PB-718 as a key product.
- ***Our preclinical drug candidates PB-2301 and PB-2309*** have the potential to be a promising GLP-1/GIP dual receptor agonist and GLP-1/GIP/GCG triple receptor agonist, respectively. Our focus in developing novel dual and triple agonists demonstrates our commitment in bringing advanced, effective and affordable treatment options to patients with chronic and metabolic diseases, as well as our determination to achieve and maintain a preeminent position in the field.

We further expand our therapeutic focus to cover other chronic diseases and develop products beyond GLP-1 receptor agonists. **PB-1902** is the first and one of the only two domestically developed clinical-stage oral μ -opioid receptor antagonist drug candidates for the treatment of OIC in China as of the Latest Practicable Date, according to CIC. It relieves the opioid-induced bowel dysfunction without compromising the analgesic effect, making it an ideal option for the treatment of OIC. **PB-722** is a GCG receptor agonist being developed for the treatment of congenital hyperinsulinemia and has been granted the Orphan Drug Designation by the FDA. PB-722 has demonstrated its safety in several animal models and its efficacy in raising and maintaining blood glucose levels in a hypoglycemic animal model. These products beyond GLP-1 receptor agonists underscores the breadth of our pipeline portfolio and our capabilities in expanding therapeutic indications.

Advanced R&D and translational medicine capabilities, underpinned by our deep insight and understanding of the chronic and metabolic disease industry, to safeguard our future growth

Our R&D team has strong expertise, deep understanding and broad development experience in chronic and metabolic diseases. Through dedicated independent research and development efforts over the years, we have established a HECTOR[®] technology platform, which encompasses a drug molecular design platform, a compound screening platform and a metabolic disease data collection. Leveraging resources of the technology platform, we had developed a diverse pipeline of six product candidates, among which three were undergoing clinical trials, including our near-commercialized Core Product PB-119, and one had received IND clearance, as of the Latest Practicable Date. We held 83 patents and patent applications, including 13 patents and 15 patent applications in relation to our Core Product, as of the same date.

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A key component of our drug molecular design platform is the PEG technology, a versatile and proven modification that can be applied to a wide array of drugs, including peptide, protein, and small molecule drugs, to optimize their physio-chemical properties. Over the years, we have accumulated deep know-how to effectively leverage the PEG technology to realize its various advantages. The benefits of PEGylation and our PEG technology platform have received multiple recognitions, including government support under both the 12th and 13th Five-Year Plans of China.

Described below are ways that PEG technology and our research and development competencies have contributed to the development of our product pipeline.

- ***Prolong half-life of compound and enhance long-acting efficacy.*** By adjusting the parameters of PEGylation, such as the length of the PEG molecules and the amount of PEGylation, we are able to increase the total molecular weight and the hydrodynamic radius of the PEGylated drug, thereby significantly slowing its clearance from the body and prolonging its half-life to achieve long-acting efficacy. We have applied the PEG technology across our portfolio, including our Core Product PB-119, for that purpose. For example, PEG technology allows for PB-119 to be administered once a week, in contrast to certain other GLP-1 receptor agonists on the market, which require dosing as frequent as twice-daily, which we believe would not only lower the total cost to patients but also improve their long-term compliance.
- ***Improve compound stability.*** The PEG technology also contributes to improved compound stability, arising from improved overall solubility and protection by the attached PEG molecules against degradation or enzymatic breakdown. As an example, PEGylation of PB-119 considerably increases the stability and half-life compared with the native GLP-1. Similarly, more stable drug molecules in the body can result in long-acting efficacy and less frequent dosing, which can potentially improve the overall treatment outcome and patients’ compliance.
- ***Reduced immunogenicity.*** As PEG molecules can shield drugs from recognition by the immune system, PEG technology is able to diminish the likelihood of generating antibodies against the therapeutic agent and may contribute to safer and more tolerable therapeutics. For example, we conducted a positive-controlled Phase I clinical trial of PB-119 (ICP-I-2015-01) to evaluate the safety and PD profiles of PB-119 compared to those of exenatide (the positive control without PEGylation), which demonstrated that PB-119 caused less immunogenicity in terms of generation of anti-drug antibody as compared to that of exenatide, to further supplement our two placebo-controlled Phase I clinical trials of PB-119.
- ***Enable new solutions.*** Our PEG technology has enabled us to creatively alter physiochemical properties of drug candidates to develop potentially favorable treatment options. For example, the PEG technology allows us to alter the ability of small molecules to traverse the blood-brain barrier by enlarging its molecular size.

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Our drug candidate PB-1902, by utilizing this drug design, specifically targets opioid receptors in the digestive tract but not in the brain. This targeted approach holds promise for designing medications that can exert their therapeutic effects within the digestive tract, potentially offering solutions for conditions such as gastrointestinal pain or motility disorders. PEG technology’s precision in modulating drug properties signifies a groundbreaking strategy in drug development, providing a platform for the creation of highly targeted and efficacious treatments.

- **Lower research costs.** Application of PEGylation to proteins have been a well demonstrated approach to improve their physio-chemical characteristics. Over the years, we have accumulated a wealth of practical know-how to develop and produce PEG molecules with medicinal quality. Such practical know-how and established technology platform allow us to apply similar technologies to a wide variety of drug candidates, thereby sparing us entirely individual designs for different molecules and enabling us to expedite the research process and lower total cost.

Our compound screening platform plays a crucial role in the drug development process. Enabled by our in-depth accumulated know-how, we utilize the compound screening platform to select the most appropriate *in vivo* and *ex vivo* screening models for lead compounds, based on the mechanism of the chronic and metabolic diseases and their corresponding targets. We believe this strategic selection process significantly enhances the success rate of our drug development endeavors.

Utilizing the metabolic disease data collection that we curated from publicly available sources and our accumulated insights, we are adept at precisely capturing pertinent disease information, medication usage, and other critical data. This enables us to evaluate the mechanism of action, efficacy, and safety of potential therapeutic targets. We efficiently identify targets that align with our product characteristics, conduct thorough analyses of the market’s existing compounds, and identify gaps in meeting clinical needs.

We believe that the significant progress we have made on our pipeline portfolio underscores our capabilities in translational medicine. We strategically pursue disease targets with ample scientific validation and extensive preclinical studies. Our approach in translational medicine also involves harnessing insights from years of accumulated clinical data, which we then utilize to refine development strategies. This process includes further exploration and validation using preclinical models. Our ultimate goal is to transition these preclinical candidates into clinical-stage products, thereby advancing them through the pipeline toward successful commercialization. Our methodical and data-driven approach ensures that each step, from target selection to commercial launch, is executed with precision and a deep understanding of both scientific and market demands.

BUSINESS

Core Product PB-119, a differentiated long-acting GLP-1 receptor agonist with multiple clinical benefits

We operate in a fast-growing chronic and metabolic disease treatment market in China. Given the chronic nature of such diseases, such patients in China require long-term and continuous treatments that are effective and more importantly, safe for repeated administration. A significant portion of the medical needs of these patients remain unaddressed, given economic burden and scarcity of medical resources. In addition, as chronic and metabolic diseases cause comorbidities across various organs, patients require disease management that delivers multiple benefits.

To serve these medical needs, we have designed our Core Product PB-119 as a drug candidate that features multiple benefits, easy administration, high compliance, and a potential to achieve competitive pricing. PB-119 is a self-developed, near-commercialized, long-acting GLP-1 receptor agonist primarily designed for the first-line treatment of T2DM and obesity. Results of our completed clinical trials have shown that PB-119 has rapid, significant and sustained glucose-lowering effects, weight loss, improvement of the overall lipid metabolism profile and reduction in blood pressure, with good safety and well-tolerance. We believe the safety and efficacy profile demonstrated in the clinical trials and competitive pricing of PB-119 would improve patient compliance, which lead to more comprehensive benefits and further enhance patient compliance.

- ***Proven safety and long-acting efficacy.*** PB-119 has exhibited a promising safety profile. Hypoglycemia is a common risk for T2DM patients undergoing treatment, which could lead to significant blood sugar level fluctuations and cardiovascular events. Grade 1, 2 and 3 hypoglycemia is defined as blood sugar concentration less than 3.9 mmol/L, less than 3.0 mmol/L, and more severe cases that involve cognition impairment, respectively. Our Phase III trials have shown that in the treatment groups, patients exhibited a low incidence of hypoglycemia, without cases of Grade 2 or 3 hypoglycemia reported at week 24. Additionally, individuals only experienced mild gastrointestinal reactions, and the overall occurrence of adverse effects was significantly lower than its competitors based on reported data.

PB-119 acted in a fast and sustained manner in the clinical trials. In the Phase III trials, the groups receiving PB-119 treatment experienced a significant reduction in HbA1c and fasting and post-prandial blood glucose levels compared to the control group as early as four weeks. In particular, PB-119 stands out with a good four-week glucose-lowering effect compared to its competing products based on reported data, and nearly 20% of patients can meet glycemic targets within just four weeks of treatment. Throughout the 52-week treatment cycle, PB-119 consistently maintained non-elevated HbA1c levels while ensuring the sustained restoration of C-peptide and insulin secretion. Overall, PB-119 achieved significant glycemic control. While no head-to-head studies were conducted, PB-119 distinguished itself as the only GLP-1 drug with a sustained glucose-lowering effect till 52 weeks and no rebound demonstrated in clinical trial, based on the published clinical trial results of the

BUSINESS

GLP-1 receptor agonists approved for commercialization, according to CIC. It demonstrated improvements across various parameters, including HbA1c, OGTT, FPG, PPG, β -cell function, and insulin resistance. We may consider conducting head-to-head clinical studies of PB-119 in the future against then-major competing products on the market to demonstrate the comparative advantages of PB-119.

- ***Differentiated multiple benefits.*** PB-119 demonstrated rapid, significant and sustained efficacy with a differentiated broad range of benefits in the clinical trials, according to CIC. While GLP-1 receptor agonists generally bring more benefits as compared to many other traditional types of T2DM treatment options, only a few long-acting GLP-1 receptor agonists are on par with PB-119 in terms of the breadth and degree of clinical benefits. In the Phase III clinical trials, PB-119 led to multiple benefits such as cardiovascular improvements, as patients observed reductions in both systolic and diastolic blood pressure, decreased levels of cholesterol, LDL-C, and triglycerides. PB-119 also resulted in remarkable weight loss in a BMI dependent manner in 52 weeks, with higher BMI values associated with increased mean weight reduction.
- ***Easy to use with potentially enhanced patient compliance.*** We believe that multiple features of PB-119 can facilitate its administration and enhance patient compliance, according to CIC, which is critical for the long-term management of chronic and metabolic diseases. For instance, the long-acting efficacy of PB-119 allows once-per-week administration that spares patients frequent subcutaneous injections, which are commonly referred to as a key reason for poor patient compliance. In addition, while dosage titrations are required by many competing products and can be difficult for patients to conduct and/or require significant medical resources, the high tolerance of PB-119 and its rapid, significant and sustained efficacy at relatively low concentrations render titrations unnecessary. It makes PB-119 easy to use for a broad range of patients and can reduce the risk of misuse. Enhanced patient compliance in turn may translate into a wide range of clinical benefits, including better disease management, improved blood pressure and symptom control, enhanced lipid management and overall health outcomes.
- ***Competitive pricing.*** We believe that the production process of PB-119 could result in significantly decreased production costs and allow competitive pricing of PB-119 following its market launch. Such expertise enables us to achieve cost-efficiency and ensure quality in the production of PB-119 through easily scalable chemical synthesis methods. The potency of PB-119 at relatively low dosage levels also allows us to pursue competitive pricing as another potential advantage, especially for patients who are more cost-sensitive in China and other emerging markets, according to CIC. We intend to pursue competitive pricing to outcompete our peers and make PB-119 accessible to and affordable for a broad range of patients.

BUSINESS

- **Wide recognition.** The benefits of PB-119 have received wide recognition, as evidenced by our publication of experimental results related to PB-119 in reputable academic journals such as *Diabetologia* and *European Journal of Drug Metabolism and Pharmacokinetics* and other influential conferences organized by the European Association for the Study of Diabetes (EASD) and American Diabetes Association (ADA). The publications included comprehensive disclosures of the study results of PB-119 and were reviewed and cited by scholars and physicians in the respective field, which raised market awareness of our brand and products. We also advanced the development of PB-119 leveraging support received from the “13th Five-Year Plan” National Major New Drug Development Science and Technology Major Projects of China.

PB-718, a long-acting GLP-1/GCG dual receptor agonist, with potential to treat obesity and NASH

PB-718 is a GLP-1/GCG dual receptor agonist that has a promising therapeutic potential for obesity and NASH. Simultaneous activation of the GLP-1 receptor and the GCG receptor creates synergistic effects of GLP-1 receptor activation, namely glucose lowering and decreased appetite, with those of GCG receptor activation, namely increased energy expenditure and reduced food intake. These effects are mutually beneficial and may lead to a more robust physiological response compared to those of GLP-1 receptor agonists alone, and provide improved glycemic control and substantial weight reduction. GLP-1/GCG dual receptor agonists have furthermore been shown to ameliorate liver fat content and fibrosis, as well as promoting liver regeneration, according to CIC. The dual receptor agonist’s potent effect may also allow for lower dosage requirements, which could translate into a better safety profile, offering a promising risk-benefit profile for patient care and potentially improving patient compliance.

In addition, we believe that PB-718, which is composed of a combination of GLP-1 receptor agonist and GCG receptor agonist, may offer the flexibility of balancing the activation of GLP-1/GCG receptors as compared to a unimolecular dual receptor agonist. Such flexibility could enable an optimal efficacy and safety profile. We advanced the development of PB-718 leveraging support received from the “12th Five-Year Plan” National Major New Drug Development Science and Technology Major Projects of China.

PB-718 demonstrated a good safety profile in a completed Phase I clinical trial in healthy participants in the United States. PB-718 was generally well tolerated, and no severe adverse events related to PB-718 were observed. Even in healthy participants, dose or treatment related body weight reductions were observed following multiple doses of PB-718, underscoring its potential to treat obesity. In addition, a single dose of PB-718 led to sustained decrease in mean ALT and AST levels, suggesting its potential application in treating NASH. In a variety of *in vitro* and *in vivo* preclinical studies in rodents and non-human primates, PB-718 also showed considerable effects in lowering body weight due to decreases in food intake and increases in energy expenditure, in reducing total cholesterol, triglyceride, liver fat, and key liver enzymes (ALT and AST), and in improving liver NAS scores.

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In April 2024, we completed the participant follow-up of a Phase Ib/IIa clinical trial of PB-718 in China for its safety, tolerability and PK profiles in obese participants. We plan to conduct the Phase IIb clinical trial afterwards. We also plan to conduct clinical development of PB-718 in jurisdictions beyond China to fully realize its market potential.

Commercial prospect evidenced by our commercialization plan and arrangement

Our near-commercialized Core Product is one of the earliest domestically developed long-acting GLP-1 receptor agonists in China, according to CIC. With years of clinical development experience across over 100 clinical trial sites in China, many of which were at top-tier hospitals, we have gained access to a comprehensive KOL and physician network in the fields of chronic and metabolic diseases. We believe the recognition by hospitals and KOLs will help to establish brand recognition and increase the awareness of Core Product and other drug candidates.

Considering the marketing and sales expenses and the relevant expertise required, we entered into a commercialization collaboration arrangement on September 13, 2024 with a leading domestic commercialization-stage pharmaceutical company regarding the future marketing and commercialization activities of PB-119 in Mainland China. The commercialization partner is one of the largest distributors of, and a leading provider of supply chain services for, pharmaceutical and healthcare products and operates one of the largest national pharmaceutical distribution networks in China. With such commercialization arrangement, we expect to benefit from its decades of market experience and know-how in navigating through the rapidly evolving China healthcare landscape, market access ability to provide umbrella coverage for a portfolio of products and sales network covering both higher- and lower-tier markets to enable broad market penetration across China. For additional information, see “— Commercialization — Collaboration Agreement for Commercializing PB-119 in Mainland China.”

We believe that the collaboration will help us establish and grow coverage and penetration in hospitals and pharmacies, which will also benefit us in ramping up sales of other chronic and metabolic disease drugs once approved and enable us to replicate the successful experience into our drugs in the future.

We believe collaborations with experienced third-party organizations with in-depth drug promotion and sales experience is an ideal path for us. Effective promotion of chronic and metabolic disease drugs requires tailored marketing strategies, including physician outreach, attendance at medical conferences, and educational initiatives. These activities are resource-intensive and often require a significant budget and may require significant upfront investment in human resources. Hiring experienced sales professionals, especially those with specialized knowledge in chronic and metabolic diseases, can also be costly. Therefore, we expect that collaborating with, instead of us hiring our own, experienced sales professionals who are well-versed not only in sales techniques but also in the complexities of metabolic disorders and the specifics of the drugs being sold, would spare us significant cash outflows and enable us to leverage the distribution network of our sales partners, while achieving relative certainty in commercial prospect, as well as expeditious market penetration following the market launch of PB-119 and other products.

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Seasoned senior management team and shareholder support

We have assembled an experienced management team comprised of well-known academic professionals and seasoned industry veterans that collectively cover every step of our product discovery and development cycle. Led by our founder and general manager, Dr. Michael Min XU, our senior management team has deep experience in the biopharmaceutical field and brings extensive research and development experience from academia, governmental institutions and pharmaceutical company to our Company. We believe our management’s complementary expertise in industry and academia differentiates us from and will continue to propel us ahead of our peers.

Dr. Michael Min XU, our founder and general manager, is a seasoned veteran with more than 20 years’ experience in the biopharmaceutical industry. Dr. XU received his Ph.D. degree in biophysics from Columbia University in 1996. Dr. XU founded multiple biotech companies for the research and development of recombinant protein and PEGylated protein. Dr. XU also holds multiple distinguished credentials for his comprehensive expertise in the biopharmaceutical industry, including National Distinguished Expert and Project Review Expert of the State Administration of Foreign Experts Affairs. Dr. XU also leads our R&D team which has strong expertise, deep understanding and broad development experience in chronic and metabolic diseases, and the majority of our core R&D personnel have been working in the biopharmaceutical industry for over 10 years.

We believe the combination of the extensive experience and expertise of our senior management team members spans the whole research, development, and business cycle of our Company. With the coordination within our senior management team and efficient execution abilities, we are able to effectively develop according to our vision and strategies.

Since our establishment, we have received investments and support from experienced healthcare investors in China. We believe this investor and shareholder base is a testament to our capabilities and prospects.

STRATEGIES

Fast-tracking the commercialization and indication expansion of PB-119

We plan to rapidly advance the development of PB-119 towards commercialization. We expect to receive the NDA approval from the NMPA and commercially launch PB-119 for the treatment of T2DM in China in 2025. Considering the increasing recognition of GLP-1-based products in China, we are confident to establish PB-119 in such market with our tailored business strategies to enable the wider access of GLP-1-based products and benefit the large patient population in China with multiple clinical benefits demonstrated by PB-119.

We believe that a potential collaboration with a commercialization partner will further ensure the prospect of future rapid commercialization and capture of market share. In preparation for the commercialization of PB-119 in China, we plan to undertake more academic promotion activities to increase communication and collaboration with hospitals, physicians

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and KOLs to raise market awareness of our brand and products. We also endeavor to enhance product affordability by pursuing reimbursement listings in the NRDL and other government-sponsored medical insurance programs at appropriate pricing levels.

Our R&D efforts on PB-119 will go beyond to-be-commercialized indications. We plan to initiate two more Phase III clinical trials in China for combination therapies of PB-119 with either basal insulin (PB119-303) to evaluate the efficacy and safety of PB-119 in T2DM patients with poor glycemic control treated with insulin glargine or with SGLT-2 inhibitor (PB119-304) to evaluate the efficacy and safety of PB-119 in T2DM patients with poor glycemic control after dagliflozin monotherapy, and we were preparing IND applications for these two Phase III clinical trials. We also plan to initiate one Phase III clinical trial (PB119-305) in China for PB-119 to evaluate cardiovascular outcomes in T2DM patients in 2026.

In light of the remarkable weight-loss efficacy of PB-119 observed in its Phase III clinical trials for T2DM, we also plan to assess the efficacy of PB-119 in the treatment of obesity. In June 2021, the NMPA approved our IND application of PB-119 for the treatment of obesity in China. We finalized the clinical trial protocol in February 2024 and received the approval from the NMPA to commence the clinical trial in April 2024. We are initiating a randomized, double-blind, placebo-controlled, multiple ascending dose Phase Ib/IIa clinical trial to evaluate the safety, tolerability and PK profiles of PB-119 in Chinese obese participants, and we completed participant enrollment in June 2024. Subject to the Phase Ib/IIa clinical trial results, we intend to further advance the clinical development of PB-119 for the treatment of obesity in China by conducting potential Phase II and/or Phase III clinical trials in accordance with the plan that we will formulate. This strategic approach aims to expand its indication coverage and contribute valuable insights to the management of these prevalent conditions.

In the overseas markets, we plan to unlock the value of our assets through commercialization collaborations with local partners. We may also seek collaborations to conduct clinical development in the United States, Europe and explore other overseas jurisdictions amongst the “Belt and Road Initiative” countries, including countries in the Middle East and South Asia, for which we have been exploring local commercial horizon and regulatory requirements.

Promote the development and clinical trial progress of our product candidates

We expect to continue to achieve and deliver major development milestones for our other drug candidates, including PB-718, PB-1902, PB-722, PB-2301 and PB-2309 to further explore their potential. Particularly, we have formulated the following plans regarding our drug candidates.

- **PB-718:** We have completed a Phase I clinical trial of PB-718 in healthy participants in the United States. We also completed the participant follow-up of a Phase Ib/IIa clinical trial of PB-718 for the treatment of obesity in China in April 2024 and we plan to initiate the Phase IIb part afterwards. We plan to communicate with the FDA

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and the EMA in 2025 regarding the plans for conducting a Phase III MRCT of PB-718 for the treatment of obesity. We also plan to submit an IND application to the NMPA in the second half of 2025 to conduct a Phase II clinical trial of PB-718 for the treatment of NASH in China. We intend to evaluate the results of such Phase II clinical trial and formulate our plan for potentially conducting Phase II and Phase III clinical trials of PB-718 for the treatment of NASH in the United States.

- PB-1902: We have completed a Phase I clinical trial of PB-1902 for the treatment of OIC in China. In October 2022, we received a written response from the CDE allowing a Phase II dose-exploration clinical trial. We plan to commence such Phase II clinical trial for the treatment of OIC in China in 2025.
- PB-722: In May 2023, the NMPA approved our IND application to conduct Phase I clinical trial of PB-722 for the treatment of congenital hyperinsulinemia in China. We plan to initiate this Phase I clinical trial in 2026.
- PB-2301: PB-2301 is currently in preclinical stage. We plan to advance PB-2301 to clinical development for the treatment of T2DM, NASH and obesity and submit the IND applications to the NMPA in 2026.
- PB-2309: PB-2309 is currently in preclinical stage. We plan to advance PB-2309 to clinical development for the treatment of T2DM, NASH and obesity and submit the IND applications to the NMPA in 2025.

We will deploy our HECTOR[®] technology platform to discover new ways to expand the applications and indications of our product portfolio. Modeling from our successes with PB-119 to date, we aim to continue discovering novel targets and approaches for GLP-1 receptor agonist development and expanding into other chronic and metabolic diseases where medical needs remain.

Enhance brand awareness and industry impact

We are committed to establishing strong connections with various participants in the healthcare industry, including physicians, hospitals, pharmaceutical companies, CROs, academic institutions and regulators. We aim to deepen our existing strategic partnerships and continue to widen our collaboration network, to facilitate the growth of our business and enhance the overall development of China’s chronic and metabolic disease treatment industry. We will further strengthen our clinical trial programs to meet the research and clinical needs of our partners.

To promote our brand name overseas, we plan to join more prominent international medical conferences and industry exhibitions, as well as publishing papers in high-impact journals. We will sponsor academic activities, establish foundations, fortify our company website, and enhance our software infrastructure. We may voluntarily donate our drugs to hospitals for emergency use or academic use by physicians and other researchers. We will

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continue to invest heavily in professional and patient education, including increasing the number of training programs that we offer physicians and providing increased information regarding GLP-1 receptor agonist treatment modalities. These initiatives collectively aim to strengthen our brand presence and solidify our commitment to excellence in the eyes of our stakeholders and the wider audience.

Continue to grow our Company into a reputable enterprise

We pride ourselves on developing innovative products based on advances in intellectual property. We have developed a portfolio of intellectual property rights to protect our technologies and products, which provides an effective entry barrier. We have successfully obtained composition of matter patent for our product candidates in many countries and regions, including China, the United States, Europe and other countries. We will continue to seek patent protection for other product candidates globally.

We plan to continue to expand the territories of our pipeline assets through out-licensing or collaboration arrangements, both in clinical and preclinical stage to maximize their clinical and commercial value. A strong emphasis will be placed on expanding the overseas footprint of our product candidates, including overseas clinical development and commercialization, such as in the “Belt and Road Initiative” countries. To that end, we will also consider pursuing business collaborations with partners in terms of joint development and commercialization of our drug candidates in international markets.

Our employees are key to our growth strategy and ability to develop and commercialize innovative drugs, and hence we will continue to recruit, train, promote and retain talents with relevant background and experience in the pharmaceutical and biotech industries. To fully support our continued growth, we will continue to invest in attracting and retaining top talent in various aspects of our operations around the world, including discovery, research and development, manufacture and commercialization. This initiative is a key part of our strategy to enrich our talent pool. By investing in the advanced education of our staff, we not only enhance their expertise and skills but also foster a culture of continuous learning and innovation within our organization. This approach ensures that our team remains at the forefront of industry knowledge and expertise, significantly benefiting our research, development, and overall business performance.

OUR PRODUCT PIPELINE

We focus on leveraging our industry experience and established R&D capabilities for the in-house discovery and development of differentiated therapeutics primarily for chronic and metabolic diseases. As of the Latest Practicable Date, we had developed a diverse pipeline of six product candidates, among which three were undergoing clinical trials and one had received IND clearance. We have applied our polyethylene glycol (“PEG”) technology to our product candidates to optimize their physiochemical properties to achieve features such as long-acting efficacy and selective targeting of receptors in the digestive tract but not in the brain.

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The following chart summarizes the development status of our drug candidates as of the Latest Practicable Date. We strategically prioritize our resources for the clinical development and/or commercialization of certain pipeline candidates, including our Core Product PB-119 and key product PB-718.

Drug candidates	MoA/Target	Development origin	Indications	Preclinical	Phase I	Phase II	Phase III	Rights	Commercialization region	NDA date	Current status/Future milestones
PB-119 ¹ ★	Long-acting GLP-1 receptor agonist	In-house	T2DM (Monotherapy) first-line	China (NMPA)				Global 	China	Submitted and accepted in September 2023 ²	Expected to be approved for marketing in China in 1H 2025
			T2DM (+Metformin) first-line	China (NMPA)					China		
			Overweight or obesity first-line	U.S. (FDA)					U.S.		Phase I and II clinical trials completed in July 2016 and July 2019, respectively, in the United States. Phase III clinical trial plan is to be finalized ³
			T2DM (Cardiovascular benefits)	China (NMPA)					China		Phase Ib/Ia clinical trial is being initiated in China, participant enrollment completed in June 2024
			T2DM (+ Basal insulin) first-line	China (NMPA)					China		IND approved by the NMPA in August 2021 and Phase III clinical trial to be initiated in 2026 in China ³
			T2DM (+SGLT-2 inhibitor) first-line	China (NMPA)					China		To prepare IND and commence a Phase III clinical trial in China in 2026
PB-718 ⁴ ☆	Long-acting GLP-1/GCG dual receptor agonist	In-house	Overweight or obesity	China (NMPA)					China		Completed participant follow-up for a Phase Ib/Ia clinical trial in China and Phase IIb clinical trial is expected to commence in China following a communication with the NMPA to be conducted in 2025
			NASH	U.S. (FDA)/EU (EMA)					U.S., EU		Phase III MRCT trial is expected to commence following a communication with the FDA and the EMA to be conducted in 2026
PB-1902 ⁵	Opioid receptor antagonist	In-house		China (NMPA)/U.S. (FDA)					China, U.S.		Phase I clinical trial completed in May 2022 in the United States, and IND for a Phase II clinical trial in China is expected to be submitted in 2H 2025
PB-722 ⁶	GCG receptor agonist	In-house	Congenital hyperinsulinemia	China (NMPA)					China		Phase I clinical trials completed in January 2022 in China, and Phase II clinical trial is expected to commence in China in 2025
PB-2301	GLP-1/GIP dual receptor agonist	In-house	T2DM/Overweight or obesity/NASH	China (NMPA)					China		IND approved by the NMPA in May 2023 and Phase I clinical trial to be initiated in China in 2026
PB-2309	GLP-1/GIP/GCG triple receptor agonist	In-house	T2DM/Overweight or obesity/NASH						China		IND submission in China expected in 2026
									China		IND submission in China expected in 2025

★ Core Product ☆ Key Product

■ Metabolic diseases ■ Digestive disease

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Abbreviations: MoA = mechanism of action; GCG = glucagon; GIP = glucose-dependent insulinotropic polypeptide; OIC = opioid-induced constipation; IND = investigational new drug; U.S. = the United States

Notes:

1. Both T2DM (monotherapy) and T2DM (+metformin) are expected to be the lead indications of PB-119. The other indications are expansions of indications. PB-119 is primarily designed for the first-line treatment of T2DM and obesity. In recent years, GLP-1 receptor agonists have been increasingly recommended for the treatment of T2DM and obesity as a result of their favored treatment outcomes demonstrated in various clinical studies and real-world applications. For additional information, see “Industry Overview — Overview of T2DM drug market — Current treatment regimen and medical needs” and “Industry Overview — Overview of obesity drug market — Current treatment regimen and medical needs.”
2. We also completed two clinical trials in the United States, namely a Phase I clinical trial to evaluate the safety, tolerability, PK and PD of PB-119 in T2DM patients, as well as a Phase II clinical trial to evaluate efficacy and safety of PB-119 in T2DM patients not well-controlled by metformin monotherapy. We intend to finalize the clinical development plan in the United States and conduct Phase III clinical trials of PB-119 for the treatment of T2DM. For additional information, see “— Core Product — Core Product PB-119, a near-commercialized, long-acting GLP-1 receptor agonist.”
3. Based on the existing good clinical efficacy and safety data of PB-119 from our completed clinical trials, we plan to further test its multiple beneficial effects in potentially reducing the risk of cardiovascular events through a Phase III cardiovascular outcome clinical trial (PB119-305). We filed IND application with the NMPA for PB119-305 in June 2021 as we did not need to conduct such Phase I or II clinical trials since the clinical trial methods including the patient population and the dosage of PB-119 would be same as our completed Phase III clinical trials. In August 2021, we received the IND approval from the NMPA for this clinical trial.
4. We irrevocably granted to TSL HK the right of first refusal of exclusive commercialization rights of PB-718 in Mainland China.
5. The Phase I clinical trial of PB-1902 was registered by Shanghai Hanmai, a subsidiary of us.
6. PB-722 has been granted the Orphan Drug Designation by the FDA.
7. We submitted one NDA of PB-119 for the treatment of T2DM (containing relevant clinical trial results of PB-119 as a monotherapy or in combination with metformin) in July 2023 which was accepted by the NMPA in September 2023.

CORE PRODUCT

Core Product PB-119, a near-commercialized, long-acting GLP-1 receptor agonist

Overview

Our Core Product PB-119 is a self-developed, near-commercialized, long-acting GLP-1 receptor agonist primarily designed for the first-line treatment of T2DM and obesity. PB-119 is a GLP-1 derivative derived from exenatide backbone with PEG chains covalently conjugated to the peptide to extend the half-life of exenatide in the circulation by increasing the relative molecular mass and decreasing the renal clearance rate. Conjugating PEG chains to drug molecules, also referred to as PEGylation, is a proven method of extending half-life of compound and enhancing long-acting efficacy, improving compound stability and reducing immunogenicity. With PEGylation, we are able to further extend the half-life of PB-119 to enable once-weekly administration compared to daily administration for exenatide.

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PB-119 features a single-dose formulation without dose titration resulted from its safety and rapid, significant and sustained efficacy at relatively low dose levels. Such a single-dose formulation eases administration that potentially enhances patient compliance, and differentiates PB-119 from the other peer products currently on the market that may be prone to misuse due to the complexity of dose titration.

PB-119 is one of the earliest domestically developed long-acting GLP-1 receptor agonists in China, according to CIC, and has demonstrated good safety and efficacy across 11 clinical trials in China and the United States. The clinical trial results have shown that PB-119 has rapid, significant and sustained glucose-lowering effects, weight loss, improvement of the overall lipid metabolism profile and reduction in blood pressure, with good safety and well-tolerance. We believe that the good safety and efficacy profile supports PB-119 as a go-to solution for selected chronic and metabolic diseases, such as T2DM and obesity, for which only suboptimal therapeutic options are widely accessible as of now.

In September 2023, the NMPA accepted our NDA of PB-119 for the treatment of T2DM in China, marking a key milestone for its upcoming commercialization. We expect to receive the NDA approval from the NMPA and commercially launch PB-119 for the treatment of T2DM in China in 2025. We plan to price PB-119 at a competitive level to make it broadly accessible to patients in need, and we intend to partner with pharmaceutical companies who have strong commercialization capability and rich experience in the therapeutic fields we are focusing on, to utilize their well-established sales networks and other resources to cost-efficiently maximize the commercial value of PB-119. For details, see “— Commercialization.”

In addition, in China, we plan to initiate two more Phase III clinical trials for combination therapies of PB-119 with either basal insulin to evaluate the efficacy of PB-119 in T2DM patients with poor glycemic control treated with insulin glargine or with SGLT-2 inhibitor to evaluate the efficacy and safety of PB-119 in T2DM patients with poor glycemic control after dagliflozin monotherapy, and one Phase III clinical trial for PB-119 to evaluate cardiovascular outcomes in T2DM patients in 2025. In light of the weight-loss efficacy of PB-119 observed in its Phase III clinical trials for T2DM, we also plan to assess the efficacy of PB-119 in the treatment of obesity. In June 2021, the NMPA approved our IND application of PB-119 for the treatment of obesity in China. We finalized the clinical trial protocol in February 2024 and received the approval from the NMPA to commence the clinical trial in April 2024. We are initiating the Phase Ib/IIa clinical trial of PB-119 for the treatment of obesity, and we completed participant enrollment in June 2024. For details, see “— Core Product — Core Product PB-119, a near-commercialized, long-acting GLP-1 receptor agonist — Commercialization and Clinical Development Plan.”

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Mechanism of Action (“MOA”)

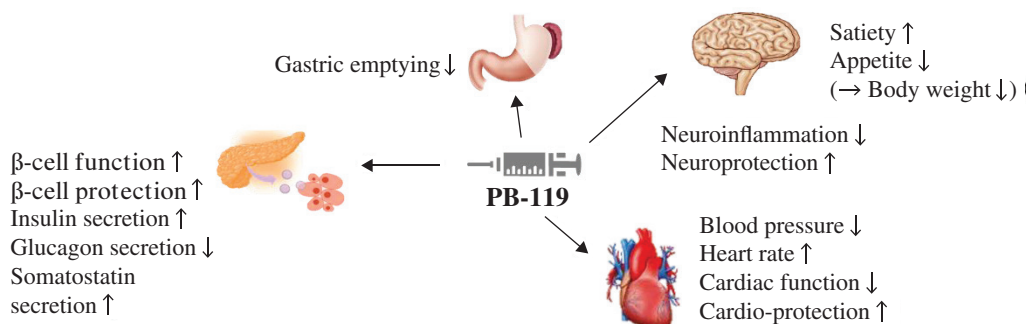
MOA of PB-119 for T2DM and Obesity

T2DM is characterized by sustained high blood glucose levels with the risk of multiple complications, such as obesity, cardiovascular diseases, diabetic retinopathy and nephropathy. Obesity is defined as abnormal or excessive fat accumulation that also leads to comprehensive health concerns. GLP-1 is a hormone produced and secreted by intestinal enteroendocrine L-cells. The primary functions of GLP-1 include insulin secretion promotion, glucagon secretion inhibition, glucose uptake and fat degradation, increasing cardiac contraction, suppressing gastric motility and appetite, and urinary sodium excretion promotion. GLP-1 receptor agonists simulate the receptor activation function of GLP-1 and are shown to decrease blood glucose levels in a glucose-dependent manner by enhancing the secretion of insulin, and thus can be used to treat T2DM and obesity.

PB-119 is a PEGylated exenatide and can bind and activate GLP-1 receptors *in vivo*, functions as a GLP-1 receptor agonist with similar physiological effects of natural human GLP-1. Polyethylene glycol (“PEG”) is a polyether compound with multiple clinical applications. PEGylation is the process of covalent attachment of PEG polymer chains to a drug substance, which subsequently referred to as a PEGylated drug product. By increasing the molecular weight of a molecule, PEGylation could impart several significant pharmacological advantages over the unmodified form, such as improved drug solubility, increased drug stability, enhanced protection from proteolytic degradation, extended circulating plasma half-life, lowered immunogenicity, reduced dosing frequency to retain efficacy but potentially to reduce toxicity, and improved clinical efficacy.

PB-119 was developed by optimizing various PEG polymer structures, lengths and linkages to the C-terminal cysteine in a synthetic exendin-4 analogue with substitution of the C-terminal serine by cysteine to enable PEGylation. Among others, PB-119 is shown to enhance insulin secretion, reduce glucagon secretion, and delay gastric emptying and suppress appetite, resulting in significant improvements in glycemic control as well as weight reduction.

The following diagram demonstrates mechanism of action of PB-119:



Source: CIC report

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Market Opportunity and Competition

T2DM is a disease characterized with elevated blood glucose levels. Insulin is a hormone produced by pancreas and regulates the metabolism of glucose from food intake. Obesity is defined as abnormal or excessive fat accumulation that presents comprehensive health concerns, such as cardiovascular diseases (“**CVDs**”), T2DM, musculoskeletal disorders, and carcinogenesis. A body mass index (“**BMI**”) over 24 kg/m² is considered overweight, and over 28 kg/m² is considered obese in China.

The following table summarizes the addressable patients and number of competing pipelines for our Core Product.

Core Product	Target Indication	Addressable Patients (million)				Number of Competitors ¹	
		China		Global		China	United States ²
		2023	2032E	2023	2032E		
PB-119 . .	T2DM	125.4	141.8	533.8	609.6	13 ³	Over 15 ⁴
PB-119 . .	Obesity	268.3	330.3	972.5	1,261.0	Over 15	Over 10

Notes:

1. “Competitors” refer only to pipelines with the same target for the same indication registered at CDE or ClinicalTrials.gov as our Core Product.
2. With active clinical trials in the United States.
3. Number of pipelines with NDA submitted to the NMPA and pipelines in Phase III clinical-stage in China.
4. Number of pipelines undergoing Phase II or Phase III clinical trials in the United States.

Our Advantages

We believe that PB-119 has the following advantages:

Comprehensive Clinical Benefits with Rapid, Significant and Sustained Efficacy

PB-119 demonstrated rapid, significant and sustained efficacy with a differentiated broad range of benefits in the clinical trials. Overall, PB-119 achieved significant glycemic control. While no head-to-head studies were conducted, PB-119 distinguished itself as the only GLP-1 drug with a sustained glucose-lowering effect till 52 weeks and no rebound demonstrated in clinical trial, based on the published clinical trial results of the GLP-1 receptor agonists approved for commercialization, according to CIC. It demonstrated improvements across various parameters, including HbA1c, OGTT, FPG, PPG, β-cell function, and insulin

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resistance. PB-119 distinguishes itself from peer products with a superior four-week glucose-lowering effect, and nearly 20% of patients can meet glycemic targets within just four weeks of treatment. Throughout the 52-week treatment cycle, PB-119 consistently maintained non-elevated HbA1c levels while ensuring the sustained restoration of C-peptide and insulin secretion. We currently focus on obtaining the NDA approval for PB-119 for the treatment of T2DM in China, and we plan to further conduct research and development activities on PB-119, including a series of Phase III clinical trials with different designs. For additional information, see “— Commercialization and Clinical Development Plan” and “Future Plans and Use of [REDACTED].” While we have conducted extensive and long-term clinical trials for PB-119 with comprehensive and reliable data, we may also consider conducting head-to-head clinical studies of PB-119 in the future against then-major competing products on the market to demonstrate the comparative advantages of PB-119.

In addition, while GLP-1 receptor agonists generally bring more comprehensive benefits as compared to many other traditional types of T2DM treatment options, only a few long-acting GLP-1 receptor agonists are on par with PB-119 in terms of the breadth and degree of resulting benefits. In the Phase III clinical trials, PB-119 led to multiple benefits such as cardiovascular improvements, as patients observed reductions in both systolic and diastolic blood pressure, decreased levels of cholesterol, LDL-C, and triglycerides. PB-119 also resulted in remarkable weight loss in a BMI dependent manner in 52 weeks, with higher BMI values associated with increased mean weight reduction.

Reduced Dosing Frequency and Improved Patient Compliance

Through the design and modification of our proprietary HECTOR[®] technology platform, we screened suitable type and molecular weight of PEG compounds to modify and form GLP-1 derivative PB-119. The rational design of PEGylation extends the *in vivo* half-life of PB-119 and enables its once-weekly dosing. In addition, PEGylation leads to stabilized blood drug concentration, achieving smooth glycemic control and preventing excessive fluctuations in blood glucose levels. This stability is beneficial in mitigating the risk of complications associated with T2DM, such as cardiovascular diseases, diabetic retinopathy and nephropathy. Our completed clinical trials indeed demonstrated a broad range of benefits of PB-119, including cardiovascular improvements, decreased levels of cholesterol, LDL-C and triglycerides in T2DM patients.

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The once-weekly dosing schedule of PB-119 significantly alleviates the burden on patients compared to the frequent once- or multiple-daily injections required by short-acting GLP-1 receptor agonists. The long-acting efficacy of PB-119 spares patients frequent subcutaneous injections which is a key reason for poor compliance for other GLP-1 receptor agonists. In addition, the incorporation of a disposable auto-injector also facilitates the storage and usage of PB-119, which further enhances patient compliance. Enhanced patient compliance in turn may translate into a wide range of clinical benefits, including better disease management, improved blood pressure and symptom control, enhanced lipid management and overall health outcomes, all of which are essential for the long-term management of chronic and metabolic diseases. We have obtained patent authorizations for PB-119 and its auto-injector in multiple jurisdictions and regions, including China, the United States, Europe, Japan, South Korea, Russia and South Africa, providing protection for our commercial interests.

Convenience Usage without Dose Titration

The most common gastrointestinal adverse effects of GLP-1 receptor agonists include nausea, vomiting, diarrhea, bloating and dyspepsia. Such adverse effects mainly occur in the first few weeks of administration in a dose-dependent manner, and the symptoms gradually diminishes with the duration of administration. The gastrointestinal adverse effects compromise patient compliance and life qualities, thus affecting the overall glucose-lowering efficacy and clinical benefits.

To enhance tolerance and alleviate side effects, the majority of the commercially available GLP-1 receptor agonists require dose titration to gradually increase the drug dosage, adding complexity and risk of drug administration. In comparison, PB-119 is intended for a consistent single-dose administration without the need for dose titration. The starting dose remains the same with the subsequent therapeutic dose, avoiding the inconvenience and risk of changes in dosing when using other formulation of GLP-1 receptor agonists. Avoiding dosage titrations may also lower the risk of misuse by patients. Upon receiving the regulatory approvals, we anticipate that PB-119 will greatly satisfy clinical needs and improve patients' medication experiences and compliance.

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PB-119 is derived from natural GLP-1 with rational structural design and PEG modifications, which almost completely retains the activity of GLP-1. As such, a promising glucose-lowering effect can be obtained even with a lower dose of PB-119, ensuring a balance between efficacy and safety to be well tolerated by patients. PB-119 has exhibited a promising safety profile. Our Phase III trials have shown that in the treatment group, patients exhibited a low incidence of hypoglycemia, without cases of Grade 2 hypoglycemia (blood glucose concentration less than 3.0 mmol/L) reported at week 24. Additionally, individuals only experienced mild gastrointestinal reactions, and the overall occurrence of adverse effects was significantly lower than its competitors based on reported data. The high tolerance of PB-119 and its rapid, significant and sustained efficacy at relatively low concentrations render titrations unnecessary, making PB-119 easy to use for a broad range of patients. Consequently, the administration of PB-119 supports a consistent dosing schedule and avoids the inconvenience and risks associated with altering drug dosage during the course of treatment. This feature greatly enhances convenience of usage and avoids the complexity and risks associated with current products on the market.

Broad Coverage of Patient Groups

With disease progression, T2DM patients are often associated with various complications such as cardiovascular diseases, rendering a single medication usually insufficient to fulfill the comprehensive clinical needs of such patients. Thus, patients prefer drugs with multiple benefit features.

With broad coverage across diverse disease stages and patients with comorbidities, PB-119 has optimized clinical value with multiple benefits. To fully realize the clinical value of PB-119 for a wider patient population, we have applied for multiple Phase III clinical trials which are approved by the NMPA. These clinical trials include PB-119 monotherapy, combination with metformin, combination with basal insulin, combination with SGLT-2 inhibitors, and cardiovascular outcomes research for T2DM patients. We believe PB-119, through both monotherapy and combination therapies, will be involved in treating patients at different disease stages and those with various comorbidities, including cardiovascular risks.

In addition, we believe that the production process of PB-119 could result in significantly decreased production costs and allow competitive pricing of PB-119 following its market launch. Such expertise is expected to enable us to achieve cost-efficiency and ensure quality in the production of PB-119 through easily scalable chemical synthesis methods. Coupled with the potency of PB-119 at relatively low dosage levels, we intend to pursue competitive pricing to outcompete our peers and make PB-119 accessible to and affordable for a broad range of patients who may be more cost-sensitive in underdeveloped regions in China and other emerging markets.

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Summary of Clinical Trials of PB-119

For the T2DM indication, we have completed a total of seven Phase I clinical trials of PB-119 in China and the United States (ICP-I-2013-08, ICP-I-2014-07, ICP-I-2015-01, CSP-PB119-US01-01, PB119-107, PB119-108, PB119-109), a total of two Phase II clinical trials in China and the United States (PB119-201 and PB119-202), and two Phase III clinical trials in China (PB119-301 and PB119-302), all were conducted for the target indication of T2DM. The following table sets forth an overview of the completed and planned clinical studies of PB-119:

Study	Study Number	Phase	Study Design	Sites	Participants	Status	Number of Enrolled Participants
T2DM	ICP-I-2013-08	Ia	Randomized, blinded, placebo-controlled, single ascending dose to evaluate safety, tolerability and PK of PB-119 in healthy participants	China	Healthy participants	Completed (February 2014 to November 2014)	70
	ICP-I-2014-07	Ib	Randomized, open-label, multiple ascending doses to evaluate safety, tolerability, PK and PD of PB-119 in healthy participants	China	Healthy participants	Completed (November 2014 to April 2016)	36
	ICP-I-2015-01	Ic	Randomized, open-label, positive-controlled, parallel multiple dose study to evaluate safety, tolerability, PK, and PD of PB-119 in drug naïve T2DM patients	China	T2DM patients	Completed (May 2015 to December 2015)	36

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Study	Study Number	Phase	Study Design	Sites	Participants	Status	Number of Enrolled Participants
	CSP-PB119-US01-01	I	Randomized, double-blind, placebo-controlled, sequential parallel group, multiple ascending dose study to evaluate the safety, tolerability, PK and PD of PB-119 in T2DM patients	United States	T2DM patients	Completed (November 2015 to July 2016)	40
	PB119-201	II	Multicenter, randomized, double-blind, parallel, placebo-controlled study to evaluate efficacy and safety of PB-119 in drug naïve T2DM patients	China	T2DM patients	Completed (June 2018 to July 2019)	251
	PB119-202	II	Multicenter, randomized, double-blind, placebo-controlled, parallel-dose cohort, multiple ascending dose study to evaluate efficacy and safety of PB-119 in T2DM patients not well-controlled by metformin monotherapy	United States	T2DM patients with over 80% being patients from the ethnic majority group (White) and over 10% being patients from ethnic minority groups (with Black or African American backgrounds)	Completed (June 2018 to July 2019)	217

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Study	Study Number	Phase	Study Design	Sites	Participants	Status	Number of Enrolled Participants
	PB119-301	III	Multicenter, randomized, double-blind, parallel, placebo-controlled study to evaluate efficacy and safety of PB-119 in drug naïve T2DM patients	China	T2DM patients	Completed (November 2020 to November 2022)	273
	PB119-302	III	Multicenter, randomized, double-blind, parallel, placebo-controlled study to evaluate efficacy and safety of PB-119 in T2DM patients not well-controlled by metformin monotherapy	China	T2DM patients	Completed (November 2020 to April 2023)	620
	PB119-107	I	Open, fixed-sequence, multiple single-dose study to evaluate PK interaction between PB-119 and rosuvastatin calcium tablets or valsartan capsules in healthy participants	China	Healthy participants	Completed (July 2022 to August 2022)	32

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Study	Study Number	Phase	Study Design	Sites	Participants	Status	Number of Enrolled Participants
	PB119-108	I	Open, fixed-sequence, multiple dose study to evaluate PK interaction between PB-119 and digoxin tablets or warfarin sodium tablets in healthy participants	China	Healthy participants	Completed (June 2022 to July 2022)	32
	PB119-109	I	Study to evaluate the PK characteristics of PB-119 in patients with different degrees of renal insufficiency and matched participants with normal renal function	China	Participants with renal insufficiency and participants with normal renal function	Completed (July 2022 to April 2023)	24
	PB119-303	III	Multicenter, randomized, double-blind, parallel, placebo-controlled study to evaluate the efficacy and safety of PB-119 in T2DM patients with poor glycemic control treated with insulin glargine (with or without metformin)	China	T2DM patients	To be initiated in 2026	N/A

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Study	Study Number	Phase	Study Design	Sites	Participants	Status	Number of Enrolled Participants
	PB119-304	III	Multicenter, randomized, double-blind, parallel, placebo-controlled study evaluating the efficacy and safety of PB-119 in T2DM patients with poor glycemic control after dagliflozin monotherapy	China	T2DM patients	To be initiated in 2026	N/A
	PB119-305	III	Long-term, multicenter, randomized, double-blind, placebo-controlled study to evaluate the effects of PB-119 on cardiovascular outcomes in T2DM patients	China	T2DM patients	To be initiated in 2026	N/A
Overweight/ Obesity . .		Ib/IIa	Randomized, double-blind, placebo-controlled, multiple ascending dose clinical trial to evaluate the safety, tolerability and PK profiles of PB-119 in Chinese obese participants	China	Obese patients	Being initiated, NMPA approval received in April 2024	N/A

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The following table sets forth an overview of results of key clinical studies of PB-119:

Study	Key Enrollment Criteria	Number of Participants Enrolled	Participating site(s) and PI	Endpoints	TEAE Reported (Mild/Moderate/ Severe/Life Threatening)	Frequently Occurring TEAE (Number of Cases)	Reasons for Discontinuation ⁽¹⁾	Material Results
PB119-107	Healthy adult participants	32	Shanghai Public Health Clinical Center, China PI: Xianmin Meng	PK parameters of rosuvastatin calcium tablets or valsartan capsules before and after PB-119 administration	rosuvastatin: 3/0/0/0 PB-119: 11/0/0/0 rosuvastatin + PB-119: 5/0/0/0 valsartan: 5/0/0/0 PB-119: 16/0/0/0 valsartan + PB-119: 2/0/0/0	PB-119 (rosuvastatin) /PB-119 (valsartan) Gastrointestinal disorder (4/6) Decreased appetite (0/5)	No discontinuation	PB-119 is generally well tolerated combined with rosuvastatin calcium tablets or valsartan capsules, with no additional safety concerns compared to either drug used alone
PB119-108	Healthy adult participants	32	Bengbu Medical University No. 1 affiliated hospital, China PI: Huan Zhou	PK parameters of digoxin tablets or warfarin sodium tablets before and after PB-119 administration	digoxin: 7/0/0/0 PB-119: 31/17/1/0 digoxin + PB-119: 4/0/0/0 warfarin: 4/1/0/0 PB-119: 27/27/0/0 warfarin + PB-119: 11/2/0/0	PB-119 (digoxin)/PB-119 (warfarin) Nausea (13/5) Vomiting (6/4)	One due to TEAE (probably related to the test drugs PB-119 + digoxin tablets)	PB-119 is generally well tolerated combined with digoxin tablets or warfarin sodium tablets, with no additional safety concerns compared to either drug used alone
PB119-109	Participants with renal insufficiency and participants with normal renal function	24	Chinese Clinical Trial Registry, West China Hospital, Sichuan University PI: Jia Miao, Ping Fu	PK parameters of PB-119	normal renal function: 17/0/0/0 mild renal insufficiency: 13/3/1/0 moderate renal insufficiency: 15/7/1/0	normal/mild/moderate renal insufficiency Gastrointestinal disorder (2/4/8) Decreased appetite (3/3/2)	No discontinuation	PB-119 is generally well tolerated in participants with different levels of renal insufficiency and normal renal function

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Study	Key Enrollment Criteria	Number of Participants Enrolled	Participating site(s) and PI	Endpoints	TEAE Reported (Mild/Moderate/Severe/Life Threatening)	Frequently Occurring TEAE (Number of Cases)	Reasons for Discontinuation ⁽¹⁾	Material Results
PB119-201	T2DM patients (drug naïve for at least 3 months before randomization) HbA1c between 7.5% to 11.0%, FPG between 4.4 to 13.3 mmol/L and BMI between 18.5 to 35.0 kg/m ² before randomization	251	Peking University Peoples Hospital, China PI: Linong Ji	change in HbA1c values relative to baseline during and at the end of the 12-week treatment period	placebo: 91/25/0/0 75 µg PB-119: 111/24/0/0 150 µg PB-119: 206/26/1/0 200 µg PB-119: 273/32/0/0	placebo/75 µg/150 µg/200 µg PB-119 Nausea (0/4/11/74) Vomiting (0/1/8/24) Dizziness (1/4/37/15) Hypoglycemia (0/8/11/7) Diarrhea (0/2/8/3)	Six (hyperglycemia), three withdrew consents, three due to TEAE (probably related to the test drug)	Compared to placebo, after 12 weeks of treatment, significant decreases were observed in HbA1c, fasting blood glucose, and postprandial 2-hour blood glucose levels in the 75 µg, 150 µg, and 200 µg PB-119 dose groups ($P < 0.001$). The rates of achieving HbA1c levels of $\leq 7.0\%$ and $\leq 6.5\%$ were significantly higher in all three dose groups compared to the placebo group ($P < 0.01$). During the double-blind treatment period, no severe drug-related adverse events occurred, and no severe hypoglycemia was reported.
PB119-202	T2DM patients not well controlled by metformin for at least 3 months before randomization HbA1c between 7.0% to 11.0%, FPG less than 13.9 mmol/L and BMI between 18.5 to 40.0 kg/m ² before randomization	217	Multiple sites in the United States PI: Dr. Stephen D. Flach	change in HbA1c values relative to baseline during and at the end of the 12-week treatment period	(reported patients) placebo: 12/6/2/0 100 µg PB-119: 7/11/0/0 150 µg PB-119: 15/11/1/0 200 µg PB-119: 11/15/0/0	placebo/100 µg/150 µg/200 µg PB-119 (reported patients) Nausea (0/3/4/5) Vomiting (0/4/1/2) Diarrhea (4/5/3/3)	Eleven due to TEAE (1/2/5/3 cases for placebo/100 µg/150 µg/200 µg PB-119 group)	The change from baseline value of HbA1c from baseline to Week 12 in the value of HbA1c were significantly greater for all three PB-119 doses versus placebo for the FAS Population: -0.8 percentage unit (p -value<0.0001) for 200 µg PB-119; -0.7 percentage unit (p -value<0.0001) for 150 µg PB-119; and -0.3 percentage unit (p -value = 0.0381) for 100 µg PB-119. PB-119 is generally well tolerated in all three dosage groups.

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Study	Key Enrollment Criteria	Number of Participants Enrolled	Participating site(s) and PI	Endpoints	TEAE Reported (Mild/Moderate/ Severe/Life Threatening)	Frequently Occurring TEAE (Number of Cases)	Reasons for Discontinuation ⁽¹⁾	Material Results		
								Changes from baseline		Changes from baseline
								24 weeks of treatment	52 weeks of treatment	
PB119-301	drug naïve T2DM patients HbA1c between 7.0% to 10.5%, FPG <15 mmol/L and BMI between 18.5 to 40.0 kg/m ² before randomization	273	The Second Xiangya Hospital of Central South University, China PI: Zhigang Zhou	change in HbA1c values relative to baseline at the end of the 24-week treatment period	Placebo: 172/372/0 PB-119: 342/59/5/0 Placebo - PB-119: 186/44/3/0 PB-119 - PB-119: 214/41/1/0	Placebo/PB-119: Hyperuricemia (7/15) Hyperlipidemia (12/6) Hypokalemia (27) Upper respiratory tract infection (16/15) Diarrhea (2/11) Nausea (1/11) Bloating (1/9) Vomiting (0/8) Elevated lipase (6/9) High blood pressure (3/8)	Proportion of patients achieving HbA1c <7% Fasting plasma glucose level Two-hour postprandial glucose level Fasting C-peptide level Two-hour postprandial C-peptide level Fasting insulin level Two-hour postprandial insulin level Insulin resistance index Pancreatic β -cell function index Blood lipid – total cholesterol Blood lipid – LDL-C Blood lipid – triglyceride Blood pressure – systolic pressure Blood pressure – diastolic pressure Weight	PB-119	Placebo	PB-119 – PB-119
								50.4%	14.2%	43.0%
								-1.263 mmol/L	-0.522 mmol/L	-1.393 mmol/L
								-2.521 mmol/L	-0.853 mmol/L	-2.293 mmol/L
								0.0333 nmol/L	-0.0217 nmol/L	0.0290 pmol/L
								0.3755 nmol/L	-0.0190 nmol/L	0.4918 nmol/L
								2.17 pmol/L	-3.07 pmol/L	-1.36 pmol/L
								60.83 nmol/L	-9.75 nmol/L	78.11 pmol/L
								-0.637	-0.374	-0.961
								18.207	1.833	16.446
								-0.115 mmol/L	0.106 mmol/L	0.196 mmol/L
								-0.119 mmol/L	0.007 mmol/L	-0.192 mmol/L
								-0.093 mmol/L	0.224 mmol/L	0.331 mmol/L
								-1.5 mmHg	0.3 mmHg	-2.1 mmHg
								-2.2 mmHg	-0.1 mmHg	-1.8 mmHg
								-0.35kg	0.52kg	-0.69kg
										-0.62 kg

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Study	Key Enrollment Criteria	Number of Participants Enrolled	Participating site(s) and PI	Endpoints	TEAE Reported (Mild/Moderate/ Severe/Life Threatening)	Frequently Occurring TEAE (Number of Cases)	Reasons for Discontinuation ⁽¹⁾	Material Results		
								Changes from baseline		Changes from baseline
								24 weeks of treatment	52 weeks of treatment	
PB119-302	T2DM patients not well-controlled by metformin monotherapy for at least eight weeks with daily dose of at least 1,000 mg HbA1c between 7.0% to 10.5%, FPG <15 mmol/L and BMI between 18.5 to 40.0 kg/m ² before randomization	620	Peking University Peoples Hospital, China PI: Linong Ji	change in HbA1c values relative to baseline at the end of the 24-week treatment period	Placebo: 300/91/4/0 PB-119: 574/109/8/0 Placebo - PB-119: 473/118/7/0 PB-119 - PB-119: 454/138/15/0	Placebo/PB-119: Hyperuricemia (39/37) Hyperlipidemia (23/26) Upper respiratory tract infection (18/13) Diarrhea (15/23) Elevated lipase (8/30)	Placebo/PB-119: voluntarily consent withdrew (18/20), discontinuation requested by participants (15/16), AE (14/14)	PB-119	Placebo	PB-119 - PB-119
								40.5%	17.9%	37.9%
								Proportion of patients achieving HbA1c <7%		45.2%
								Fasting plasma glucose level	-1.212 mmol/L	-1.187 mmol/L
								Two-hour postprandial glucose level	-0.678 mmol/L	-1.588 mmol/L
								Fasting C-peptide level	0.0750 nmol/L	0.0480 nmol/L
								Two-hour postprandial C-peptide level	0.3407 nmol/L	0.3809 nmol/L
								Fasting insulin level	12.781 pmol/L	4.792 pmol/L
								Two-hour postprandial insulin level	52.00 pmol/L	75.48 pmol/L
								Insulin resistance index	0.287	-0.323
								Pancreatic β -cell function index	22.857	14.948
								Blood lipid - total cholesterol	0.037 mmol/L	-0.080 mmol/L
								Blood lipid - LDL-C	-0.033 mmol/L	-0.049 mmol/L
								Blood lipid - triglyceride	0.064 mmol/L	0.127 mmol/L
								Blood pressure - systolic pressure	-2.5 mmHg	-2.0 mmHg
								Blood pressure - diastolic pressure	-1.4 mmHg	-1.0 mmHg
								Weight	-0.56 kg	-0.56 kg

(1) Such discontinuation had no material impact on the progress of the respective clinical trials.

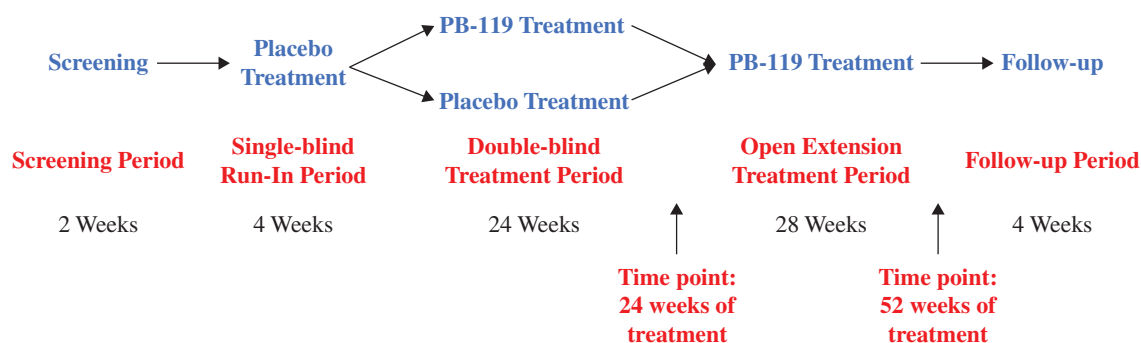
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The following sets forth an overview of the key clinical studies of PB-119:

PB119-301: A multicenter, randomized, double-blind, parallel, placebo-controlled Phase III study to evaluate efficacy and safety of PB-119 in drug naïve T2DM patients in China

Overview. This was a multicenter, randomized, double-blind, parallel, placebo-controlled study to evaluate efficacy and safety of PB-119 in drug naïve T2DM patients. The primary objective for this study was to evaluate the efficacy of 150 µg PB-119 compared to placebo in drug naïve T2DM patients by the change in HbA1c from baseline after 24 weeks of treatment.

Trial design. The study included a maximum 2-week screening period, a 4-week single-blind run-in period, a 24-week double-blind treatment period, a 28-week open extension treatment period and a 4-week safety follow-up period. The following chart shows the five-period design for this study.



Source: Company data, clinical study report

A total of 273 T2DM patients were enrolled in this Phase III clinical trial. After the screening period, the patients were administered with placebo once a week subcutaneously in the 4-week single-blind run-in period. The patients were then randomized 1:1 into two dosing groups for 24-week double-blind treatment, with 137 patients in a PB-119 treatment group to receive subcutaneous injection of 150 µg PB-119 once a week and 136 patients in a placebo treatment group to receive subcutaneous injection of placebo once a week. All patients were next entered the 28-week open extension treatment period to receive subcutaneous injection of 150 µg PB-119 once a week. Next, safety visit was performed in the 4-week safety follow-up period.

The primary efficacy endpoint of this study was to evaluate change in HbA1c values relative to baseline at the end of the 24-week double-blind treatment period. The primary endpoint was established based on the guidelines of the NMPA to demonstrate the clinical superiority of PB-119 over placebo, such as glycemic control measured by the change of HbA1c values. The key inclusion criteria for the study included but not limited to: (1) male or female patients aged ≥18 years and ≤75 years at screening; (2) patients with confirmed T2DM who met the 1999 World Health Organization diagnostic criteria; (3) patients who had received dietary and exercise interventions for at least 8 weeks prior to screening and had not received

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any antidiabetic medications in the 8 weeks prior to screening; (4) patients with HbA1c $\geq 7.5\%$ and $\leq 11.0\%$ at screening and HbA1c $\geq 7.0\%$ and $\leq 10.5\%$ before randomization; and (5) BMI ≥ 18.5 kg/m² and ≤ 40.0 kg/m² at screening and before randomization. The key exclusion criteria included but not limited to: (1) patients who had been diagnosed with type one diabetes, diabetes due to pancreatic injury, or a specific type of diabetes caused by another disease; (2) patients who had used medications that may affect glucose metabolism; (3) patients who had used insulin for more than 14 consecutive days in the six months prior to screening; (4) patients who had acute complications of diabetes within six months prior to screening or prior to randomization; or (5) patients who had heart conditions within six months prior to screening or prior to randomization.

Trial Status. This Phase III clinical trial of PB-119 was initiated in November 2020 and completed in November 2022 in China.

Efficacy data. This study demonstrated that PB-119 monotherapy can rapidly and effectively lower glucose and stabilize it up to 52 weeks. The improvement at 52 weeks was more significant than that at 24 weeks. In particular, the key efficacy data for the study included but not limited to:

HbA1c value: The mean (SD) baseline HbA1c values were 8.47 (0.806)% and 8.53 (0.813)% in the PB-119 treatment and placebo treatment groups, respectively. Early response of PB-119 was observed at week 4 with a rapid reduction of -0.82% (95% CI -0.90 to -0.74) in HbA1c levels ($p < 0.001$), and the reduction in HbA1c was sustained during the extended treatment period with -1.39% (95% CI -1.58 to -1.19) at week 52. HbA1c rapidly decreased to 7.63% (0.80) by week 4 of PB-119 treatment, and the change from baseline was significantly greater than that in the placebo treatment group (8.21% (1.05)). At the end of the 24-week double-blind treatment period, HbA1c was 7.11 (0.907)% in the PB-119 treatment group and 7.87 (1.019)% in the placebo treatment group, and the mean change in HbA1c from baseline was -1.37% (95% CI -1.53 to -1.20) in the PB-119 treatment group versus -0.63% (95% CI -0.81 to -0.45) in the placebo treatment group. The reduction in HbA1c was significantly greater with PB-119 treatment group than placebo treatment group ($p < 0.001$). The study demonstrated that the reduction in HbA1c from baseline in the PB-119 treatment group was significantly better than that in the placebo treatment group.

Changes in proportion of patients achieving HbA1c $< 7\%$: At 4-week of double-blind treatment, the proportion of patients achieving HbA1c $< 7\%$ in the PB-119 treatment group was 18.8% (25 cases). At 24-week of double-blind treatment, the proportion of patients achieving HbA1c $< 7\%$ in the PB-119 treatment group was 50.4% (66 cases), which was significantly higher than 14.2% (18 cases) in the placebo treatment group, with a statistically significant difference ($p < 0.05$). At 52 weeks, the proportion of patients achieving HbA1c $< 7\%$, who were in the PB-119 treatment group during the 24-week of double-blind treatment period and received PB-119 during the 28-week open extension treatment period (the “**PB-119 — PB-119 treatment group**”), remained stable compared with 24 weeks (43.0% in 52 weeks vs. 50.4% in 24 weeks). In addition, the proportion of patients achieving HbA1c $< 7\%$, who switched from the placebo treatment group during the 24-week of double-blind treatment period to PB-119

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treatment during the 28-week open extension treatment period (the “**placebo — PB-119 treatment group**”), increased to 47.2% compared to 14.2% in 24 weeks and was similar to the proportion in the PB-119 treatment group at 24 weeks (50.4%) in the double-blind treatment period.

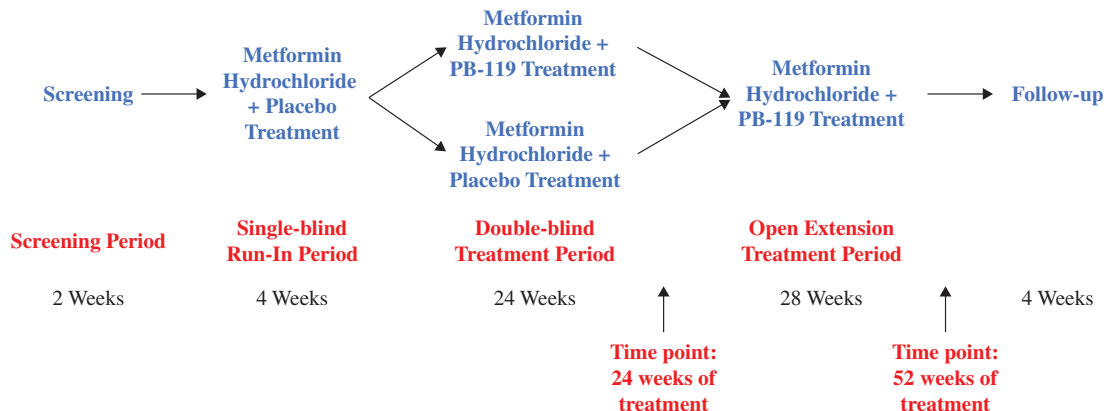
Safety data. PB-119 was generally well tolerated with an overall safety profile similar to that of placebo. The majority of AEs were mild to moderate. The most common adverse reaction was gastrointestinal, with low incidence, occurring most frequently in the first four weeks of treatment with decreased incidence or disappearance after eight weeks of treatment. But gastrointestinal adverse reaction was transient and well tolerated. More important, highest incidence of AEs in the PB-119 group in the double-blind period was gastrointestinal system disorders (24.1%, 33/137), with nausea incidence of 8.0%, vomiting incidence of 5.8%, and diarrhea incidence of 8.0%. Among comparable marketed weekly formulations of GLP-1 receptor agonists, the incidences of nausea, vomiting, and diarrhea were 23.9%, 6.9% and 10.8% in the 1.0 mg semaglutide monotherapy study, 19.0%, 8.6% and 10.0% in the 1.5 mg dulaglutide monotherapy study, and 11.3%, 4.8% and 10.9% in the 2.0 mg exenatide microspheres monotherapy study, respectively, according to publicly available clinical trial results. PB-119 led to relatively low gastrointestinal AEs, taking into account the published results of other GLP-1 receptor agonists, although no head-to-head comparisons were conducted in the clinical trials of PB-119. We may consider conducting head-to-head clinical studies of PB-119 in the future against then-major competing products on the market to demonstrate the comparative advantages of PB-119. In addition, the incidence of hypoglycemia was low, with no hypoglycemia below 3.0 mmol/L or severe hypoglycemia. No patients discontinued treatment or withdrew from the study due to hypoglycemia. The incidence of injection site reactions was low and most of them occurred within the first four weeks of treatment, and no patients were terminated or withdrawn from the study due to injection site reactions. The proportion of patients terminating treatment and withdrawing from the study due to AEs was similar to placebo.

PB119-302: A multicenter, randomized, double-blind, parallel, placebo-controlled Phase III study to evaluate efficacy and safety of PB-119 in T2DM patients not well-controlled by metformin monotherapy

Overview. This was a multicenter, randomized, double-blind, parallel, placebo-controlled Phase III clinical trial to evaluate efficacy and safety of PB-119 in T2DM patients not well-controlled by metformin monotherapy. The primary objective for this study was to evaluate the efficacy of 150 µg PB-119 treatment in combination with metformin hydrochloride compared to placebo treatment in T2DM patients not well-controlled by metformin monotherapy.

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Trial design. Similar to PB119-301, the PB119-302 Phase III clinical trial also included a maximum 2-week screening period, a 4-week single-blind run-in period, a 24-week double-blind treatment period, a 28-week open extension treatment period and a 4-week safety follow-up period. The following chart shows the five-period design for this study.



Source: Company data, clinical study report

A total of 620 T2DM patients were enrolled in this Phase III clinical trial. After the screening period, the patients were administered with placebo once a week subcutaneously in addition to metformin hydrochloride in the 4-week single-blind run-in period. The patients were then randomized 1:1 into two dosing groups for 24-week double-blind treatment with 310 patients in a PB-119 treatment group to receive subcutaneous injection of 150 µg PB-119 once a week in addition to metformin hydrochloride, and the other 310 patients in a placebo treatment group to receive subcutaneous injection of placebo once a week in addition to metformin hydrochloride. All patients subsequently entered the 28-week open extension treatment period to receive subcutaneous injection of 150 µg PB-119 once a week in addition to metformin hydrochloride treatment. Afterwards, safety visit was performed in the 4-week safety follow-up period.

The primary efficacy endpoint of this study was to evaluate change in HbA1c values relative to baseline at the end of the 24-week double-blind treatment period. The primary endpoint was established based on the guidelines of the NMPA to demonstrate the clinical superiority of PB-119 over placebo, such as glycemic control measured by the change of HbA1c values. The key inclusion criteria for the study included but not limited to: (1) male or female patients aged ≥ 18 years and ≤ 75 years at screening; (2) patients with confirmed T2DM who met the 1999 World Health Organization diagnostic criteria; (3) patients who had received a stable dose of metformin hydrochloride monotherapy for ≥ 8 weeks prior to screening based on dietary and exercise interventions and a dose of metformin hydrochloride for ≥ 1500 mg/days or as maximally tolerated dose (< 1500 mg/days but ≥ 1000 mg/days); (4) patients with HbA1c $\geq 7.5\%$ and $\leq 11.0\%$ at screening and HbA1c $\geq 7.0\%$ and $\leq 10.5\%$ before randomization; and (5) BMI ≥ 18.5 kg/m² and ≤ 40.0 kg/m² at screening and before randomization. The key exclusion criteria included but not limited to: (1) patients who had been diagnosed with type 1 diabetes, diabetes due to pancreatic injury, or a specific type of

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diabetes caused by another disease; (2) patients who had used drugs other than metformin that may affect glucose metabolism within 8 weeks prior to screening or prior to randomization; (3) patients who had used insulin for more than 14 consecutive days in the six months prior to screening; (4) patients who had acute complications of diabetes within six months prior to screening or prior to randomization; (5) patients who had heart conditions within six months prior to screening or prior to randomization.

Trial Status. The Phase III study of PB-119 was initiated in November 2020 and completed in April 2023 in China.

Efficacy data. The study demonstrated that PB-119 combined with metformin can effectively lower glucose and maintain a high HbA1c level for 52 weeks. In particular, the key efficacy data for the study included but not limited to:

HbA1c value: The mean (SD) baseline HbA1c values were 8.48 (0.863)% and 8.46 (0.790)% in the PB-119 treatment and placebo treatment groups, respectively. At week 4, PB-119 led to a significantly superior reduction in HbA1c to placebo (-0.72% (95%CI, -0.78 to -0.67) vs -0.28% (95%CI, -0.34 to -0.23); $p < 0.001$). Approximately 73% (218/297) of patients in the PB-119 group achieved >0.5% reduction in HbA1c at week 4 from the baseline levels. HbA1c rapidly decreased to 7.76% (0.85) by week 4 of PB-119 treatment, and the change from baseline was significantly greater than that in the placebo treatment group (8.16% (0.93)). At the end of the 24-week double-blind treatment period, HbA1c was 7.22 (0.880)% in the PB-119 treatment group and 7.73 (0.872)% in the placebo treatment group, and the least squares means of changes from baseline (95% CI) were -1.27 (-1.37, -1.16)% and -0.70 (-0.80, -0.60)% respectively. the differences between the two treatment groups were statistically significant (the least squares mean 95% CI -0.57 (-0.71, -0.43)%, $P < 0.001$). The study demonstrated that the reduction in HbA1c from baseline in the PB-119 treatment group was significantly better than that in the placebo treatment group. The treatment response was prolonged during the open-label extension treatment period, with a reduction of -1.19% (-1.32 to -1.05) from baseline at week 52 in the PB-119 group ($p < 0.001$).

Changes in proportion of patients achieving HbA1c <7%: At 4-week of double-blind treatment, the proportion of patients achieving HbA1c <7% in the PB-119 treatment group was 15.8% (47 cases). At 24-week of double-blind treatment, the proportion of patients achieving HbA1c <7% in the PB-119 treatment group was 40.5% (115 cases), that was significantly higher than 17.9% (50 cases) in the placebo treatment group, with a statistically significant difference ($p < 0.05$). At 52 weeks, the proportion of patients achieving HbA1c <7%, who were in the PB-119 in addition to metformin hydrochloride treatment group during the 24-week of double-blind treatment period and received PB-119 in addition to metformin hydrochloride during the 28-week open extension treatment period (the “**PB-119 — PB-119 treatment group**”), was 37.9%, remaining stable compared with 40.5% in 24 weeks. In addition, the proportion of patients achieving HbA1c <7%, who switched from the placebo in addition to metformin hydrochloride treatment group during the 24-week of double-blind treatment period to PB-119 in addition to metformin hydrochloride treatment during the 28-week open extension

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treatment period (the “**placebo — PB-119 treatment group**”), increased to 45.2% compared to 17.9% in 24 weeks, slightly higher than the proportion in the PB-119 treatment group at 24 weeks (40.5%) in the 24-week double-blind period.

Safety data. PB-119 was safe and generally well tolerated. The majority of treatment emergent adverse events (“**TEAEs**”) were mild to moderate. The most common AEs were gastrointestinal reactions such as nausea, vomiting and diarrhea, with low incidence and mild reaction. The gastrointestinal adverse reaction was transient and well tolerated. Most of AEs occurred within the first four weeks of treatment and resolved with continuation of treatment with decreased incidence or disappearance after eight weeks of treatment. More importantly, the incidence of gastrointestinal disorders in the double-blind PB-119 group was 20.0% (62/310), with nausea at 4.2%, vomiting at 4.8%, and diarrhea at 7.4%. Among comparable marketed weekly formulations GLP-1 receptor agonists, the incidence of nausea, vomiting, and diarrhea are 13.4%, 6.6% and 16.9% in the 1 mg semaglutide in combination with metformin treatment study, 17%, 12%, and 13% in the 1.5 mg dulaglutide in combination with metformin treatment study, respectively, according to publicly available clinical trial results. Thus, PB-119 led to relatively low gastrointestinal TEAEs, taking into account published results of other GLP-1 receptor agonists, although no head-to-head comparisons were conducted in the clinical trials of PB-119. We may consider conducting head-to-head clinical studies of PB-119 in the future against then-major competing products on the market to demonstrate the comparative advantages of PB-119. In addition, the incidence of hypoglycemic events was low and no severe hypoglycemia occurred. No patients were terminated or withdrawn from the study due to hypoglycemic events. The incidence of localized injection site reactions was low, most of which occurred within the first four weeks of treatment. No patients were terminated or withdrawn from the study due to localized injection site reactions.

Commercialization and Clinical Development Plan

Commercialization Plan

Leveraging our regulatory experiences, we plan to rapidly advance the development of PB-119 towards commercialization. We expect to receive the NDA approval from the NMPA and commercially launch PB-119 for the treatment of T2DM in China in 2025.

Considering the marketing and sales expenses and the relevant expertise required, we entered into a commercialization collaboration arrangement on September 13, 2024 with a leading domestic commercialization-stage pharmaceutical company regarding the future marketing and commercialization activities of PB-119 in Mainland China. The commercialization partner is one of the largest distributors of, and a leading provider of supply chain services for, pharmaceutical and healthcare products and operates one of the largest national pharmaceutical distribution networks in China. With such commercialization arrangement, we expect to benefit from its long-term expertise and skills in adapting to the fast-changing China healthcare environment, excellent market entry capability to offer comprehensive coverage for a range of products and widespread sales network reaching both high-end and low-end markets to ensure wide market coverage across China.

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By working with third-party commercialization partners, we expect to secure the potential of future fast commercialization and market share growth. Moreover, we plan to conduct more academic marketing activities to improve communication and cooperation with hospitals, doctors and KOLs to increase market recognition of our brand and products. We will also strive to improve product accessibility by seeking reimbursement listings in the NRDL and other state-funded medical insurance programs at suitable price levels.

As PB-119 had not been approved for commercialization, and when such approval can be obtained remains uncertain, we had not initiated commercial production of PB-119 as of the Latest Practicable Date. We plan to continue to collaborate with CDMO partners for the commercial production of PB-119, which will mainly consist of raw material production and formulation production, and we expect to scale up the current in-house and external manufacturing activities to achieve the commercial scale. For raw materials, we intend to continue manufacturing the PEG molecules in-house, leveraging our expertise in and proven track record of generating such molecules, and outsourcing peptide productions to third-party service provider. We currently plan to expand the collaborations with our suppliers, and we plan to initiate relevant negotiations when we have more clarity on when PB-119 may be approved for commercialization. We do not foresee any major obstacles to reach an agreement with our suppliers to scale up the raw material and service supplies to meet our commercial production needs. We plan to prepare raw materials in advance according to the production plan to enable continuous on-rolling production, with an estimated maximum annual production capacity over 10 million units of PB-119. We expect to achieve the estimated production capacity in a step-wise fashion, taking into account our actual commercialization plan for a particular year reflecting the market needs and our market position, both of which will be closely tracked and analyzed once PB-119 is commercialized. We anticipate to achieve our future production plans by leveraging our in-house capacity and external resources, as we believe there are sufficient manufacturing capacities by potential service suppliers on the market.

We plan to take comprehensive quality control measures that adhere to GMP standards during the process, including but not limited to, reviewing inspection reports from raw material manufacturers, internal inspections before raw materials are released for PB-119 production, and sampling tests of PB-119 final products for compliance with the quality standards approved by regulatory authorities before releasing for market sales. In light of our in-depth understanding of the PEGylation technology and PB-119, we do not expect to encounter any material issues in relation to the commercial production or, if required, technology transfer.

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Clinical Development Plan

In China, upon receiving the NDA approval of PB-119, we plan to initiate two more Phase III clinical trials for combination therapies of PB-119 with either basal insulin (PB119-303) to evaluate the efficacy and safety of PB-119 in T2DM patients with poor glycemic control treated with insulin glargine or with SGLT-2 inhibitor (PB119-304) to evaluate the efficacy and safety of PB-119 in T2DM patients with poor glycemic control after dapagliflozin monotherapy, and one Phase III clinical trial (PB119-305) for PB-119 to evaluate cardiovascular outcomes in T2DM patients in 2026. In addition, we may also consider conducting head-to-head clinical studies of PB-119 in the future against then-major competing products on the market to demonstrate the comparative advantages of PB-119.

PB119-303 is a multicenter, randomized, double-blind, parallel, placebo-controlled Phase III clinical trial to evaluate the efficacy and safety of PB-119 in T2DM patients with poor glycemic control treated with insulin glargine (with or without metformin). The primary objective for this study is to evaluate the efficacy of 150 µg of PB-119 in combination with insulin glargine (with or without metformin) compared with placebo in the treatment of T2DM patients with poor glycemic control treated with insulin glargine (with or without metformin), by measuring the changes in HbA1c at 24 weeks of treatment compared with baseline. The primary efficacy endpoint of this study is the change in HbA1c values relative to baseline at the end of the 24-week double-blind treatment period. We were preparing an IND application for this clinical trial as of the Latest Practicable Date and we plan to submit the IND application to the NMPA in the second half of 2025. We plan to initiate the PB119-303 clinical trial in 2026 and submit the supplemental NDA to the NMPA in 2028.

PB119-304 is a multicenter, randomized, double-blind, parallel, placebo-controlled Phase III clinical trial evaluating the efficacy and safety of PB-119 in T2DM patients with poor glycemic control after dapagliflozin monotherapy. The primary objective for this study is to evaluate the efficacy of 150 µg PB-119 in combination with dapagliflozin, an SGLT-2 inhibitor, compared to placebo for T2DM patients with poor glycemic control after dapagliflozin monotherapy, by measuring the changes in HbA1c at 24 weeks of treatment compared with baseline. The primary efficacy endpoint of this study is the change in HbA1c values relative to baseline at the end of the 24-week double-blind treatment period. We were preparing an IND application for this clinical trial as of the Latest Practicable Date and we plan to submit the IND application to the NMPA in the second half of 2025. We plan to initiate the PB119-304 clinical trial in 2026 and submit the supplemental NDA to the NMPA in 2028.

PB119-305 is a long-term, multicenter, randomized, double-blind, placebo-controlled Phase III clinical trial to evaluate the effects of PB-119 on cardiovascular outcomes in T2DM patients. The primary objective for this study is to validate that, compared with placebo, the addition of PB-119 to current glucose-lowering therapy reduces the risk of major adverse cardiovascular events in T2DM patients, including complex cardiovascular related death, nonfatal myocardial infarction, or nonfatal stroke. The primary endpoint of this study is the reduction of the risk of major adverse cardiovascular events in T2DM patients. We received the IND approval from the NMPA for this clinical trial in August 2021.

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In June 2021, the NMPA approved our IND application of PB-119 for the treatment of obesity in China. We finalized the clinical trial protocol in February 2024 and received the approval from the NMPA to commence the clinical trial in April 2024. We are initiating a randomized, double-blind, placebo-controlled, multiple ascending dose Phase Ib/IIa clinical trial to evaluate the safety, tolerability and PK profiles of PB-119 in Chinese obese participants, and we completed participant enrollment in June 2024. The primary objective is to evaluate the safety and tolerability of PB-119 on obese participants in China. The secondary objectives include to evaluate the efficacy, immunogenicity, PK and PD profiles of PB-119 on obese participants in China. The primary endpoint of this study is the change of body weight of obese participants relative to baseline at the end of the 20-week double-blind treatment period. The Phase Ib/IIa clinical trial is considered one complete clinical trial instead of two separate trials.

We enrolled 32 obese participants in the ascending dose cohort. According to the protocol, the experiment group to receive PB-119 consists of 24 randomized participants and the placebo group consists of the other eight randomized participants. Subject to the clinical trial results of the ascending dose cohort, we may further enroll additional obese participants in an optimized dose cohort.

The participants will receive a series of ascending dose once-weekly subcutaneous injection of test drug if the cohort satisfies the pre-determined dose escalation standards. Specifically, the participants will receive PB-119 or placebo QW with various doses for a 20-week treatment period. The participants will then enter a 4-week safety follow-up period after their respective final dosing.

Subject to the Phase Ib/IIa clinical trial results, we intend to further advance the clinical development of PB-119 for the treatment of obesity in China by conducting potential Phase II and/or Phase III clinical trials in accordance with the plan that we will formulate. Taking into account its development status in China, we may also expand the clinical development of PB-119 in other jurisdictions.

Furthermore, GLP-1 receptor agonists are also shown to lower inflammation and oxidative stress in the brain, which in turns could potentially enhance nerve growth and reduce the accumulation of proteins associated with Alzheimer’s disease. Thus, we believe that PB-119 may serve as a potential treatment method for Alzheimer’s disease and plan to investigate and expand PB-119 for the treatment of such indication.

Based on available data from preclinical and clinical studies, we do not expect to include any contraindications for PB-119, and therefore we do not anticipate the market potential of PB-119 to be negatively affected by any contraindications.

We had not received any relevant regulatory agency’s objections to our clinical development plans as of the Latest Practicable Date.

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Licenses, Rights and Obligations

We internally discovered and developed PB-119, and maintain the global rights to develop and commercialize this drug candidate.

On June 29, 2017, we entered into an agreement with TSL HK (the “**TSL Agreement**”), pursuant to which we irrevocably granted to TSL HK the right of first refusal of exclusive commercialization rights of PB-119 and PB-718 in Mainland China. Pursuant to the terms of the TSL Agreement, we are required to send a written notice to TSL HK after completion of Phase III clinical trials and prior to filing the marketing authorization applications with the NMPA for PB-119 and PB-718, respectively (the “**First Refusal Notice**”). The First Refusal Notice shall set forth terms and conditions of commercialization offered by a third party procured by us. TSL HK could exercise its right of first refusal within the agreed period after receipt of the First Refusal Notice, provided that it must match the terms and conditions offered by the third party as provided in the First Refusal Notice.

In May 2023, in accordance with the TSL Agreement and based on mutual agreements, the right of first refusal of the exclusive commercialization of PB-119 of TSL HK was terminated. This was primarily due to commercial reasons and prioritization in strategic focus of TSL HK. TSL HK will not be involved in the commercialization of PB-119 in China thereafter. The right of first refusal of the exclusive commercialization of PB-718 of TSL HK was not affected by such termination. See “— Clinical-stage Products — PB-718, a long-acting GLP-1/GCG dual receptor agonist — Licenses, Rights and Obligations.”

On September 13, 2024, we entered into a commercialization collaboration arrangement with a leading domestic commercialization-stage pharmaceutical company in China for PB-119. With such commercialization arrangement, we expect to benefit from its decades of market experience and know-how in navigating through the rapidly evolving China healthcare landscape, market access ability to provide umbrella coverage for a portfolio of products and sales network covering both higher- and lower-tier markets to enable broad market penetration across China. We believe that the collaboration will establish a solid foundation for our future commercialization. For additional information, see “— Commercialization — Collaboration Agreement for Commercializing PB-119 in Mainland China.”

Material Communications with Competent Authorities

For T2DM studies in China, we have completed three Phase I clinical trials (ICP-I-2013-08, ICP-I-2014-07, and ICP-I-2015-01) and the NMPA had no objection for us to commence our subsequent Phase II clinical trial in China. We have further completed one Phase II clinical trial (PB119-201) for T2DM in China and the NMPA confirmed no objection to commence Phase III clinical trials.

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In July 2023, we submitted the NDA of PB-119 for the treatment of T2DM in China to the NMPA. As part of the NDA, we submitted materials regarding multiple clinical trials for the treatment of T2DM we had conducted for PB-119, including seven Phase I clinical trials (ICP-I-2013-08, ICP-I-2014-07, ICP-I-2015-01, CSP-PB119-US01-01, PB119-107, PB119-108, and PB119-109), two Phase II clinical trials (PB119-201 and PB119-202), and two Phase III clinical trials (PB119-301 and PB119-302). The materials we submitted included multiple safety (including the occurrences of adverse events) and efficacy parameters measured in such clinical trials. For ICP-I-2013-08, ICP-I-2014-07, ICP-I-2015-01 and CSP-PB119-US01-01 Phase I clinical trials, the major parameters measured were safety and tolerability parameters, PK and PD profiles of PB-119 administration. For PB119-107, PB119-108 and PB119-109 Phase I clinical trials, the major parameters measured were PK profiles after PB-119 administration, and PK profiles of other corresponding drugs before and after PB-119 administration. For PB119-201 and PB119-202 Phase II clinical trials, the major parameters measured were the change of HbA1c levels after administration of PB-119 as compared to the baselines, as well as other efficacy and safety parameters. For PB119-301 and PB119-302 Phase III clinical trials, the major parameters measured were the change of HbA1c levels after administration of PB-119 as compared to the baselines, as well as other efficacy and safety parameters. For details of the parameters (and statistical power where applicable) we measured and submitted to the NMPA regarding such clinical trials, see the tables presented under “— Core Product PB-119, a near-commercialized, long-acting GLP-1 receptor agonist — Summary of Clinical Trials of PB-119.” The NMPA accepted the NDA of PB-119 for the treatment of T2DM in September 2023 without raising any material issue with the materials we submitted and did not require any revision or impose any condition impacting the NDA submission. We do not expect the application or approval status of such NDA to adversely affect our future IND applications and/or NDAs for other indications of PB-119 in China.

On October 22, 2024, the NMPA issued a notification to us to supplement certain requested information on pharmacy and clinical pharmacology before our NDA can be approved. As of the Latest Practicable Date, we have submitted the responses to the notification issued by the NMPA.

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The following table sets forth details of our material communications with competent authorities for our ongoing and completed clinical trials. Overall, the competent authorities did not require any revisions or impose any conditions impacting the expected major safety and efficacy parameters as stated in the IND application or the overall design of the ongoing and completed clinical trials, and their suggestions of focus (if any) are included below where applicable.

Study	Study number	Phase	Competent authorities	Study sites	IND approval date		Details of communications	Status
T2DM	ICP-I-2013-08	Ia ⁽¹⁾	NMPA	China	September 2013	(1)	We filed IND application with the NMPA for the clinical development of PB-119, the NMPA accepted our IND application in April 2012.	Completed
	ICP-I-2014-07	Ib ⁽¹⁾	NMPA	China				Completed
	ICP-I-2015-01	Ic ⁽¹⁾	NMPA	China				Completed
	PB119-107	I ⁽²⁾	NMPA	China	September 2013 and September 2017	(2)	In September 2013, the NMPA issued IND approval for us to commence the Phase I clinical development of PB-119, required us to submit report on pharmacological studies annually upon approval to commence Phase I and Phase II clinical trials, and recommended us to communicate with the NMPA regarding relevant issues of pharmacological study before Phase III study, with no recommended material revisions to the study protocol or design and recommended us to monitor the potential renal safety risks and immunogenicity. The Phase I clinical development was conducted with PB-119 as a monotherapy.	Completed
	PB119-108	I ⁽²⁾	NMPA	China				Completed
	PB119-109	I ⁽²⁾	NMPA	China				Completed
	PB119-201	II	NMPA	China				Completed
	PB119-301	III	NMPA	China				Completed
	PB119-302	III	NMPA	China				Completed
						(3)	After completion of Phase Ia/Ib/Ic clinical trials (ICP-I-2013-08, ICP-I-2014-07 and ICP-I-2015-01), we submitted a Phase II/III clinical trial application to the NMPA of PB-119. The clinical trial application also included optimized quality standards we voluntarily adopted. The NMPA accepted our application in June 2017.	
						(4)	In September 2017, following its review of the clinical trial results of our Phase I clinical trials, the NMPA issued an umbrella IND approval for Phase II and Phase III clinical trials, required us to communicate with the NMPA regarding pharmacological studies prior to commencing the Phase III clinical trial, and recommended us to communicate with the NMPA regarding clinical studies at key points during the clinical development or prior to commencing the Phase III clinical trial. The NMPA also asked us to continue to complete the pharmacological studies included in the IND approval issued in September 2013. The NMPA did not raise any material issue or recommendation to the study protocol or design and recommended us to monitor the potential safety risks.	

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Study	Study number	Phase	Competent authorities	Study sites	IND approval date	Details of communications	Status
	PB119-303	III	NMPA	China	IND application to be submitted to the NMPA	(5) We completed the Phase II clinical trial (PB119-201). (6) In January 2020, we applied for a communication meeting with the NMPA regarding the commencement of two Phase III clinical trials (PB119-301 and PB119-302). The CDE reviewed the completed clinical trial results and we communicated with the CDE on our plan for the two Phase III clinical trials. The NMPA subsequently confirmed in writing with no objection to the commencement of the two Phase III clinical trials, with no recommended material revisions to the study protocol or design. The NMPA confirmed the dosages of PB-119 included in the design of the two Phase III clinical trials were acceptable and recommended us to continue the investigation of the relationship between dosage levels and efficacy profiles of PB-119.	To be initiated in 2026
	PB119-304	III	NMPA	China	IND application to be submitted to the NMPA		To be initiated in 2026
	PB119-305	III	NMPA	China	August 2021	(7) We completed the two Phase III clinical trials (PB119-301 and PB119-302). (8) In June 2021, we filed IND application with the NMPA for Phase III clinical trial (PB119-305). (9) The CDE reviewed the completed clinical trial results and our plan for the Phase III clinical trial. In August 2021, the NMPA issued the IND approval for the Phase III clinical trial (PB119-305), with no recommended material revisions to the study protocol or design. The NMPA recommended us to monitor the potential safety risks and risk control of the cardiovascular outcomes according to relevant guidance principles. (10) We completed the other three Phase I trials (PB119-107, PB119-108, and PB119-109). (11) In July 2023, we submitted the NDA of PB-119 for the treatment of T2DM in China to the NMPA, which was accepted by the NMPA in September 2023. (12) We plan to apply new IND approvals for the two Phase III clinical trials (PB119-303, PB119-304) and initiate the three Phase III clinical trials (PB119-303, PB119-304, and PB119-305) after the NDA approval for T2DM. ⁽³⁾	To be initiated in 2026

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Notes:

- (1) We conducted the three Phase I clinical trials with different protocols to evaluate safety, tolerability, PK and PD for PB-119. The ICP-I-2013-08 trial is the randomized, blinded, placebo-controlled, and single ascending dose study, the ICP-I-2014-07 trial is the randomized, open-label, and multiple ascending doses study, and the ICP-I-2015-01 trial is the randomized, open-label, positive-controlled, parallel multiple dose study to evaluate safety, tolerability, PK, and PD of PB-119 in drug naïve T2DM patients.
- (2) We conducted the three Phase I clinical trials with different protocols. The three Phase I clinical trials are all studies for special populations and thus they do not affect the Phase II and Phase III studies and NDA approval. The PB119-107 trial is to evaluate PK interaction between PB-119 and rosuvastatin calcium tablets or valsartan capsules in healthy participants; the PB119-108 is to evaluate PK interaction between PB-119 and digoxin tablets or warfarin sodium tablets in healthy participants; and the PB119-109 is to evaluate PK characteristics of PB-119 in participants with different degrees of renal insufficiency and matched participants with normal renal function. We conducted PB119-107 and PB119-108 trials to evaluate the drug-drug interactions with statin drugs and warfarin sodium tablets, respectively, according to the Technical Guidelines for Drug Interaction Studies issued by the NMPA in 2021; and conducted PB119-109 trial to evaluate the PK characteristics of PB-119 in patients with different degrees of renal insufficiency and matched participants with normal renal function.
- (3) We plan to initiate three more Phase III clinical trials (PB119-303, PB119-304, and PB119-305) with different protocols in 2026, in order to further evaluate the safety and efficacy for PB-119 monotherapy and combination therapy. PB119-303 is a multicenter, randomized, double-blind, parallel, placebo-controlled study to evaluate the efficacy and safety of PB-119 in T2DM patients with poor glycemic control treated with insulin glargine (with or without metformin); PB119-304 is a multicenter, randomized, double-blind, parallel, placebo-controlled study evaluating the efficacy and safety of PB-119 in T2DM patients with poor glycemic control after dagliflozin monotherapy; and PB119-305 is a long-term, multicenter, randomized, double-blind, placebo-controlled study to evaluate the effects of PB-119 on cardiovascular outcomes in T2DM patients. We plan to apply new IND approvals for PB119-303 and PB119-304 in accordance with Measures for the Administration of Drug Registration issued in 2020 because the two Phase III clinical trials plan to use the combination therapy of PB-119 and insulin glargine or dagliflozin. We strategically plan to initiate long-term studies such as the PB119-305 clinical trial after receiving the NDA approval of PB-119 for its lead indication T2DM.

For T2DM studies in the United States, we filed an IND application with the FDA for the Phase I clinical trial (CSP-PB-119-US01-01) and the overall clinical trial designs in May 2015. The FDA did not have any comments, objections or clinical holds during the 30-day clearance period. We initiated the Phase I clinical trial in November 2015 and completed it in July 2016. We did not receive any objections from the FDA regarding the commencement of the Phase II clinical trial (PB119-202), and we initiated the clinical trial in June 2018 and completed it in July 2019. We also had a type C guidance meeting with the FDA in January 2022, during which the FDA provided guidance and recommendations for the design of pivotal Phase III clinical trials of PB-119 in the United States. We intend to finalize the clinical development plan in the United States and conduct Phase III clinical trials of PB-119 for the treatment of T2DM in collaboration with a reputable local partner, considering the financial resources required for such clinical trials. As of the Latest Practicable Date, we had not identified or was in negotiation with any local partner in the United States for such purpose. We currently plan to seek out-licensing and/or co-development opportunities with such local partner, and we expect the primary source of income to receive upon PB-119's commercial launch in the United States would be royalty incomes. Subsequent to the Phase III clinical trials, we also intend to formulate a detailed commercialization plan for PB-119 in the United States.

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Based on the clinical trials completed, our clinical development demonstrates that for T2DM, PB-119 has been developed beyond concept stage, because either in China or the United States, we have completed Phase I clinical trial for PB-119, respectively, and the competent authorities had no objections for us to initiate Phase II clinical trials of PB-119 for the treatment of T2DM. We have also completed Phase II and Phase III clinical trials of PB-119 for the treatment of T2DM in China.

In June 2021, the NMPA also approved our IND application of PB-119 for the treatment of obesity in China with no recommended material revisions to the study protocol or design, and recommended us to monitor the potential safety risks. We strategically focused our resources to advance PB-119 for its lead indication T2DM to establish PB-119 and ourselves in the market first. After our NDA of PB-119 for the treatment of T2DM was accepted by the NMPA in September 2023, we promptly finalized the clinical trial protocol of PB-119 for the treatment of obesity in February 2024 and received the approval from the NMPA to commence the clinical trial in April 2024. We are initiating a randomized, double-blind, placebo-controlled, multiple ascending dose Phase Ib/IIa clinical trial to evaluate the safety, tolerability and PK profiles of PB-119 in Chinese obese participants, and we completed participant enrollment in June 2024.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET PB-119 SUCCESSFULLY.

CLINICAL-STAGE PRODUCTS

PB-718, a long-acting GLP-1/GCG dual receptor agonist

Overview

PB-718 is a novel long-acting GLP-1/glucagon (“**GCG**”) dual receptor agonist primarily designed for the treatment of obesity and NASH. PB-718 simultaneously activates both the GLP-1 and GCG receptors. This dual activation leads to a synergistic effect that surpasses the efficacy of either receptor agonist alone, characterized by significant weight loss and reduced appetite. Composed of a combination of GLP-1 receptor agonist and GCG receptor agonist, we believe that PB-718 may offer the flexibility of balancing the activation of GLP-1/GCG receptors to achieve optimal efficacy and safety profiles. This is because complementary mechanisms of action provide the opportunity to achieve earlier and more sustainable glycemic control with increased patient adherence and reduced side-effect profiles. There is also the potential to reduce disease progression and vascular complication risk. In addition, our preliminary study results showed that PB-718 decreased lipid accumulation in liver which prevents hepatic inflammation and subsequent liver fibrosis.

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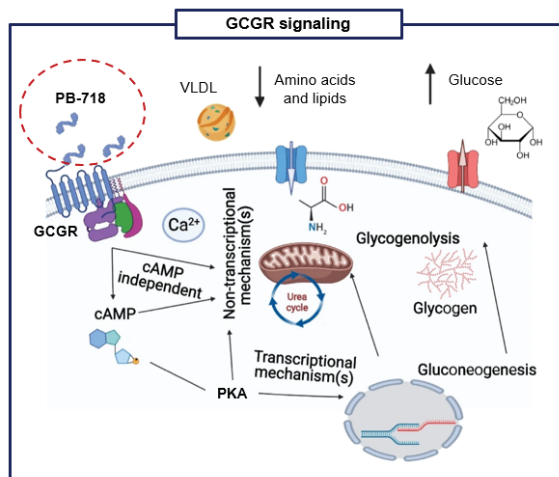
We also applied PEGylation to extend the half-life of PB-718, thereby reducing the dosing frequency to just once a week, which we believe could similarly enhance the patient compliance and convenience of administration. We completed a Phase I clinical trial (PB718-001) for PB-718 on healthy participants in the United States which demonstrated good safety and efficacy profiles of PB-718. We have also completed the participant follow-up for a Phase Ib/IIa clinical trial to evaluate PB-718 for the treatment of obese patients in China.

Mechanism of Action

MOA of PB-718 for Obesity and NASH

The activation of GLP-1 receptors in the hypothalamus inhibits satiety and reduces stomach motility leading to body weight loss, while their activation in pancreatic β cells promotes glucose-dependent insulin secretion resulting in lowering of plasma glucose. Meanwhile, glucagon is a peptide hormone that raises blood sugar levels and activation of GCG receptors in the liver and adipose tissues increases lipolysis and energy expenditure while promoting glycogen hydrolysis in the liver, resulting in the increase of hepatic glucose output. Through balancing the activation of the two receptors, synergistic or additive pharmacology effects could be achieved, including weight loss, improvement in lipid profiles and eventually, amelioration of NASH, while not compromising glycemic control benefits from GLP-1 activation. Compared to a single molecule approach, PB-718 potentially offers the flexibility of balancing the activation of GLP-1 receptors and GCG receptors through adjusting their molar ratios to achieve optimal efficacy and safety profiles.

The following diagram demonstrates mechanism of action of PB-718 regarding how a GCG receptor agonist activates the GCG signaling pathway. For details of functions of a GLP-1 receptor agonist and its activation of the GLP-1 signaling pathway, see “— Core Product — Core Product PB-119, a near-commercialized, long-acting GLP-1 receptor agonist — Mechanism of Action.”



Source: *Diabetologia*, CIC report

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Market Opportunity and Competition

NASH

NASH is an advanced form of non-alcoholic fatty liver disease, which is caused by abnormal accumulation of fat in the liver. Such excessive fat causes inflammation and damage that leads to NASH. The risk factors of NASH include, among others, T2DM, insulin resistance, obesity, high blood cholesterol and triglycerides, with a combination of which often simultaneously present in NASH patients. The prevalence of NASH in China is 41.5 million in 2023 and is expected to reach 50.8 million in 2032, with CAGR of 2.3%.

NASH is a chronic and progressive disease with Rezdiffra as the only FDA-approved treatment option as of the Latest Practicable Date, according to CIC. NASH patients are usually given lifestyle intervention and certain drugs depending on the risk levels, including T2DM drugs and Vitamin E. The medical needs persist particularly for patients with relatively advanced NASH symptoms, where severe liver damage including fibrosis and cirrhosis are present, which are usually irreversible in nature without effective treatment options. According to CIC, as of the Latest Practicable Date, there was no GLP-1 receptor-targeted drug approved specifically for the treatment of NASH globally. In March 2024, resmetirom, a thyroid hormone receptor β -selective agonist developed by Madrigal Pharmaceuticals Inc., became the first drug receiving marketing approval from the FDA for the treatment of NASH patients with moderate to advanced liver fibrosis. As of the Latest Practicable Date, there were a number of product candidates under clinical development in the United States, 10 of which were GLP-1 receptor-targeted. There were five GLP-1 receptor-targeted drug candidates under clinical development for the treatment of NASH in China, as of the same date.

Obesity

Obesity is also a non-neglectable public health issue in China and globally, which is sometimes associated with other metabolic diseases such as NASH as well. According to CIC, as of the Latest Practicable Date, there were seven GLP-1/GCG dual receptor agonist candidates under clinical development for the treatment of obesity in the United States. As of the Latest Practicable Date, there were three GLP-1/GCG dual receptor agonist candidates under clinical development for the treatment of obesity in China.

Our Advantages

We believe that PB-718 has the following advantages:

Optimal Fine-tuning of Dual Receptors Activation Level

Simultaneous activation of GLP-1 receptor and GCG receptor achieves superior effects through their synergistic mechanisms compared to agonists for either receptor alone. The synergy is influenced by the relative activation levels of GLP-1 receptor and GCG receptor *in vivo*. Maximizing the synergy of downstream signaling pathways mediated by both receptors at appropriate activation levels optimally improves weight and metabolic-related obesity and fatty liver disease. PB-718 was selected from multiple candidates to achieve optimal receptor activation, aiming to maximize weight loss and disease improvements while maintaining a strong safety profile. The optimal activation levels of both receptors *in vivo* contribute to PB-718's good safety and efficacy results in clinical and preclinical research.

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Inducing Weight Loss and Improvement in NASH

Preclinical studies conducted in various animal models of NASH, including mice with metabolism-related fatty liver disease induced by high-fat and high-sugar diet and spontaneous metabolism-related fatty liver disease in rhesus monkeys, demonstrate significant weight reduction and improvement in liver histopathological changes and fibrosis with PB-718.

In a mouse model of obesity and NASH induced by a high-fat and high-sugar diet, repeated administration of PB-718 for four months significantly inhibited animal weight gain, improved lipid metabolism and liver function, and ameliorated pathological changes such as liver cell steatosis, ballooning, and fibrosis. Compared to the negative control group, a dose of 10 nmol/kg PB-718 after four months of repeated administration led to a 35% reduction in body weight, a decrease of 2.5 points in NAS score, and a significantly lower fibrosis score than the negative control group.

Moreover, repeated administration of PB-718 to rhesus monkeys with spontaneous NASH showed dose-dependent reduction in monkey weight, lowering of blood lipid levels, reduction of liver fat accumulation, and improvement in liver cell steatosis. After eight weeks of once-a-week administration, doses of 7.5 µg/kg and 15 µg/kg PB-718 significantly reduced rhesus monkey weight by approximately 11% and 9%, respectively, compared to the placebo group. Additionally, PB-718 significantly improved serum lipid metabolism indicators, including total cholesterol and low-density lipoprotein. Animals in the PB-718 group exhibited a significant decrease in liver NAS score compared to the placebo group. Thus, preclinical study results validated the superior efficacy of PB-718 over single receptor agonists in animal models, providing crucial evidence for further clinical validation of PB-718’s effectiveness in improving metabolism-related fatty liver disease.

Reduced Dosing Frequency and Improved Patient Compliance

NASH patients often require long-term treatment and intervention in lifestyles, which pose significant burden and negatively impact the life qualities of such patients. As a novel drug candidate, PB-718 is able to maintain a relatively stable level *in vivo* which enables a once-weekly administration route. The reduction in administration frequency potentially assuages the inconvenience from frequent dosages. The enhanced patient compliance could further contribute to an optimal plasma drug level and bring significant clinical benefits to NASH patients.

Summary of Clinical Trials of PB-718

We have completed a Phase I clinical trial (PB718-001) of PB-718 on healthy participants in the United States in May 2022 which showed good safety and PK profiles of PB-718. PB-718 was also shown to have promising weight loss effects on these participants. We also completed the participant follow-up of a Phase Ib/IIa clinical trial (PB718-101) to evaluate the safety, tolerability and preliminary efficacy of PB-718 on obese participants in China in April 2024.

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The following table sets forth an overview of results of key clinical studies of PB-718:

Study	Key Enrollment Criteria	Number of Participants Enrolled	Participating site(s) and PI	Endpoints	TEAE Reported (Mild/Moderate/ Severe/Life Threatening)	Frequently Occurring TEAE (Number of Subjects)	Reasons for Discontinuation ⁽¹⁾	Material Results
PB718-001	Healthy adult participants	82	Covance Clinical Research Unit Inc., the United States	Safety, tolerability, PK and PD parameters	Part A: Placebo: 3/0/0/0 PB-718: 37/9/0/1	Part A: Gastrointestinal disorder (Placebo/PB-718: 2/13)	Two participants due to TEAEs (coronavirus infection), one participant withdrew consent and one participant was lost to follow-up	PB-718 was considered safe and well tolerated when administered as single doses and multiple doses up to 400 µg
			PI: Hugh A. Coleman, DO		Part B: Placebo: 1/0/0/0 PB-718: 32/14/0/0	Dizziness (Placebo/PB-718: 2/2)		
						Part B: Gastrointestinal disorder (PB-718: 11) Headache (Placebo/PB-718: 1/5) Decreased appetite (PB-718: 3)		

(1) Such discontinuation had no material impact on the progress of the respective clinical trials.

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PB718-001: A Phase I, randomized, double-blind, placebo-controlled, single- and multiple-dose escalating study to evaluate the safety, tolerability, PK and PD profiles of PB-718 following subcutaneous administration in healthy participants in the United States

Overview. This was a Phase I, randomized, double-blind, placebo-controlled, single- and multiple-dose escalating study to evaluate the safety, tolerability, PK and PD profiles of PB-718 on healthy participants in the United States. The primary objective was to evaluate the safety and tolerability of single- and multiple-doses of PB-718 subcutaneous injection in healthy participants. The secondary objectives included the evaluation of the PK and PD profiles of single- and multiple-dose of PB-718 subcutaneous injection. The primary safety and tolerability endpoints included, among others, incidence, causality, and severity of AEs and incidence of laboratory abnormalities, based on hematology, clinical chemistry and urinalysis test results. The secondary endpoints included, among others, a series of PK outcome endpoints and a series of PD endpoints of PB-718. The endpoints were established to study the characteristics of PB-718 and determine the doses to be studied in subsequent clinical trials.

Trial design. Part A of this Phase I clinical trial comprised a single dose, sequential group design. Overall, 55 healthy participants were randomized and divided equally into seven groups (A1 to A7). Group A6 enrolled seven participants while the other groups enrolled eight participants each. Each participant participated in one treatment period only and resided at the clinical research unit ("CRU") from Day-2 (two days before first dose administration) to Day 15. Participants attended a follow up visit on Day 28 (± 2 days).

In each of Groups A1 to A7, six participants were randomized to receive PB-718 and the other two participants (one participant for Group A6) were randomized to receive placebo. All doses were administered subcutaneously in the abdomen on Day 1. Participants were fasted for at least 10 hours prior to dosing until approximately 30 minutes post dose. There was a minimum of 10 days between dose escalations for each group.

Sentinel dosing occurred for all groups in Part A. Each group was divided into two cohorts, with the first cohort being dosed 96 hours before the second cohort. The first cohort comprised two participants, including one participant who received PB-718 and one participant who received placebo. The second cohort comprised six participants (five participants for Group A6), including five participants (four participants for Group A6) who received PB-718 and one participant who received placebo. Safety and tolerability of each completed dose were evaluated during the Safety Review Committee meeting. The A1 to A7 groups were dosed with escalating dosages of PB-718.

Part B of this Phase I clinical trial comprised a multiple dose, sequential group design. Overall, 27 participants were randomized and approximately equally divided in three groups (Groups B1 to B3), with each group consisting of nine, eight and 10 participants, respectively. Each participant was included in one treatment period only and resided at the CRU from Day 2 until Day 5, and then for 72 hours following dosing on Days 8, 15, and 22, respectively, such that each participant received four doses. Participants returned for non-residential visits between Days 7 and 50. The CRU contacted participants on Days 13 and 20. All participants attended a follow up visit 28 days (± 2 days) after their final dose.

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In each of Groups B1 to B3, seven, six and eight participants were randomized to receive PB-718, respectively, and the other two participants in each group were randomized to receive placebo. All doses were administered subcutaneously in the abdomen on Day 1, 8, 15, and 22. Participants were fasted for at least 10 hours prior to dosing until approximately 30 minutes post dose. The total daily dose administered in Part B did not exceed the highest single dose given in Part A that was shown to be safe and well tolerated. The B1 to B3 Groups were dosed with escalating dosages of PB-718. All doses are measured in the form of the GLP-1 receptor agonist.

Trial status. We initiated this Phase I clinical trial in July 2020 and completed the trial in May 2022 in the United States.

Safety data. One SAE of Grade 4 (life threatening) abortion induced was reported following administration of 5 µg PB-718; however, this event was not considered, by the investigator, to be related to test drug, and did not result in the discontinuation of the participant from the study. Two participants were discontinued from the study due to a TEAE; one participant for a TEAE of Grade 1 (mild) SARS-CoV-2 positive test result and one participant for a TEAE of Grade 2 (moderate) coronavirus infection. Both events leading to subject discontinuation were considered, by the investigator, to not be related to the test drug. The most commonly reported TEAEs were nausea and vomiting following singles doses of PB-718, which were similar following multiple doses of PB-718, where nausea, vomiting, headache, diarrhea, dyspepsia and decreased appetite were the most commonly reported TEAEs. Given the mechanism of action of PB-718, gastrointestinal disorders and metabolism and nutrition disorders were known and expected. There were no treatment- or dose-related trends and no clinically significant findings in the clinical laboratory evaluations, vital signs data, 12-lead ECG data, or physical examination findings during the study.

PK data. Following a single dose of PB-718, the GLP-1 receptor agonist appeared slowly in plasma, with a median $t_{\max}$ between 14 and 42 hours post dose, and was eliminated with a geometric mean $t_{1/2}$ of approximately 57.0 to 75.9 hours. The GCG receptor agonist also appeared slowly in plasma, with a median $t_{\max}$ between 10 and 24 hours post dose, and was eliminated with a geometric mean $t_{1/2}$ of approximately 27.5 to 36.7 hours.

Following multiple doses of PB-718 over the 100 µg to 400 µg dose range on Day 1, 8, 15, and 22, the GLP-1 receptor agonist and the GCG receptor agonist accumulation in plasma varied with dose, with accumulation ratios of 0.868-1.32 and 0.701-1.34, respectively. For the GLP-1 receptor agonist, the geometric mean $t_{1/2}$ was approximately 51.6 to 72.1 hours on Day 1 and 50.6 to 67.7 hours on Day 22. For the GCG receptor agonist, the geometric mean $t_{1/2}$ was approximately 29.5 to 33.6 hours on Day 1 and 29.5 to 33.3 hours on Day 22. Systemic exposure to the GLP-1 receptor agonist and the GCG receptor agonist following doses on Days 1, 8, 15, and 22 was found to be dose proportional over the 100 µg to 400 µg dose range.

Efficacy data. There were dose or treatment related trends on changes from baseline in body weight of healthy participants following multiple doses of PB-718. The largest mean decreases were 0.900 kg following a single dose of 200 µg PB-718 and 2.60 kg following multiple doses of 400 µg PB-718.

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Following a single dose of 200 µg PB-718, sustained decreases up to Day 15 were observed in mean ALT, ALP, and GGT (mean decreases from baseline ranging from 0.500 IU/L to 4.17 IU/L, 2.67 IU/L to 6.17 IU/L, and 5.50 IU/L to 5.83 IU/L, respectively). Following a single dose of 50 µg PB-718, sustained decreases up to Day 15 were observed in mean ALT, AST, cholinesterase, and GGT (mean decreases from baseline ranging from 1.33 IU/L to 6.00 IU/L, 1.50 IU/L to 2.83 IU/L, 27.0 IU/L to 93.5 IU/L, and 0.500 IU/L to 2.67 IU/L, respectively). Following single and multiple doses of PB-718 up to 400 µg decreases from baseline in the mean fasting plasma glucose were observed, although not in a dose-dependent manner. Furthermore, fasting and postprandial glucose also declined within 60 minutes post dose.

PB718-101: A Phase Ib/IIa, randomized, double-blind, placebo-controlled, multiple-dose escalating study to evaluate the safety, tolerability and PK profiles of PB-718 in obese participants in China

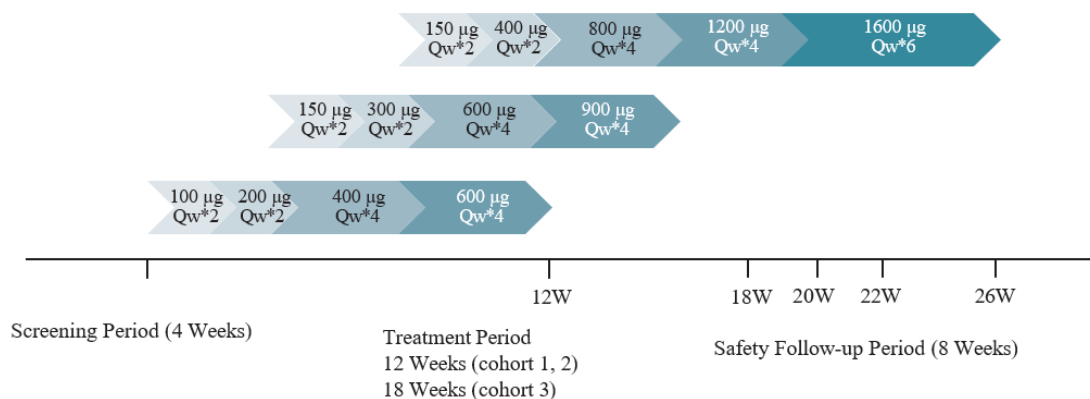
Overview. We have conducted a Phase Ib/IIa randomized, double-blind, placebo-controlled, multiple-dose escalating study to evaluate the safety, tolerability and PK profiles of PB-718 in obese participants in China. The primary objective is to evaluate the safety and tolerability of multiple-doses of PB-718 subcutaneous injection in obese participants. The secondary objectives include the evaluation of the PK profile of PB-718, the preliminary evaluation of efficacy of PB-718, and the evaluation of immunogenicity of PB-718 in obese participants. The exploratory objectives include the evaluation of the relationship between PB-718 exposure and its effects, the PD profile of PB-718, and the effects of PB-718 on the QT interval of obese participants.

Trial design. We enrolled 36 obese participants who were randomized and divided equally into three cohorts (Cohort 1, 2 and 3) with 12 participants each. Nine participants in each cohort were randomized to receive PB-718 and the other three participants were randomized to receive placebo. Cohorts 1 and 2 will receive a 12-week treatment and Cohort 3 will receive an 18-week treatment. Afterwards all three cohorts will have an 8-week safety follow up period. All doses are measured in the form of the GLP-1 receptor agonist.

For Cohort 1 and 2, the participants will receive the corresponding injections once a week on Day 1, 8, 15, 22, 29, 36, 43, 50, 57, 64, 71 and 78. Participants are required to be fasted for at least 10 hours prior to dosing. For Cohort 1, the participants are given doses of 100 µg for week 1 and 2, 200 µg for week 3 and 4, 400 µg for week 5 to 8, and 600 µg for week 9 to 12, respectively, given that the participant is well tolerated under each dosage before proceeding to the next dosage stage. For Cohort 2, the participants will start receiving dosages after week 4 when the participants in Cohort 1 have satisfied the pre-determined dose escalation standards. The participants of Cohort 2 are given doses of 150 µg for week 5 and 6, 300 µg for week 7 and 8, 600 µg for week 9 to 12, and 900 µg for week 13 to 16, respectively, given that the participant is well tolerated under each dosage before proceeding to the next dosage stage.

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For Cohort 3, the participants will start receiving dosages after week 8 when the participants in Cohort 2 have satisfied the pre-determined dose escalation standards. The participants of Cohort 3 are given doses of 150 µg for week 9 and 10, 400 µg for week 11 and 12, 800 µg for week 13 to 16, 1,200 µg for week 17 to 20, and 1,600 µg for week 21 to 26, respectively, given that the participant is well tolerated under each dosage before proceeding to the next dosage stage. The following diagram illustrates the dosing schedule and arrangements of Cohort 1, 2 and 3.



Source: Company data, clinical study report

The pre-determined dose escalation standards are met only when (1) 50% or fewer of the participants in each dosing level exhibit AEs with at least Grade 2 that are probably related to the test drug (PB-718 or placebo), (2) one third or fewer of the participants in each dosing level exhibit AEs with at least Grade 3 that are probably related to the test drug (PB-718 or placebo), and (3) none of the participants in each dosing level exhibit SAE that is probably related to the test drug (PB-718 or placebo).

Trial status. We initiated this Phase Ib/IIa clinical trial in July 2023 and we completed the participant follow-up of this Phase Ib/IIa clinical trial in April 2024.

Clinical Development Plan

For the obesity/overweight indication, we completed the participant follow-up of the Phase Ib/IIa clinical trial of PB-718 for the treatment of obesity in China in April 2024 and the final clinical study report is expected to be ready by the second half of 2025. We plan to communicate with the NMPA in the second half of 2025 regarding our Phase IIb clinical trial plan to seek their further suggestions, if any, before commencing such Phase IIb clinical trial of PB-718 for the treatment of obesity in China. We also expect to commence a Phase III clinical trial of PB-718 for the treatment of obesity after obtaining results for the Phase IIb trial. Subject to the clinical trial results, we plan to submit the NDA for PB-718 to the NMPA in as early as 2028. We also plan to communicate with the FDA and the EMA in 2026 regarding the plans for conducting a Phase III MRCT of PB-718 for the treatment of obesity. We expect to commence the Phase III MRCT of PB-718 in 2027. Subject to the clinical trial results, we plan to submit the NDA for PB-718 to the FDA in as early as 2029.

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For the NASH indication, we plan to submit an IND application to the NMPA in the second half of 2025 and commence a Phase II clinical trial of PB-718 in China after obtaining the IND. We intend to evaluate the results of such Phase II clinical trial and formulate our plan for potentially conducting Phase II and Phase III clinical trials of PB-718 for the treatment of NASH in the United States.

As of the Latest Practicable Date, there had not been a GLP-1/GCG dual receptor agonist approved for the treatment of NASH or obesity in China or the United States. For additional information, see “Industry Overview.” While we are currently not required to conduct head-to-head clinical studies for PB-718, in the future we may consider conducting head-to-head clinical studies against then-major competing products on the market to demonstrate the comparative advantages of PB-718.

We had not received any relevant regulatory agency’s objections to our clinical development plans as of the Latest Practicable Date.

Licenses, Rights and Obligations

We internally discovered and developed PB-718, and maintain the global rights to develop and commercialize this drug candidate.

On June 29, 2017, we entered into an agreement with TSL HK (the “**TSL Agreement**”), pursuant to which we irrevocably granted to TSL HK the right of first refusal of exclusive commercialization rights of PB-119 and PB-718 in Mainland China. If TSL HK exercises its right of first refusal pursuant to the terms of the TSL Agreement, TSL HK and we shall come to an agreement in relation to the commercialization of PB-718 within the agreed period from receipt of its exercise notice of right of first refusal. In May 2023, in accordance with the TSL Agreement and based on mutual agreements, the right of first refusal of the exclusive commercialization of PB-119 of TSL HK was terminated. The right of first refusal of the exclusive commercialization of PB-718 entrusted by us to TSL HK is not affected by the terminated right of first refusal of the exclusive commercialization of PB-119. For details, please refer to “— Core Product — Core Product PB-119, a near-commercialized, long-acting GLP-1 receptor agonist — Licenses, Rights and Obligations.”

Material Communications with Competent Authorities

In April 2019, we conducted a Type B Pre-IND meeting with the FDA to discuss and confirm the preclinical program/data and to receive guidance and feedback from the FDA on the overall clinical investigational plan of PB-718 for the treatment of NASH¹ in the United States. Overall, the FDA issued acknowledgement and expressed no objection to our clinical trial plan of PB-718 for the treatment of NASH during the meeting, with no recommended material revisions to the study protocol or design. In July 2019, we submitted the IND application to the FDA to conduct clinical trial of PB-718 in the United States. During the 30-day clearance period ending in August 2019, the FDA had no objection for us to conduct a Phase I clinical trial of PB-718 in healthy participants in the United States.

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In March 2023, we communicated with the NMPA regarding our overall plans to conduct clinical trials of PB-718 for the treatment of obese patients in China, and we submitted the IND application to the NMPA. The CDE reviewed results of the Phase I clinical trial in the United States. In May 2023, the NMPA approved our IND application to conduct a Phase Ib/IIa clinical trial of PB-718 for the treatment of obese patients in China, with no recommended material revisions to the study protocol or design.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET PB-718 SUCCESSFULLY.

PB-1902, a potential first-in-class oral selective opioid receptor antagonist for the treatment of OIC

Overview

PB-1902 is a potential first-in-class oral selective opioid receptor antagonist for the treatment of OIC, a common adverse reaction in patients undergoing long-term opioid therapy for cancer pain and other chronic pain conditions. OIC can lead to severe gastrointestinal complications and adversely impact the quality of life for patients. Constipation may manifest early in the administration of opioid drugs and persist throughout their usage. Conventional medications for chronic constipation offer limited efficacy in addressing OIC. Opioid receptor antagonists are proved to be an effective therapeutic approach for improving OIC. However, such opioid receptor antagonists could partially hinder the central pain-relieving effect of opioid drugs. Additionally, all approved opioid receptor antagonists in China require daily subcutaneous injection, posing inconvenience to patients.

We are developing PB-1902 as the potential first-in-class oral selective opioid receptor antagonist in China. It is designed to effectively alleviate opioid-induced bowel dysfunction without diminishing the central pain-relieving effects of opioids, rendering PB-1902 as an ideal treatment option for OIC. We have completed two Phase I clinical studies which showed good safety, tolerability, PK and PD profiles of PB-1902 in healthy participants in China. In October 2022, the NMPA responded in writing with no objection for us to conduct a Phase II clinical trial of PB-1902 for the treatment of OIC in China. We plan to commence the Phase II clinical trial in China in 2025.

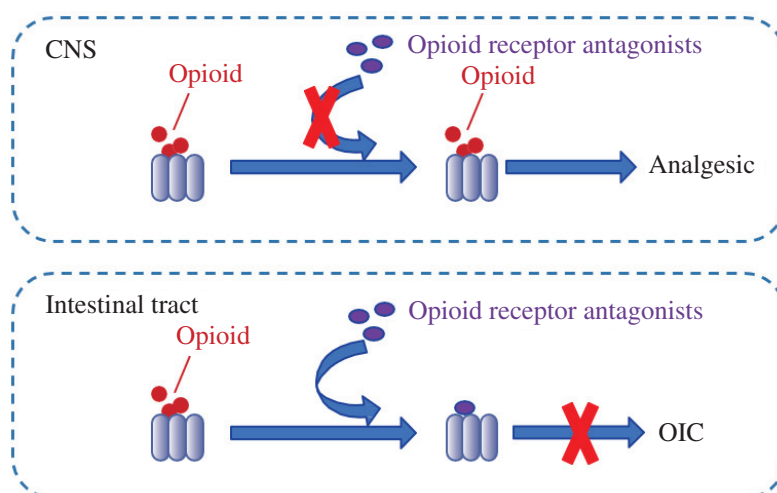
Mechanism of Action

Opioid analgesics alleviate moderate to severe pain of patients by binding to the μ receptors in the central nervous system. Simultaneously, opioid drugs also bind to μ receptors in the gastrointestinal tract, inhibiting gastrointestinal motility, reducing bile and pancreatic secretion, and causing constipation. Naltrexone and naloxone are both non-selective antagonists of opioid receptors. While both compounds can alleviate the symptoms of OIC, they can also cross the blood-brain barrier and antagonize the analgesic effects of opioid drugs in the central nervous system.

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PB-1902 is a PEG-modified derivative of naltrexone. As a μ receptor antagonist, PB-1902 effectively binds to intestinal μ receptors, competitively reducing the binding of opioid drugs to receptors in the intestine, alleviating constipation caused by the long-term use of such drugs. Due to the increased molecular weight resulted from the PEGylation, it is difficult for PB-1902 to cross the blood-brain barrier to counteract the central pain-relieving effects of opioid drugs. Therefore, when used in combination with opioid analgesics, the central analgesic effects of opioid drugs are not affected while adverse outcomes of opioid drugs on the gastrointestinal tract are alleviated. Such mechanism renders PB-1902 as a potential ideal treatment for OIC that can antagonize the peripheral gastrointestinal effects of opioid receptor activation while avoiding interference with the central analgesic effects of opioid drugs.

The following diagram demonstrates mechanism of action of PB-1902:



Source: Company data

Market Opportunity and Competition

OIC is the most common gastrointestinal adverse effects associated with opioid pharmacotherapy which negatively affects pain management and life quality of patients. The occurrence of OIC is common among patients using even low dosages of opioid drugs. Usually, the symptoms of OIC does not spontaneously decrease over time. Consequently, the OIC patient group is growing steadily along with the rapid increase of cancer incidents and other severe pain indications. The incidence of OIC in China grew from 3.2 million in 2018 to 4.6 million in 2023 with a CAGR of 7.5%. The incidence of OIC in China is expected to further grow to 7.1 million in 2032 with a CAGR of 5.0% from 2023 to 2032.

For patients with OIC, laxatives are usually given as the first-line treatment option. However, laxatives could only partially alleviate the symptoms for some of the OIC patients with limited clinical benefits. As a result, opioid receptor antagonists are being developed as potentially more effective treatment options. The majority of the commercially available opioid

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receptor antagonists are not selectively targeting intestinal opioid receptors, whereas the binding of opioid receptors in the central nervous system could partially hinder the central pain-relieving effect of opioid drugs. Therefore, a selective μ receptor antagonist represents the optimal combination of treating OIC while simultaneously maintain the functions of opioid drugs.

As of the Latest Practicable Date, there were two drugs approved by the NMPA for the treatment of OIC in China, which are both non-selective opioid receptor antagonists. There were 10 clinical-stage drug candidates for the treatment of OIC in China, being seven μ -opioid receptor antagonists, two non-selective opioid receptor antagonists and one CLCN2 activator, respectively. As of the Latest Practicable Date, PB-1902 was the first and one of the only two domestically developed clinical-stage oral μ -opioid receptor antagonist drug candidates for the treatment of OIC in China, according to CIC. We believe PB-1902 has the potential to be among the standard line of treatment options given its balanced clinical benefits and convenience of oral usage.

Our Advantages

We believe that PB-1902 has the following advantages:

Convenience Usage as in Oral Form

As of the Latest Practicable Date, there were only two approved opioid receptor antagonists in oral formulations in China. The peripheral opioid receptor antagonists available for the treatment of OIC are primarily in the form of naloxone injections which requires daily subcutaneous administration. As one of the only two domestically developed clinical-stage oral PAMORA drug candidates for the treatment of OIC in China, PB-1902 has the potential to significantly enhance patient compliance and usage convenience.

Minimal Effects on the Analgesic Functions of Opioid Drugs

PB-1902 can effectively alleviate constipation without compromising the peripheral opioid receptor antagonism of opioid analgesics. Preclinical research results demonstrated that within the dose range of 41.4-165.5 mg/kg, PB-1902 efficiently counteracted the inhibitory effects of opioid analgesics on intestinal motility, promoting bowel movements in mice without impacting the analgesic effects of opioid analgesics. In comparison to similar drugs, PB-1902 exhibited a broader clinical dosage range. This characteristic makes it less susceptible to the reduction of opioid analgesic effects due to dose escalation. Consequently, PB-1902 has the potential to adapt to a wider range of clinical dosages required by OIC patients with varying severity.

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Summary of Clinical Trials of PB-1902

We have completed two Phase I clinical studies of PB-1902 in China to evaluate the safety, tolerability and PK profiles of PB-1902 in healthy participants in China.

The following table sets forth an overview of results of key clinical studies of PB-1902:

Study ⁽¹⁾	Key Enrollment Criteria	Number of Participants Enrolled	Participating site(s) and PI	Endpoints	TEAE Reported (Mild/Moderate/ Severe/Life Threatening)	Frequently Occurring TEAE (Number of Subjects)	Reasons for Discontinuation ⁽²⁾	Material Results
PB1902-M-02-Ia-01 . . .	Healthy adult participants	50	Yiyang Central Hospital, Human PI: Yuehong Zeng, Wei Li	Safety, tolerability and PK parameters	Placebo: 3/0/0/0 10 mg PB-1902: 2/0/0/0 30 mg PB-1902: 21/0/0/0 60 mg PB-1902: 15/0/0/0 120 mg PB-1902: 10/0/0/0 240 mg PB-1902: 20/0/0/0	Gastrointestinal disorder (120 mg/240 mg PB-1902: 1/4) Skin rash (240 mg PB-1902: 3) Dizziness (240 mg PB-1902: 2)	One participant voluntarily withdrew before the treatment period	PB-1902 was generally well tolerated within the single dose range of 10 mg to 240 mg, and the PK parameters of PB-1902 exhibited a dose-dependent manner

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Study ⁽¹⁾	Key Enrollment Criteria	Number of Participants Enrolled	Participating site(s) and PI	Endpoints	TEAE Reported (Mild/Moderate/ Severe/Life Threatening)	Frequently Occurring TEAE (Number of Subjects)	Reasons for Discontinuation ⁽²⁾	Material Results
PB1902-M-02-Ia-02 . . .	Healthy adult participants	30	Yiyang Central Hospital, Hunan PI: Yuehong Zeng, Wei Li	Safety, tolerability and PK parameters	Placebo: 9/0/0/0 30 mg PB-1902: 6/0/0/0 60 mg PB-1902: 9/0/0/0	Gastrointestinal disorder (placebo/30 mg/ 60 mg PB-1902: 2/8/4) Chest pain (60 mg PB-1902: 4)	No discontinuation	PB-1902 was generally well tolerated with multiple doses of 30mg and 60 mg, and there was no statistically significant drug accumulation after multiple doses of PB-1902

(1) We designed two separate Phase I studies for PB-1902 in sequential order to be more cautious about the first-in-human clinical trial of PB-1902 and cabin its scope to facilitate execution. PB1902-M-02-Ia-01 was a single ascending dose study and PB1902-M-02-Ia-02 was a multiple ascending dose study. Participants in different groups of the first study received corresponding levels of single dose of PB-1902 to establish the safety, tolerability and PK profiles of PB-1902. Based on the results, we subsequently selected two doses (30 mg and 60 mg) for the second study, which extended the evaluation to repeated dosing, assessing the effects of PB-1902 accumulation and the body’s response to prolonged exposure.

(2) Such discontinuation had no material impact on the progress of the respective clinical trials.

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PB1902-M-02-Ia-01: A Phase I, randomized, double-blind, placebo-controlled, single ascending dose study to evaluate the safety, tolerability and PK profiles of PB-1902 on healthy participants in China

Overview. This was a Phase I randomized, double-blind, placebo-controlled, single ascending dose study to evaluate the safety, tolerability and PK profiles of PB-1902 on healthy participants in China. The results showed that PB-1902 was generally well tolerated within the single dose range of 10 mg to 240 mg, and the PK parameters of PB-1902 exhibited a dose-dependent manner.

Trial design. 50 healthy participants were enrolled in this Phase I clinical study and were randomized into five groups. The first group consisted of two participants who received a single dose of 10 mg PB-1902. The other four groups were dosed after the first group was dosed and reported satisfactory safety data. The other four groups were consisted of 12 participants each, with 10 of these participants received the test drug (PB-1902) and the other two participants received placebo. The dosages for these four groups were 30 mg, 60 mg, 120 mg and 240 mg, respectively. PB-1902 or placebo was administered orally in the morning on the test day. Of those 50 enrolled participants, 49 completed the study as planned and one participant withdrew from the study before dosing.

Trial status. We initiated this Phase I clinical study of PB-1902 in April 2021 and completed the trial in October 2021 in China.

Safety data. Out of the total 50 enrolled participants, the 49 participants who completed the study were included in the safety analysis set. 32 out of the 42 participants who were dosed with PB-1902 reported a total of 68 AE incidents, all of which were of Grade 1 in severity. There was no SAE or discontinuation from the study due to AE occurrence. The major AEs included abnormalities in laboratory parameters (including elevated triglycerides, elevated bilirubin, decreased potassium, decreased blood glucose), T-wave abnormalities in electrocardiograms, decreased blood pressure and skin rash. The other seven participants in the safety analysis set who were dosed with placebo reported a total of three AE incidents, all of which were of Grade 1 in severity. There was no SAE or discontinuation from the study due to AE occurrence.

BUSINESS

PK data. Among the 42 participants who were dosed with PB-1902, the PK parameters of PB-1902 mainly exhibited a dose-dependent manner, as shown in the table below.

Main pharmacokinetic parameters (PKPS) of PB-1902 after single oral administration of different doses of PB-1902 capsules in 42 participants

PKPS (unit)	Dose Level (Mean±SD(CV%))				
	10mg (N=2)	30mg (N=10)	60mg (N=10)	120mg (N=10)	240mg (N=10)
C_{max} (ng/mL) . . .	0.5388±0.4175 (77.50)	1.060±0.7919 (74.70)	4.120±4.130 (100.2)	81.30±58.57 (72.04)	217.0±207.0 (95.38)
$*T_{max}$ (h)	06.50 (4.98,8.01)	5.00 (0.99,11.97)	4.49 (2.99,23.96)	3.49 (2.98,4.99)	2.99 (1.99,3.99)
AUC_{0-t} (ng·h/mL).	7.88±6.13 (77.89)	12.9±9.22 (71.01)	27.05±11.29 (41.72)	221.42±123.17 (55.63)	555.21±318.35 (57.34)
$t_{1/2}$ (h)	18.08±10.11 (55.94)	23.61±10.06 (42.63)	26.85±13.39 (49.85)	52.84±18.35 (34.72)	39.75±11.44 (28.79)

Source: Company data, clinical study report

PB1902-M-02-Ia-02: A Phase I, randomized, double-blind, placebo-controlled, multiple ascending dose study to evaluate the safety, tolerability and PK profiles of PB-1902 on healthy participants in China

Overview. This was a Phase I randomized, double-blind, placebo-controlled, multiple ascending dose study to evaluate the safety, tolerability and PK profiles of PB-1902 on healthy participants in China. The results showed that PB-1902 was generally well tolerated with multiple doses of 30 mg and 60 mg, and there was no statistically significant drug accumulation after multiple doses of PB-1902.

Trial design. 30 healthy participants were enrolled in this Phase I clinical study and were randomized into two groups with 15 participants each. Within each group, 10 of the total 15 participants received the test drug (PB-1902) and the other five participants received placebo. The daily dosages for the two groups were 30 mg and 60 mg, respectively. The participants were administered with corresponding PB-1902 or placebo QD for 10 consecutive days. All of these 30 enrolled participants completed the study as planned.

Trial status. We initiated this Phase I clinical study of PB-1902 in November 2021 and completed the trial in January 2022 in China.

Safety data. 15 out of the 20 participants who were dosed with PB-1902 reported a total of 37 AE incidents, all of which were of Grade 1 in severity. There was no SAE or discontinuation from the study due to AE occurrence. The major AEs included abnormalities in laboratory parameters, nausea, abdominal pain and diarrhea. Four out of the 10 participants who were dosed with placebo reported a total of nine AE incidents, all of which were of Grade 1 in severity. There was no SAE or discontinuation from the study due to AE occurrence.

BUSINESS

PK data. Among the 20 participants receiving PB-1902, the PK parameters of PB-1902 exhibited a dose-dependent manner as shown in the table below. The accumulation analysis also showed that there was no statistically significant drug accumulation after multiple doses of PB-1902.

Main pharmacokinetic parameters (PKPS) of PB-1902 after oral administration of different doses of PB-1902 capsules in 42 participants

PKPS	Group Details (Mean±SD)			
	30mg (N=10)		60mg (N=10)	
	Day 1	Day 10	Day 1	Day 10
C_{min} (ng/mL)	/	0.2786±0.1419(50.96)	/	0.9196±0.6410(69.71)
C_{max} (ng/mL) (multiple doses: C_{min})	1.729±3.342(193.2)	1.904±3.669(192.6)	10.64±14.64(137.6)	6.164±7.130(115.7)
C_{trough} (ng/mL)	/	0.511±0.4268(85.18)	/	1.777±1.297(72.98)
$*T_{max}$ (h) (multiple doses: T_{trough})	2.99(1.99,11.99)	1.00(0.49,3.00)	3.49(1.99,11.99)	2.99(0.99,3.99)
$t_{1/2}$ (h)	13.95±10.34(74.08)	39.00±10.74(27.54)	32.12±46.95(146.2)	39.32±11.77(29.94)

Source: Company data, clinical study report

Clinical Development Plan

We plan to commence the Phase II clinical trial in China to evaluate the efficacy and safety of PB-1902 for the treatment of patients with cancer pain and OIC in 2025. We expect to complete this Phase II clinical trial in 2027. The design of such Phase II clinical trial is summarized below. We also expect to commence a Phase III clinical trial for PB-1902 after obtaining results for the Phase II clinical trial. Subject to the clinical trial results, we plan to submit the NDA for PB-1902 to the NMPA in as early as 2029.

A Phase II, randomized, double-blind, placebo-controlled, multiple ascending dose study to evaluate the safety, tolerability and PK profiles of PB-1902 on healthy participants in China

Overview. We plan to commence a multicenter, randomized, double-blind, placebo-controlled multiple ascending dose Phase II clinical trial in China to evaluate the efficacy and safety of PB-1902 for the treatment of patients with cancer pain and OIC in 2025. The primary objective is to evaluate the efficacy of PB-1902 on patients with cancer pain and OIC. The secondary objectives include the safety and PK profiles of PB-1902 on patients with cancer pain and OIC.

Trial design. We plan to enroll approximately 168 patients with cancer pain and OIC. Each patient’s participation in the trial is expected to last for approximately eight weeks, comprising a screening period of up to two weeks, an OIC confirmation period for two weeks, a double-blind treatment period for two weeks, and a follow-up period for two weeks. Patients meeting the screening requirements will be randomized on Day 1 and divided equally into four groups to receive 20 mg, 40 mg, 60 mg PB-1902 or placebo QD during the treatment period from Day 1 to Day 14 in a double-blind manner.

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Throughout the treatment period, the patients will self-assess bowel movement activities, cancer pain severity, abdominal symptoms, among others, by recording in a diary card. On Day 1, Day 7 and Day 15, the patients will return to the research center for efficacy and safety assessments. After the treatment period, the patients will enter a safety follow-up period, and the final visit will be conducted on Day 28 to assess safety after discontinuation of the medication.

The primary efficacy endpoint of this trial is the change from baseline in spontaneous bowel movements (SBM) per week over the 2-week treatment period. The baseline is calculated as the average number of SBM per week during the two-week OIC confirmation period before dosing.

The safety endpoints include AEs, pain intensity assessed using the Numeric Rating Scale (NRS), Clinical Opiate Withdrawal Scale (COWS) assessment, changes in average weekly opioid drug dosage from baseline during the treatment period, vital sign changes, changes in electrocardiogram (ECG) results, physical examination changes and clinical laboratory examination results.

We had not received any relevant regulatory agency’s objections to our clinical development plans as of the Latest Practicable Date.

Licenses, Rights and Obligations

We internally discovered and developed PB-1902, and maintain the global rights to develop and commercialize this drug candidate.

Material Communications with Competent Authorities

In November 2020, the NMPA approved our IND applications to conduct two Phase I clinical trials (M-02-Ia-01 and M-02-Ia-02) to evaluate the safety, tolerability and PK profiles of PB-1902 single and multiple ascending doses on healthy participants in China. We first conducted the single ascending dose Phase I study (M-02-Ia-01) and subsequently conducted the multiple ascending dose Phase I study (M-02-Ia-02), and both Phase I clinical studies were under the same clinical trial sponsor. In July 2022, we applied for and conducted a Type II meeting with the CDE of the NMPA, seeking a communication with the CDE regarding a discussion of the Phase I clinical trial results and permission to commence a Phase II clinical trial. The CDE reviewed the Phase I clinical trial results and our plan to conduct a Phase II clinical trial for PB-1902 in China. In October 2022, we received a written response from the CDE allowing a Phase II dose-exploration clinical trial, with no recommended material revisions to the study protocol or design.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET PB-1902 SUCCESSFULLY.

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PB-722, a long-acting GCG receptor agonist for the treatment of congenital hyperinsulinemia

Overview

PB-722 is a long-acting GCG receptor agonist for the treatment of congenital hyperinsulinemia, a rare hereditary endocrine disease whose patients experience constant hypoglycemia induced by hyperinsulinemia. Congenital hyperinsulinemia is the most common cause of severe and persistent hypoglycemia in newborns and infants and is characterized by excessive or unregulated insulin secretion and recurrent severe hypoglycemia. It requires prompt and aggressive treatment to prevent neurological sequelae. If remain untreated, congenital hyperinsulinemia can lead to permanent brain damage, resulting in conditions such as epilepsy and cerebral palsy. Congenital hyperinsulinemia was included in the Rare Disease Catalog of China First Edition in 2018. As of the Latest Practicable Date, there was no approved drug for the treatment of congenital hyperinsulinemia.

PB-722 is created by a single amino acid modification of human glucagon and PEGylation on the modification site. PB-722 has demonstrated its safety in several animal models and has been shown to be effective in raising and maintaining blood glucose levels in a hypoglycemic animal model. We believe the good safety and efficacy profile demonstrates the potential of PB-722 for the treatment of congenital hyperinsulinemia which lacks effective treatment options. In May 2023, the NMPA approved our IND application to conduct clinical trial of PB-722 for the treatment of congenital hyperinsulinemia in China, rendering PB-722 the first drug candidate with IND approval for the treatment of congenital hyperinsulinemia in China. We plan to initiate a randomized, double-blind, placebo-controlled, dose-escalating Phase I clinical trial to test the safety, tolerability, PK and PD profiles of PB-722 single dose subcutaneous injection in 2026. In May 2021, PB-722 was granted the Orphan Drug Designation by the FDA.

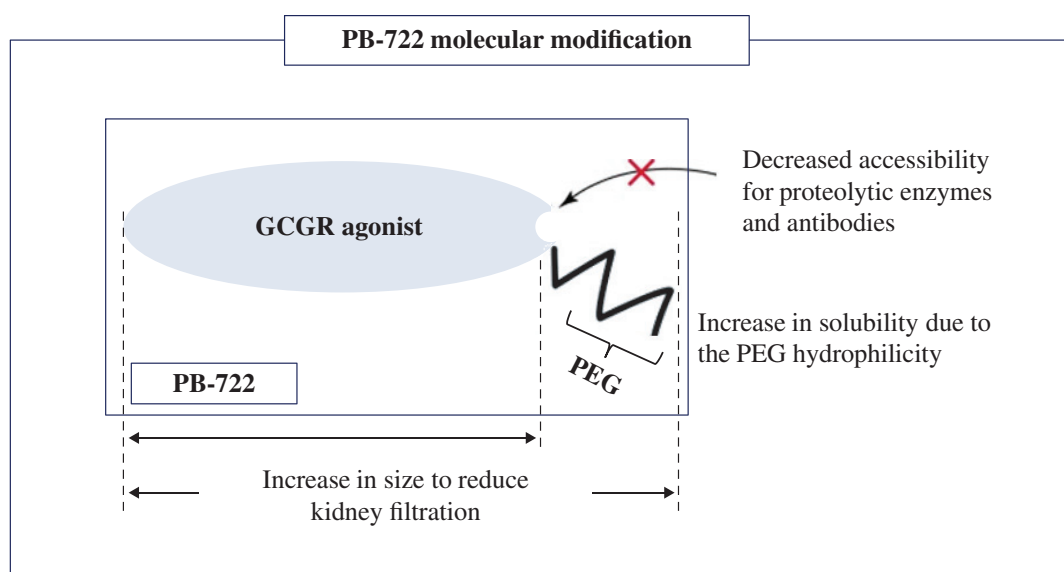
Mechanism of Action

Glucagon is an important hormone secreted by pancreatic α cells, which triggers a series of downstream metabolic reactions by activating the GCG receptors. Glucagon stimulates the hydrolysis of fats and glycogen in the liver, leading to increased blood glucose and lipid concentrations. Glucagon also promotes glycogenolysis and gluconeogenesis in the liver, leading to a significant increase in blood glucose levels.

For patients with congenital hyperinsulinemia, glucagon is initially used in clinical practice for rapid blood glucose elevation in cases of severely low blood glucose when the patient could not consume food. However, the short half-life (5-10 minutes) of glucagon limits its long-term application and it is generally reserved for emergency treatment of severe hypoglycemia.

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PB-722 is created by a single amino acid modification of human glucagon and PEGylation on the modification site. The amino acid sequence of the active site of the glucagon derivative is identical to natural glucagon. By binding to the GCG receptors *in vivo*, PB-722 exhibits pharmacological effects similar to glucagon. PB-722 is able to retain its activity with extended half-life. PB-722 acts as a long-acting GCG receptor agonist that increases blood glucose levels persistently, thereby treating hypoglycemic symptoms in patients with congenital hyperinsulinism. The following diagram illustrates the design of PB-722 and benefits of such design. For details of functions of a GCG receptor agonist and its activation of the GCG signaling pathway, see “— Clinical-stage Products — PB-718, a long-acting GLP-1/GCG dual receptor agonist — Mechanism of Action.”



Source: Wiley Interdiscip Rev Nanomed Nanobiotechnol., Biodrugs, Curr Opin Chem Biol., CIC report

Market Opportunity and Competition

As a rare disease, the patient group of congenital hyperinsulinemia is relatively small. The incidence of congenital hyperinsulinemia globally grew from 2.8 thousand in 2018 to 3.4 thousand in 2023 with a CAGR of 4.3%. The incidence of congenital hyperinsulinemia globally is expected to further grow to 4.9 thousand in 2032 with a CAGR of 4.0% from 2023 to 2032. However, since there is currently no approved drug for the treatment of congenital hyperinsulinemia globally, there remains significant medical needs for such patients and the successful development of drugs for congenital hyperinsulinemia will bring considerable socio-economic benefits.

The current treatment options of congenital hyperinsulinemia include diazoxide, octreotide, glucagon, and sirolimus. While diazoxide initially shows good efficacy, rapid tolerance often limits its long-term use, and common adverse reactions include elevated liver enzymes and asymptomatic gallbladder disorders, typically resolving on their own. Therefore, as the treatment duration extends, the need for continuous rotation of new drugs or alternative treatment approaches persists.

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As of the Latest Practicable Date, there was no drug product being approved for the treatment of congenital hyperinsulinemia globally. There were six clinical-stage drug candidates for the treatment of congenital hyperinsulinemia globally. As of the Latest Practicable Date, PB-722 was the first and only drug candidate with IND approval for the treatment of congenital hyperinsulinemia in China, according to CIC.

Clinical Development Plan

In May 2023, the NMPA approved our IND application to conduct Phase I clinical trial of PB-722 for the treatment of congenital hyperinsulinemia in China. We plan to initiate a randomized, double-blind, placebo-controlled, dose-escalating Phase I clinical trial to test the safety, tolerability, PK and PD profiles of PB-722 single dose subcutaneous injection in China in 2026. The primary objective of this Phase I clinical trial is to evaluate the safety and tolerability of PB-722 single dose subcutaneous injection in healthy Chinese adults. The secondary objective is to evaluate the PK and PD profiles of PB-722 single dose subcutaneous injection in healthy Chinese adults. We also expect to commence a Phase II clinical trial for PB-722 in 2027.

We plan to enroll 60 healthy participants in the Phase I clinical trial. We will randomize the participants into five groups with 12 participants in each group. Four groups will be the test groups and the other will be the positive control group. Within each test group, nine participants will receive the test drug (PB-722) injection (1ml: 1.5mg) and the other three participants will receive a corresponding placebo injection. For the positive control group, nine participants will receive the positive control (a commercially available human glucagon for injection product, 1ml: 1mg) and the other three participants will receive a corresponding placebo injection. The four test groups will receive 0.25 mg, 0.75 mg, 1.5 mg and 2.0 mg of PB-722 or placebo, respectively. The participants in a higher dose group will only start to receive the dosing when the participant from the lower dose group meet the pre-determined dose escalation standards.

The investigators will conduct safety assessment and determine whether participants in the next dosage group could proceed to receive dosing or to terminate the participation in the following clinical trial. The pre-determined dose escalation standards are met only when (1) fewer than 50% of the participants in each dosing level exhibit AEs with at least Grade 2 that are probably related to the test drug (PB-722 or placebo), (2) fewer than one third of the participants in each dosing level exhibit AEs with at least Grade 3 that are probably related to the test drug (PB-722 or placebo), (3) fewer than one sixth of the participants in each dosing level exhibit AEs that lead to discontinuation from the trial which are probably related to the test drug (PB-722 or placebo), and (4) none of the participants in each dosing level exhibit SAE that is probably related to the test drug (PB-722 or placebo).

We had not received any relevant regulatory agency’s objections to our clinical development plans as of the Latest Practicable Date.

BUSINESS

Licenses, Rights and Obligations

We internally discovered and developed PB-722, and maintain the global rights to develop and commercialize this drug candidate.

Material Communications with Competent Authorities

In February 2023, we submitted an IND application to the NMPA for PB-722 and was accepted by the NMPA. The CDE reviewed the preclinical study results and our plan to conduct a Phase I clinical trial for PB-722 in China. In May 2023, the NMPA approved our IND application to conduct Phase I clinical trial of PB-722 for the treatment of congenital hyperinsulinemia in China, with no recommended material revisions to the study protocol or design.

In May 2021, PB-722 was granted the Orphan Drug Designation by the FDA. As of the Latest Practicable Date, we were preparing for submitting the IND application to the FDA for PB-722 for the treatment of congenital hyperinsulinemia in the United States and we planned to formulate a concrete timeline of submitting the IND application to the FDA.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET PB-722 SUCCESSFULLY.

SELECTED PRECLINICAL-STAGE PRODUCTS

PB-2301, a potentially promising GLP-1/GIP dual receptor agonist for the treatment of T2DM, NASH and Obesity

We believe that PB-2301 has the potential to be a promising GLP-1/GIP dual receptor agonist for the treatment of T2DM, NASH and obesity. We are conducting multiple preclinical studies to test the safety and efficacy profile of PB-2301. We believe PB-2301 has the potential to further enhance the performance of current GLP-1 receptor agonist candidates. We plan to advance PB-2301 to clinical development for the treatment of T2DM, NASH and obesity and submit the IND applications to the NMPA in 2026 and initiate the Phase I clinical trials after obtaining the IND. We internally discovered and developed PB-2301, and maintain the global rights to develop and commercialize this drug candidate.

PB-2309, a potentially promising GLP-1/GIP/GCG triple receptor agonist for the treatment of T2DM, NASH and Obesity

We believe that PB-2309 has the potential to be a promising GLP-1/GIP/GCG triple receptor agonist for the treatment of T2DM, NASH and obesity. We are conducting multiple preclinical studies to test the safety and efficacy profile of PB-2309. We believe PB-2309 has the potential to further enhance the performance of current GLP-1 receptor agonist candidates. We plan to advance PB-2309 to clinical development for the treatment of T2DM, NASH and

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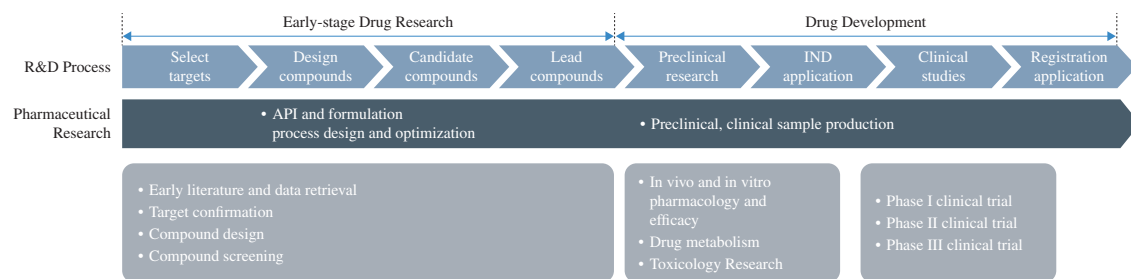
obesity and submit the IND applications to the NMPA in 2025 and initiate the Phase I clinical trials in as early as 2026. We internally discovered and developed PB-2309, and maintain the global rights to develop and commercialize this drug candidate.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET PB-2301 and PB-2309 SUCCESSFULLY.

RESEARCH AND DEVELOPMENT

R&D Strategy

We focus on leveraging our industry experience and established R&D capabilities for the in-house discovery and development of differentiated therapeutics primarily for chronic diseases with a particular emphasis on metabolic disorders. Utilizing our proprietary technology platforms, we design and screen innovative molecular entities with novel mechanisms, forming a product pipeline with synergistic advantages and multiple benefits. We aim to provide more effective, safe, convenient and affordable treatment options for a wide range of chronic and metabolic disease patients. We have established a complete research and development framework from early drug development to registration and industrialization, as shown in the diagram below.



Source: Company data

R&D Team

Our R&D team has strong expertise, deep understanding and broad development experience in chronic and metabolic diseases. As of the Latest Practicable Date, the vast majority of our R&D team members had obtained at least bachelor’s degrees, and ten members of our R&D team had obtained advanced degrees, including four members with doctorate degrees and six members with master’s degrees. Our R&D team is led by a team of world-class scientists with years of drug development experience. For instance, Dr. Michael Min XU, our founder, chairman of the Board and executive Director, has extensive research and managerial experience in the pharmaceutical industry. He received a Ph.D. degree in biophysics from Columbia University in 1996, during which time he published multiple research papers in high-profile scientific journals. He was also involved in the operations and strategic planning of multiple companies in the biotech industry, for instance, he served as the general manager of a China-based pharmaceutical company, and he was a Director of a biotech company in the

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United States. Our core R&D personnel consists of eight members covering the fields of chemistry, biology, pharmacology and medicine. The majority of our core R&D personnel have been working in the biopharmaceutical industry for over 10 years. The core R&D personnel involved in the development of the Core Product are mostly remained employed by us. The following table sets forth a breakdown of the number of R&D team by function as of the Latest Practicable Date:

Functions	Location	Number of employees
Drug Discovery	China	10
Clinical Development	China	7
Regulatory Affairs	China	2
Total		<u>19</u>

The following table sets forth the identities, positions, expertise of our core R&D personnel and their involvement and contributions to the R&D activities since the discovery of PB-119 and PB-718 and up to the Latest Practicable Date. No core R&D personnel involved in the development of PB-119 and PB-718 has left the Group, other than two departures due to personal reasons.

Identities	Positions	Expertise	Involvement and contributions to the R&D activities since the discovery of PB-119 and PB-718	Date of joining our Group
Dr. Michael Min XU . .	Founder and general manager	Over 20 years' experience in the biopharmaceutical industry	Drug discovery of PB-119 and PB-718	July 10, 2001
Fengying Zhao	Director of Clinical Development	Over 10 years' experience of drug discovery in pharmaceutical companies	Clinical trial design and management of PB-119 and PB-718	February 6, 2023
Dr. Nengyin Liu	Senior Vice President of Drug Discovery	Over 20 years' experience of drug discovery in global leading pharmaceutical companies	PK, PD and safety studies of PB-119 and PB-718	August 15, 2022

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Identities	Positions	Expertise	Involvement and contributions to the R&D activities since the discovery of PB-119 and PB-718	Date of joining our Group
Dr. Jianhui Wang . . .	Vice President of Drug Discovery	Over 20 years’ experience of drug discovery of multiple modalities	PK, PD and safety studies of PB-119 and PB-718	February 20, 2017
Yinghui Zhang . . .	Research Director of Drug Discovery	Over 15 years’ experience of biopharmaceutical R&D	Drug Discovery of PB-119 and PB-718	July 1, 2008
Dr. Ya Pei . .	Senior Researcher of Drug Discovery	Over 10 years’ experience of drug R&D since doctoral research	PK, PD and safety studies of PB-119 and PB-718	May 22, 2023
Chuan Wang . . .	Senior Project Manager of Drug Discovery	Over 7 years’ experience of small molecule drug discovery	Toxicology studies of PB-119 and PB-718	November 1, 2021
Chuanzhen Liu	Director of Regulatory Affairs	Over 10 years of pharmaceutical regulatory affairs experience in leading companies	Regulatory affairs of PB-119 and PB-718	December 26, 2022

In 2023 and 2024, we recorded R&D expenses of RMB236.7 million and RMB95.4 million, respectively, with R&D expenses of RMB60.5 million and RMB33.5 million attributable to the Core Product, respectively. The decrease of our R&D expenses incurred on our Core Product was in line with our advancement of the Core Product PB-119 from the Phase III clinical stage to the NDA filing in 2023. While there may be fluctuations in the amount of future R&D expenses in light of the different developmental stages of our pipeline candidates, for example, there may be a decrease of R&D expenses in 2024, we anticipate to continue to significantly invest in our R&D efforts, since we plan to expand the indications and combination therapies of our Core Product, advance the development of our key product and bring more candidates along clinical trials and conduct additional preclinical studies.

Drug Discovery

As of the Latest Practicable Date, many of our drug discovery members had over a decade of relevant work experience. We have worked on our product candidates’ advancement for more than 13 years and developed our product candidates in-house. The majority of our drug discovery team members have obtained post-graduate degrees, with respective expertise in biology, medicinal chemistry, drug metabolism and pharmacokinetics, chemistry and early

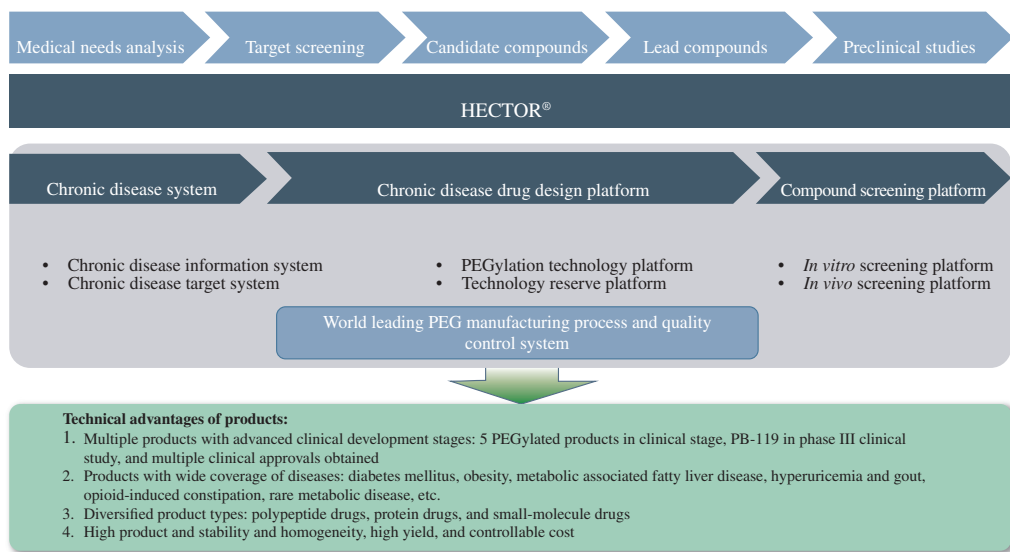
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clinical areas, which together support our product development. Our proprietary in-house drug discovery capabilities comprise (i) identifying medical needs and integrating real-world data, network pharmacology, known and established molecules with desired therapeutic benefits to design novel, multifunctional drug candidates; (ii) performing *in vitro* and *in vivo* assays of drug candidates including but not limited to pharmacological activities, pharmacokinetics and toxicities; and (iii) developing formulations, and analytical assays for quality control and assurance. During the drug discovery stage, our R&D chemistry team carries out synthesis and optimization of the target molecules for potential drug candidates. During the drug evaluation stage, our drug discovery team coordinates and accomplishes preclinical R&D activities in relation to the product candidates’ pharmacology, pharmacokinetics and toxicology.

Our Platforms

We have established a Highly Effective Target Screening & Molecule Modifier Platform (HECTOR[®]). Through HECTOR[®], we leverage our sophisticated experience in drug molecular design and turn our in-depth understanding of medical needs and target mechanisms in the field of metabolic diseases into drug candidates with competitive edge for subsequent development. We have developed different types of products and have successfully advanced the products to different stages of clinical trials. We also continue to design, screen, and develop compounds to provide novel pharmaceutical products with competitive advantages for the treatment of patients with metabolic diseases.

The following chart illustrates the structure of HECTOR[®]:



Source: Company data

Our HECTOR[®] platform mainly consists of three functional components: metabolic disease data collection, drug molecular design platform, and compound screening platform.

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Metabolic Disease Data Collection

Our metabolic disease collection covers approximately 35 metabolic diseases including cardiovascular and cerebrovascular diseases, gastrointestinal diseases, renal diseases, neurological diseases, ophthalmology, hematology, orthopedics, tumor adjuvant therapy and rare diseases. The metabolic disease target collection encompasses approximately 150 different targets of marketed drugs or investigational products for metabolic diseases. Based on the data collection, our R&D team can accurately capture the data of relevant diseases, major marketed drugs and investigational drugs, in order to evaluate the mechanisms of actions, efficacy and safety of potential therapeutic targets. We also utilize such information to analyze the advantages and shortcomings of available therapeutic modalities, screen out targets that meet our product development strategy and further enhance their characteristics and potential clinical value.

Drug Molecular Design Platform

We have established a metabolic disease drug molecular design platform leveraging our in-depth expertise in PEGylation. PEGylation is a versatile and proven manner of modification that can be applied to a wide array of drugs, including peptide, protein, and small molecule drugs, to optimize their physio-chemical properties. We have applied our know-how in PEG technology, which we believe constitutes a critical part of our core research and development competencies, to realize various benefits of the technology.

Described below are ways that PEG technology and our research and development competencies have contributed to the development of our product pipeline.

- ***Prolong half-life of compound and enhance long-acting efficacy.*** By adjusting the parameters of PEGylation, such as the length of the PEG molecules and the amount of PEGylation, we are able to increase the total molecular weight and the hydrodynamic radius of the PEGylated drug, thereby significantly slowing its clearance from the body and prolonging its half-life to achieve long-acting efficacy. We have applied the PEG technology across our portfolio, including our Core Product PB-119, for that purpose. For example, PEG technology allows for PB-119 to be administered once a week, in contrast to certain other GLP-1 receptor agonists on the market that require dosing as frequent as twice-daily, which we believe would not only lower the total cost to patients but also improve their long-term compliance.
- ***Improve compound stability.*** The PEG technology also contributes to improved compound stability, arising from improved overall solubility and protection by the attached PEG molecules against degradation or enzymatic breakdown. As an example, PEGylation of PB-119 considerably increases the stability and half-life compared with the native GLP-1. Similarly, more stable drug molecules in the body can result in long-acting efficacy and less frequent dosing, which can potentially improve the overall treatment outcome and patients’ compliance.

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- **Reduced immunogenicity.** As PEG molecules can shield drugs from recognition by the immune system, PEG technology is able to diminish the likelihood of generating antibodies against the therapeutic agent and may contribute to safer and more tolerable therapeutics. For example, a positive-controlled Phase I clinical trial of PB-119 (ICP-I-2015-01) demonstrated that PB-119 caused less immunogenicity in terms of generation of anti-drug antibody as compared to that of exenatide (the positive control without PEGylation). Therefore, applying PEGylation to drugs not only addresses concerns related to immunogenicity, but has also potentially contributes to the development of safer and more tolerable therapeutic interventions.
- **Enable new solutions.** PEG technology has emerged as a transformative force in altering the physiochemical properties of small molecules to enhance their ability to traverse the blood-brain barrier, enabling us to develop PB-1902 to specifically target opioid receptors in the digestive tract. This targeted approach holds promise for designing medications that can exert their therapeutic effects within the digestive tract, potentially offering solutions for conditions such as gastrointestinal pain or motility disorders. PEG technology’s precision in modulating drug properties signifies a groundbreaking strategy in drug development, providing a platform for the creation of highly targeted and efficacious treatments.
- **Lower research costs.** Application of PEGylation to proteins have been a well demonstrated approach to improve their physio-chemical characteristics. Over the years, we have accumulated a wealth of practical know-how to develop and produce PEG molecules with medicinal quality. Such practical know-how and established technology platform allow us to apply similar technologies to a wide variety of drug candidates, thereby sparing us entirely individual designs for different molecules and enabling us to expedite the research process and lower total cost.

Compound Screening Platform

We have established a compound screening platform based on extensive experience with the use of a wide range of metabolic disease related experimental models and drugs that have been tested upon. According to the mechanism of the selected metabolic disease and the target mechanism, suitable *in vivo* and *in vitro* screening models are selected by us to screen candidate compounds and to potentially obtain expected lead compounds. Our *in vivo* screening platform is based on multiple animal models and covers approximately 20 metabolic diseases with various mechanisms. We have also established an *in vitro* screening platform with cell lines that are of high importance on metabolic diseases of our interests. Additionally, we have also accumulated a rich collection of research data on major marketed drugs and investigational drugs targeting proven disease-related pathways, which enables us to efficiently confirm the competitive advantages of compounds in terms of efficacy and safety and to obtain optimized compounds that meet our desired characteristics. We are leveraging the AI-powered drug discovery in the development of our new products pipeline.

BUSINESS

Clinical Development

Clinical Development Team

As of the Latest Practicable Date, our clinical development team consisted of seven members, including scientists and physicians with strong drug development experience, who participate in clinical development strategy development, clinical trial protocol design, clinical trial operation organization, drug safety monitoring, and clinical trial quality control. Many of our clinical development team members had over a decade of relevant work experience. Among our clinical development team members, 29% have obtained post-graduate degrees. Our clinical development team is generally responsible for the development of our Core Product and other pipeline products.

Clinical Trial Design and Implementation

Our clinical development team manages all stages of clinical trials, including protocol design and oversees, operations/conduct, and the collection and analysis of clinical data. Our rapid trial advancements are driven by (i) our strategic decision to initiate clinical phase trials based on our outstanding preclinical results, (ii) rigorous trial design, (iii) long-term partnership with various hospitals and principal investigators from different regions and (iv) seamless execution.

Our clinical operations team is also responsible for the selection of trial sites. Our site selection criteria include the site’s overall experience, understanding of the disease state, access to relevant experts and patients, geographical coverage, regulatory and quality management, range of services, staff proficiency, and technology. We have collaborated with numerous hospitals and PIs located in China and the United States that can support our clinical trials of different indications at different stages. We believe the size and geographic diversity of these facilities provide us with an advantage in implementing large-scale clinical trials and also enable us to conduct multiple clinical trials concurrently. With the support of our partner hospitals, we are capable of recruiting participants from specific populations for studies that would otherwise be difficult to fulfill enrollment.

In 2022 and 2023, we cooperated with 10 and 10 leading PIs, respectively, to conduct the clinical trials of our drug candidates. To the best of our Company’s knowledge, none of them have any past or present relationships with our Group, our Directors, shareholders, senior management or any of their respective associates. The PIs are responsible for conducting site-level clinical research activities according to our trial protocols and in accordance with laws, regulations, and the GCP Guideline, a quality standard for the overall conduct of the clinical trial. Each trial has a leading PI with primary responsibility to ensure compliance with trial protocol and good clinical practice over the entire trial.

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Relationship with CROs and SMOs

We collaborate with CROs and SMOs to conduct and support our preclinical and clinical studies in line with industry practice. We select our CROs and SMOs by weighing various factors. Upon business engagement, we assess CROs and SMOs based on their business focus, capabilities and overall market recognition. Secondly, we also value the R&D capabilities of the CROs and SMOs and the management skills of their leaders based on their experience and previous track record. Overall, we aim to select CROs and SMOs that have optimal compatibility with our preclinical and clinical development programs. When collaborating with CROs and/or SMOs on a given project, our project leader takes a comprehensive approach to manage such project and closely monitors the progress, engages in regular communication with the CRO and/or SMO teams to understand project milestones and identify potential risks. Simultaneously, the project leader maintains close contact with the financial departments of both our Company and the CRO/SMO organization, implementing stringent financial controls at different stages of the project to ensure its timely and quality completion. Upon project completion, we will conduct a thorough review and provides feedback to enhance the efficiency of future collaborations with the CRO and SMO organizations.

In terms of the involvement and contributions of each of the major CROs and SMOs to the development of our product candidates, the preclinical CROs mainly provide us with services related to preclinical toxicity and safety evaluations, such as animal studies, of our product candidates in accordance with agreed study design and under our supervision. The clinical CROs provide us with an array of services necessary for complex clinical trials in accordance with agreed trial design and under our supervision. SMOs provide a comprehensive suite of services to assist us in implementing and managing clinical trials, including trial preparation, clinical safety management, data management, and report preparation. We choose to engage a CRO and SMO based on the complexity and workload of a specific trial. We closely monitor the work of our CROs and SMOs and provide specific directions to ensure the quality and efficiency of the trial execution. This approach allows us to leverage the experience of our in-house team to better focus on critical clinical trial elements, such as trial design, data analysis and decision-making. All studies of our product candidates on humans are conducted in compliance with the applicable laws, regulations and in line with the industry standards. We believe our ability to conduct and work closely with CROs and SMOs to conduct preclinical studies and clinical trials helps us to shorten the time required for product development as well as generate the requisite data in a reliable and efficient way.

We mainly determine the service fees paid to the CROs and SMOs in accordance with market prices of similar services, the number of enrolled patients, the duration of the clinical trials, and the quality and contents of the services provided.

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During the Track Record Period, we engaged 12 CROs and seven SMOs in 2022, 13 CROs and seven SMOs in 2023, and ten CROs in 2024, respectively. We did not incur expenses to SMOs pursuant to the prescribed clinical trial milestones in 2024. All of our top five major CROs and SMOs engaged in each year during the Track Record Period are Independent Third Parties. The following table sets forth the details of our major CROs and SMOs engaged during the Track Record Period:

Major CROs	Background	Involvement and Contribution	Commencement of Business Relationship	Transaction Amount Each Period
<i>(RMB in thousand)</i>				
<i>For the year ended December 31, 2023</i>				
Hangzhou Tigermed Consulting Co., Ltd (杭州泰格醫藥科技股份有限公司)	Founded in 2004, it is the industry’s leading integrated biopharmaceutical R&D service platform, providing innovative R&D solutions across the entire cycle for the global pharmaceutical and medical device industries.	Safety and efficacy evaluation, clinical trial execution for our Core Product and other product candidates	Since 2011	62,310.0
IQVIA RDS (Shanghai) Co., Ltd. (艾昆緯醫藥科技(上海)有限公司)	Founded in 2013, it is a leader in the global healthcare industry. Utilizing data, technology, advanced analysis, and expertise, IQVIA works alongside customers and partners to accelerate innovations that enable better healthcare outcomes.	Clinical trial execution, data management and analysis, safety and efficacy evaluation for our product candidates	Since 2021	44,517.7
ICON Clinical Research Limited (ICON 臨床研究有限公司)	Founded in 1990, it is a global provider of consulting, and outsourced development and commercialisation services to pharmaceutical, biotechnology, medical device and government and public health organisation.	Safety and efficacy evaluation, clinical trial execution for our product candidates	Since 2021	12,477.9

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Major CROs	Background	Involvement and Contribution	Commencement of Business Relationship	Transaction Amount Each Period
				(RMB in thousand)
Teddy Clinical Research Laboratory Limited (上海觀合醫藥科技股份有限公司)	Founded in 2016, it is committed to providing pharmaceutical companies, CROs, and scientific research institutions with laboratory services related to drug clinical research.	Central laboratory services for the Phase III clinical trials of our Core Product	Since 2017	6,453.2
Shanghai InnoStar Bio-tech Co., Ltd. (上海益諾思生物技術股份有限公司)	Founded in 2010, it is a industry leading CRO that provides comprehensive and one-stop new drug research and development services in compliance with both domestic and international submission standards for global pharmaceutical companies and research institutions.	Safety and efficacy evaluation for our product candidates	Since 2019	5,205.9
<i>For the year ended December 31, 2024</i>				
Hangzhou Tigermed Consulting Co., Ltd (杭州泰格醫藥科技股份有限公司)	Founded in 2004, it is the industry’s leading integrated biopharmaceutical R&D service platform, providing innovative R&D solutions across the entire cycle for the global pharmaceutical and medical device industries.	Safety and efficacy evaluation, clinical trial execution for our Core Product and other product candidates	Since 2011	11,002.2
Hunan Huize Biopharma Co., Ltd. (湖南慧澤生物醫藥科技有限公司)	Founded in 2014, it is a industry leading CRO that provides comprehensive new drug research and development services from preclinical to clinical stages for global pharmaceutical companies and research institutions.	Clinical trial execution for our Core Product	Since 2021	6,630.2

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Major CROs	Background	Involvement and Contribution	Commencement of Business Relationship	Transaction Amount Each Period
				<i>(RMB in thousand)</i>
IQVIA RDS (Shanghai) Co., Ltd. (艾昆緯醫藥科技(上海)有限公司) . .	Founded in 2013, it is a leader in the global healthcare industry. Utilizing data, technology, advanced analysis, and expertise, IQVIA works alongside customers and partners to accelerate innovations that enable better healthcare outcomes.	Clinical trial execution, data management and analysis, safety and efficacy evaluation for our product candidates	Since 2021	3,185.0
Teddy Clinical Research Laboratory Limited (上海觀合醫藥科技股份有限公司)	Founded in 2016, it is committed to providing pharmaceutical companies, CROs, and scientific research institutions with laboratory services related to drug clinical research.	Central laboratory services for clinical trials of our Core Product and other product candidates	Since 2017	956.4
CRO A	Founded in 2015, it is a subsidiary of a company listed on the Hong Kong Stock Exchange that primarily provides R&D services to companies and research institutions in relation to biologics drugs.	Technical services for development of our product candidates	Since 2018	789.0

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Major SMOs	Background	Involvement and Contribution	Commencement of Business Relationship	Transaction Amount Each Period (RMB in thousand)
<i>For the year ended December 31, 2023</i>				
WuXi MedKey Med-Tech Development (Shanghai) Co., Ltd. (上海藥明津石醫藥科技有限公司).	Founded in 2009, it is the subsidiary of WuXi App Tec that primarily provides SMO services to companies and research institutions for the R&D of new drugs.	Assist us in implementing and managing clinical trials for our product candidates in China, including trial preparation, clinical safety management, data management, and report preparation	Since 2021	5,063.8
SMO ClinPlus Co., Ltd. (普蕊斯(上海)醫藥科技開發股份有限公司)	Founded in 2013, it is one of the leading SMOs in China to provide pharmaceutical companies and research institutions with clinical trial and site management services.	Assist us in implementing and managing clinical trials for our product candidates in China, including trial preparation, clinical safety management, data management, and report preparation	Since 2018	4,861.0
LinkStart SMO Co., Ltd. (北京聯斯達醫藥科技發展有限公司)	Founded in 2012, it is one of the leading SMOs in China to provide pharmaceutical companies and research institutions with clinical trial and site management services.	Assist us in implementing and managing clinical trials for our product candidates in China, including trial preparation, clinical safety management, data management, and report preparation	Since 2018	2,861.3
Hangzhou Simo Co., Ltd. (杭州思默醫藥科技有限公司) . . .	Founded in 2011, it is the subsidiary of Hangzhou Tigermed Consulting Co., Ltd. that primarily provides SMO services to pharmaceutical companies and research institutions.	Assist us in implementing and managing clinical trials for our product candidates in China, including trial preparation, clinical safety management, data management, and report preparation	Since 2018	2,508.7
Beijing Beisikang Pharmaceutical Technology Co., Ltd. (北京貝思康醫藥科技有限公司) . .	Founded in 2016, it engaged in technology development, technology transfer, technical services in the field of biopharmaceutical technology, as well as health consulting and related activities.	Assist us in implementing and managing clinical trials for our product candidates in China, including trial preparation, clinical safety management, data management, and report preparation	Since 2021	207.7

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Regulatory Affairs

Our regulatory affairs team is responsible for the regulatory approval process of our drug candidates, including assembling application dossiers for IND and NDA, addressing inquiries from relevant authorities and monitoring our R&D projects to ensure their compliance with relevant regulations. Our regulatory affairs team is led by Ms. Chuanzhen Liu, who has over 10 years of pharmaceutical regulatory affairs experience in multiple leading companies and has successfully applied for multiple INDs/NDAs in China. Our regulatory affairs team manages the regulatory submission process for our drug candidates, which requires filings to be made to and approved by the relevant authorities before clinical trials and commercialization can be initiated. The regulatory affairs team prepares and manages regulatory filings by drafting filing dossiers, addressing regulatory questions and conducting CMC and GMP readiness assessments for our drug candidates. We possess extensive knowledge and experience with regard to regulatory filings in China and the U.S. With our presence and expertise in both the U.S. and China, we can design our clinical trials to maximize operational efficiency.

In light of the above, we believe that we have sufficient resources and experience to conduct and oversee our research and development activities and clinical trial programs efficiently. Supported by the wholesome functions covered by our research and development teams, the comprehensive expertise and experience of our R&D personnel in their respective fields, and our well-established relationships with CROs and SMOs, we have established a track record of advancing three in-house developed product candidates to various clinical programs, including advancing our Core Product to the near-commercialization stage with NDA accepted by the NMPA. To maintain competitive with other large pharmaceutical conglomerates and biotech market players in similar fields, we will continue to monitor the needs and expand our R&D team as needed, and we will collaborate with R&D and commercialization partners when such collaboration suits our best interest. We expect our R&D resources and experience to further propel our product development in the future.

CHEMISTRY, MANUFACTURING & CONTROLS (“CMC”)

CMC Team

As of the Latest Practicable Date, our CMC team consisted of 13 professionals with extensive experience in process development, production and quality management from well-known biopharmaceutical and pharmaceutical companies. Our CMC team is led by Mr. Zhaopeng Liu, who has over 10 years of CMC managing experience in a leading pharmaceutical company in China and has led CMC affairs of over 20 drug development programs. Many of our CMC team members had over a decade of relevant work experience. Our CMC team specialized in preclinical and clinical support throughout the drug development process. The CMC function in our Company plays a critical role in drug development. It is responsible for developing safe, robust, and economically sound production processes for our drug substances and drug products, and ensuring their quality meets regulatory requirements.

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Collaboration with CDMO Partners

As of the Latest Practicable Date, we did not have commercialization-scale manufacturing facility. Currently we do not have any plans to establish our own manufacturing facilities to support our preclinical and clinical studies or produce future commercial supplies. We collaborate with CDMOs (including CMOs) to conduct and support our preclinical and clinical studies in line with industry practice. We believe our major CDMO partners possess sufficient production capacity and commercial production experience in the key compounds for our R&D activities such as peptide compounds. In terms of the involvement and contributions of each of the major CDMO partners (including CMOs) to the development of our product candidates, we collaborate with our CDMO partners to manufacture certain raw materials and drug substances of our product candidates to supply for preclinical studies and clinical trials. We did not experience any product quality issues including and not limited to unsuccessful release of production or product recall, in respect of the products manufactured by our CDMO partners during the Track Record Period. Under our agreement with our CDMO partners, the CDMO partners are required to perform their services according to the prescribed time frame as set out in the agreement. Usually, we pay the CDMO partners in installments, with a specified credit period. Our CDMO partners are responsible for manufacturing our required products in accordance with certain product specifications, in compliance with cGMP requirements (where applicable), our quality standards and other applicable laws and regulations. We retain all the intellectual property rights and grant our CDMO partners the right to use our intellectual property rights for such manufacturing and packaging activities during the contract period, while no technology transfer is arranged or deemed necessary. We are entitled to inspect and audit our CDMO partner’s manufacturing process. We mainly determine the service fees paid to the CDMOs in accordance with market prices of similar services, the number of products manufactured, and the quality and contents of the services provided. We do not share our IPs, know-hows and trade secrets with CDMOs. We currently plan to source future commercial supplies of our drugs following their marketing approval from CDMOs as well. For future commercial production of PB-119, we anticipate to expand our collaboration with the major CDMO partners to achieve the commercial-scale manufacturing, and we intend to negotiate with the major CDMO partners at a stage closer to the anticipated commercialization. Regardless of whether we collaborate with the same major CDMO partners for the commercial production, we believe that there are sufficient production capacities in the industry to enable us to achieve the production plans.

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During the Track Record Period, we engaged eight and three CDMOs in 2023 and 2024, respectively. All of our top five major CDMOs engaged in each year during the Track Record Period are Independent Third Parties. The following table sets forth the details of our major CDMOs engaged during the Track Record Period:

Major CDMOs	Background	Involvement and Contribution	Commencement of Business Relationship	Transaction Amount Each Period
<i>(RMB in thousand)</i>				
<i>For the year ended December 31, 2023</i>				
Chinese Peptide Company (中肽生化有限公司) . . .	Founded in 2001, it is one of the leading CRDMOs in China to provide pharmaceutical companies and research institutions with integrated laboratory R&D and production services.	Process development, quality analysis research and manufacture active pharmaceutical ingredients of our product candidates	Since 2016	1,906.0
BioDuro Biotechnology (Jiangsu) Co., Ltd. (保諾生物科技(江蘇)有限公司) . . .	Founded in 2019, it is committed to providing pharmaceutical companies and research institutions with laboratory R&D and production services.	Process R&D and manufacture samples of our product candidates	Since 2021	1,440.0
Hangzhou Ausia Biological Technology Company, LTD (杭州澳亞生物技術股份有限公司) .	Founded in 1993, it is one of the leading CMOs in China to provide pharmaceutical companies and research institutions with formulation production services.	Process formulation manufacturing and filing of our Core Product and other product candidates	Since 2018	1,342.3
Chengdu Shengnuo Biopharmaceutical Co., Ltd. (成都聖諾生物製藥有限公司)	Founded in 2004, it is committed to providing pharmaceutical companies and research institutions with laboratory R&D and production services.	Process development, quality analysis research and manufacture active pharmaceutical ingredients of our Core Product	Since 2010	1,079.7
Sinotherapeutics Inc. (上海宣泰醫藥科技股份有限公司)	Founded in 2012, it is committed to providing pharmaceutical companies and research institutions with laboratory R&D and production services.	Process formulation development, analytical method development and validation, cGMP manufacturing of our product candidates	Since 2017	850.0

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Major CDMOs	Background	Involvement and Contribution	Commencement of Business Relationship	Transaction Amount Each Period
(RMB in thousand)				
<i>For the year ended December 31, 2024</i>				
Chengdu Shengnuo Biopharmaceutical Co., Ltd. (成都聖諾生物製藥有限公司).	Founded in 2004, it is committed to providing pharmaceutical companies and research institutions with laboratory R&D and production services.	Process development, quality analysis research and manufacture active pharmaceutical ingredients of our Core Product	Since 2010	7,329.3
Chinese Peptide Company (中肽生化有限公司). . .	Founded in 2001, it is one of the leading CRDMOs in China to provide pharmaceutical companies and research institutions with integrated laboratory R&D and production services.	Process development, quality analysis research and manufacture active pharmaceutical ingredients of our product candidates	Since 2016	4,444.8
Hangzhou Ausia Biological Technology Company, LTD (杭州澳亞生物技術股份有限公司).	Founded in 1993, it is one of the leading CMOs in China to provide pharmaceutical companies and research institutions with formulation production services.	Process formulation manufacturing and filing of our Core Product	Since 2018	1,910.1

We plan to continue to engage CDMOs to support our preclinical and clinical studies as well as manufacturing of our products upon their commercialization, taking into account the well-established and cost-efficient collaboration model with CDMOs in the pharmaceutical industry, our collaboration history with CDMO partners, as well as the sufficient capabilities possessed by available CDMOs to support our research and development activities. According to CIC, it is industry norm to engage CDMOs and utilize their equipment and resources required for mass production of drug substances, which could be costly in particular for biotech companies in the early stage of commercialization that are ramping up their production capacities. We believe it is more cost efficient to leverage the existing production facilities of the available CDMOs, which could potentially drive down the unit costs of our drug candidates. For potential risks associated with engaging such third-party CDMOs, see “Risk Factors — We work with third parties to manufacture a portion of our drug candidates for clinical development and future commercialization. Our business could be harmed if those third parties fail to deliver sufficient quantities of products.”

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COMMERCIALIZATION

Our Marketing Strategy

During the Track Record Period and as of the Latest Practicable Date, we did not have any commercialized product. Our Core Product is one of the earliest domestically developed long-acting GLP-1 receptor agonists in China, according to CIC, upon obtaining the regulatory approvals from the NMPA.

Competing with other industry participants in the rapidly growing GLP-1 market in China requires a well-thought-out strategy that leverages key strengths and addresses market dynamics. Establishing strong partnerships with local healthcare providers and institutions can be pivotal. Collaborating with renowned Chinese hospitals and healthcare professionals not only builds credibility but also facilitates access to a vast patient pool. We maintain rigorous criteria to select the principal investigators (PI) of our ongoing or prospective clinical trials, taking into account factors such as their credentials, academic achievements, recognition and past experience in their respective fields. We believe the academic influence, authenticity and market recognition of potential PIs would contribute to the successful management and further development of our clinical trials, as well as facilitate our future market entry and recognition. We plan to conduct more academic marketing activities to improve communication and cooperation with hospitals, doctors and KOLs to increase market recognition of our brand and to educate physicians and patients on the potential benefits of our products. Pricing strategies should be competitive yet sustainable, catering to the affordability factor in the Chinese market. Additionally, investing in extensive market research to understand the unique needs and preferences of Chinese patients and healthcare providers can guide product development and marketing efforts. Moreover, fostering innovation and differentiation in GLP-1 products by focusing on superior efficacy, ease of administration, and reduced side effects can provide a compelling edges.

We have established an in-house marketing team that is primarily responsible for the related business activities, such as formulation of commercialization strategies, conducting academic marketing campaigns, and collaboration discussions with potential business partners. However, considering the potentially significant sales cost, we do not intend to build our internal sales team. Instead, we plan to form a win-win cooperation with selected commercialization partners to leverage their access to a wide range of pharmacies, clinics and hospitals, to better capture the market potential and maximize the value of our Core Product. In particular, we plan to partner with pharmaceutical companies who have strong commercialization capability and rich experience in the therapeutical fields we are focusing on, to utilize their well-established sales networks and other resources to achieve mutually beneficial results and maximize the commercial value of our drug candidates.

While we plan to continue developing our current pipeline products and future candidates in-house in the short- to mid-term, we may also seek commercialization collaboration opportunities with potential domestic and overseas partners to further propel our product development. As part of our domestic commercialization efforts, we entered into a

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commercialization collaboration arrangement on September 13, 2024 with a leading domestic commercialization-stage pharmaceutical company regarding the future marketing and commercialization activities of PB-119 in Mainland China. With such commercialization arrangement, we expect to benefit from its decades of market experience and know-how in navigating through the rapidly evolving China healthcare landscape, market access ability to provide umbrella coverage for a portfolio of products and sales network covering both higher- and lower-tier markets to enable broad market penetration across China. We believe that the collaboration will establish a solid foundation for our future commercialization.

Considering the increasing recognition of GLP-1-based products in China, we believe our pipeline will be able to establish in such market taking into account our tailored business strategies that focusing on core markets as well as expanding our coverage in the broad lower-tier markets, in order to enable the wider access of GLP-1-based products and benefit the large patient population in China with considerable market potential. Furthermore, we intend to develop our Core Product PB-119 as an affordable, quality domestic alternative option for patients in need in China and we anticipate it to be a competitive product in the marketplace in light of its multiple clinical benefits. For instance, PB-119 distinguished itself as the only GLP-1 receptor agonist with a sustained glucose-lowering effect till 52 weeks and no rebound demonstrated in clinical trial, and led to relatively low gastrointestinal AEs, based on the published results of other GLP-1 receptor agonists while no head-to-head studies were conducted. The high tolerance of PB-119 and its rapid, significant and long-acting efficacy also allows once-per-week administration that spares patients frequent subcutaneous injections, and renders dosage titrations which are required by many competing products unnecessary, potentially further improving patient compliance and enhancing the overall treatment outcomes. In particular, upon the marketing approval of our Core Product PB-119, we plan to adopt tailored business strategies at different stages of its commercial cycle. Prior to its inclusion in the NRDL, we aim to increase the accessibility of PB-119 and gradually accumulates the patient base by leveraging our future commercialization partner’s sales network and experience and collaborating with the partner to conduct significant promotion activities to improve market awareness and our brand recognition by physicians and patients, and actively seek entry into hospitals and clinics nationwide as well as coverage on e-commerce platforms to broaden our patient base by educating industry participants, including physicians, through presentation of the advantages of PB-119 in various academic and industry conferences. We also believe that for a drug with potentially significant beneficial results that can manifest in a potentially fast pace, like PB-119, word-of-mouth referrals can also establish a favorable market reputation and increase the patient base and physicians’ willingness to prescribe, especially considering that PB-119 is positioned to be an affordable medication for a wide group of patients. In the first year after its inclusion in the NRDL, we expect the competitive pricing of PB-119 would further expand its market share by increasing its coverage in urban hospitals. From the second year onwards, we plan to pursue comprehensive coverage of PB-119 in urban hospitals, community clinics and subsequently lower-tier markets in China. We believe the combination of PB-119 and its auto-injector further facilitates its usage in various scenarios catering to the needs of patients. We also plan to maintain robust after-sales services to enhance patient compliance and further strengthen our bond with the community and enhance our market presence. We also expect to effectively penetrate into such markets

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utilizing the well-established resources of our commercialization partners including their coverage of sales networks, experience in commercializing pharmaceutical products nationwide as well as brand recognition. We plan to select such commercialization partners who have strong commercialization capability and rich experience in the therapeutical fields we are focusing on, to leverage their access to a wide range of pharmacies, clinics and hospitals, and to utilize their well-established sales networks and other resources to achieve mutually beneficial results and cost-efficiently maximize the commercial value of our product candidates.

In the overseas markets, we plan to unlock the value of our assets through commercialization collaborations with local partners, and we plan to seek out-licensing and/or co-development opportunities with such local partners for the development of our product candidates. For instance, we intend to finalize the clinical development plan of PB-119 in the United States and conduct Phase III clinical trials for the treatment of T2DM in collaboration with a reputable local partner, considering the financial resources, familiarity with local regulations and executions required for such clinical trials. We plan to select such local partners who have proven track record of commercializing products with rich experience in the therapeutical fields we are focusing on, their local presence including clinical access and network coverage as well as brand recognition, to achieve fast market penetration and maximize commercial opportunities of our drug products effectively and efficiently. We expect such a local partner to share the potentially significant development costs with us and leverage its local network to facilitate various aspects of the clinical development, such as clinical site establishment, patient enrollment, material supplies and regulatory communications. For the overseas market, we generally plan to take a step-wise approach and plan to formulate a more concrete plan after we commercialize PB-119 in China, to ensure we allocate our resources and focus on the most important and imminent milestones. As of the Latest Practicable Date, we had not selected or initiated any negotiations with a local partner in the United States for any potential co-development and/or commercialization of PB-119. We may also seek collaborations to conduct clinical development and launch our product candidates upon regulatory approval in other overseas markets such as Europe and jurisdictions amongst the “Belt and Road Initiative” countries, including countries in the Middle East and South Asia.

Pricing

We will determine the prices of our products based on a number of factors, including our costs of production, prices of other similar products, our technology advantages, product quality, health economics, market trends and changes in the levels of supply and demand. In China, we intend to determine pricing based on the affordability to Chinese patients and the price of comparable peer products to not only ensure our products, once approved for commercialization, can be accessed by the vast patient population in China and also secure a sustainable revenue stream to support our future growth and R&D endeavors. The pricing in overseas markets may vary to suit specific conditions in each territory, and we will determine the prices based on a discussion with our local partners and taking into account, among other things, the pricing of multinational competitors in the same market. We endeavor to enhance our product affordability by pursuing reimbursement listings in the NRDL and other

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government-sponsored medical insurance programs at appropriate pricing levels. Inclusion into the NRDL is evaluated and determined by the relevant government authorities and we may face significant competition for successful inclusion. If we fail to have our Core Product included in the NRDL after commercialization, we may need to seek alternatives such as commercial private insurance coverage of our Core Product.

PB-119 is expected to be commercialized in China in 2025. We expect that PB-119 will be priced at a competitive level that is closer to the lower end of our pricing estimates once included into the NRDL, which we believe would render PB-119 accessible and affordable for a broad range of patients, in particular who have limited medical or financial resources.

Collaboration Agreement for Commercializing PB-119 in Mainland China

We entered into a commercialization collaboration arrangement (the “**Collaboration Agreement**”) on September 13, 2024 with a leading China-based pharmaceutical company (the “**Commercialization Partner**”) regarding the future marketing and commercialization activities of PB-119 in Mainland China (the “**Territory**”). The Commercialization Partner is an A-share listed company that has decades of experience in marketing and distributing drugs and medical equipment in China, covering all major markets and provinces in China, including first-tier cities such as Beijing, Shanghai and Guangzhou and other major cities, with established experience in chronic and metabolic diseases. Its direct sales channel covers a large amount of drug stores nationwide, and can access a wide range of terminal pharmacies nationwide. The Commercialization Partner has maintained long-standing partnerships with over 1,000 domestic and international suppliers. As of December 31, 2023, the Commercialization Partner had over 3,000 employees based on publicly available information. Given that the market for chronic and metabolic disease is relatively dispersed, we believe such a commercialization collaboration, by leveraging the existing and well-established sales network of the Commercialization Partner, may be a more cost-effective and efficient way to achieve relative certainty in commercial prospect as well as expeditious market penetration.

Collaboration management. We and the Commercialization Partner (the “**Parties**”) shall establish a joint steering committee (the “**JSC**”) consisting of representatives appointed by each party for the overall coordination and discussion of activities under the Collaboration Agreement. The functions of the JSC include, among others, reviewing and discussing annual promotion plans and modifications, evaluating and discussing commercialization activities of PB-119, discussing regulatory matters that may affect the Collaboration Agreement, discussing remedial and adjustment plans for supply shortages, discussing supply prices, sales targets and other objectives, and discussing matters related to the inclusion of PB-119 in the NRDL and national or provincial centralized procurement.

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Exclusive arrangement. We have granted the Commercialization Partner an exclusive right to promote and commercialize PB-119 in the Territory. We have also granted the Commercialization Partner, among others, the right to use the technology secrets, patents and authorized brands solely for purposes of commercializing PB-119 in the Territory. During the term of the Collaboration Agreement, without prior written consent from us, the Commercialization Partner or any of its subsidiaries shall not directly or indirectly (including, but not limited to, through collaboration with third parties) market or promote any competing products within the Territory. The “**competing products**” refer to pharmaceutical products with a similar mechanism of action as PB-119 (i.e., drugs that target GLP-1 receptor).

IP rights. Pursuant to the Collaboration Agreement, we granted the Commercialization Partner an exclusive, sublicensable license to promote and commercialize PB-119 in the Territory. We also granted the Commercialization Partner, among others, the right to use the technology secrets, patents and authorized brands (the “**granted IP rights**”) solely for purposes of commercializing PB-119 in the Territory. Other than the granted IP rights, we possess and retain all intellectual property rights related to PB-119 or any improvements thereto, regardless of whether created by us or the Commercialization Partner. Other than expressly provided, no license to the intellectual property related to PB-119 is granted by the Collaboration Agreement.

Market entry and regulatory matters. Under the Collaboration Agreement, we shall be responsible for obtaining and maintaining marketing authorization for the sale and production of PB-119 in the Territory. We will be the marketing authorization holder (the “**MAH**”) for PB-119. We shall also make commercially reasonable efforts to enable inclusion of PB-119 in the NRDL after obtaining the drug registration certificate.

Manufacturing and supply. We will be responsible for the manufacturing and supply of PB-119 to the Commercialization Partner. Within a specified period before the first commercial sale of PB-119, both parties shall execute a distribution agreement regarding the supply of PB-119. We shall provide PB-119 to the Commercialization Partner at a supply price calculated based on the winning bid price and a percentage value mutually agreed upon by both parties. The “**winning bid price**” refers to the price publicly announced on the applicable drug procurement platform. We will bear the cost of returns or exchanges due to quality issue arising from the production or transportation of PB-119 (excluding issues resulting from subsequent distribution, logistics, or warehousing processes). In other circumstances, once PB-119 is sold to the Commercialization Partner or its designated primary distributor, we will not accept returns or exchanges.

Promotion and commercialization. The Commercialization Partner shall prepare the annual promotion plan (the “**annual promotion plan**”) for promoting and marketing PB-119 within the Territory and be primarily responsible for implementing the plan. The Commercialization Partner shall use commercially reasonable efforts to achieve the commercialization targets for PB-119 in the Territory agreed upon by both parties.

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With respect to the promotion activities carried out by the Commercialization Partner, we agree to pay certain promotion service fee (the “**Promotion Service Fee**”) to the Commercialization Partner. The amount of the Promotional Service Fee will be calculated as a product of (a) the annual base amount of promotion service fee, (b) a specified fee rate and (c) the key performance indication (the “**KPI**”) achievement rate. The annual base amount of promotion service fee is calculated as a product of the winning bid price and the specified sales target. The KPI achievement rate is a weighted sum of the respective achievement rates of sales target, coverage of hospitals and pharmacies, hospital and pharmacy visits and promotion activities, respectively. The specified fee rate will be adjusted according to the status of NRDL inclusion of PB-119. Following the NRDL inclusion of PB-119, the specified rate will range between low- to mid-double digits, reflecting the time since such inclusion and whether PB-119 is also included in the national centralized procurement programs. Prior to the NRDL inclusion, the Promotion Service Fee is expected to be a majority of the annual base amount of promotion service fee, and depending on the KPI achievement rate, be adjusted upwards. Provided that the Commercialization Partner can meet all the KPI achievement rate, the Promotion Service Fee can reach up to substantially all of the annual base amount of promotion service fee. Taking into account the payments we are entitled to receive as specified in the Collaboration Agreement, the expected timetable of PB-119’s NRDL inclusion and the overall arrangement for the Promotion Service Fee payment, we believe the commercial arrangement is in line with industry practice for newly approved drugs, as confirmed by CIC.

The Commercialization Partner shall bear the costs and other expenses (unless otherwise agreed) to independently or through its agents conduct various commercialization activities within the Territory related to PB-119.

Upfront and milestone payments. As part of the consideration for granting the commercialization rights to the Commercialization Partner and subject to the terms and conditions of the Collaboration Agreement, and provided that the drug registration certificate for PB-119 is received no later than a specified date, we are entitled to receive from the Commercialization Partner, within a specified period after we obtain the drug registration certificate for PB-119 issued by the NMPA, (i) a one-time upfront payment of slightly over RMB100 million (the “**Upfront Payment**”) and (ii) a one-time milestone payment (the “**Milestone Payment**”), the amount of which is based on the timing of obtaining such drug registration certificate, and the minimum amount of the Milestone Payment is low-double digit million RMB.

Term and termination. The Commercialization Partner may terminate the Collaboration Agreement pursuant to the terms of the Collaboration Agreement. Under the Collaboration Agreement, if we fail to obtain the drug registration certificate for PB-119 from the NMPA by March 31, 2025, our Commercialization Partner has the right to unilaterally terminate the agreement upon written notice. However, if such termination notice is not provided by the Commercialization Partner by June 30, 2025, the Collaboration Agreement will remain in effect, in which case both parties may need to engage in further negotiations regarding potential adjustments to the milestone events and payments. Unless terminated earlier, the Collaboration Agreement shall remain in effect until December 31, 2030 (the “**Initial Term**”).

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Subsequent terms shall automatically extend for five years following the expiration of the Initial Term and each subsequent term, unless either party provides prior written notice of non-renewal. Notwithstanding the foregoing, if the Commercialization Partner achieves a specified percentage of the accumulated sales targets during the Initial Term alone or including any of the subsequent term(s), we will cooperate and not issue a notice of non-renewal if the Commercialization Partner intends to renew for any subsequent term.

The Collaboration Agreement may be terminated by either party if (i) the other party materially breaches its obligations under the Collaboration Agreement and fails to remedy within 30 days after the no-fault party demands remedy in writing, (ii) the other party undergoes certain enumerated financial stress, such as bankruptcy, receivership, dissolution or liquidation, or (iii) PB-119 fails to obtain the regulatory approval for commercialization from the NMPA due to safety or efficacy considerations. We may terminate the Collaboration Agreement if the Commercialization Partner experiences a change-of-control event that is deemed by us to have a material adverse impact on the manufacturing or commercialization of PB-119. The Commercialization Partner may terminate the Collaboration Agreement if PB-119 is withdrawn from the market.

INTELLECTUAL PROPERTY

Intellectual property rights are pivotal to the success of our business. Our commercial future will depend, in part, on our ability to acquire and protect our intellectual property rights for commercially significant technologies, inventions and know-how. This includes acquisition of new patents, defense of existing patents, and protection of our trade secrets. We will also have to operate without infringing, misappropriating, or otherwise violating third parties’ valid, enforceable intellectual property rights.

In China, we currently hold the patent for the composition of matter for our Core Product PB-119 which simultaneously protects its active ingredient and its intended indications for T2DM and obesity. The patent for the composition of matter has an expiration date of April 22, 2030, and may be extended until 2035 upon the marketing approval of PB-119, with the implementation of patent term adjustment policies. Our applications for the patent for pharmaceutical formulation and the patent for the manufacturing process for PB-119 are also currently under review. Once approved, we believe such patents will further provide IP protection to our commercial interest in our Core Product.

In the United States, we also hold the patent for the composition of matter for PB-119 with an expiration date of April 23, 2030. We intend to seek global patent protection of the formulation of PB-119 to further extend the term of patent protection and our competitive edge. We believe such patent strategies could provide comprehensive IP protection for our pipeline candidates in order to maximize their clinical application and commercial prospects.

As of the Latest Practicable Date, we held 83 patents and patent applications, including 13 patents and 15 patent applications in relation to our Core Product, and we did not hold any patents in relation to our PEGylation technology and the HECTOR[®] platform. As advised by

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our IP counsel, our Directors believe that our current patents and patent applications will render sufficient IP protection to the development and commercialization of our product candidates. According to the freedom-to-operate (“FTO”) search and analysis conducted by our IP counsel on PB-119 and PB-718 in China, our Directors and our IP counsel believe that the Company can implement the product technology of PB-119 and PB-718 in China without any material risk of patent infringement. As of the Latest Practicable Date, based on information in the public domain and as advised by our IP counsel, there was no application for patent term adjustments or extensions of third-party claims that may pose a material and adverse impact on the Company’s patent applications in targeted jurisdictions of the Company. As of the Latest Practicable Date, we had not received any material concerns or inquiries from relevant competent authorities that makes us to believe that any of the pending patent applications will be rejected. As advised by our IP counsel, we believe that in the event of any pending patent applications being not approved, this would not adversely affect the commercialization of our product candidates in any material respects. The following table sets forth an overview of our material granted patents and filed patent applications in connection with our clinical and preclinical drug candidates as of the Latest Practicable Date:

Product	Name of Patent ⁽¹⁾	Jurisdiction	Application/ Patent Numbers	Application Dates	Approval Dates	Status	Patent Expiration ⁽²⁾	Patent Owner	Patent Inventor	Market commercial rights of the Company
PB-119	Novel extendin variant and conjugate thereof	Mainland China, United States, Korea, Japan, Germany, Russia, South Africa, Great Britain, France, Brazil, Italy	CN201080018053.6, US13/265809, KR1020117027747, JP2012506327, DE602010023980.2, RU2011147083, ZA2011/08484 , EP10766649.7, EP10766649.7, BRPI1014416, IT502015000028202	2010/4/23	Mainland China: 2013/10/9 United States: 2013/11/5 Korea: 2014/1/15 Japan: 2016/6/22 Russia: 2014/9/20 South Africa: 2013/1/30 Germany, France, Italy, Great Britain: 2015/4/15 Brazil: 2021/11/23	Granted	Mainland China: 2030/4/22 United States, Korea, Japan, Germany, Russia, South Africa, Great Britain, France, Brazil, Italy: 2030/4/23	PEGBIO CO., LTD.	ZHANG LIJIE; ZHOU XIANGJUN; LUO XIAOSU; ZHANG YINGHUI; XU MIN; WANG YONGXIANG; GONG NIAN	Ownership

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Product	Name of Patent ⁽¹⁾	Jurisdiction	Application/ Patent Numbers	Application Dates	Approval Dates	Status	Patent Expiration ⁽²⁾	Patent Owner	Patent Inventor	Market commercial rights of the Company
	Preparation method of exenatide variant and polyethylene glycol conjugate thereof	Mainland China	CN202110943914.1	2021/8/17	N/A	Filed	N/A	PEGBIO CO., LTD.	XU MIN; WANG XIANGQUAN; XU CAIDING	Ownership
Pharmaceutical composition containing pegylated exenatide variant and application thereof		Mainland China, Taiwan, The United Arab Emirates, Brazil, Eurasian, Egypt, Europe, Indonesia, Mexico, Malaysia, The Philippines, Saudi Arabia, Thailand, United States, Vietnam, South Africa	CN202111126033.7, TW111134787, AEP2024-00668, BR1120240049248, EA202490647, EG/P/2024/401, EP22871850.8, P00202403068, MX/a/2024/003280, PI2024001586, PH12024550683, SA1120241423, TH2401001811, US18/691803, VNI-2024-01772, ZA2024/02197	Mainland China: 2021/9/24 Taiwan: 2023/12/1 2022/9/14 The United Arab Emirates, Brazil, Eurasian, Egypt, Europe, Indonesia, Mexico, Malaysia, The Philippines, Saudi Arabia, Thailand, United States, Vietnam, South Africa: 2022/9/13	Mainland China: N/A Taiwan: 2023/12/1 The United Arab Emirates, Brazil, Eurasian, Egypt, Europe, Indonesia, Mexico, Malaysia. The Philippines, Saudi Arabia, Thailand, United States, Vietnam: N/A South Africa: 2024/11/27	Mainland China: Filed Taiwan: Granted The United Arab Emirates, Brazil, Eurasian, Egypt, Europe, Indonesia, Mexico, Malaysia. The Philippines, Saudi Arabia, Thailand, United States, Vietnam: Filed South Africa: Granted	Mainland China: N/A Taiwan: 2042/9/13 The United Arab Emirates, Brazil, Eurasian, Egypt, Europe, Indonesia, Mexico, Malaysia. The Philippines, Saudi Arabia, Thailand, United States, Vietnam: N/A South Africa: 2042/9/13	PEGBIO CO., LTD.	HOU YINJU; XU MIN	Ownership

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Product	Name of Patent ⁽¹⁾	Jurisdiction	Application/ Patent Numbers	Application Dates	Approval Dates	Status	Patent Expiration ⁽²⁾	Patent Owner	Patent Inventor	Market commercial rights of the Company
	Compound medicine composition and application thereof	Mainland China	CN202310132942.4	2023/2/17	N/A	Filed	N/A	PEGBIO CO., LTD.	XU MIN; ZHANG YINGHUI	Ownership
PB-1902	Opioid receptor antagonist conjugate and use thereof	Mainland China, United States, Japan, Korea, Australia, Hong Kong, Germany, Great Britain, France	CN201610072859.2, US16/074268, JP2018541303, KR1020187023852, AU2017214071, HK19123123.2, DE602017065025.0, EP17746954.1, EP17746954.1	Mainland China: 2016/2/2 United States: 2022/4/26 Japan, Korea, Australia, Japan: 2021/5/12 Great Britain, France: 2017/1/26 Hong Kong: 2017/1/26	Mainland China: 2020/2/4 United States: 2022/4/26 Japan, Korea, Japan: 2021/5/12 Korea: 2021/4/2 Australia: 2020/6/11	Granted	Mainland China: 2036/2/1 United States: 2039/2/21 Japan, Korea, Australia, Hong Kong, Germany, Great Britain, France: 2037/1/26	SHANGHAI HANMAI BIO- PHARMA CO., LTD.	HE Mei	Ownership
	Solid salt form and crystal form of opioid receptor antagonist conjugate, and preparation method, composition, and use thereof	Mainland China	CN202211262369.0	Mainland China: 2022/10/14	N/A	Filed	N/A	SHANGHAI HANMAI BIO- PHARMA CO., LTD.	HE Mei	Ownership

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Product	Name of Patent ⁽¹⁾	Jurisdiction	Application/ Patent Numbers	Application Dates	Approval Dates	Status	Patent Expiration ⁽²⁾	Patent Owner	Patent Inventor	Market commercial rights of the Company
PB-722	Polypeptide conjugate and use thereof in preparation of drug for treating diseases related to glucose metabolism	Mainland China, United States,	CN202110819329.0, US18/576449	Mainland China, 2021/7/20 United States: 2022/7/20	N/A	Filed	N/A	PEGBIO CO., LTD.	Mainland China: XU MIN; SUN GAO; ZHANG YINGHUI United States: XU MIN; ZHANG YINGHUI	Ownership
	Pharmaceutical compositions comprising glucagon conjugates and uses thereof	Mainland China	CN202111333356.3	2021/11/11	N/A	Filed	N/A	PEGBIO CO., LTD.	XU MIN	Ownership

Abbreviations: PCT = Patent Cooperation Treaty

Notes:

- (1) Unless otherwise indicated, patents and patent applications within the same family are disclosed once.
- (2) The patent expiration date is estimated without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

The term of an individual patent may vary based on the countries/regions in which it is granted. The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extension or adjustment, the availability of legal remedies in a particular country/region and the validity and enforceability of the patent. We cannot provide any assurance that patents will be issued with respect to any of our pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned, or in-licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our product candidates and the methods of manufacturing the same.

With the support of FTO analysis on PB-119 and PB-718, our Directors were not aware of any instances of confirmed infringement of third parties’ IP rights in relation to our PB-119 and PB-718 in China, during the Track Record Period and up to the Latest Practicable Date. As advised by our IP counsel, taking into account the development status of our products, our Directors believe that conducting a FTO analysis in China is sufficient to evaluate the risk of infringement of third parties’ IP rights in any material aspects. Having considered the foregoing view of the Company and the view of the IP counsel, and based on the due diligence

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work conducted by the Sole Sponsor, nothing has come to the Sole Sponsor’s attention that would reasonably cause the Sole Sponsor to disagree with the foregoing view of the Company in relation to infringement of IP rights in any material respect.

We may rely, in some circumstances, on trade secret and/or confidential information to protect aspects of our product candidates. We seek to protect our proprietary product candidates and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors, and invention assignment agreements with our employees. We have entered into confidentiality agreements with our senior management and key members of our R&D team and other employees who have access to trade secrets or confidential information about our business. Our standard employment contract, which we used to employ each of our employees, provides that we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of such employee’s work.

These agreements may not provide sufficient protection of our trade secret and/or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secret and/or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secret and/or confidential information may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. Please see “Risk Factors — Risks Relating to Our Intellectual Property Rights” in this Document for a description of risks related to our intellectual property.

We conduct our business under the brand name of “PegBio.” As of the Latest Practicable Date, we held 101 trademarks and trademark applications in Mainland China and Hong Kong. We are also the owner of one copyright and one domain name.

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 material 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.

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OUR SUPPLIERS

During the Track Record Period, our major suppliers primarily consisted of CROs, SMOs, CDMOs and we did not experience any material disputes with our suppliers. We do not rely on any of such suppliers as we believe that adequate alternative sources for such supplies of relevant services/raw materials (such as active pharmaceutical ingredient of our drug candidates) exist, and we have developed alternative sourcing strategies for these supplies. We will establish necessary relationships with alternative sources based on supply continuity risk assessment. We generally have credit periods of 30 days.

Below is a summary of the key terms of a typical agreement with our CROs, SMOs and CDMOs.

- *Services.* The CRO, SMO or CDMO provides us with services such as implementing a clinical research project, manufacturing products and/or providing materials as specified in the master agreement and completing ad-hoc work orders.
- *Term.* The CRO, SMO or CDMO is required to perform its services according to the prescribed time frame set out in the master agreement or a work order.
- *Payment.* We are required to make payments to the CRO, SMO or CDMO according to the payment schedule agreed by the parties.
- *Confidentiality.* We and the CRO, SMO or CDMO agree to keep confidential any information in relation to the performance of the master agreement.
- *Credit terms.* We usually arrange payment within 30 days of receipt of invoice from CRO, SMO or CDMOs. Installment payments will be made in accordance with the milestone payment arrangements specified in the agreement.
- *Intellectual property.* We own all intellectual property derived from the clinical research project, and we are entitled to apply patent for such intellectual properties.
- *Liabilities and termination.* The liability of a CRO, SMO or CDMO arises at the failure to provide services in accordance with the agreed upon service schedule, and our liability arises at the failure to make timely arrangements for payment in accordance with credit terms. If either party is prevented from or delayed in the performance of its obligations under the agreement by force majeure for more than 60 consecutive or aggregate days or if either party is in breach of the agreement and fails to remedy its breach for more than 30 days after notice is given by the non-breaching party, the non-breaching party shall have the right to terminate the agreement immediately by written notice to such breaching party. The CDMOs we engaged will be liable for medical events and accidents that occur as a result of non-compliance with the quality of drugs manufactured by the CDMO.

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In 2023 and 2024, our purchases from our five largest suppliers in each period in aggregate amounted to RMB137.1 million and RMB32.6 million, respectively, representing 66.3% and 47.5% of our total corresponding purchases in such periods, respectively, and our purchases from the largest supplier in each period accounted for 33.0% and 16.0% of our total corresponding purchases, respectively. All of our five largest suppliers in each year during the Track Record Period are Independent Third Parties. Our material increase in the expenses attributable to the five largest suppliers during the Track Record Period is in line with the advancement of clinical trials of our Core Product.

The following table sets forth details of our five largest suppliers during the Track Record Period.

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship	Purchase Amount	% of Total Purchases for the Period
					(RMB in thousand)	
<i>For the year ended December 31, 2023</i>						
Hangzhou Tigermid Consulting Co., Ltd. 杭州泰格醫藥科技股份有限公司	Founded in 2004, it is the industry’s leading integrated biopharmaceutical R&D service platform, providing innovative R&D solutions across the entire cycle for the global pharmaceutical and medical device industries.	CRO services	Settle in accordance with the milestones in the contract	Since 2011	68,154	33.0%
IQVIA RDS (Shanghai) Co., Ltd. 艾昆緯醫藥科技(上海)有限公司	Founded in 2013, It is a leader in the global healthcare industry. Utilizing data, technology, advanced analysis, and expertise, IQVIA works alongside customers and partners to accelerate innovations that enable better healthcare outcomes.	CRO services	Settle in accordance with the milestones in the contract; net 30 days upon invoice receipt	Since 2021	44,518	21.5%
ICON Clinical Research Limited (ICON 臨床研究有限公司)	Founded in 1990, it is a global provider of consulting, and outsourced development and commercialisation services to pharmaceutical, biotechnology, medical device and government and public health organisation.	Clinical Laboratory	30 days	Since 2021	12,478	6.0%

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Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship	Purchase Amount	% of Total Purchases for the Period
					(RMB in thousand)	
Teddy Clinical Research Laboratory Limited. 上海觀合醫藥科技股份有限公司	Founded in 2016, it is committed to providing pharmaceutical companies, CROs, and scientific research institutions with laboratory services related to drug clinical research.	CRO services	60 days	Since 2017	6,453	3.1%
Pharmaron Beijing Co., Ltd. 康龍化成(北京)新藥科技股份有限公司	Founded in 2004, it provides a broad spectrum of research, development and manufacturing services for the life sciences industry. Its capabilities span drug discovery, preclinical and clinical development process across multiple therapeutic modalities.	SMO and CRO services	Settle in accordance with the milestones in the contract	Since 2018	5,511	2.7%
Total					<u>137,114</u>	<u>66.3%</u>

For the year ended December 31, 2024

Hangzhou Tigermed Consulting Co., Ltd. (杭州泰格醫藥科技股份有限公司)	Founded in 2004, it is the industry’s leading integrated biopharmaceutical R&D service platform, providing innovative R&D solutions across the entire cycle for the global pharmaceutical and medical device industries.	CRO services	Settle in accordance with the milestones in the contract	Since 2011	11,002	16.0%
Chengdu Shengnuo Biopharmaceutical Co., Ltd. (成都聖諾生物製藥有限公司)	Founded in 2004, it is committed to providing pharmaceutical companies and research institutions with laboratory R&D and production services.	CDMO services	Settle in accordance with the milestones in the contract	Since 2010	7,329	10.7%
Hunan Huize Biopharma Co., Ltd. (湖南慧澤生物醫藥科技有限公司)	Founded in 2014, it is a industry leading CRO that provides comprehensive new drug research and development services from preclinical to clinical stages for global pharmaceutical companies and research institutions.	CRO services	Settle in accordance with the milestones in the contract	Since 2021	6,630	9.7%

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Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship	Purchase Amount	% of Total Purchases for the Period
					(RMB in thousand)	
Chinese Peptide Company (中肽生化有限公司)	Founded in 2001, it is one of the leading CRDMOs in China to provide pharmaceutical companies and research institutions with integrated laboratory R&D and production services.	CDMO services	Settle in accordance with the milestones in the contract	Since 2016	4,445	6.5%
IQVIA RDS (Shanghai) Co., Ltd. (艾昆緯醫藥科技(上海)有限公司)	Founded in 2013, It is a leader in the global healthcare industry. Utilizing data, technology, advanced analysis, and expertise, IQVIA works alongside customers and partners to accelerate innovations that enable better healthcare outcomes.	CRO services	Settle in accordance with the milestones in the contract; net 30 days upon invoice receipt	Since 2021	3,185	4.6%
Total					32,591	47.5%

None of our Directors or any Shareholder who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the [REDACTED], nor any of their respective associates had any interest in any of our five largest suppliers during the Track Record Period. All of our five largest suppliers in each year during the Track Record Period are Independent Third Parties.

COMPETITION

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, competition and a strong emphasis on proprietary drugs. While we believe our pipeline of clinical and preclinical stage proprietary assets, leading R&D capability, technology platforms and seasoned management team provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, and public and private research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future.

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We focus on leveraging our industry experience and established R&D capabilities for the in-house discovery and development of differentiated therapeutics primarily for chronic diseases with a particular emphasis on metabolic disorders. We face fierce competition from existing products and product candidates under development in the market. See “Industry Overview” for more details on the competitive landscape of the various markets in which we compete. We may also face potential competition from existing products used off-label for T2DM. Those existing products may also be developed to expand their indications targeted by the Core Product. We face uncertainties in clinical trial development which are subject to a variety of factors, including satisfactory safety and efficacy results from clinical trials, successful enrollment of patients, and performance of CROs and other parties involved in clinical trial development and others.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. In addition to employee social and medical insurances, our principal insurance policies also cover adverse events in clinical trials. We currently do not maintain insurance for environmental liability or property loss. Please refer to “Risk Factors — Risks Relating to our Business and Industry — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.” in this Document.

We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period, we had not made or been the subject of any material insurance claims.

EMPLOYEES

As of the Latest Practicable Date, we had 64 employees in total, all of whom were located in China. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Functions	Number of employees by function	Percentage (%)
Research and Development*	19	29.7
CMC	13	20.3
Business strategy and Corporate Development	18	28.1
General and Administrative	14	21.9
Total	<u>64</u>	<u>100.0</u>

* Includes our drug discovery, regulatory affairs, and clinical development personnel.

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We enter into individual employment contracts with our employees covering salaries, employee benefits, workplace safety, confidentiality and non-competition, work product assignment clause and grounds for termination.

To maintain our workforce’s quality, knowledge, and skill levels, we provide continuing education and training programs, including internal training, to improve their technical, professional or management skills. We also provide training programs to our employees from time to time to ensure their awareness and compliance with our policies and procedures in various aspects. Furthermore, we provide various incentives and benefits to our employees, including competitive salaries, bonuses and share-based payment, particularly our key employees.

Our employees’ remuneration comprises salaries, bonuses, provident funds, social security contributions, and other welfare payments. We have made contributions to our employees’ social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds pursuant to applicable laws and regulations. We had complied with all statutory social security insurance fund and housing fund obligations applicable to us under the laws and regulations in China in all material aspects during the Track Record Period and as of the Latest Practicable Date. During the Track Record Period, we engaged third-party human resources agencies to pay social insurance premium and housing provident funds on behalf of us, as requested by the relevant employees, because such employees prefer their social insurance premium and housing provident funds to be paid at their respective resident places, for convenience of utilizing such benefits locally. Such arrangement, although not uncommon in China, is not in strict compliance with relevant PRC laws and regulations. As of the Latest Practicable Date, the third-party human resources agencies provided such funds for five of our employees. In 2023 and 2024, the social insurance premium and housing provident fund paid through the third-party human resources agencies amounted to RMB609.4 thousand and RMB723.9 thousand, respectively, and the agencies had made full contributions accordingly. On the basis that as of the Latest Practicable Date, (i) such employees had confirmed such arrangement that the third-party human resources agencies pay the social insurance premium and housing provident funds for them on behalf of us, and had raised no objections in relation thereto, (ii) there had been no disputes between us, such employees and the third-party human resources agencies with regard to such arrangement, and (iii) we had not received any notice of rectification from, or been imposed any administrative penalty by, the relevant governmental authorities as a result of such arrangement, as advised by our PRC Legal Adviser, the risk of us being subject to material penalties as a result of paying the social insurance premium and housing provident funds for the relevant employees through third-party agencies which thus have a material adverse effect on our financial condition or results of operations taken as a whole is relatively low. Please refer to the section headed “Risk Factors — Risks Relating to Doing Business in the Jurisdictions We Operate — We are subject to risks in relation to our social insurance and housing provident fund contributions.” in this Document.

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To prevent any future recurrences of such non-compliance, we have established and implemented the following internal control measures and procedures: (i) our human resources department has inspected our payment of social insurance premium and housing provident funds for our employees and found out the reasons for engaging third-party human resources agencies, made records and followed up; (ii) we will prepare and maintain regular reports in respect of our payment of social insurance premium and housing provident funds for our employees for review by our Board and the head of our human resources department; (iii) we will regularly communicate with the relevant competent authorities and, where necessary, consult with our PRC Legal Adviser, to ensure that our calculation and payment methods are in compliance with the relevant laws and regulations; (iv) we will regularly consult with our PRC Legal Adviser to understand whether we are at risk of non-compliance with the relevant laws and regulations; and (v) we will provide regular internal trainings to our Directors, senior management personnel and other responsible staff on the relevant laws and regulations and consult with our PRC Legal Adviser, where necessary, on the updates thereof.

Workplace Safety

We have adopted and maintained a series of rules, standard operating procedures, and measures to maintain our employees’ healthy and safe environment. We implement safety guidelines to set out information about potential safety hazards and procedures. We require employees to participate in safety training to familiarize themselves with the relevant safety rules and procedures. Also, we have policies in place and have adopted relevant measures to ensure the hygiene of our work environment and the health of our employees.

Our PRC Legal Adviser has confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material penalty in relation to health, work safety, social and environmental protection.

PROPERTIES

As of the Latest Practicable Date, we did not own any real property. We did not lease any properties overseas. We believe our current facilities are sufficient to meet our near-term needs, and additional space can be obtained on commercially reasonable terms to meet our future needs.

The following table sets forth the details of our leased properties as of the Latest Practicable Date:

Actual usage	Location	GFA (sq.m)	Expiry Date
Office	Hangzhou, China	2,399.9	February 13, 2031
Production	Suzhou, China	2,217.0	February 28, 2026
Office	Shanghai, China	259.7	June 30, 2025
Office	Beijing, China	N/A (9 shared workspaces)	April 16, 2026

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We plan to comply with the lease agreement registration requirement regarding our lease agreements. However, as the filing of the lease agreements requires the coordination of both lessors and lessees, the lessors may not cooperate and complete the registration in a timely manner.

As of the Latest Practicable Date, no single property interest that formed part of non-property activities had a carrying amount of 15%, and no single property interest that formed part of property activities had a carrying amount of 1%, of our total assets. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Cap. 32L of the Laws of Hong Kong), this Document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, which requires a valuation report with respect to our Group’s interests in land or buildings.

As of the Latest Practicable Date, none of our lease agreements for properties in China had been registered with relevant authorities in China. Our PRC Legal Adviser is of the view that the non-registration of lease agreements will not affect the validity of the lease agreements, but the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and if we fail to so rectify, we may be subject to a fine of between RMB1,000 and RMB10,000 for each of these leasing properties. For further details, please see the sections headed “Risk Factors — Risks Relating to Doing Business in the Jurisdictions We Operate — We are subject to risks associated with our leased properties.”

PERMITS, LICENSES AND OTHER APPROVALS

As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations and such licenses, permits and certifications all remain in full effect. For more details regarding the laws and regulations to which we are subject, see “Regulatory Overview” in this Document. We had not experienced any material difficulty in renewing such licenses, permits, approvals and certificates during the Track Record Period and up to the Latest Practicable Date, and we currently do not expect to have any material difficulty in renewing them when they expire, if applicable. There is no material legal impediment in renewing such licenses, permits, approvals and certificates as they expire in the future as long as we are in compliance with applicable laws, regulations and rules. During the Track Record Period and up to the Latest Practicable Date, we had not been penalized by any government authorities for any non-compliance relating to maintenance and renewal of our material licenses, permits, approvals and certificates.

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The following table sets forth the details of our material licenses, permits and approvals as of the Latest Practicable Date:

<u>License/Permit</u>	<u>Issuing Authority</u>	<u>Holder</u>	<u>Grant Date</u>	<u>Expiration Date</u>
Drug Manufacturing License (No. 蘇 20230017) (藥品生產許可證(編號:蘇 20230017))	Jiangsu MPA	Company	November 15, 2024	April 16, 2028
Notice of Acceptance for New Drug Application (No. CXHS2300088) (新藥上市申請受理通知(編號: CXHS2300088))	NMPA	Company	September 25, 2023	N/A
Notice of Approval for Supplemental Application of Clinical Drug Trial (No. 2024LB00248) (藥物臨床試驗補充申請批准通知書(編號: 2024LB00248))	NMPA	Company	April 19, 2024	N/A
Notice of Approval for Clinical Drug Trial (No. 2023LP00961) (藥物臨床試驗批准通知書(編號: 2023LP00961))	NMPA	Company	May 22, 2023	N/A
Notice of Approval for Clinical Drug Trial (No. 2023LP00838) (藥物臨床試驗批准通知書(編號: 2023LP00838))	NMPA	Company	May 6, 2023	N/A
Notice of Approval for Clinical Drug Trial (No. 2021LP01309) (藥物臨床試驗批准通知書(編號: 2021LP01309))	NMPA	Company	August 20, 2021	N/A

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License/Permit	Issuing Authority	Holder	Grant Date	Expiration Date
Notice of Approval for Clinical Drug Trial (No. 2021LP00818) (藥物臨床試驗批准通 知書(編號: 2021LP00818))	NMPA	Company	June 2, 2021	N/A
Orphan Drug Designation of PB-722 for Congenital Hyperinsulinemia	FDA	Company	May 17, 2021	N/A
Notice of Approval for Clinical Drug Trial (No. 2020LP00816) (藥物臨床試驗批准通 知書(編號: 2020LP00816))	NMPA	Shanghai Hanmai	November 27, 2020	N/A
Notice of Approval for Clinical Drug Trial (No. 2020LP00817) (藥物臨床試驗批准通 知書(編號: 2020LP00817))	NMPA	Shanghai Hanmai	November 27, 2020	N/A
Notice of Approval for Supplementary Application for Clinical Drug Trial (No. 2020LB00079) (藥物臨床試驗補充申 請批准通知書(編號: 2020LB00079))	NMPA	Company	August 20, 2020	N/A
Approval for PB718-001 Clinical Trial for Non-alcoholic Steatohepatitis	FDA	Company	August 30, 2019	N/A
Approval for PB119-202 Clinical Trial for Type 2 Diabetes Mellitus	FDA	Company	June 11, 2018	N/A
Approval Opinion Notification (No. 2017L04761) (審批意見通知件 (編號: 2017L04761))	NMPA	Company	September 21, 2017	N/A

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License/Permit	Issuing Authority	Holder	Grant Date	Expiration Date
Drug Clinical Trial Approval (No. 2017L04762) (藥物臨床試驗批件 (編號: 2017L04762)) . .	NMPA	Company	September 21, 2017	N/A
Approval for PB119-US01-01 Clinical Trial for Type 2 Diabetes Mellitus	FDA	Company	May 15, 2015	N/A
Drug Clinical Trial Approval (No. 2013L01889) (藥物臨床試驗批件 (編號: 2013L01889)) . .	NMPA	Company	September 7, 2013	N/A
Drug Clinical Trial Approval (No. 2013L01890) (藥物臨床試驗批件 (編號: 2013L01890)) .	NMPA	Company	September 7, 2013	N/A

ENVIRONMENTAL, SOCIAL AND GOVERNANCE

Board oversight and management of ESG matters

We actively integrate Environmental, Social and Governance (“**ESG**”) into our business management. Our Board takes ESG risks and opportunities that may arise as one of the key considerations when making strategies or decisions in relation to major transactions, and also considers mitigation measures in advance for potential risks identified.

We have taken the lead in setting up a three-member ESG working group to take charge of our ESG-related matters, and formulated the ESG Policy of the Company. The objective of the working group is to improve our ESG performance under the supervision and management of the Board of Directors, enhance our core competitiveness and sustainable development ability, enhance the capital market’s recognition of our ESG work, build the Company into a sustainable development enterprise and become a leader in ESG in the biopharmaceutical industry. Our ESG working group comprises Ms. Xiaojun WANG, our Executive Director and Chief Financial Officer, Mr. Yifeng HUANG, our Board secretary and Mr. Yiming QIAN, our head of production, so that all our departments are actively involved in the disclosure of information and actions related to our sustainability initiatives, under the supervision and management of the Board.

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The ESG working group is responsible to the Board of Directors. The ESG working group shall report to the Board of Directors on ESG-related matters of the Company no less than once a quarter. The proposals passed at the working group meeting and the voting results shall be reported to the Board of Directors in writing. The ESG working group’s responsibilities include, among others, any matters relating to the Company’s ESG endeavors:

- formulate the Company’s ESG related strategies, objectives, key issues and risks, and provide recommendations and approvals to the Board;
- communicate with various stakeholders to identify, evaluate and monitor ESG issues in a timely manner, and follow up and make recommendations to the Board in a timely manner when any changes occur or potential risks exist;
- formulate policies, systems and work plans related to ESG matters of the Company, and to report regularly to the Board on the progress and effectiveness;
- check and supervise the practice and implementation of ESG related matters in the Company, review the content of ESG related information disclosure, and provide suggestions and approval to the Board of Directors;
- provide ESG related training and materials to the board.

After [REDACTED], we intend to implement a comprehensive top-down governance structure for ESG initiatives. This approach will enhance the Board’s oversight and management capabilities regarding the Company’s ESG commitments and performance. To ensure that our Board of Directors and all employees have sufficient knowledge for the implementation of ESG policy and make appropriate judgments on ESG matters, our ESG working group has fully studied the HKEX’s Environmental, Social and Governance Reporting Guidelines and other relevant disclosure guidelines including, but not limited to, ISSB’s IFRS S2 and GRI, and will regularly provide ESG related training to the Board of Directors and all employees. In addition, if deemed necessary by the ESG working group, professional third-party ESG consultants may also be hired to provide ESG training to the Board of Directors.

ESG Key Topics

According to HKEX’s Environmental, Social and Governance Reporting Guidelines and the management requirements for material topics in the GRI (Global Reporting Initiative) Sustainability Reporting Guidelines, we identify our ESG key topics in three steps: (1) preliminary screening of topics: identify and summarize issues relevant to the company based on the domestic and international standards and policies followed by GRI standards, SDGs, healthcare and life sciences industry policy analysis and peer benchmarking; (2) stakeholder communication: we communicate with the Company’s internal and external stakeholders, including the government and regulatory agencies, shareholders and [REDACTED], customers, staff, etc., combined with stakeholder research and internal and external expert

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opinions, to obtain the materiality of the topics evaluation; (3) comprehensive analysis of results: the Board of Directors shall review the completeness and accuracy of the ESG key topics, and finally determine ESG key topics and its materiality of the Company:

ESG Key Topics	Materiality	Potential risks/opportunities	Partial quantitative index
Product Responsibility			
Product		Product responsibility shows our	Product recall for quality
Quality and		commitment to patients’ health,	and safety reasons
Safety	Highly Material	safety and data privacy. We regard	(pieces)
R&D and		product responsibility as one of the	Number of intellectual
Innovation . .	Highly Material	core values of our company	property rights held
		development, and are committed to	(pieces)
		providing high-quality and accessible	
		innovative medicines to meet the	
		treatment needs of chronic patients.	
Employee Rights and Benefits			
Benefits	Moderately	A healthy and developing work	Social insurance rate for
	Material	environment is essential for the	employees (%)
Development .	Moderately	stability of employees and the	Employee training
	Material	sustainable development of the	coverage (%)
Diversity	Moderately	company, as well as stimulating their	Percentage of female
	Material	creativity and passion for work,	employees (%)
Health and		thereby driving the continued growth	Number of work-related
Safety	Moderately	of the company’s business. When the	deaths (persons) and
	Material	rights and interests of employees are	proportion (%)
		fully protected, they are more likely	
		to devote themselves to their work	
		and play to their maximum potential.	
		Diversified training programs help	
		employees to continuously improve	
		their skills and knowledge, meet the	
		needs of employees’ personal	
		growth, and train more talents with	
		professional literacy and innovative	
		ability for the company to lay a	
		solid foundation for the long-term	
		development of the company.	

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ESG Key Topics	Materiality	Potential risks/opportunities	Partial quantitative index
Governance			
Diversity of the Board of Directors and Senior Management.	Moderately Material	Failure to maintain good business ethics can have compliance implications and harm the interests of shareholders. Good business ethics build a positive image of the company.	Percentage of female board members (%)
Business Ethics and Anti-Corruption .	Highly Material		Number of corruption proceedings received and concluded (cases)
Environment			
Waste Management.	Moderately Material	To actively prevent climate change and protect the environment is the responsibility and obligation of every business and citizen. Failure to meet these responsibilities adequately can not only damage a company’s reputation, but also lead to the risk of increasingly stringent regulation and fines.	Total amount of hazardous waste generated (tons)
Resource Consumption and Carbon Emissions . .	Moderately Material		Total energy (e.g. electricity) consumption (MWh), total water consumption (tons)
Responding to Climate Change. . . .	Highly Material		Scope 1 emissions (tonnes of CO ₂ equivalent), Scope 2 emissions (tonnes of CO ₂ equivalent) and density (CO ₂ equivalent/person)

After [REDACTED], the ESG working group will continuously evaluate the issues and their importance each year, taking into account the latest policy requirements, the benchmarking of substantive issues in the industry, the Company’s business focus for the year and the investigation of various stakeholders, and review the changes in indicators and report them to the Board of Directors for review.

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Product Responsibility

Product Safety and Quality

We consider product safety and quality paramount to our business, and we have established a comprehensive quality system to ensure product safety and quality. At the same time, we have established strict management regulations for the commissioned manufacturers to ensure that the quality of the products and services can meet relevant regulations and the requirements of both parties. To ensure that the production conditions and quality management of the production site meet or continue to meet regulatory and product requirements, we will conduct sufficient and reliable quality audits of the commissioned manufacturers, usually by on-site audits. Usually divided into initial audit and periodic audit.

We will implement “full participation” in safety and quality control work, cultivate employee safety and quality awareness through the establishment of a knowledge management system, and provide multi-level safety and quality control trainings to all employees.

R&D and Innovation

We have established HECTOR[®] (Highly Effective Target Screening & Molecule Modifier Platform) based on our in-depth understanding in the field of metabolic diseases. Combined with our rich experience in rational drug molecule design, we have identified advantageous lead compounds for further drug development through an efficient screening system.

Through HECTOR[®], we have developed different types of innovative products including peptides, small molecule compounds and protein-based compounds covering different types of metabolic diseases and have successfully advanced them to different stages of clinical trials.

In addition, we keep abreast of the cutting edge of science and technology and continue to innovate, through which we continue to design, screen and develop innovative compounds, in order to provide a wide range of innovative pharmaceutical products with advantages for patients with metabolic diseases.

Governance

We have developed key governance policies and procedures that incorporate a range of best practices, including:

Diversification of the Board of Directors and Senior Management. Our Board has a diverse and inclusive composition, and female candidates are given due consideration in the formation of the Board.

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Business Ethics and Anti-Corruption. All of our employees are required to sign the “Commitment on Integrity and Self-discipline,” in which they undertake to strictly comply with the laws and regulations and all the relevant regulations on integrity and self-discipline management formulated by the Company during their working period, and will never ask for bribes or engage in any other improper behaviors from the related units or relations, nor offer or ask for bribes, either directly or indirectly, to or from the employees of the Company or their relations. We have established strict material and service procurement processes, and our procurement business follows the Procurement Management Regulations to ensure that our procurement activities are carried out in an orderly and compliant manner. We have strengthened our anti-corruption management of suppliers in the procurement process by requiring an explicit statement in the contracts signed with suppliers that neither party shall solicit, accept, offer or give any benefits other than those stipulated in the contract to the other party or the other party’s managers, staff or other relevant personnel, including but not limited to explicit or implicit deductions, cash, gift cards, in-kind items, marketable securities, trips or other benefits of a non-physical nature, or else it constitutes a material breach of the contract. If such benefits are customary or usual practice in the industry, they must be expressly stated in the contract, otherwise it is also a material breach of contract.

Risk Management. The Company has established a strict risk management and internal control system. For ESG-related risks, the ESG Working Group is responsible for formulating the Company’s ESG-related risks, providing recommendations and reporting to the Board of Directors, as well as timely following up and providing recommendations to the Board of Directors when any changes occur or potential risks exist.

Employee Rights and Benefits

We actively endeavor to establish a sound and standard human resources management system and system to fully protect the legitimate rights and benefits of our employees. We strictly abide by the relevant PRC labor laws and regulations.

Benefits

In addition to basic salary and salary for duties, we also provide benefits such as meal subsidy, communication subsidy, travelling subsidy, staff and their children’s welfare, activity fund, employee physical examination and other benefits. At the same time, we offer additional incentives such as the Pegbio President’s Award, the Pegbio Outstanding Manager’s Award, the Pegbio Outstanding Employee Award, the Pegbio Special Award, the Pegbio Star of the Month, and the Pegbio Cheque. In addition, we offer both short-term incentives (targeted year-end awards) and long-term incentives (such as stock options) designed to reward excellence and long-term service to the Company.

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Development

In order to systematize the Company’s job system and provide employees with a clear direction for career development in the Company and to ensure reasonable and fair job advancement, we have formulated the Promotion Management System, which provides two promotion paths: promotion in the original technical job system or promotion from general to managerial positions, and which will be assessed and come into effect in April and October of each year.

Diversity

We endeavor to create a working atmosphere of diversity and equality, openness and inclusivity, collaboration and mutual support, and to provide fair, just and reasonable job opportunities. The anti-discrimination policy is clearly stated in the Employee Handbook, which states that we shall not engage in or support any decision based on race, social class, religious beliefs, disability, gender, sexual orientation, age, marital status, pregnancy, union membership or political affiliation in deciding on labor matters such as hiring, remuneration, training opportunities, promotion, termination of labor relations or retirement. It does not interfere with the right of employees to observe their beliefs and customs, freedom of religious belief and protects normal religious practices. Sexual harassment is also expressly prohibited.

Health and Safety

We recognize the health and safety of our employees as an important social responsibility. In order to improve our employees’ safety awareness, and enable them to master basic safety knowledge and self-protection skills, we have formulated the “Safety Training and Education Management Policies.” The training includes safety standard laws and regulations, general environmental management, safety technology, our office environment and related accident cases. We also organize a fire safety promotion activity and a fire practical exercise activity on an annual basis.

Environmental Protection

Resource Consumption and Carbon Emissions

Our primary energy consumption is electricity purchased from the grid, which is also a major source of our carbon emissions. We are therefore committed to improving our energy efficiency and reducing our carbon emissions. Apart from electricity, we also consume petrol and water resources.

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The total volume and intensity of our consumption of various resources in the Track Record Period are shown below:

	For the year ended December 31,	
	2023	2024
Water consumption		
Total water consumption (cubic metres)	1,008	1,200
Intensity of consumption (cubic metres/person) . . .	14.4	18.8
Power consumption		
Total Power Consumption (MWH).	288.083	391.342
Intensity of consumption (MWH/person)	4.12	6.11
Petrol consumption		
Petrol consumption (tonnes)	7.968	7.875
Intensity of petrol consumption (tonnes/person) . . .	0.11	0.12

Our Scope 1 and Scope 2 emissions and total emissions in the Track Record Period are shown as follows:

	For the year ended December 31,	
	2023	2024
	<i>CO₂ eq.</i>	<i>CO₂ eq.</i>
Scope 1 emissions (tonnes)	23.34	23.06
Scope 2 emissions (tonnes)	164.29	223.18
Total greenhouse gas emissions (tonnes)	187.63	246.25
Greenhouse gas emission intensity		
(tonnes/person)	2.68	3.85

Going forward, we will continue to take measures to control the consumption of resources and energy in our daily operations, thereby controlling carbon emissions. However, taking into account the significant increase in the level of our production activities in 2023 compared to 2022, we will continue our efforts to reduce emissions by actively promoting green office practices to enhance our staff’s awareness of green and low-carbon practices, as well as conducting regular inspections and replacement of old office equipment to ensure their energy-efficient operation. In addition, we are considering the replacement of gasoline official vehicles with electric ones. We will monitor our water and electricity consumption to identify irregularities in a timely manner. Based on this, we believe that our intensity of greenhouse gas emissions (tonnes/person) and electricity consumption (MWH/person) will decrease by 3% in 2024 compared to 2023.

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We prioritize the reduction of Scope 3 carbon emissions and are dedicated to promoting sustainable practices across our operations. Internally, we advocate for the utilization of video conferencing to minimize unnecessary travel expenses among employees. Additionally, we endorse eco-friendly office practices, including the reduction of disposable product usage, and actively encourage green commuting alternatives. Furthermore, we extend our commitment to environmental stewardship to our supplier management processes. We mandate compliance with all pertinent environmental regulations and laws, ensuring the safe handling, transportation, storage, and responsible disposal of waste, air emissions, and wastewater.

In alignment with the directives of the Chinese government, we have established greenhouse gas reduction targets across various temporal dimensions, to attain carbon peaking at the operational level by 2030 and achieve carbon neutrality within our operations by 2060. Recognizing electricity consumption as a significant contributor to our greenhouse gas emissions, we acknowledge the imperative of reducing our carbon footprint to mitigate climate change risks. Accordingly, we have implemented rigorous measures to manage electricity consumption effectively, which include initiatives such as the replacement of conventional lighting with energy-efficient LED fixtures and upgrading to Grade 2 or higher energy-efficient equipment. To foster a culture of energy conservation among our staff, we require measures such as dimming or turning off non-essential lights during breaks and overtime periods, as well as powering down idle computers or setting them to energy-saving modes. At the end of each workday and before holidays, thorough checks are conducted to ensure all unnecessary electrical appliances are disconnected.

Through the concerted efforts outlined above, we have achieved a notable 9.5% reduction in greenhouse gas emissions in 2023 compared to 2022, underscoring our commitment to environmental sustainability and responsible resource management.

To conserve water resources and minimize usage, we advocate for all employees to diligently turn off taps when not in use and promptly address any leaks or inefficiencies in our water facilities through regular inspections. Additionally, we are committed to installing water-saving equipment where feasible to further enhance conservation efforts.

The implementation of these measures may entail initial investments in acquiring more efficient equipment. However, we firmly believe that these investments will yield long-term benefits, including reduced energy and water costs.

We believe our ESG performance is in line with industry practice as we are on par with other industry leaders (HKEX [REDACTED] biopharmaceutical companies) in terms of resource consumption and greenhouse gas emissions. We made reference to the ESG performance (including energy consumption levels, greenhouse gas emissions, etc.) disclosed in the document and annual reports of the leading companies in the industry, and determined that our ESG performance is comparable to that of the leading companies in the industry. Specifically, the total electricity consumption of the above companies in 2022 is between 200 MWH and 3,600 MWH, and the total greenhouse gas emissions are between 100 tonnes and 2,200 tonnes.

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Waste Management

We have established a management system in respect of environmental protection, which specifies the methods of collecting, depositing and disposing of various types of wastes, in order to control our potential pollution and to comply with the requirements of the governmental departments and the relevant laws and regulations.

For hazardous waste, we have formulated the “Hazardous Substances Management System,” which requires that discarded chemicals should not be poured into toilets and underground drains, and should be classified and stored in dedicated collection bins according to requirements, and sealed for storage. Currently, our major types of hazardous wastes are the pollutants generated during the research and development process, including waste gas, waste liquid and solid waste. Among them, the waste gas is mainly volatile experimental solvents, which is then processed through the waste gas processing device. The waste liquid mainly includes conventional organic solvents and laboratory liquids, which are then classified and collected, and handed over to qualified third-party suppliers for processing. The solid waste includes centrifugal separation residue, adsorbent material from filtration, reagent packaging and other solid waste generated in our experiments, which are collected by us and handed over to the qualified third-party suppliers for solid waste disposal.

For non-hazardous waste, we have set up waste segregation in our office and we encourage our staff to follow the 3R principles (Reduce, Reuse, Recycle) to recycle paper, cardboard, aluminum cans and glass.

Our waste in the Track Record Period are shown as follows:

	For the year ended December 31,	
	2023	2024
Hazardous waste (tonnes)	6.695	3.646

Climate Change

We recognize that climate change is a global issue and a prevalent environmental challenge globally. In order to ensure our long-term resilience to climate risk, we have made reference to the recommendations of the Task Force on Climate-related Financial Disclosures to establish a climate change management system at four levels, namely, governance structure, strategy development, risk management, and setting of indicators and targets, to identify the risks and opportunities associated with climate change and to improve our climate change management initiatives.

- Governance structure: Climate change is an important element of our substantive issues. The Board of Directors oversees and manages the Company’s ESG issues, including climate change.

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- Strategy development: In order to understand the risks and opportunities of climate change for our business, we identified and assessed the risks and opportunities arising from climate change based on the potential financial impacts and the likelihood of events occurring.
- Risk management: We regularly communicate with various stakeholder groups through various channels. We also actively carry out management actions in the areas of resource conservation and emission reduction.
- Indicators and targets: We monitor the performance of climate change management by measuring and monitoring indicators related to energy and GHG emissions, including energy consumption, per capita energy intensity, total GHG emissions and per capita GHG emissions intensity.

We will continue to monitor and actively reduce our emissions and will continue to report our emissions statistics to [REDACTED] annually after [REDACTED], while making adjustments to our intensity targets as appropriate based on our operating conditions.

Climate Change Risks and Opportunities

Based on the disclosure methods and recommendations of the Task Force on Climate-related Financial Disclosures working group, we conducted the following analysis on climate change related risks, potential impacts (financial/non-financial), and mitigation measures:

Climate-related risks	Potential Financial Impact	Mitigation Measures
Future extreme weather events such as hurricanes, floods, high temperatures and extreme cold are frequent. . .	• Hazards such as damage to production facilities and disruption of logistics and transport could result in lower operating revenues and higher operating costs; • Higher energy costs for office and production facilities.	• Develop contingency plans to minimise the impact of severe weather; • Adjustment of operating hours to cater for persistent extreme weather.
More stringent climate and carbon emission policies, laws and regulations and supervision.	• Production interruptions due to power restrictions, over-emission, etc. and consequent reduction in revenue, fines, etc. • Higher operating costs due to upgraded equipment.	• Explore the possibility of applying renewable or clean energy in office and production facilities; • To actively promote energy conservation and emission reduction.

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Climate-related risks	Potential Financial Impact	Mitigation Measures
Low-carbon green transformation poses higher low-carbon technology requirements for enterprise-related businesses	• Increase in research and development costs due to new technology development; • Decrease in operating income due to peer competition.	• Incorporating green and low-carbon concepts into research and development, and proactively promoting green and low-carbon transformation.
Reputation risk from failure to meet the requirements of climate change or ESG issues	• Decrease in operating income due to a decrease in the availability of investment financing or a decrease in sales.	• Established an ESG Committee and working group to actively respond to ESG-related issues and disclose ESG reports on a timely basis.
Climate-related opportunities	Potential Financial Impact	
Energy Saving and Emission Reduction		Lower energy costs
Green Finance Opportunities		Lower financing costs

LEGAL PROCEEDINGS AND NON-COMPLIANCE

Legal Proceedings

During the Track Record Period and up to the Latest Practicable Date, we were not a party to any actual or threatened legal or administrative proceedings that has a material adverse effect on our financial condition or results of operations. We are committed to maintaining the standards of compliance with the laws and regulations applicable to our business. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business.

Legal Compliance

According to our PRC Legal Adviser, during the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any material non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our business, financial condition or results of operations. Our Directors confirmed that we had complied with all material applicable laws and regulations for our operations and we were not involved in any material or systemic non-compliance incidents.

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Our legal team is responsible for building, developing and improving our compliance management system to ensure our compliance culture is embedded into our everyday workflow. The legal team conducts compliance training for our employees and identifies, assesses, and reports compliance risks and expectations in a timely manner. Our legal team will also work with the senior management team to monitor and evaluate the effectiveness of our compliance function and structure to ensure that we comply with applicable laws and regulations.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We are exposed to various risks in our business operations, and we believe that risk management is important to our success. For more details, see “Risk Factors — Risks Relating to Our Business and Industry” in this Document. Our Directors oversee and manage the overall risks associated with our operations. We have prepared written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code and Corporate Governance Report as set out in Appendix C1 to the Listing Rules.

To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [REDACTED], we have adopted or will continue to adopt, among other things, the following risk management measures:

- establish an Audit Committee to review and supervise our financial reporting process and internal control system;
- adopt various policies to ensure compliance with the Listing Rules, including but not limited to aspects related to risk management, connected transactions and information disclosure;
- provide anti-corruption and anti-bribery compliance training periodically to our senior management and employees to enhance their knowledge and compliance with applicable laws and regulations; and
- attend training sessions by our Directors and senior management in respect of the relevant requirements of the Listing Rules and duties of directors of companies [REDACTED] in Hong Kong.

Internal Control

We have employed an independent internal control consultant to assess our internal control system in connection with the [REDACTED]. The internal control consultant has conducted a review procedure on our internal control system in certain aspects, including financial reporting and disclosure controls, corporate level controls, information system control management and other procedures for our operations. We had improved our internal

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control system by adopting and implementing the corresponding enhanced internal control measures. Going forward, we will continue to regularly review and improve these internal control policies, measures and procedures.

We have also appointed external legal counsel to advise us on compliance matters, such as compliance with the regulatory requirements on clinical R&D, which is also monitored by our legal compliance team. Under our whistle blowing policy, we make our internal reporting channel open and available for our employees to report, on an anonymous basis, any non-compliance incidents and acts, including bribery and corruption. Reported incidents and persons will be investigated and appropriate measures will be taken in response to the findings. We have also established anti-bribery guidelines and compliance requirements. After considering the remedial actions we have taken, our Directors are of the view that our internal control system is adequate and effective for our current operations.

We plan to provide our Directors, senior management, and relevant employees with continuous training programs and updates regarding the relevant laws and regulations regularly to proactively identify any concerns and issues relating to any potential non-compliance.

Anti-bribery

We maintain a strict code of conduct and anti-corruption policies among our employees and distributors. We believe we will be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry. We strictly prohibit bribery or other improper payments in our business operations. This prohibition applies to all business activities, anywhere globally, whether involving government officials or healthcare professionals. Improper payments prohibited by this policy include bribes, kickbacks, excessive gifts or entertainment, or any other payment made or offered to obtain an undue business advantage. We keep accurate books and records that reflect transactions and asset dispositions in reasonable detail. Requests for false invoices or payment of unusual, excessive or inadequately described expenses should be rejected and promptly reported. Misleading, incomplete or false entries in our books and records are never acceptable. We will also ensure that future commercialization team personnel comply with applicable promotion and advertising requirements, including restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

We have adopted comprehensive internal control measures for anti-corruption and anti-bribery by (i) providing regular anti-corruption and anti-bribery compliance training for senior management and employees, including daily compliance team meeting, annual compliance training and other ad hoc compliance training sessions, to enhance their knowledge and compliance with applicable law and regulations; (ii) monitoring books, records and accounts with respect to supplier management, tendering and bidding process management and financial payment management to identify any false, misleading or undisclosed entries; (iii) establishing whistle-blowing mechanisms and encouraging all employees, suppliers, customers and other third parties to report suspicious activities and violations of the policies.

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Conflict of Interest and Non-Competition

Our code of conduct clearly defines the scope of conflicts of interest, including supplier and customer relationships, hospitality and gifts, financial interests and personnel matters. Our employees, including but not limited to our Directors and R&D team members, may not have or be suspected of having a personal interest in business dealings with our suppliers, customers, competitors or distributors; accept monetary, financial or other benefits from our suppliers, customers, competitors or distributors; have close relatives who work for our suppliers, customers, competitors or distributors; serve as a consultant or director in an association or company in the same market or industry. At the same time, employees shall keep confidential information strictly confidential and agree on the definition of confidential information, the content covered, the use of intellectual properties, including but not limited to any transfer of know-how, acquisition of technologies, and potential breach liabilities.

Our employee agreements have included non-competition clauses, which prohibit employees from engaging in or directly or indirectly assisting any third party to engage in the same, similar and competitive business activities as our Company for a period of two years from the date of termination of employment. Any of our employees shall not, without prior written approval from our Company, own, manage, operate or control any other entity that competes with our Company.

Data Privacy Protection

We have established procedures to protect the confidentiality of patients’ data. We implement strict internal policies to govern the collection, handling, storage, retrieval of, and access to our patients’ personal data and medical records and protect the security and confidentiality of personal information to ensure compliance with all applicable national or international rules and regulations on data protection and privacy. We usually require our personnel to collect and safeguard personal information in their possession. Our information technology network is configured with multiple layers of protection to secure our databases and servers. We have also implemented a variety of protocols and procedures to safeguard our data assets and prevent unauthorized access to our network. According to the GCP and relevant regulations, access to clinical trial data has been strictly limited to authorized personnel. In order to strengthen the management of our database, ensure the normal and effective operation of the database, and ensure the security of the database, we have designated database administrator to carry out the responsibilities of daily maintenance, authority control, security protection and other management of the database. Additionally, we require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Data are to be used only for the intended use, as agreed by the patients and consistent with the informed consent form.

Furthermore, we enter into confidentiality agreements with our employees who have access to any aforementioned privacy information. The confidentiality agreements provide that, among other things, these employees are legally obligated not to misuse the confidential information while in office, to surrender all confidential information in possession while

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resigning, and to retain their confidential obligations after they leave office. We also implement a series of measures to ensure our employees’ compliance with our data security measures. For instance, we provide training to our employees on relevant data security policies.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any breach of confidential client information or any other client information-related incidents which could cause a material adverse effect on our business, financial condition or results of operations. Our PRC Legal Adviser has confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material penalty in relation to data privacy, and had been in compliance with the relevant PRC laws and regulations in all material aspects in this regard.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board comprises nine Directors, including two executive Directors, four 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 out information regarding the Directors.

Name	Age	Position/Title	Date of Appointment as a Director	Date of Joining Our Group	Roles and Responsibilities
Executive Directors					
Dr. Michael Min XU . [60]		Chairman of the Board, executive Director and general manager	May 2008	July 2001	Overall strategic planning, business direction and operational management of our Group
Ms. Xiaojun WANG (王小軍) [57]		Executive Director and chief financial officer	December 2020	September 2001	Overall strategic planning, financial management and financial reporting of our Group
Non-executive Directors					
Dr. Xiangjun ZHOU . . [61]		Non-executive Director	September 2020	August 2019	Providing strategic advice and making recommendation on the operation and management of our Group
Dr. Yuhong XU (徐宇虹) [56]		Non-executive Director	September 2020	September 2020	Providing strategic advice and making recommendation on the operation and management of our Group

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Position/Title	Date of Appointment as a Director	Date of Joining Our Group	Roles and Responsibilities
Ms. Ting ZHAI (翟婷)	[47]	Non-executive Director	March 2021	March 2021	Providing strategic advice and making recommendation on the operation and management of our Group
Mr. Hongkai LI (李宏凱)	[43]	Non-executive Director	September 2020	September 2020	Providing strategic advice and making recommendation on the operation and management of our Group
Independent non-executive Directors					
Dr. Jiancun ZHANG. . . [60]		Independent non-executive Director	December 2020	December 2020	Participating in the decision making for our Company’s significant events, and advising on issues relating to corporate governance, audit and remuneration and assessment of our Directors, Supervisors and senior management
Dr. Yangyang CHEN (陳秧秧)	[46]	Independent non-executive Director	December 2020	December 2020	Participating in the decision making for our Company’s significant events, and advising on issues relating to corporate governance, audit and remuneration and assessment of our Directors, Supervisors and senior management

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Position/Title	Date of Appointment as a Director	Date of Joining Our Group	Roles and Responsibilities
Ms. Xinpeng FAN (范新鹏)	[45]	Independent non-executive Director	February 2024	February 2024	Participating in the decision making for our Company’s significant events, and advising on issues relating to corporate governance, audit and remuneration and assessment of our Directors, Supervisors and senior management

Executive Directors

Dr. Michael Min XU, aged [60], is the chairman of the Board, an executive Director and the general manager of our Company, and is primarily responsible for overall strategic planning, business direction and operational management of our Group. Dr. XU founded our business when Pan-Asia was established in July 2001, and has been serving as the executive director and chairman of the board of directors of Pan-Asia from December 2001 to its de-registration in May 2023. Dr. XU has also been serving as the executive director of Shanghai Hanmai, Shanghai Maiji and PegBio Suzhou since February 2021, February 2021 and January 2025, respectively.

Dr. XU has over 30 years of working and management experience in the healthcare sector. Prior to founding our Group, Dr. XU served as the ophthalmologist in the Second Affiliated Hospital of Xiangya Medical College (湘雅醫學院第二附屬醫院) from September 1986 and May 1988. From 1992 to 1996, he served as a researcher in the Center of Molecular Recognition and Departments of Physiology and Cellular Biophysics, College of Physicians and Surgeons, Columbia University. From August 2014 to July 2022, Dr. XU served as an executive director of Crossbay Life Science Technologies Inc.. Dr. XU has published a total of six articles in magazines, including Science. After founding our Group, Dr. XU has been engaged in drugs/biologics translational research and development, including but not limited to leading the R&D projects of PEGylated interferon alpha-2b product, PEGylated interferon tau product and PEGylated interleukin-2 product for pharmaceutical companies from 2002 to 2004.

Dr. XU has been serving as an independent non-executive director of Kintor Pharmaceutical Limited (開拓藥業有限公司) (a company listed on the Hong Kong Stock Exchange, stock code: 9939) since August 2019.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Dr. XU received his bachelor’s degree in medicine in July 1986 from Hunan Medical University (湖南醫科大學) (currently known as Xiangya School of Medicine at Central South University (中南大學湘雅醫學院)) in the PRC, and his doctorate degree in biophysics in February 1996 from Columbia University in the City of New York in the United States.

Ms. Xiaojun WANG (王小軍), aged [57], is an executive Director and the chief financial officer of our Company, and is primarily responsible for overall strategic planning, financial management and financial reporting of our Group. Ms. WANG served as the financial manager of our Company from July 2008 to December 2020, a Supervisor from May 2008 to July 2019, and secretary to the Board from December 2020 to May 2023.

Prior to joining our Group, Ms. WANG was engaged in financial accounting works in the 1990s. Ms. WANG received her bachelor’s degree in accounting in July 2003 from China Central Radio and TV University (中央廣播電視大學) in the PRC, and her master’s degree in accounting in June 2018 from Shanghai National Accounting Institute (上海國家會計學院) in the PRC. Ms. WANG was granted with the qualification of accountant (會計師) by the Ministry of Personnel of the PRC (中華人民共和國人事部) (currently known as the Ministry of Human Resources and Social Security of the PRC (中華人民共和國人力資源和社會保障部)) in May 1998.

Non-executive Directors

Dr. Xiangjun ZHOU, aged [61], is a non-executive Director, and is primarily responsible for providing strategic advice and making recommendation on the operation and management of our Group. Previously, Dr. ZHOU served as a Supervisor from August 2019 to September 2020.

Prior to joining our Group, Dr. ZHOU was once affiliated with Stanford University in the United States in the late 1990s, where he was engaged in research work in the field of cell biology. Dr. ZHOU served as a professor of molecular pharmacology at the School of Pharmacy in the Shanghai Jiao Tong University (上海交通大學) from January 2003 to August 2005. From January 2009 to July 2015, he served as the vice president of R&D at Shenzhen Yuanxing Biomedical Technology Co., Ltd. (深圳市源興生物醫藥科技有限公司).

Dr. ZHOU has been serving as a director since July 2013 and subsequently an executive director and general manager since November 2022 in Shenzhen Yuanzheng Cell Medical Technology Co., Ltd. (深圳源正細胞醫療技術有限公司), a member of the board of directors of Hengrui Yuanzheng (Shanghai) Biotechnology Co., Ltd. (恒瑞源正(上海)生物科技股份有限公司) since July 2015, the chairman of the board of directors of Shenzhen Yuanxing Gene Technology Co., Ltd. (深圳源興基因技術有限公司) since August 2015, and an executive director and general manager of Junyi Highland Intelligent Technology (Shenzhen) Co., Ltd. (君宜高地智能技術(深圳)有限公司) since August 2019.

Dr. ZHOU received his doctorate degree in biomedical sciences in May 1997 from University of Hawaii at Manoa in the United States.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Dr. Yuhong XU (徐宇虹), aged [56], is a non-executive Director, and is primarily responsible for providing strategic advice and making recommendation on the operation and management of our Group.

Dr. XU has over 25 years of experience in research and development of medical products. From January 2000 to December 2019, she served as a professor at the School of Pharmacy in the Shanghai Jiao Tong University (上海交通大學).

Dr. XU has been serving as the chairman of the board of directors of Shanghai Tarisa Biotechnology Co., Ltd. (上海塔瑞莎生物技術有限公司) since July 2013. She has been serving as the director and the general manager of Hangzhou HighField Biopharmaceuticals, Inc. (杭州高田生物醫藥有限公司) since April 2013, and has been serving as its chairlady of the board of directors since December 2017. She has also been serving as a professor at the School of Pharmacy in the Dali University (大理大學) since September 2019.

Dr. XU received her bachelor’s degree in electronics and information systems in July 1990 from Peking University (北京大學) in the PRC, and her doctorate degree in biophysics in September 1997 from State University of New York at Buffalo in the United States.

Ms. Ting ZHAI (翟婷), aged [47], is a non-executive Director, and is primarily responsible for providing strategic advice and making recommendation on the operation and management of our Group.

Since October 2010, Ms. ZHAI has been serving as a finance manager and a vice president of Mingly China Growth Fund, L.P., and a finance manager and a vice president of Million Power Growth Venture Capital Co., Ltd. (高投名力成長創業投資有限公司). Since October 2012, she has been serving as a finance manager and a vice president of Mingxin China Growth Fund. Since February 2021, Ms. ZHAI has been serving as a director of Beijing Kejingyuan Technology Co., Ltd. (北京科淨源科技股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 301372).

Ms. ZHAI received her college diploma (大專學歷) in accounting in January 2011 from Shanghai University of Finance and Economics (上海財經大學) in the PRC.

Mr. Hongkai LI (李宏凱), aged [43], is a non-executive Director, and is primarily responsible for providing strategic advice and making recommendation on the operation and management of our Group.

Prior to joining our Group, Mr. LI worked in Tianjin Chunfa Biotechnology Group Co., Ltd. (天津春發生物科技集團有限公司) from September 2007 to April 2010. From May 2010 to March 2011, he worked in Tianjin Science and Technology Development and Investment Corporation (天津科技發展投資總公司). From April 2011 to December 2011, he worked in Tianjin Dacheng Equity Investment Fund Partnership (Limited Partnership) (天津大成股權投資基金合夥企業(有限合夥)). From January 2012 to July 2012, he worked in Tianjin Ebang Chuangzhan Equity Investment Fund Management Co., Ltd. (天津易邦創展股權投資基金管理

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

有限公司). Subsequently, Mr. LI worked in Huajin (Tianjin) Investment Management Co., Ltd. (華金(天津)投資管理有限公司) from December 2012 to February 2016, in Tasly Pharmaceutical Group Co., Ltd. (天士力醫藥集團股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 600535) from March 2016 to May 2016, in Tianjin Tasly Health Industry Investment Management Partnership (Limited Partnership) (天津天士力健康產業投資管理合夥企業(有限合夥)) from June 2016 to March 2019, and in Tianjin Tasly Health Industry Investment Management Partnership (Limited Partnership) (天津天士力健康產業投資管理合夥企業(有限合夥)) from July 2019 to March 2022. From December 2019 to June 2022, Mr. LI served as a non-executive director of Pharnext SA (a company listed on Euronext, symbol: ALPHA.PA).

Since April 2022, Mr. LI has been serving as the head of the investment management department of Huajin (Tianjin) Investment Management Co., Ltd. (華金(天津)投資管理有限公司).

Mr. LI received his bachelor’s degree in economics in June 2004 from Nankai University (南開大學) in the PRC, and his master’s degree in marketing and management in December 2005 from Loughborough University in the United Kingdom.

Independent non-executive Directors

Dr. Jiancun ZHANG, aged [60], is an independent non-executive Director, and is primarily responsible for participating in the decision making for our Company’s significant events, and advising on issues relating to corporate governance, audit and remuneration and assessment of our Directors, Supervisors and senior management.

Prior to joining our Group, Dr. ZHANG was once affiliated with Duke University and Gilead Sciences, Inc. in the United States in the 1990s, when he was engaged in research work in the field of chemistry and biotechnology. From January 2002 to December 2004, he served as the chief scientific officer and vice president of Shenzhen Tsinghua Yuanxing Biomedical Technology Co., Ltd. (深圳市清華源興生物醫藥科技有限公司) (currently known as Shenzhen Yuanxing Biomedical Technology Co., Ltd. (深圳市源興生物醫藥科技有限公司)). Dr. ZHANG served as the partner of Guangzhou Henghui Pharmaceutical Technology Partnership (Limited Partnership) (廣州恒惠醫藥科技合夥企業(有限合夥)) from April 2018 to May 2021.

Since 2005, Dr. ZHANG has been serving as a researcher at Guangzhou Institute of Biomedicine and Health, Chinese Academy of Sciences (中國科學院廣州生物醫藥與健康研究院). Since March 2013, he has been serving as the chairman of the board of directors and the general manager of Guangzhou Hengnokang Pharmaceutical Technology Co., Ltd. (廣州市恒諾康醫藥科技有限公司). Dr. ZHANG has also been serving as a director of Guangzhou Yixi Biotechnology Co., Ltd. (廣州億喜生物科技有限公司), and the general partner of Guangzhou Tongsheng Nuokang Investment Enterprise (Limited Partnership) (廣州市同盛諾康投資企業(有限合夥)) since December 2016.

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Dr. ZHANG received his bachelor’s degree in chemistry in July 1984 from Fudan University (復旦大學) in the PRC, and his doctorate degree in organic chemistry in August 1990 from University of Pittsburgh in the United States.

Dr. Yangyang CHEN (陳秧秧), aged [46], is an independent non-executive Director, and is primarily responsible for participating in the decision making for our Company’s significant events, and advising on issues relating to corporate governance, audit and remuneration and assessment of our Directors, Supervisors and senior management.

Prior to joining our Group, Dr. CHEN served as a lecturer in the School of Business from July 2007 to June 2010 and an associate professor in the School of International Finance and Law from July 2010 to December 2017 respectively in East China University of Political Science and Law (華東政法大學).

Dr. CHEN has been serving as the director of MPAcc Center in the School of Business of East China University of Political Science and Law since January 2018, an independent director of Ningbo Jiayin Mechanical and Electrical Technology Co., Ltd. (寧波佳音機電科技股份有限公司) since September 2021, and an independent director of Centennial Insurance Asset Management Co., Ltd. (百年保險資產管理有限責任公司) since August 2022.

Dr. CHEN received her bachelor’s degree in accounting in July 2001, her master’s degree in accounting in July 2004, and her doctorate degree in accounting in June 2007 from Xiamen University (廈門大學) in the PRC.

Ms. Xinpeng FAN (范新鵬), aged [45], was appointed as an independent non-executive Director effective from February 2024. She is primarily responsible for participating in the decision making for our Company’s significant events, and advising on issues relating to corporate governance, audit and remuneration and assessment of our Directors, Supervisors and senior management.

Ms. FAN has professional experiences in global investment banking, capital market financing, mergers and acquisitions, as well as corporate finance management in the Chinese consumer industry. Prior to joining our Group, Ms. FAN worked in leading global investment banks and accounting firms, including as an auditor of Deloitte Touche Tohmatsu (德勤會計師事務所) from September 2004 to June 2007, an associate of Merrill Lynch (Asia Pacific) Limited (美林(亞太)有限公司) from January 2008 to February 2009, and a manager of PricewaterhouseCoopers (Hong Kong) (普華永道會計師事務所(香港)) from March 2009 to April 2010. From May 2010 to March 2022, she served as an executive director under the investment banking division of Morgan Stanley Asia Limited (摩根士丹利亞洲有限公司). From March 2022 to March 2023, Ms. Fan served as the chief financial officer and group vice president of EastGarden (HK) International Company Limited (宜格(香港)國際有限公司). From March 2023 to February 2024, Ms. Fan served as the chief financial officer of Dali Foods Group Company Limited (達利食品集團有限公司).

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Ms. FAN has been serving as an independent non-executive director of Tongdao Liepin Group (同道獵聘集團), a company listed on the Hong Kong Stock Exchange (stock code: 6100), since September 12, 2023. From June 2024, Ms. FAN has been the managing director of HSBC Holdings plc, a company listed on the Hong Kong Stock Exchange (stock code: 5) and London Stock Exchange (stock code: HSBA).

Ms. FAN obtained her bachelor’s degree in economics in June 1999 from Beijing Technology and Business University (北京工商大學) in the PRC, and her master’s degree in accounting in August 2004 from the University of Texas at Austin in the United States. Ms. FAN has been a member of the American Institute of Certified Public Accountants since March 2006.

SUPERVISORY COMMITTEE

Our Supervisory Committee consists of three Supervisors. The Supervisors include two shareholders’ representative Supervisors and one employee Supervisor. The shareholders’ representative Supervisors and the employee Supervisor are elected at the Shareholders’ meetings and the staff representative assembly, respectively, for a term of three years, which is renewable upon re-election and re-appointment. The functions and duties of the Supervisory Committee include reviewing financial reports and business reports prepared by the Board and overseeing the financial and business performance of our Group.

The following table sets out information in respect of the Supervisors.

Name	Age	Position/Title	Date of Appointment as a Supervisor	Date of Joining Our Group	Roles and Responsibilities
Ms. Mengjiao WANG (王夢嬌)	[32]	Chairlady of the Supervisory Committee, and the employee representative Supervisor	November 2022	July 2013	Supervising the performance of our Directors and members of senior management, supervising the financial activities and business operations of the Company, and performing other supervisory duties

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Position/Title	Date of Appointment as a Supervisor	Date of Joining Our Group	Roles and Responsibilities
Mr. Yongjun KONG (孔勇軍)	[52]	Supervisor	December 2020	December 2020	Supervising the performance of our Directors and members of senior management, supervising the financial activities and business operations of the Company, and performing other supervisory duties
Mr. Dong LI (李東)	[36]	Supervisor	February 2024	February 2024	Supervising the performance of our Directors and members of senior management, supervising the financial activities and business operations of the Company, and performing other supervisory duties

Supervisors

Ms. Mengjiao WANG (王夢嬌), aged [32], is the chairlady of our Supervisory Committee and an employee representative Supervisor, and is primarily responsible for supervising the performance of our Directors and members of senior management, supervising the financial activities and business operations of the Company, and performing other supervisory duties. Ms. WANG has also been working in our Company since July 2013.

Ms. WANG received her college diploma (大專學歷) in accounting and auditing in June 2013 from Jiangsu Union Technical Institute (江蘇聯合職業技術學院) in the PRC.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Yongjun KONG (孔勇軍), aged [52], is a Supervisor, and is primarily responsible for supervising the performance of our Directors and members of senior management, supervising the financial activities and business operations of the Company, and performing other supervisory duties.

Prior to joining our Group, Mr. KONG worked in Suzhou Industrial Park Heyu Technology Financial Group Co., Ltd. (蘇州工業園區禾裕科技金融集團有限公司) from March 2008 to June 2010. From June 2010 to January 2014, he worked in Suzhou Jingfeng Zhengde Equity Investment Management Partnership (Limited Partnership) (蘇州景風正德股權投資管理合夥企業(有限合夥)). From March 2012 to May 2021, Mr. KONG served as a director of Suzhou Ailong Technology Co., Ltd. (蘇州艾隆科技股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 688329). From January 2014 to July 2018, he worked in Suzhou Industrial Park Yuanhe Chongyuan Equity Investment Fund Management Co., Ltd. (蘇州工業園區元禾重元股權投資基金管理有限公司). From July 2018 to June 2020, he worked in Suzhou Clover Tree Investment Management Co., Ltd. (蘇州三葉樹投資管理有限公司).

Mr. KONG has been serving as a director of Jiangsu Youlian Testing Technology Service Co., Ltd. (江蘇省優聯檢測技術服務有限公司) since April 2006, a director of Suzhou Jingfeng Zhengde Enterprise Management Co., Ltd. (蘇州景風正德企業管理有限公司) since May 2010, a director of Suzhou Ziyu Investment Consulting Co., Ltd. (蘇州孜玉投資諮詢有限公司) since August 2011, a supervisor of Urumqi Yinchuang Phase I Equity Investment Co., Ltd. (烏魯木齊銀創一期股權投資有限公司) since December 2011, a supervisor of Shenzhen Yuanhe Hengfeng Private Equity Investment Fund Management Co., Ltd. (深圳元核亨風私募股權投資基金管理有限責任公司) since October 2017, a supervisor of Suzhou Industrial Park Liwoshi Business Consulting Co., Ltd. (蘇州工業園區利沃實商務諮詢有限公司) since December 2017, and an investment director and a partner of Suzhou Zhongxin Innovation Investment Management Co., Ltd. (蘇州中鑫創新投資管理有限公司) (currently known as Suzhou Zhongxin Innovation Private Equity Fund Management Co., Ltd. (蘇州中鑫創新私募基金管理有限公司)) since July 2020.

Mr. KONG received his bachelor's degree in finance in July 1995 from Shanghai University of Finance and Economics (上海財經大學) in the PRC, and his master's degree in business administration in November 2011 from The University of Hong Kong in Hong Kong.

Mr. Dong LI (李東), aged [36], is a Supervisor, and is primarily responsible for supervising the performance of our Directors and members of senior management, supervising the financial activities and business operations of the Company, and performing other supervisory duties.

Mr. LI served as the chief operating officer at Shanghai Caihui Investment Co., Ltd. (上海財薈投資有限公司) from September 2018 to September 2019. Mr. LI has also been serving as a senior manager of appreciation management department at Yingke Innovation Asset Management Co., Ltd. (盈科創新資產管理有限公司) since August 2020.

Mr. LI received his bachelor's degree in financial management through self-study from East China University of Political Science and Law (華東政法大學) in the PRC in July 2017.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

SENIOR MANAGEMENT

The following table sets out information regarding the members of senior management of our Company.

Name	Age	Position/Title	Date of Appointment as a Senior Management	Date of Joining Our Group	Roles and Responsibilities
Dr. Michael Min XU .	[60]	Chairman of the Board, executive Director and general manager	May 2008	July 2001	Overall strategic planning, business direction and operational management of our Group
Ms. Xiaojun WANG (王小軍)	[56]	Executive Director and chief financial officer	July 2008	September 2001	Overall strategic planning, financial management and financial reporting of our Group
Mr. Yifeng HUANG (黃一峰)	[36]	Secretary of the Board and joint company secretary	May 2023	November 2022	Business operations, capital management, public relations, investor relations, and company secretarial matters of our Group

Dr. Michael Min XU, aged [60], is the chairman of the Board, an executive Director and the general manager of our Company. See “— Executive Directors” above for details of his biography.

Ms. Xiaojun WANG (王小軍), aged [56], is an executive Director and the chief financial officer of our Company. See “— Executive Directors” above for details of her biography.

Mr. Yifeng HUANG (黃一峰), aged [36], is the secretary of the Board and our joint company secretary, and is primarily responsible for business operations, capital management, public relations, investor relations, and company secretarial matters of our Group. Mr. HUANG joined our Group in November 2022 as assistant of the Board, and has been serving as the secretary of the Board since May 2023. He was appointed as our joint company secretary in January 2024.

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Prior to joining our Group, Mr. HUANG served as a manager in Country Garden Holdings Company Limited (碧桂園控股有限公司) (a company listed on the Hong Kong Stock Exchange, stock code: 2007) from July 2015 to April 2016. From May 2016 to December 2017, he served as the general counsel and executive general manager in Shenzhen Qianhai Zhongke Lechuang Fund Management Co., Ltd. (深圳前海中科樂創基金管理有限公司). From January 2018 to February 2019, he served as the vice general manager of legal matters in Kaisa Group Holdings Ltd. (佳兆業集團控股有限公司) (a company listed on the Hong Kong Stock Exchange, stock code: 1638). From February 2019 to November 2020, he worked in Kaisa Health Group Holdings Limited (佳兆業健康集團控股有限公司) (a company listed on the Hong Kong Stock Exchange, stock code: 876) as the general counsel, the head of securities matters, and the fund general manager. From November 2019 to November 2020, Mr. HUANG served as the executive director and the general manager in Kaisa Health Equity Fund Management (Guangzhou) Co., Ltd. (佳兆業健康股權投資基金管理(廣州)有限公司). From November 2020 to April 2022, he served as the secretary to the board of directors in Qinghai Pharmaceutical Co., Ltd. (青海製藥有限公司).

Mr. HUANG received his bachelor’s degree in law in June 2009 from Shenzhen University (深圳大學) in the PRC, and his master’s degree in law in March 2012 from Hosei University in Japan. Mr. HUANG also completed his doctoral courses in law in March 2018 from Hosei University in Japan. Mr. HUANG was granted (i) the qualification of secretary to the board of directors by the Shenzhen Stock Exchange in September 2020, (ii) the legal professional qualification by the Ministry of Justice of the PRC (中華人民共和國司法部) in March 2013, and (iii) the fund practicing qualification by the Asset Management Association of China (中國證券投資基金業協會) in December 2015.

CONFIRMATION FROM OUR DIRECTORS

Rule 8.10 of the Listing Rules

Save as disclosed below, 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, either directly or indirectly, with our Company’s business which would require disclosure under Rule 8.10 of the Listing Rules.

Dr. Yuhong XU (徐宇虹), our non-executive Director, currently also serves as the chairlady of the board of directors and the general manager of Hangzhou HighField Biopharmaceuticals, Inc. (杭州高田生物醫藥有限公司) (“**HighField**”), a limited liability company established in the PRC. As of the Latest Practicable Date, Dr. Yuhong XU (徐宇虹) controlled approximately 49% voting rights of HighField through her direct shareholding and controlled entities.

HighField is principally engaged in the research and development of lipid-based therapeutics for cancer treatment. According to the information provided by HighField, as of the Latest Practicable Date: (i) HighField’s R&D efforts primarily pertained to leveraging its lipid technology to develop therapeutics that elicit anti-cancer immune responses; and (ii)

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HighField had two clinical-stage product candidates, both for cancer treatment, namely K16 (which combines a lipid bilayer structure and all-trans retinoic acid) and K1 (a lipid bilayer system with HER2-targeted antibodies).

HighField’s platform technology in lipid therapeutics includes lipid nanoparticles (“LNPs”) that can be used in the gene therapy. HighField is engaged in the development of mRNA vaccines and other immune cell gene editing studies using its LNP technology. In June 2024, HighField reported an animal study data using LNPs that contain an mRNA encoding a fusion protein of a GLP-1 analogue and a pH sensitive binder of human FcRn. The mRNA is loaded in lipid nanostructure particles designed for subcutaneous administration and local mRNA delivery. The LNP construct is called HFG1. As of the Latest Practicable Date, HighField was evaluating the preclinical feasibility of HFG1. While the structure and formulation of HFG1 is distinct from our PB-119, HFG1 might nonetheless directly or indirectly compete with our PB-119 due to the underlying mechanism of action association with GLP-1 receptor agonists and potentially similar therapeutic indications. That said, according to the information provided by HighField, HFG1 was one of the gene therapy drug candidates HighField is testing based on its LNP technology, the only GLP-1 related product candidate and the only one for the treatment of diabetes of HighField as of the Latest Practicable Date.

Our Directors believe that we are capable of performing our business independently of, and at arm’s length from HighField based on the following grounds:

- (i) Dr. Yuhong XU (徐宇虹) is only one of our non-executive Directors, and is not and will not be involved in the daily management and operation of both our Company and HighField. Further, other than Dr. Yuhong XU (徐宇虹), our Directors and members of our senior management do not hold any position in HighField;
- (ii) we have appointed three independent non-executive Directors, comprising one-third of our Board in order to promote the interests of our Company and our Shareholders as a whole;
- (iii) each of our Directors (including Dr. Yuhong XU (徐宇虹)) is aware of his/her fiduciary duties and responsibilities under the Listing Rules as a director, which require that he/she acts in the best interests of our Company and our Shareholders as a whole;
- (iv) as stated above, HighField’s R&D efforts primarily pertain to leveraging its lipid technology to develop therapeutics that elicit anti-cancer immune responses, with HFG1 as its only GLP-1 related product candidate and the only one for the treatment of diabetes. In comparison, we focus on the in-house discovery and development of innovative therapies, primarily peptide and small molecule drugs, for chronic diseases with a particular emphasis on metabolic disorders. As such, our Directors consider that HighField and our Company have different R&D focus areas that do not materially overlap with each other; and

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

- (v) our Company has established relevant corporate governance measures to avoid conflicts of interest between our Group on one hand, and any Director or Shareholder on the other hand. In the event of matters where Dr. Yuhong XU (徐宇虹) has a material interest arising out of her interests in HighField, Dr. Yuhong XU (徐宇虹) shall abstain from voting on the relevant resolutions of our Board or our general meeting of Shareholders.

Our Directors consider that the above measures are sufficient for the purpose of avoiding any potential material competition between our Group and Dr. Yuhong XU (徐宇虹)’s interests in HighField under Rule 8.10(2) of the Listing Rules.

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 in January 2024, and (ii) understands his or her obligations as a director of a [REDACTED] under the Listing Rules.

Rule 3.13 of the Listing Rules

Each of the independent non-executive Directors has confirmed (i) his/her independence as regards each of the factors referred to in Rules 3.13(1) to (8) of the Listing Rules, (ii) he/she has no past or present financial or other interest in the business of the Company or its subsidiaries or any connection with any core connected person of the Company under the Listing Rules as of the Latest Practicable Date, and (iii) that there are no other factors that may affect his/her independence at the time of his/her appointments.

GENERAL

Save as disclosed above, none of the Directors, Supervisors or members of senior management of our Company has been a director of any [REDACTED] the securities of which are [REDACTED] on any securities market in Hong Kong or overseas in the three years immediately preceding the date of this Document.

None of the Directors, Supervisors or members of the senior management of our Company is related to any other Directors, Supervisors and members of the senior management of our Company.

On September 25, 2024, Shenzhen Qianhai Cooperation Zone People’s Court (深圳前海合作區人民法院) accepted the complaint for civil action (the “**Lawsuit**”) of Shenzhen Guanbang Venture Capital Partnership (Limited Partnership) (深圳市觀邦創業投資合夥企業(有限合夥)) (“**Guanbang**”) against Dr. Xiangjun ZHOU, Ms. Qin Zhihong (秦志紅) (spouse of Dr. Xiangjun ZHOU), Shenzhen Yuanxing Gene Technology Co., Ltd. (深圳源興基因技術有限公司) (“**Yuanxing Gene**”) and Shenzhen Yuanji Technology Partnership (Limited Partnership) (深圳市源基科技合夥企業(有限合夥)) (“**Yuanji**”, of which the general partner is Dr. Xiangjun ZHOU) (collectively, the “**Defendants**”), whereby Guanbang: (i) claimed that the Defendants

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entered into agreements (the “**Yuanxing Gene Agreements**”) with it on November 2, 2023, pursuant to which Dr. Xiangjun ZHOU agreed to purchase the shares of Yuanxing Gene from Guanbang; and (ii) claimed RMB23,279,726 against the Defendants for breaching of the Yuanxing Gene Agreements, including failure of Dr. Xiangjun Zhou to pay the consideration for the purchase of shares of Yuanxing Gene from Guanbang. As of the Latest Practicable Date, the date of the trial of the Lawsuit has not yet been fixed.

Dr. Xiangjun ZHOU joined us in 2019 and has served as our Director since September 2020. Given (1) that Dr. Xiangjun ZHOU has consistently acted in good faith in the interests of our Company when serving as our Director and has duly applied his extensive experiences and extensive resources to support our development, (2) that no court has made a dispositive ruling on the plaintiff’s claim in the Lawsuit, (3) to the best of our knowledge, we are not aware of any affirmative specific facts that make us to believe that Dr. Xiangjun ZHOU is unsuitable to act as a director of a [REDACTED] company, and (4) Dr. Xiangjun ZHOU’s deep experience in the biotechnology industry, our Directors are of the view that the Lawsuit does not impact Dr. Xiangjun ZHOU’s suitability to serve as a Director of our Company under Rules 3.08 and 3.09 of the Listing Rules. Excepting the Lawsuit disclosed above, our Directors confirmed that to the best of their knowledge, there is no other matter that needs to be brought to the attention of the Stock Exchange and Shareholders relating to Dr. Xiangjun ZHOU during his tenure at our Company.

Given that (1) the Lawsuit does not involve any companies within our Group; and (2) Dr. Xiangjun ZHOU, as a non-executive Director of our Company, has not participated in the day-to-day management of our Company, our Directors believe that the Lawsuit will not have any material adverse impact on the business and/or operations of our Group despite the uncertainty of its outcome. Our Company will closely monitor the developments of the Lawsuit and will review the above should the facts change, new information become available or the case proceed further.

Save as disclosed herein, to the best knowledge, information and belief of our Directors and Supervisors having made all reasonable inquiries, there was no other matter with respect to the appointment of our Directors or Supervisors that needs to be brought to the attention of the Shareholders and there was no information relating to our Directors or Supervisors that is required to be disclosed pursuant to Rule 13.51(2)(h) to (v) of the Listing Rules as of the Latest Practicable Date.

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JOINT COMPANY SECRETARIES

Mr. Yifeng HUANG (黃一峰), aged [36], is the secretary of the Board and our joint company secretary. See “— Senior Management” above for details of his biography.

Ms. Yuen Mui CHAN (陳婉梅) was appointed as our joint company secretary in January 2024 with effect from the [REDACTED].

Ms. CHAN has over 15 years of experience in corporate secretarial and commercial administration fields. Ms. CHAN currently serves as a manager of Entity Solutions of Computershare Hong Kong Investor Services Limited.

Ms. CHAN obtained her bachelor of business administration degree with honors from Hong Kong Baptist University and her master of corporate governance degree from The Hong Kong Polytechnic University. She is an associate member of both The Hong Kong Chartered Governance Institute and The Chartered Governance Institute in the United Kingdom.

BOARD COMMITTEES

Our Board delegates certain responsibilities to various committees. In accordance with the relevant PRC laws and regulations and the Corporate Governance Code as set out in the Appendix C1 to the Listing Rules, our Company has formed four Board committees, namely the Audit Committee, the Remuneration and Appraisal Committee, the Nomination Committee and the Strategy and Development Committee.

Audit Committee

We have established an Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraph D.3 of Part 2 of the Corporate Governance Code. The Audit Committee consists of three Directors, namely Ms. Xinpeng FAN (范新鹏), Dr. Xiangjun ZHOU and Dr. Yangyang CHEN (陳秧秧). Ms. Xinpeng FAN (范新鹏), who holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules, serves as the chairperson of the Audit Committee. The primary duties of the Audit Committee include, but not limited to, the following:

- proposing the appointment or change of external auditors to our Board, and monitoring the independence of external auditors and evaluating their performance;
- guiding internal audit work;
- examining the financial information of our Company, reviewing financial reports and statements of our Company and giving comments on relevant matters;

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- assessing the effectiveness of internal control;
- coordinating the communication among management, internal audit department, related departments and external audit agency; and
- dealing with other matters that are authorized by the Board or involved in relevant laws and regulations.

Remuneration and Appraisal Committee

We have established a Remuneration and Appraisal Committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and paragraph E.1 of Part 2 of the Corporate Governance Code. The Remuneration and Appraisal Committee consists of three Directors, namely Dr. Jiancun ZHANG, Ms. Xiaojun WANG (王小軍) and Ms. Xinpeng FAN (范新鵬). Dr. Jiancun ZHANG serves as the chairperson of the Remuneration and Appraisal Committee. The primary duties of the Remuneration and Appraisal Committee include, but not limited to, the following:

- formulating individual remuneration plans for Directors and members of the senior management in accordance with the terms of reference of the job responsibilities, the importance of their positions as well as the remuneration benchmarks for the relevant positions in other comparable companies;
- examining the criteria of performance evaluation of Directors and the senior management of our Company, and conducting annual performance evaluation;
- supervising the implementation of the remuneration plan of the Company; and
- dealing with other matters that are authorized by the Board.

Nomination Committee

We have established a Nomination Committee with written terms of reference in compliance with Rule 3.27A of the Listing Rules and paragraph B.3 of Part 2 of the Corporate Governance Code. The Nomination Committee consists of three Directors, namely Dr. Jiancun ZHANG, Dr. Michael Min XU and Ms. Xinpeng FAN (范新鵬). Dr. Jiancun ZHANG serves as the chairperson of the Nomination Committee. The primary duties of the Nomination Committee include, but not limited to, the following:

- making recommendations to our Board with regards to the size and composition of our Board based on our Company’s business operation, asset scale and equity structure;

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

- researching and developing standards and procedures for the election of our Board members, general managers and members of the senior management, and making recommendations to our Board;
- conducting extensive search and providing to our Board suitable candidates for Directors, general managers and other members of the senior management;
- examining our Board candidates, general manager and members of the senior management and making recommendations to our Board;
- assessing and reviewing the independence of independent non-executive Directors; and
- dealing with other matters that are authorized by our Board.

Strategy and Development Committee

We have established a Strategy and Development Committee with written terms of reference in compliance with the Corporate Governance Code. The Strategy and Development Committee consists of three Directors, namely Dr. Michael Min XU, Dr. Xiangjun ZHOU and Dr. Yuhong XU (徐宇虹). Dr. Michael Min XU serves as the chairperson of the Strategy and Development Committee. The primary duties of the Strategy and Development Committee include, but not limited to, the following:

- researching and making recommendations on the Company’s long-term development strategic planning;
- researching and making recommendations on major investment and financing programs that are required to be approved by the Board under the Articles of Association;
- researching and making recommendations on major capital operation and asset management projects which are required to be approved by the Board under the Articles of Association;
- researching and making recommendations on other major matters affecting the development of the Company;
- examining the implementation of the above matters; and
- dealing with other matters that are authorized by our Board.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into an employment contract and a non-competition agreement with our key management members and technical personnel, with a term of three years. Below sets forth the key terms of these contracts we enter into with our key management members and technical personnel.

Confidentiality

Scope of confidential information: Information the employee shall keep confidential includes but is not limited to: decisions of the Company, financial information, technical information, human resources information and clients’ information and matters known within certain scope of personnel during certain period of time.

Confidentiality obligation: The employee shall (i) not disclose the Company’s secret in private communications or business interactions, talk about Company’s secrets in the public, disseminate the Company’s secrets among staff, nor disclose the Company’s secrets for his/her own interests or for the benefit of others or in retaliation, and (ii) take timely remedial measures and promptly report to the office of the Board when aware that the Company’s secrets have been leaked or are likely to be leaked. The confidentiality obligation shall continue to be in effect during the course of employment and after the departure of the employee.

Ownership of intellectual work products

The right of use, license, ownership and related intellectual property rights of any technology, software and other fruits developed by the employee using the Company’s information, materials, substances, equipment and tools shall belong to the Company, and the employee shall use or license others to use them according to the instruction from the Company.

Non-competition

Term and scope: The non-competition obligation is effective during the course of employment and within 12 months after the termination of the employment, unless written consent from the Company otherwise has been obtained.

Non-competition obligation: The employee shall not, in the PRC, (i) engage in business as a partner, employee, consultant, officer, supervisor, manager, agent, assistant, investor manager that competes with or is similar to the Company’s business, (ii) directly or indirectly own, purchase, establish or prepare to establish a company and operate a business that competes with or is similar to the Company’s business, or (iii) establish, design, finance, occupy, lease, operate, manage, invest in, or hold office in a business that competes with or is similar to the Company’s business.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

REMUNERATION OF DIRECTORS AND SUPERVISORS

Our Directors and Supervisors received their remuneration in the form of fees, salaries, allowances, discretionary bonuses, share-based compensation, retirement benefit scheme contributions and other benefits in kind.

For the two financial years ended December 31, 2023 and 2024, the aggregate amount of emoluments of our Directors recorded in the profit or loss amounted to RMB31.64 million and RMB121.55 million respectively.

For the two financial years ended December 31, 2023 and 2024, the aggregate amount of emoluments of our Supervisors recorded in the profit or loss amounted to RMB0.45 million and RMB1.12 million respectively.

Under the arrangement currently in force, we estimate the total compensation before taxation to be accrued to our Directors and our Supervisors for the year ending December 31, 2025 to be RMB93.22 million.

For the two financial years ended December 31, 2023 and 2024, there were two and two Directors among the five highest paid individuals, respectively. The total emolument for the remaining individuals among the five highest paid individuals for the two financial years ended December 31, 2023 and 2024 were RMB7.96 million and RMB19.86 million respectively.

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 any subsidiary of our Company.

During the Track Record Period, none of our Directors or Supervisors waived any remuneration. Save as disclosed above, no other payments have been paid, or are payable, by our Company or any of our subsidiary to our Directors, Supervisors or the five highest paid individuals during the Track Record Period.

[REDACTED] EQUITY INCENTIVE PLAN

We adopted the [REDACTED] Equity Incentive Plan and established the Equity Incentive Platform. See “Statutory and General Information — [REDACTED] Equity Incentive Plan” in Appendix IV for further details.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

CORPORATE GOVERNANCE CODE

Our Company is committed to achieving high standards of corporate governance with a view to safeguarding the interests of our Shareholders. To accomplish this, our Company intends to comply with Corporate Governance Code set out in Appendix C1 to the Listing Rules and the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix C3 to the Listing Rules after the [REDACTED].

Pursuant to paragraph C.2.1 of Part 2 of the Corporate Governance Code, companies [REDACTED] on the Stock Exchange are expected to comply with, but may choose to deviate from the requirement that the responsibilities between chairman and chief executive should be segregated and should not be performed by the same individual. We do not have a separate chairman and chief executive and Dr. Michael Min XU currently performs the roles of the chairman of our Board and the general manager of our Company. Dr. XU has assumed the role of general manager of our Company since May 2008. He has extensive experience in the business operations and management of our Group. Our Board believes that, in view of his experience, personal profile and his roles in our Company as mentioned above, Dr. XU is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our general manager. The Board also believes that vesting the roles of both chairman and general manager in the same person has the benefit of (i) ensuring consistent leadership within the Group, (ii) enabling more effective and efficient overall strategic planning and execution of strategic initiatives of the Board, and (iii) facilitating the flow of information between the management and the Board for the Group. The Board considers that the balance of power and authority for the present arrangement will not be impaired, and this arrangement will enable the Company to make and implement decisions promptly and effectively. The Board will continue to review and consider splitting the roles of chairman of the Board and general manager of the Company at a time when it is appropriate by taking into account the circumstances of the Group as a whole.

Save as disclosed above, our Directors consider that upon [REDACTED], we will comply with all applicable code provisions of the Corporate Governance Code as set out in Appendix C1 to the Listing Rules.

BOARD DIVERSITY POLICY

In order to enhance the effectiveness of our Board, to maintain the high standard of corporate governance and to achieve the goal of a sustainable and balanced development of the Company, we have adopted the board diversity policy which sets out the objective and approach to achieve and maintain diversity of our Board. Pursuant to the board diversity policy, we seek to achieve board diversity through the consideration of a number of factors when selecting the candidates to our Board, including but not limited to gender, skills, age, professional experience, knowledge, cultural background, and length of service. The ultimate decision of the appointment will be based on merit and the contribution which the selected candidates will bring to our Board.

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Our Directors have a balanced mix of knowledge and skills, including overall management and strategic development, medicine, biophysics, biology, biomedicine, accounting, economics, marketing, and chemistry. We have three independent non-executive Directors with different industry backgrounds, representing one-third of the members of our Board. Our Company has evaluated the structure, size and composition of our Board, and is of the opinion that the structure of our Board is reasonable, and the experience and skills of the Directors in various aspects and fields can enable our Company to maintain a high standard of operations.

Besides, we particularly recognize the importance of gender diversity. Our Board currently consists of five female Directors and four male Directors. We have taken, and will continue to take, steps to promote gender diversity at all levels of our Company, including but without limitation to our Board and senior management levels. Going forward, we will continue to work to enhance gender diversity of our Board when selecting and recommending suitable candidates for Board appointments, and will at least have one female Director and will ensure that our female management members will get equal opportunities to develop and perform so as to eventually be equipped to step up as a member of our Board. Our Company also intends to promote gender diversity at the mid to senior level so that our Company can maintain a balanced gender ratio at different levels. Taking into account our existing business model and specific needs as well as the different background of our Directors, the composition of our Board satisfies our board diversity policy.

Our Nomination Committee is responsible for ensuring the diversity of our Board members. After the [REDACTED], our Nomination Committee will examine the board diversity policy from time to time to ensure its continued effectiveness and in particular use their efforts to identify and recommend suitable female candidates for the Board’s consideration in the future, and we will disclose in our corporate governance report about the implementation of the board diversity policy on an annual basis.

COMPLIANCE ADVISER

We have appointed Rainbow Capital (HK) Limited as our compliance adviser (the “**Compliance Adviser**”) pursuant to Rules 3A.19 and 3A.23 of the Listing Rules. The Compliance Adviser will provide us with guidance and advice as to compliance with the Listing Rules and other applicable laws, rules, codes and guidelines. Pursuant to Rule 3A.23 of the Listing Rules, the Compliance Adviser will advise our Company in certain circumstances including:

- (a) before the publication of any regulatory announcement, circular or financial report;
- (b) where a transaction, which might be a notifiable or connected transaction, is contemplated, including share issues and share repurchases;

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- (c) where we propose to use the [REDACTED] of the [REDACTED] in a manner different from that detailed in this Document or where our business activities, developments or results deviate from any forecast, estimate or other information in this Document; and
- (d) where the Hong Kong Stock Exchange makes an inquiry to our Company regarding unusual movements in the price or [REDACTED] volume of its [REDACTED] securities or any other matters in accordance with Rule 13.10 of the Listing Rules.

Pursuant to Rule 3A.24 of the Listing Rules, the Compliance Adviser will, on a timely basis, inform our Company of any amendment or supplement to the Listing Rules that are announced by the Hong Kong Stock Exchange. The Compliance Adviser will also inform our Company of any new or amended law, regulation or code in Hong Kong applicable to us, and advise us on the continuing requirements under the Listing Rules and applicable laws and regulations.

The term of the appointment will commence on the [REDACTED] and is expected to end on the date on which our Company complies with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED].

SUBSTANTIAL SHAREHOLDERS

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and the conversion of our Unlisted Shares to H Shares, the following persons will have an interest and/or short position in the Shares or the underlying Shares which would fall to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or, will be, directly or indirectly interested in 10% or more of the nominal value of any class of our share capital carrying rights to vote in all circumstances at general meetings of our Company:

Name of Shareholder	Nature of Interest	As of the Latest Practicable Date		Immediately following the [REDACTED]		
		Number of Shares	Approximate percentage of shareholding in our total share capital	Number of Shares ⁽¹⁾	Approximate percentage of shareholding in Unlisted Shares/ H Shares ⁽²⁾	Approximate percentage of shareholding in our total share capital ⁽²⁾
Dr. Michael Min XU ⁽³⁾	Beneficial owner	58,081,874	15.84%	[REDACTED]	[REDACTED]%	[REDACTED]%
				[REDACTED]	[REDACTED]%	[REDACTED]%
	Interest in controlled corporation	29,175,230	7.96%	[REDACTED]	[REDACTED]%	[REDACTED]%
Mingly ⁽⁴⁾	Beneficial owner	34,852,074	9.50%	[REDACTED]	[REDACTED]%	[REDACTED]%
				[REDACTED]	[REDACTED]%	[REDACTED]%
Mingly China Growth Partners, L.P. ⁽⁴⁾	Interest in controlled corporation	34,852,074	9.50%	[REDACTED]	[REDACTED]%	[REDACTED]%
				[REDACTED]	[REDACTED]%	[REDACTED]%
Shanghai Sujie ⁽³⁾	Beneficial owner	29,175,230	7.96%	[REDACTED]	[REDACTED]%	[REDACTED]%
Ms. Xiaojun WANG (王小軍) ⁽³⁾	Interest in controlled corporation	29,175,230	7.96%	[REDACTED]	[REDACTED]%	[REDACTED]%
Mingfei QIAN (錢明飛) ⁽⁵⁾	Interest in controlled corporation	12,539,710	3.42%	[REDACTED]	[REDACTED]%	[REDACTED]%
Suzhou Industrial Park Zhongxin Huiyuan Investment Center (Limited Partnership) (蘇州工業園區中鑫惠遠投資中心(有限合伙)) (“Zhongxin Huiyuan”) ⁽⁶⁾	Beneficial owner	11,705,026	3.19%	[REDACTED]	[REDACTED]%	[REDACTED]%
				[REDACTED]	[REDACTED]%	[REDACTED]%
				[REDACTED]	[REDACTED]%	[REDACTED]%
Suzhou Chinese Consortium Holdings Co., Ltd. (蘇州中方財團控股股份有限公司) (“Suzhou CCH”) ⁽⁶⁾⁽⁷⁾	Interest in controlled corporation	13,231,769	3.61%	[REDACTED]	[REDACTED]%	[REDACTED]%
				[REDACTED]	[REDACTED]%	[REDACTED]%
				[REDACTED]	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Nature of Interest	As of the Latest Practicable Date		Immediately following the [REDACTED]		
		Number of Shares	Approximate percentage of shareholding in our total share capital	Number of Shares ⁽¹⁾	Approximate percentage of shareholding in Unlisted Shares/H Shares ⁽²⁾	Approximate percentage of shareholding in our total share capital ⁽²⁾
Qiang XU (許強) ⁽⁶⁾⁽⁷⁾	Interest in controlled corporation	13,231,769	3.61%	[REDACTED]	[REDACTED]%	[REDACTED]%
Yuxiang YUAN (袁玉祥) ⁽⁶⁾	Interest in controlled corporation	11,705,026	3.19%	[REDACTED]	[REDACTED]%	[REDACTED]%
Zhi LI (李直) ⁽⁶⁾	Interest in controlled corporation	11,705,026	3.19%	[REDACTED]	[REDACTED]%	[REDACTED]%
Pingtian Yingke Shengxin Venture Capital Partnership (Limited Partnership) (平潭盈科盛鑫創業投資合夥企業(有限合夥)) (“ Pingtian Yingke ”) ⁽⁵⁾	Beneficial owner	8,468,396	2.31%	[REDACTED]	[REDACTED]%	[REDACTED]%
Xiangdong LIU (劉響東) ⁽⁵⁾	Interest in controlled corporation	8,468,396	2.31%	[REDACTED]	[REDACTED]%	[REDACTED]%
Huzhou Qiyuan Zhixin Equity Investment Partnership (Limited Partnership) (湖州啟緣致欣股權投資合夥企業(有限合夥)) (“ Huzhou Qiyuan ”) ⁽⁸⁾	Beneficial owner	5,452,433	1.49%	[REDACTED]	[REDACTED]%	[REDACTED]%
Wuxi Guofa Capital Operation Co., Ltd. (無錫市國發資本運營有限公司) (“ Wuxi Guofa ”) ⁽⁸⁾	Interest in controlled corporation	5,452,433	1.49%	[REDACTED]	[REDACTED]%	[REDACTED]%
Wuxi Guolian Development (Group) Co., Ltd. (無錫市國聯發展(集團)有限公司) (“ Wuxi Guolian Group ”) ⁽⁸⁾	Interest in controlled corporation	5,452,433	1.49%	[REDACTED]	[REDACTED]%	[REDACTED]%
Zhaokai MAO (毛照凱) ⁽⁸⁾	Interest in controlled corporation	5,452,433	1.49%	[REDACTED]	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Notes:

1. The letter “L” denotes the person’s long position in the Shares.
2. The calculation is based on the total number of [REDACTED] Unlisted Shares and [REDACTED] H Shares in issue immediately after completion of the [REDACTED] since [REDACTED] Unlisted Shares will be converted into H Shares and [REDACTED] H Shares will be [REDACTED] pursuant to the [REDACTED].
3. Shanghai Sujie was established in the PRC as a limited partnership, of which Ms. Xiaojun WANG (王小軍) is acting as the sole general partner, and Dr. Michael Min XU owns approximately 93.10% interest as a limited partner as of the Latest Practicable Date. As such, Ms. Xiaojun WANG (王小軍) and Dr. Michael Min XU are deemed to be interested in the Shares held by Shanghai Sujie under the SFO.
4. Mingly is a limited partnership incorporated in Cayman Islands, of which the general partner is Mingly China Growth Partners, L.P. As such, Mingly China Growth Partners, L.P. is deemed to be interested in the Shares held by Mingly under the SFO.
5. Pingtan Yingke is a limited partnership established in the PRC. The general partner of Pingtan Yingke is Yingke Innovation Asset Management Co., Ltd. (盈科創新資產管理有限公司) (“**Yingke Innovation**”), which is held as to approximately 39.365% by Mingfei QIAN (錢明飛). Pingtan Yingke Shengmei Venture Capital Partnership (Limited Partnership) (平潭盈科盛美創業投資合夥企業(有限合夥)) (“**Pingtan Shengmei**”) holds approximately 60% partnership interests in Pingtan Yingke as a limited partner. Pingtan Shengmei is held as to approximately 99.998% by Shangpu Industrial Investment Development (Hengqin) Co., Ltd. (尚浦產投發展(橫琴)有限公司) (“**Shangpu Investment**”) as a limited partner, and as to approximately 0.002% by Yingke Innovation as the general partner. Shangpu Investment is held as to approximately 95% by Shangxin Medical and Health Management (Pingtan) Co., Ltd. (尚信醫療健康管理(平潭)有限公司) (“**Shangxin Medical**”), which is held as to 95% by Shanghai Laiyuan Enterprise Management Co., Ltd. (上海萊緣企業管理有限公司) (“**Shanghai Laiyuan**”), which is in turn held as to 99% by Xiangdong LIU (劉響東). As such, Yingke Innovation, Mingfei QIAN (錢明飛), Pingtan Shengmei, Shangpu Investment, Shangxin Medical, Shanghai Laiyuan and Xiangdong LIU (劉響東) are deemed to be interested in the Shares held by Pingtan Yingke under the SFO.

Zibo Yingke Jiyun Venture Capital Partnership (Limited Partnership) (淄博盈科吉運創業投資合夥企業(有限合夥)) (the “**Zibo Yingke**”) is a limited partnership established in the PRC. The general partner of Zibo Yingke is Yingke Innovation. As such, Yingke Innovation and Mingfei QIAN (錢明飛) are deemed to be interested in the [REDACTED] Unlisted Shares held by Zibo Yingke upon the completion of the [REDACTED] under the SFO.
6. Zhongxin Huiyuan is a limited partnership established in the PRC. The general partner of Zhongxin Huiyuan is Suzhou Industrial Park Zhongxin Dayi Investment Management Partnership (Limited Partnership) (蘇州工業園區中鑫大一投資管理合夥企業(有限合夥)) (“**Zhongxin Dayi**”). Zhongxin Dayi’s general partner is Suzhou Industrial Park Haijia Enterprise Management Consulting Partnership (Limited Partnership) (蘇州工業園區海嘉企業管理諮詢合夥企業(有限合夥)) (“**Haijia**”), and is held as to 35% by Suzhou Zhongxin Innovation Private Equity Fund Management Co., Ltd. (蘇州中鑫創新私募基金管理有限公司) (“**Suzhou Zhongxin**”). Haijia’s general partner is Guangdong Haisel Medical Technology Co., Ltd. (廣東海思爾醫療科技有限公司) (“**Guangdong Haisel**”), and is held as to 30% by Yuxiang YUAN (袁玉祥). Guangdong Haisel is held as to 99% by Zhi LI (李直). Suzhou Zhongxin is held as to 40% by each of Suzhou CCH and Qiang XU (許強). As such, Zhongxin Dayi, Haijia, Suzhou Zhongxin, Guangdong Haisel, Yuxiang YUAN, Zhi LI, Suzhou CCH and Qiang XU (許強) are deemed to be interested in the Shares held by Zhongxin Huiyuan under the SFO.
7. Zhongxin Hengxiang is a limited partnership established in the PRC. The general partner of Zhongxin Hengxiang is Suzhou Zhongxin Innovation Private Equity Fund Management Co., Ltd. (蘇州中鑫創新私募基金管理有限公司), which is owned as to 40% by Suzhou CCH and 40% by Qiang XU (許強). As such, Suzhou CCH and Qiang XU (許強) are deemed to be interested in the Shares held by Zhongxin Hengxiang under the SFO.

SUBSTANTIAL SHAREHOLDERS

8. Huzhou Qiyuan is a limited partnership established in the PRC. The general partner of Huzhou Qiyuan is Shanghai Yicun Private Equity Fund Management Co., Ltd. (上海一村私募基金管理有限公司) (“**Shanghai Yicun**”). Huzhou Qiyuan is held as to approximately 31.56% by Xi’an Chuyang Financial Consulting Partnership (Limited Partnership) (西安楚陽財務諮詢合夥企業(有限合夥)) (“**Xi’an Chuyang**”) as a limited partner. Shanghai Yicun is held as to 99% by V Capital Co., Ltd. (一村資本有限公司) (“**V Capital**”), which is in turn held as to approximately 41.92% by Wuxi Guolian Industrial Investment Private Equity Fund Management Co., Ltd. (無錫國聯產業投資私募基金管理有限公司) (“**Guolian PE**”) and approximately 40.92% by Jiangxi Huaxicun Co., Ltd. (江西華西村股份有限公司) (“**Jiangxi Huaxicun**”). Guolian PE is held as to 55% by Wuxi Innovation Investment Group Co., Ltd. (無錫市創新投資集團有限公司) (“**Wuxi Innovation**”) and 30% by Wuxi Guolian Industrial Investment Group Co., Ltd. (無錫國聯實業投資集團有限公司) (“**Wuxi Guolian Investment**”). Wuxi Innovation is held as to 73% by Wuxi Guofa, a wholly-owned subsidiary of State-owned Assets Supervision and Administration Commission of Wuxi Municipal People’s Government (無錫市人民政府國有資產監督管理委員會) (“**Wuxi SASAC**”). Wuxi Guolian Investment is wholly owned by Wuxi Guolian Group, which is held as to approximately 61.23% by Wuxi SASAC and approximately 32.09% by Wuxi Guofa. Xi’an Chuyang is held as to approximately 62.61% by Zhaokai MAO (毛照凱). As such, Shanghai Yicun, Xi’an Chuyang, V Capital, Guolian PE, Jiangxi Huaxicun, Wuxi Innovation, Wuxi Guolian Investment, Wuxi Guofa, Wuxi Guolian Group and Zhaokai MAO (毛照凱) are deemed to be interested in the Shares held by Huzhou Qiyuan under the SFO.

Save as disclosed above and the section headed “Appendix IV — Statutory and General Information — Further Information about our Directors, Supervisors, Senior Management and Substantial Shareholders,” our Directors are not aware of any person who will, immediately following completion of the [REDACTED], have any interest and/or short position in the Shares or underlying Shares of our Company which will be required to be disclosed to our Company and the Stock Exchange pursuant to the provisions of Divisions 2 and 3 of Part XV of the SFO, or, who are, directly or indirectly interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meeting of the Company or any other member of our Group.

SHARE CAPITAL

This section presents certain information regarding our share capital before and upon completion of the [REDACTED].

BEFORE THE COMPLETION OF THE [REDACTED]

As of the Latest Practicable Date, the issued share capital of our Company was RMB366,672,032, comprising 366,672,032 Unlisted Shares of nominal value RMB1.00 each.

UPON THE COMPLETION OF THE [REDACTED]

Immediately following the completion of the [REDACTED] and the conversion of certain Unlisted Shares into H Shares, the issued share capital of our Company will be as follows:

Description of Shares	Number of Shares	Approximate Percentage of the Total Share Capital of our Company
Unlisted Shares in issue	[REDACTED]	[REDACTED]%
H Share to be converted from Unlisted Shares . . .	[REDACTED]	[REDACTED]%
H Shares to be issued under the [REDACTED] . .	[REDACTED]	[REDACTED]%
Total	[REDACTED]	100.00%

RANKING

Upon completion of the [REDACTED], the Shares will consist of H Shares and Unlisted Shares. H Shares and Unlisted Shares are all ordinary Shares in the share capital of our Company. However, apart from certain qualified domestic institutional investors in the PRC, the qualified PRC investors under the Shanghai — Hong Kong Stock Connect or the Shenzhen — Hong Kong Stock Connect and other persons who are entitled to hold our H Shares pursuant to relevant PRC laws and regulations or upon approvals of any competent authorities, H Shares generally cannot be [REDACTED] for by or [REDACTED] between [REDACTED] of the PRC.

Unlisted Shares and H Shares 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 paid by us in Hong Kong dollars or Renminbi (as the case may be), or in the form of H Shares.

SHARE CAPITAL

CONVERSION OF OUR UNLISTED SHARES INTO H SHARES

According to the regulations issued by the CSRC, the holders of our Unlisted Shares may, at their own option, authorize the Company to file with the CSRC for conversion of their respective Unlisted Shares to H Shares, and such converted Shares may be [REDACTED] and [REDACTED] on an overseas stock exchange provided that the required filings with the securities regulatory authorities of the State Council for the conversion, [REDACTED] and [REDACTED] of such converted Shares have been completed. Additionally, such conversion, [REDACTED] and [REDACTED] shall meet any requirement of internal approval process and in all respects comply with the regulations prescribed by the securities regulatory authorities of the State Council and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange. Save as disclosed in this Document and to the best knowledge of our Directors, we are not aware of the intention of such existing Shareholders to convert their Unlisted Shares.

If any of the Unlisted Shares are to be converted, [REDACTED] and [REDACTED] as H Shares on the Stock Exchange, the filings with the relevant PRC regulatory authorities, including the CSRC, and the approval of the Stock Exchange are necessary for such conversion. Based on the procedures for the conversion of Unlisted Shares into H Shares as set forth below, we will [REDACTED] for the [REDACTED] of all or any portion of the Unlisted Shares on the Stock Exchange as H Shares in advance of any proposed conversion after the [REDACTED] to ensure that the conversion process can be completed promptly upon notice to the Stock Exchange and delivery of Shares for entry on the [REDACTED]. As the [REDACTED] of additional Shares after the [REDACTED] on the Stock Exchange is ordinarily considered by the Stock Exchange to be a purely administrative matter, it does not require such prior [REDACTED] for [REDACTED] at the time of our [REDACTED] in Hong Kong. No Shareholder voting is required for the conversion of such Shares or the [REDACTED] and [REDACTED] of such converted Shares on an overseas stock exchange. Any [REDACTED] for [REDACTED] of the converted shares on the Stock Exchange after our [REDACTED] is subject to prior notification by way of announcement to inform our Shareholders and the public of any proposed conversion.

After all the requisite filings have been completed and approvals have been obtained, the relevant Unlisted Shares will be withdrawn from the [REDACTED], and our Company will re-register such Shares on the [REDACTED] maintained in Hong Kong and instruct the [REDACTED] to issue [REDACTED]. Registration on the [REDACTED] of our Company will be on the conditions that (i) the [REDACTED] lodges with the Stock Exchange a letter confirming the entry of the relevant H Shares on the [REDACTED] and the due dispatch of [REDACTED]; and (ii) the admission of the H Shares to be [REDACTED] on the Stock Exchange complies with the Listing Rules and the General Rules of HKSCC and the HKSCC Operational Procedures in force from time to time.

Until the converted Shares are re-registered on the [REDACTED] of our Company, such Shares would not be [REDACTED] as H Shares. For details of our existing Shareholders' proposed conversion of Unlisted Shares into H Shares, see “History, Development and Corporate Structure — Capitalization”.

SHARE CAPITAL

TRANSFER OF SHARES ISSUED PRIOR TO THE [REDACTED]

Pursuant to the PRC Company Law, our Shares issued prior to the [REDACTED] shall not be transferred within one year from the [REDACTED].

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 hold in our Company cannot be transferred within one year from the [REDACTED], nor within half a year after they leave their positions as Directors, Supervisors or members of the senior management in our Company.

See “[REDACTED]” for details of the lock-up undertakings.

[REDACTED] EQUITY INCENTIVE PLAN

We adopted the [REDACTED] Equity Incentive Plan and established the Equity Incentive Platform. See “Statutory and General Information — [REDACTED] Equity Incentive Plan” in Appendix IV for further details.

GENERAL MANDATE TO ISSUE SHARES AND REPURCHASE MANDATE

Subject to the [REDACTED] becoming unconditional, our Directors have been granted general unconditional mandates to issue and repurchase our Shares. See “Appendix IV — Statutory and General Information — Further Information about our Company — Resolutions of our Shareholders” for further details.

SHAREHOLDERS’ GENERAL MEETING

See “Appendix III — Summary of Articles of Association” for details of circumstances under which our general Shareholders’ meeting is required.

FINANCIAL INFORMATION

You should read the following discussion and analysis with our consolidated financial information, including the notes thereto, included in the Accountants’ Report in Appendix I to this Document. Our consolidated financial information has been prepared in accordance with HKFRSs, which may differ in material aspects from generally accepted accounting principles in other jurisdictions, including the United States. You should read the entire Accountants’ Report and not merely rely 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 our assumptions and analysis in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. However, whether actual outcomes and developments will meet our expectations and predictions depends on a number of risks and uncertainties. In evaluating our business, you should carefully consider the information provided in the section headed “Risk Factors” and “Business” in this Document.

For the purpose of this section, unless the context otherwise requires, references to the years of 2023 and 2024 refer to our financial year ended December 31 of each year. Unless the context otherwise requires, financial information described in this section is described on a consolidated basis. Discrepancies between totals and sums of amounts listed in this section in any table or elsewhere in this document may be due to rounding.

OVERVIEW

We have cultivated a diverse pipeline of six product candidates to capture the market potential in prevalent chronic and metabolic diseases, including T2DM, obesity, NASH, OIC and congenital hyperinsulinemia. Our Core Product PB-119 is one of the earliest domestically developed long-acting GLP-1 receptor agonists in China, according to CIC. For additional information on our drug candidates, see the section headed “Business.”

We strategically focus on chronic diseases with a particular emphasis on metabolic disorders, as they feature a significant and growing market opportunity and considerable medical needs. Chronic and metabolic diseases, encompassing a spectrum of conditions such as diabetes, obesity and NASH, are increasingly prevalent worldwide driven by changing lifestyles and aging populations. According to CIC, metabolic diseases are among the fastest growing diseases worldwide, and they are also among the most common diseases in China.

FINANCIAL INFORMATION

We currently have no products approved for commercial sale and have not generated any revenue from product sales. We had not been profitable and incurred operating losses during the Track Record Period. In 2023 and 2024, we had total loss for the year of RMB279.2 million and RMB283.4 million, respectively. Our total loss for the year mainly resulted from research and development expenses, as well as administrative expenses.

As the new drug application (“NDA”) for PB-119 have been accepted by the NMPA, we expect to commercialize PB-119 in China in the near future. Subsequent to the [REDACTED], we expect to incur costs associated with operating as a [REDACTED]. We expect that our financial performance will fluctuate from period to period due to the development status of our drug candidates, timeline and terms of potential collaboration with our partners, regulatory approval timeline and commercialization of our drug candidates.

BASIS OF PRESENTATION

Our consolidated financial information has been prepared in accordance with all applicable HKFRSs, which comprise all applicable individual HKFRSs, Hong Kong Accounting Standards (the “HKASs”) and Interpretations issued by the Hong Kong Institute of Certified Public Accountants (the “HKICPA”). All applicable new and revised HKFRSs that are effecting during the Track Record Period had been adopted by us in the preparation of the consolidated financial information. The consolidated financial information has been prepared under the historical cost convention, except for financial assets and liabilities at fair value. Further details of the material accounting policy information adopted are set out in Note 2 to the Accountants’ Report set out in Appendix I to this Document.

SIGNIFICANT FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations and financial condition have been, and are expected to continue to be, principally affected by a number of factors, many of which may be beyond our control. A discussion of the key factors is set out below.

Development and Commercialization of Our Drug Candidates

Our business and results of operations depend on our ability to successfully develop and commercialize our differentiated drug candidates, including our Core Product PB-119. The NDA for PB-119 in China for T2DM was accepted by the NMPA in September 2023, marking a key milestone for its upcoming commercialization.

As of the Latest Practicable Date, we had cultivated a diverse pipeline of six product candidates to capture the market potential in prevalent chronic and metabolic diseases, including T2DM, obesity, NASH, OIC and congenital hyperinsulinemia. We expect to continue to achieve and deliver major development milestones for our drug candidates beyond PB-119, including PB-718, PB-1902, PB-722, PB-2301 and PB-2309. Our business and results of operations depend on our drug candidates demonstrating good safety and efficacy results, and our ability to obtain the requisite regulatory approvals for our drug candidates.

FINANCIAL INFORMATION

Although we currently have no product approved for commercial sale and have not generated any revenue from product sales, we expect to commercialize one or more of our drug candidates over the coming years as they move towards the final stages of development. Our ability to generate revenue from our drug candidates is dependent on multiple factors, including but not limited to our ability to obtain regulatory approvals, secure adequate manufacturing capacity, collaboration with competent third-party sales partners, as well as making our products accessible to, affordable for and accepted by the vast population who are in need of quality products that brings comprehensive benefits for chronic and metabolic diseases.

Our Research and Development Expenses

Our results of operations are significantly affected by our cost structure, which primarily consists of research and development expenses. We believe our ability to successfully develop drug candidates is the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing quality drug candidates requires significant investments of financial resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, we have invested a significant amount of financial resources in research and development to advance and expand our pipeline of clinical- and preclinical-stage drug candidates. The research and development expenses we incurred in 2023 and 2024 amounted to RMB236.7 million and RMB95.4 million, respectively. See “— Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income — Research and Development Expenses” for detailed information.

We expect our research and development expenses to continue to be a major component in our cost structure. As we expand the indications and combination therapies of our Core Product PB-119, advance more candidates along clinical trials and conduct additional preclinical studies, we expect to incur additional costs in relation to, among other things, preclinical study and clinical trial expenses, CMC expenses, raw materials procurements, manufacturing and sales and marketing. Beyond research and development expenses, we anticipate increasing legal, compliance, accounting, insurance and investor and public relations expenses associated with being a [REDACTED] in Hong Kong.

Funding for Our Operations

During the Track Record Period, we funded our operations primarily through interest-bearing borrowings and equity financing. Going forward, in the event of the successful commercialization of one or more of our drug candidates, we expect to primarily fund our operations with revenue generated from sales of our commercialized drug products. We may also require further funding through financing, public or private offerings, debt financing, collaboration and licensing arrangements or other sources. Any fluctuation in the funding for our operations will impact our cash flow and our results of operations.

FINANCIAL INFORMATION

MATERIAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGEMENTS AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles that conform with HKFRSs. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues, costs and expenses. We evaluate our estimates and judgments on an ongoing basis, and our actual results may differ from these estimates. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

We set forth below those accounting policies that we believe are of critical importance to us or involve the most significant estimates and judgments used in the preparation of our consolidated financial statements. Our material accounting policies and estimates, which are important for an understanding of our financial condition and results of operations, are set forth in detail in Notes 2 and 3 to the Accountants’ Report in Appendix I to this Document.

Material Accounting Policies

Leased Assets

At inception of a contract, we assess whether the contract is, or contains, a lease. This is the case if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Control is conveyed where the customer has both the right to direct the use of the identified asset and to obtain substantially all of the economic benefits from that use.

As a lessee

Where the contract contains lease component(s) and non-lease component(s), we have elected not to separate non-lease components and accounts for each lease component and any associated non-lease components as a single lease component for all leases.

At the lease commencement date, we recognize a right-of-use asset and a lease liability, except for leases that have a short lease term of 12 months or less and leases of low-value items. When we enter into a lease in respect of a low-value item, we decide whether to capitalize the lease on a lease-by-lease basis. If not capitalized, the associated lease payments are recognized in profit or loss on a systematic basis over the lease term.

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Where the lease is capitalized, the lease liability is initially recognized at the present value of the lease payments payable over the lease term, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, using a relevant incremental borrowing rate. After initial recognition, the lease liability is measured at amortized cost and interest expense is recognized using the effective interest method. Variable lease payments that do not depend on an index or rate are not included in the measurement of the lease liability and are charged to profit or loss as incurred.

The right-of-use asset recognized when a lease is capitalized is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentives received. The right-of-use asset is subsequently stated at cost less accumulated depreciation and impairment losses. Depreciation is calculated using the straight line method over the unexpired term of lease.

Refundable rental deposits are accounted for separately from the right-of-use assets in accordance with the accounting policy applicable to investments in non-equity securities carried at amortized cost. Any excess of the nominal value over the initial fair value of the deposits is accounted for as additional lease payments made and is included in the cost of right-of-use assets.

The lease liability is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in our estimate of the amount expected to be payable under a residual value guarantee, or if we change its assessment of whether it will exercise a purchase, extension or termination option. When the lease liability is remeasured in this way, a corresponding adjustment is made to the carrying amount of the right-of-use asset, or is recorded in profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

The lease liability is also remeasured when there is a lease modification, which means a change in the scope of a lease or the consideration for a lease that is not originally provided for in the lease contract, if such modification is not accounted for as a separate lease. In this case the lease liability is remeasured based on the revised lease payments and lease term using a revised discount rate at the effective date of the modification.

In the consolidated statement of financial position, the current portion of long-term lease liabilities is determined as the present value of contractual payments that are due to be settled within twelve months after the reporting period.

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Share-based Payments

The fair value of share-based payment awards granted to employees is recognized as an employee cost with a corresponding increase in a reserve within equity. The fair value is measured at grant date by reference to the market price or the valuer’s valuation of the underlying shares. Where the employees have to meet vesting conditions before becoming unconditionally entitled to the shares, the total estimated fair value of the shares is spread over the vesting period, taking into account the probability that the shares will vest.

During the vesting period, the number of equity-settled share-based payments award that is expected to vest is reviewed. Any resulting adjustment to the cumulative fair value recognized in prior years is charged/credited to the profit or loss for the year of the review, unless the original employee expenses qualify for recognition as an asset, with a corresponding adjustment to the capital reserve. On vesting date, the amount recognized as an expense is adjusted to reflect the actual number of equity-settled share-based payments award that vest (with a corresponding adjustment to the capital reserve), except where forfeiture is only due to not achieving vesting conditions that relate to the market price of the Company’s shares. The equity amount is recognized in the capital reserve until either the equity-settled share-based payments award is exercised (when it is included in the amount recognized in share capital for the shares issued) or the equity-settled share-based payments award expires (when it is released directly to retained profits).

Significant Accounting Judgements and Estimates

Research and Development Expenses

Development expenses incurred on our pipeline are capitalized and deferred only when the we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, our intention to complete and the our ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and the ability to measure reliably the expenditure during the development. Development expenses which do not meet these criteria are expensed when incurred. Management will assess the progress of each of the research and development projects and determine the criteria met for capitalization. All development expenses were expensed when incurred during the Track Record Period.

Recognition of Deferred Tax Assets

Deferred tax assets in respect of tax losses carried forward and deductible temporary differences are recognized and measured based on the expected manner of realization or settlement of the carrying amount of the relevant assets and liabilities, using tax rates enacted or substantively enacted at the end of each reporting date. In determining the carrying amounts of deferred tax assets, expected taxable profits are estimated which involves a number of assumptions relating to the operating environment of us and require a significant level of judgement exercised by our Directors. Any change in such assumptions and judgement would affect the carrying amounts of deferred tax assets to be recognized and hence the net profit in future years.

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Impairment of Non-Financial Assets

During the Track Record Period, the Directors of the Company considered that the Group did not identify any impairment indicators for property, plant and equipment, right-of-use assets and intangible assets by reviewing the internal and external sources of information. If any such indication exists, the asset’s recoverable amount is estimated by using the value in use model. Value in use was calculated by preparing discounted cash flows and any shortfall of the recoverable amount against the carrying amounts would be recognized as impairment.

Management reviewed of the year-end balance and assessment of the impairment indication for each respective year, the Group did not make any impairment for the property, plant and equipment, right-of-use assets and intangible assets for the years ended December 31, 2023 and 2024.

Estimation of Fair Value of Financial Instruments

Fair value hierarchy

Fair values are categorized into the three-level hierarchy as defined in HKFRS 13, *Fair value measurement*. The level into which a fair value measurement is classified is determined with reference to the observability and significance of the inputs used in the valuation technique as follows:

- Level 1 valuations: Fair value measured using only Level 1 inputs i.e. unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2 valuations: Fair value measured using Level 2 inputs i.e. observable inputs which fail to meet Level 1, and not using significant unobservable inputs. Unobservable inputs are inputs for which market data are not available.
- Level 3 valuations: Fair value measured using significant unobservable inputs.

During the Track Record Period, we had certain financial assets categorized within Level 3 of fair value measurement (“**Level 3 Financial Assets**”). Our Level 3 Financial Assets include wealth management products and banks deposits. We have a team performing valuations for the financial instruments categories into Level 3 of the fair value hierarchy. The team reports directly to the chief financial officer. Valuation assessment with analysis of changes in fair value measurement is prepared by the team at each reporting date and is reviewed and approved by the chief financial officer.

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	Fair value at December 31, 2023	Fair value measurements as at December 31, 2023 categorized into		
		Level 1	Level 2	Level 3
	RMB'000	RMB'000	RMB'000	RMB'000
Recurring fair value measurement				
Financial assets:				
– Wealth management products	15,765	–	–	15,765
– Negotiable certificate of deposits with banks	247,313	–	–	247,313

	Fair value at December 31, 2024	Fair value measurements as at December 31, 2024 categorized into		
		Level 1	Level 2	Level 3
	RMB'000	RMB'000	RMB'000	RMB'000
Recurring fair value measurement				
Financial assets:				
– Wealth management products	15,133	–	–	15,133
– Negotiable certificate of deposits with banks	138,522	–	–	138,522

During the Track Record Period, there were no transfers between Level 1 and Level 2, or transfers into or out of Level 3. Our policy is to recognize transfers between levels of fair value hierarchy as of the end of each of the reporting period in which they occur.

The fair values of wealth management products and negotiable certificate of deposits with banks have been estimated using a discounted cash flow valuation model based on assumptions that are not supported by observable market prices or rates. The valuation requires the Directors to make estimates about the expected future cash flows including expected future interest return on maturity of the wealth management products. The Directors believe that the estimated fair values resulting from the valuation technique are reasonable, and that they were the most appropriate values at the end of reporting periods.

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In relation to the valuation of the Level 3 Financial Assets, our Directors had reviewed the valuation works and results and the financial statements prepared in accordance with HKFRSs, and had obtained sufficient understanding of the valuation model, methodologies and techniques on which the valuation is based. Based on the above, our Directors are of the view that the valuation analysis performed during the Track Record Period is fair and reasonable, and our financial statements are properly prepared. In addition, our Directors are satisfied with the valuation work for the Level 3 Financial Assets performed during the Track Record Period.

Our Reporting Accountants have conducted their work in accordance with Hong Kong Standard on Investment Circular Reporting Engagement 200 “Accountants’ Reports on Historical Financial Information in Investment Circulars” (“**HKSIR 200**”) issued by HKICPA in order to express an opinion on the Historical Financial Information (as defined in the Appendix I to this Document) as a whole. The Reporting Accountants’ opinion on the Historical Financial Information for the Track Record Period as a whole is set out in Appendix I to this Document.

In relation to the fair value assessment of the financial assets requiring Level 3 measurements under the fair value classification, the Sole Sponsor has conducted relevant due diligence work, including but not limited to, (i) obtaining and reviewing the terms of the relevant wealth management products agreement; (ii) discussing with the Company to understand its methodology, assumptions and information relied upon in respect of the valuation of the Level 3 financial assets of the Group and our views on the fairness and reasonableness of the assumptions, basis and approaches of the valuation; (iii) discussing with the Company and the reporting accountants to understand the work performed in relation to such valuation; and (iv) reviewing the relevant notes in the Accountants’ Report as contained in Appendix I to this Document and the reporting accountants’ opinion on the historical financial information as a whole for the Track Record Period. Based upon the due diligence work conducted by the Sole Sponsor as stated above and having considered the views of the Directors and the reporting accountants, nothing material has come to the Sole Sponsor’s attention that would cause the Sole Sponsor to question the valuation in respect of the financial assets requiring Level 3 measurements under the fair value classification.

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DESCRIPTION OF SELECTED COMPONENTS OF STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

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

	For the Year Ended December 31,	
	2023	2024
	RMB'000	RMB'000
Other net income	14,635	7,007
Selling and marketing expenses	–	(7,150)
Research and development expenses	(236,731)	(95,427)
Administrative expenses	(55,358)	(185,282)
Loss from operations	(277,454)	(280,852)
Finance costs	(1,727)	(2,499)
Loss before taxation	(279,181)	(283,351)
Income tax	–	–
Loss for the year	<u>(279,181)</u>	<u>(283,351)</u>
Attributable to:		
Equity shareholders of the Company	(278,999)	(283,158)
Non-controlling interests	(182)	(193)
Loss and total comprehensive income for the year	<u>(279,181)</u>	<u>(283,351)</u>

Other Net Income

Our other net income primarily consists of net realized and unrealized gain on financial instruments carried at fair value through profit or loss (“**FVPL**”), government grants, interest income on deposits with banks and others.

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The following table sets forth a breakdown of our other net income for the periods indicated.

	For the Year Ended December 31,	
	2023	2024
	RMB'000	RMB'000
Net realized and unrealized gain on financial instruments carried at FVPL	6,325	6,013
Government grants	2,806	267
Interest income on deposits with banks	5,285	802
Others	219	(75)
Total	14,635	7,007

Net realized and unrealized gain on financial instruments carried at FVPL mainly represents gains resulting from changes in the fair value of our wealth management products and negotiable certificate of deposits with banks. Our government grants mainly represent incentives we received from the local governments. Such incentives are granted primarily for compensation of expenditure arising from research activities and preclinical and clinical trial activities.

Research and Development Expenses

Our research and development expenses primarily consisted of (i) third-party contracting expenses, includes the early-stage discovery expenses, preclinical expenses and clinical trial expenses for our drug candidates, (ii) staff costs, primarily consisting of salaries and benefits for our R&D team, (iii) cost of materials and consumables, (iv) share-based compensation expenses, (v) depreciation and amortization expenses; and (vi) others. The following table sets forth a breakdown of our research and development expenses for the periods indicated.

	For the Year Ended December 31,	
	2023	2024
	RMB'000	RMB'000
Third-party contracting expenses	190,420	35,913
Staff costs	28,000	19,524

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	For the Year Ended December 31,	
	2023	2024
	RMB'000	RMB'000
Cost of materials and consumables	7,205	12,052
Share-based compensation expenses	7,076	24,855
Depreciation and amortization expenses	2,564	1,682
Others	1,466	1,401
Total	236,731	95,427

In 2023 and 2024, we recorded R&D expenses of RMB236.7 million and RMB95.4 million, respectively, with R&D expenses of RMB60.5 million and RMB33.5 million, representing 25.6% and 35.1% of total R&D expenses, attributable to the Core Product, respectively. All our R&D expenses for the Core Product during the Track Record Period were used for its clinical studies and regulatory filings.

The following table sets forth a breakdown of our research and development expenses by drug candidates for the periods indicated.

	For the Year Ended December 31,	
	2023	2024
	RMB'000	RMB'000
PB-119	60,508	33,489
PB-718	24,554	27,439
Other candidates⁽¹⁾	151,669	34,499
Total	236,731	95,427

Note:

- Our other drug candidates include PB-1902, PB-722, PB-2301 and PB-2309

The decrease of our R&D expenses incurred on our Core Product from RMB60.5 million in 2023 to RMB33.5 million in 2024 was in line with our advancement of the Core Product PB-119 from the Phase III clinical stage to the NDA filing in 2023. We completed the Phase III clinical trial of PB-119 for the treatment of T2DM in 2023, for which we recognized a significant amount of R&D expenses in the same year. We incurred fewer R&D expenses for PB-119 in 2024 as compared to 2023, mainly because the Phase Ib/IIa clinical trial of PB-119 for the treatment of overweight or obesity that was initiated in the first half of 2024 was still at its early stage in 2024.

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The decrease of our R&D expenses incurred on other candidates (except PB-718) from RMB151.7 million in 2023 to RMB95.4 million in 2024 was mainly because we focused our limited resources on advancing the commercialization of PB-119 and allocated less fund in the development of other candidates.

The fluctuation of our R&D expenses for other drug candidates was in line with their related clinical trials. We anticipate to continue to significantly invest in our R&D efforts, since we plan to expand the indications and combination therapies of our Core Product, advance the development of our key product and bring more candidates along clinical trials and conduct additional preclinical studies.

Administrative Expenses

Our administrative expenses primarily consist of share-based compensation expenses, staff costs, professional and consulting service fees, depreciation and amortization and others. The following table sets forth a breakdown of our administrative expenses for the periods indicated.

	For the Year Ended December 31,	
	2023	2024
	RMB'000	RMB'000
Share-based compensation expenses	28,037	120,613
Staff costs	17,464	14,334
Professional and consulting service fees	4,351	37,315
Depreciation and amortization expenses	1,043	733
Others	4,463	12,287
Total	<u>55,358</u>	<u>185,282</u>

Selling and Marketing Expenses

We did not incur any selling and marketing expenses in the year ended December 31, 2023, because the most advanced product candidate in our pipeline, namely our Core Product PB-119, was under clinical development and/or regulatory docket preparation. The NMPA accepted the NDA of PB-119 for the treatment of T2DM in China in September 2023. In anticipation of the upcoming commercialization of PB-119, we incurred RMB7.2 million selling and marketing expenses in the year ended December 31, 2024 primarily in relation to the salary of related employees and conferences that we attended to enhance the market awareness of PB-119.

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Finance Costs

Our finance costs consist of interest on interest-bearing borrowings and lease liabilities. The following table sets forth the components of our finance costs for the periods indicated:

	For the Year Ended December 31,	
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>
Interest on interest-bearing borrowings	1,599	2,392
Interest on lease liabilities	128	107
Total	<u>1,727</u>	<u>2,499</u>

Income Tax

During the Track Record Period, we recorded no income tax expense. Our Directors confirm that, during the Track Record Period, we had made all the required tax filings with the relevant tax authorities in the relevant jurisdictions and had paid all outstanding tax liabilities and we were not aware of any outstanding or potential disputes with such tax authorities.

We are subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which we are domiciled and operate.

PRC

Under the Law of the PRC on Enterprise Income Tax, or the EIT Law, and Implementation Regulation of the EIT Law, the tax rate of our PRC subsidiaries is 25% during the Track Record Period.

According to the tax incentive policies promulgated by the State Tax Bureau of the PRC in September 2022, an additional 100% of qualified research and development expenses incurred for the years ended December 31, 2023 and 2024 is allowed to be deducted from taxable income.

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PERIOD-TO-PERIOD COMPARISON OF RESULTS OF OPERATIONS

Year Ended December 31, 2024 Compared to Year Ended December 31, 2023

Other Net Income

Our other net income decreased by 52.1% from RMB14.6 million in 2023 to RMB7.0 million in 2024, primarily due to a decrease of interest income on bank deposits by RMB4.5 million and a decrease of government grants by RMB2.5 million. The decrease in interest income on bank deposits was primarily because we did not purchase new call deposit in 2024. The decrease in government grants was because we were awarded certain subsidies for conducting clinical trials and R&D activities in 2023 but not in 2024. The amount of government grants that we receive depends on factors such as the status of our pipeline programs and the eligibility of such government grants, as well as the timing that the government grants are appropriated.

Research and Development Expenses

Our research and development expenses decreased from RMB236.7 million in 2023 to RMB95.4 million in 2024. The decrease was in line with our advancement of the Core Product from the Phase III clinical stage to the NDA filing in 2023.

Administrative Expenses

Our administrative expenses increased by 234.7% from RMB55.4 million in 2023 to RMB185.3 million in 2024. The increase was primarily attributable to (i) the increased share-based compensation expenses by RMB92.6 million, mainly due to (a) the one-off share-based compensation expenses incurred for the cancellation of certain RSUs, (b) the new grant of RSUs to certain administrative personnel in the first half of 2024, and (c) the changes in the vesting conditions of RSUs in February 2024; and (ii) increased professional and consulting service fees primarily incurred in connection with the [REDACTED] by RMB33.0 million in 2024. For further details of share-based compensation transactions, see Note 22 of the Accountants’ Report set out in Appendix I to this Document.

Selling and Marketing Expenses

We started to incur selling and marketing expenses in 2024 for the commercialization of our Core Product PB-119. In 2024, we incurred RMB7.2 million selling and marketing expenses primarily in relation to the salary of related employees and conferences that we attended to enhance the market awareness of PB-119.

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Finance Costs

Our finance costs increased from RMB1.7 million in 2023 to RMB2.5 million in 2024. This increase was primarily due to an increase of RMB0.8 million in interest on interest-bearing borrowings.

Loss for the Year

For the reasons described above, our loss for the year increased from RMB279.2 million in 2023 to RMB283.4 million in 2024.

DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The following table sets forth our consolidated statements of financial position as of the dates indicated.

	As of December 31,	
	2023	2024
	RMB'000	RMB'000
Non-current assets		
Property, plant and equipment	3,692	3,572
Right-of-use assets	3,256	1,527
Intangible assets	975	863
Other non-current assets	14,651	22,101
Total non-current assets	22,574	28,063
Current assets		
Prepayments and other receivables	5,254	8,247
Financial assets at FVPL	263,078	153,655
Cash and cash equivalents	77,147	28,392
Total current assets	345,479	190,294
Current liabilities		
Trade and other payables	97,793	56,394
Interest-bearing borrowings	65,775	100,003
Lease liabilities	1,419	1,269
Total current liabilities	164,987	157,666
NET CURRENT ASSETS	180,492	32,628

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	As of December 31,	
	2023	2024
	RMB'000	RMB'000
Total assets less current liabilities	203,066	60,691
Non-current liabilities		
Lease liabilities	1,713	221
Deferred income	6,000	3,000
	<u>7,713</u>	<u>3,221</u>
NET ASSETS	<u>195,353</u>	<u>57,470</u>
CAPITAL AND RESERVES		
Share capital	366,672	366,672
Reserves	(176,792)	(314,482)
Total equity attributable to equity shareholders of the Company	189,880	52,190
Non-controlling interests	<u>5,473</u>	<u>5,280</u>
TOTAL EQUITY	<u>195,353</u>	<u>57,470</u>

The following table sets forth our current assets and current liabilities as of the dates indicated.

	As of December 31,		As of
	2023	2024	February 28,
	RMB'000	RMB'000	2025 (unaudited)
Current assets			
Inventories	—	—	69
Prepayments and other receivables	5,254	8,247	10,372
Financial assets at FVPL	263,078	153,655	129,508
Cash and cash equivalents	77,147	28,392	26,566
Total current assets	345,479	190,294	166,515
Current liabilities			
Trade and other payables	97,793	56,394	35,392
Interest-bearing borrowings	65,775	100,003	110,072
Lease liabilities	1,419	1,269	1,817
Total current liabilities	164,987	157,666	147,281
NET CURRENT ASSETS	180,492	32,628	19,234

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During the Track Record Period, we maintained a net current assets position. The decrease in net current assets during the Track Record Period was primarily due to ongoing operating cash outflows, which was primarily driven by the progresses in our research and development activities.

We recorded net current assets of RMB32.6 million as of December 31, 2024 as compared to net current assets of RMB180.5 million as of December 31, 2023. The decrease in net current assets was primarily due to the decrease in financial assets at fair value through profit or loss (“FVPL”) of RMB109.4 million and the increase in interest-bearing borrowings of RMB34.2 million, partially offset by the trade and other payables of RMB41.4 million. Such changes were primarily due to our ongoing operating cash outflows, which was primarily driven by the progresses in our research and development activities.

We recorded net assets of RMB57.5 million as of December 31, 2024 as compared to net assets of RMB195.4 million as of December 31, 2023. The decrease in net assets was primarily due to our loss for the year of RMB283.4 million, partially offset by equity-settled share-based payments of RMB145.5 million credited to capital reserve.

Prepayments and Other Receivables

Prepayments and other receivables primarily consist of prepayments to suppliers, and other debtors and deposits. The following table sets forth our prepayments and other receivables as of the dates indicated.

	As of December 31,	
	2023	2024
	RMB'000	RMB'000
Prepayments to suppliers	5,204	2,886
Prepayments for [REDACTED] expenses	[REDACTED]	[REDACTED]
Other debtors and deposits	50	3,362
Total	[REDACTED]	[REDACTED]

Our prepayments and other receivables increased from RMB[REDACTED] as of December 31, 2023 to RMB[REDACTED] as of December 31, 2024, primarily due to the increase of RMB3.3 million in other debtors and deposits primarily resulting from the increase in receivables from a supplier for the settlement of a R&D project, and an increase of RMB[REDACTED] of prepayments for [REDACTED] expenses in connection with the [REDACTED].

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Financial Assets at FVPL

Financial assets at FVPL represents our wealth management products and negotiable certificate of deposits with banks. During the Track Record Period, we purchased certain wealth management products and negotiable certificate of deposits with banks in order to generate reasonable low risk returns. The maturity date of wealth management products is within 1 year from each reporting date or redeemable on demand. During the years ended December 31, 2023 and 2024, we invested in certain negotiable certificate of deposits with banks in PRC. The negotiable certificate of deposits carried at fixed interest rate range from 3.1% to 3.2% per annum. Our financial assets at FVPL decreased from RMB263.1 million as of December 31, 2023 to RMB153.7 million as of December 2024, primarily attributable to sales of certain negotiable certificate of deposits in 2024.

With regards to the purchase of wealth management products, we have formulated the investment policy of diversifying risks and generating steady returns on the premise of ensuring the safety of funds. Our Chief Financial Officer and the finance department are mainly responsible for making, implementing and supervising our investment decisions. We have implemented the following treasury policies and internal authorization controls:

- We have formulated the internal control measures to control our process of investment in wealth management products and negotiable certificate of deposits with banks;
- Our Board authorizes and supervises the Chief Financial Officer to approve through a strict review and decision-making process, and our Chief Financial Officer is responsible for the approval of our material investments in wealth management products and negotiable certificate of deposits with banks;
- Our finance department is responsible for the analysis and research of investments in wealth management products and negotiable certificate of deposits with banks, as well as the long-term routine management of such investments; and
- Investments in wealth management products and negotiable certificate of deposits with banks could be made when we have surplus cash that is not required for our short-term working capital purposes and in no event beyond the amount authorized by our senior management team.

Prior to making an investment, we evaluate the sufficiency of our remaining working capital for our business needs, operating activities, research and development and capital expenditures following the proposed investment. We adopt a prudent approach in selecting financial assets. Our investment strategy related to financial assets focuses on minimizing the financial risks by reasonably and conservatively matching the maturities of the portfolio to anticipated operating cash needs, while generating desirable investment returns for the benefits of our shareholders. We make investment decisions related to financial assets on a case-by-case

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basis after thoroughly considering a number of factors, including but not limited to the macro-economic environment, general market conditions, risk control and credit of invested subjects, our own working capital conditions, and the expected profit or potential loss of the investment.

To the extent that we will have surplus cash that is not required for our short-term working capital purposes, we will continue to consider investing in wealth management products and negotiable certificate of deposits with banks taking into account the considerations above as appropriate to be in the best interest of the Company. Our investments in wealth management products and negotiable certificate of deposits with banks after the [REDACTED] will be subject to compliance with Chapter 14 of the Listing Rules.

Cash and Cash Equivalents

The following table below sets forth a breakdown of our cash and cash equivalents by currency as of the dates indicated.

	As of December 31,	
	2023	2024
	RMB'000	RMB'000
Cash at banks	77,147	28,392
Cash and cash equivalent	77,147	28,392

Our cash and cash equivalents increased by 63.2% from RMB77.1 million as of December 31, 2023 to RMB28.4 million as of December 31, 2024, primarily due to our net cash used in operating activities.

Trade and other Payables

Our trade and other payables primarily consist of trade payables, accrued payroll, tax payables and other payables and accruals.

	As of December 31,	
	2023	2024
	RMB'000	RMB'000
Trade payables	90,613	35,123
Accrued payroll	6,340	3,958
Tax payables	806	429
Other payables and accruals	34	16,884
Total	97,793	56,394

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Our trade and other payables decreased from RMB97.8 million as of December 31, 2023 to RMB56.4 million as of December 31, 2024, primarily due to the decreased of RMB55.5 million in trade payables, which was primarily driven by our settlement of trade payables with the relevant suppliers.

As of February 28, 2025, RMB5.9 million, representing 16.7% of trade payables as of December 31, 2024 were subsequently settled.

Interest-Bearing Borrowings

The following table sets forth the breakdown of our interest-bearing bank borrowings as of the date indicated:

	As of December 31,	
	2023	2024
	RMB'000	RMB'000
Bank Loans	50,047	91,582
Trade finance loans	15,728	8,421
Total	65,775	100,003

As of December 31, 2023 and 2024, all of the above interest-bearing borrowings were unsecured and carried at amortized cost. All these interest-bearing borrowings are to be settled within one year. We incurred bank loans of RMB91.6 million as of December 31, 2024 for our research and development and daily operating expenses. As of December 31, 2024, our unutilized credit facilities amounted to RMB60.1 million. During the Track Record Period, the loans drew down under the letter of credit facilities by us of RMB23.9 million and RMB8.4 million, respectively, were issued by a bank in the PRC in favour of us to settle the trade payables to a supplier, which is also a shareholder of the Company. Based on the terms of the agreement, we should repay these amount to the bank upon the maturity.

Lease liabilities

The following table sets forth our lease liabilities as of the dates indicated:

	As of December 31,	
	2023	2024
	RMB'000	RMB'000
Within 1 year	1,419	1,269
After 1 year but within 2 years	1,497	221
After 2 year but within 5 years	216	—
Total	3,132	1,490

Our lease liabilities decreased from RMB3.1 million as of December 31, 2023 to RMB1.5 million as of December 31, 2024 due to the scheduled payment of such lease contracts.

FINANCIAL INFORMATION

LIQUIDITY AND CAPITAL RESOURCES

Overview

We monitor and maintain a level of cash and cash equivalents deemed adequate to finance our operations and mitigate the effects of fluctuations in cash flows. In addition, we monitor the utilization of borrowings and, from time to time, evaluate the options to renew the borrowings upon expiry based on our actual business requirement. We relied on equity financing as the major sources of liquidity during the Track Record Period.

During the Track Record Period, we incurred negative cash flows from our operations and substantially all of our operating cash outflows resulted from our research and development and administrative activities. Our operating activities used RMB233.3 million and RMB183.4 million of cash in 2023 and 2024, respectively. We expect to generate more cash flow from our operating activities, through launching and commercializing our products and enhancing our cost containment capacity and operating efficiency. In order to bring to fruition our research and development objectives, we will ultimately need additional funding sources and there can be no assurances that they will be made available.

Cash Flows

	Year ended December 31,	
	2023	2024
	RMB'000	RMB'000
Operating activities		
Cash used in operations	(233,283)	(183,442)
Income tax paid	—	—
Net cash used in operating activities	(233,283)	(183,442)
Investing activities		
Payment for the purchase of property, plant and equipment	(617)	(876)
Payment for the purchase of intangible assets	—	(207)
Proceeds from sale of land use right	25,490	—
Payment for purchase of financial assets measured at FVPL	(518,420)	(10,142)
Proceeds from redemptions of financial assets measured at FVPL	595,169	125,578
Net cash generated from investing activities	101,622	114,353

FINANCIAL INFORMATION

	Year ended December 31,	
	2023	2024
	RMB'000	RMB'000
Financing activities		
Proceeds from interest-bearing borrowings	50,000	91,510
Interest paid for interest-bearing borrowings	(1,389)	(2,142)
Payment for interest-bearing borrowings	(31,708)	(65,956)
Payment for capital element of leases liabilities	(2,064)	(1,287)
Payment for interest element of leases liabilities	(128)	(107)
Payment for [REDACTED] expenses	[REDACTED]	[REDACTED]
Capital contributions from investors	133,800	—
Net cash generated from financing activities	148,511	20,334
Net increase/(decrease) in cash and cash equivalents.	16,850	(48,755)
Effects of foreign exchange rate changes	1	—
Cash and cash equivalents at the beginning of		
the year	60,296	77,147
Cash and cash equivalents at the ending of		
the year	77,147	28,392

Operating Activities

In 2024, our net cash used in operating activities was RMB183.4 million, which was primarily attributable to our cash used in operations, adjusted by (i) equity-settled share-based payment expenses of RMB145.5 million, (ii) net realized and unrealized gain on financial instruments carried at FVPL of RMB6.0 million, and (iii) finance costs of RMB2.5 million.

In 2023, our net cash used in operating activities was RMB233.3 million, which was primarily attributable to our cash used in operations, adjusted by (i) equity-settled share-based payment expenses of RMB35.1 million, (ii) net realized and unrealized gain on financial instruments carried at FVPL of RMB6.3 million, and (iii) depreciation of right-of-use assets of RMB2.1 million.

FINANCIAL INFORMATION

We plan to improve our net operating cash flow position in view of potential net operating cash inflow which we expect to generate after successful commercialization of our product candidates.

- Rapidly advance the clinical development and commercialization of our Core Product and other pipeline products after obtaining the relevant regulatory approvals. In particular, we plan to rapidly advance the development of PB-119 towards commercialization. We expect to receive the NDA approval from the NMPA and commercially launch PB-119 for the treatment of T2DM in China in 2025. After the commercialization of our products, we expect to generate more cash from our operating activities. As we optimize our product portfolio and cost structure, increase the sales of our products, and continue to grow our business, we expect to generate a steady inflow of cash from operations in the foreseeable future; and
- Adopt comprehensive measures to effectively control our cost and operating expenses. For example, we plan to continue to regularly evaluate our existing and future arrangements and actively seek strategic cooperation with our major suppliers to improve procurement efficiency and lower our cost of procurement.

Investing Activities

In 2024, our net cash generated from investing activities was RMB114.4 million, which was primarily attributable to proceeds from redemptions of financial assets measured at FVPL of RMB125.6 million, and was partially offset by (i) payment for purchase of financial assets measured at FVPL of RMB10.1 million, and (ii) payment for the purchase of property, plant and equipment of RMB0.9 million.

In 2023, our net cash generated from investing activities was RMB101.6 million, which was primarily attributable to (i) proceeds from redemptions of financial assets measured at FVPL of RMB595.2 million, and (ii) proceeds from sale of land use right of RMB25.5 million. This was mainly because, as part of our strategic adjustment, we returned the land use rights, which we initially intended for the construction of our own production base and research and development center back to the government. Our net cash generated from investing activities was partially offset by payment for purchase of financial assets measured at FVPL of RMB518.4 million.

Financing Activities

In 2024, we had RMB20.3 million of net cash inflow from financing activities, primarily attributable to proceeds from interest-bearing borrowings of RMB91.5 million, and was partially offset by payment for interest-bearing borrowings of RMB66.0 million.

In 2023, we had RMB148.5 million of net cash inflow from financing activities, primarily attributable to the capital contributions from investors of RMB133.8 million in relation to the series F+ equity financing and proceeds from interest-bearing borrowings of RMB50.0 million.

FINANCIAL INFORMATION

CASH OPERATING COSTS

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

	For the Years Ended December 31,	
	2023	2024
	RMB'000	RMB'000
R&D cost		
<i>R&D costs for Core Product</i>		
Third-party contracting costs	31,118	33,166
Staff costs	10,385	9,374
Raw material costs	5,368	2,677
Others	819	999
<i>R&D costs for other products candidates</i>		
Third-party contracting costs	121,188	48,006
Staff costs	17,616	10,150
Raw material costs	15,739	12,901
Others	2,940	402
Workforce employment	17,306	20,632
Consulting fee	4,351	31,768
Non-income taxes, royalties and other		
gov charges	170	679

Note:

- (1) Others include rental fees, property management fees and other miscellaneous expenses.

WORKING CAPITAL CONFIRMATION

Our Directors are of the opinion that, taking into account the financial resources available, including cash and cash equivalents, wealth management product and negotiable certificate of deposits with banks and the estimated net [REDACTED] from the [REDACTED], as well as our cash burn rate, we have sufficient working capital to cover at least 125% of our costs, including research and development expenses and administrative expenses 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 and lease payments. We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] in the [REDACTED], based on an [REDACTED] of HK\$[REDACTED] per [REDACTED]. Assuming an average cash burn rate going forward of 1.0 time the level in 2023, we estimate that our cash at bank and on hand, wealth management products and negotiable certificate of deposits with banks as of December 31, 2024 will be able to maintain our financial viability for [REDACTED] from December 31,

FINANCIAL INFORMATION

2024 taking into account the estimated net [REDACTED] from the [REDACTED]. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing, if needed, with a minimum buffer of 12 months.

INDEBTEDNESS

The following table sets forth the breakdown of our indebtedness as of the dates indicated:

	As of December 31,		As of
	2023	2024	February 28,
	RMB'000	RMB'000	2025
			RMB'000
			(unaudited)
Current			
Interest-bearing borrowings	65,775	100,003	110,072
Lease liabilities	1,419	1,269	1,817
Non-current			
Lease liabilities	1,713	221	7,290
Total	<u>68,907</u>	<u>101,493</u>	<u>119,179</u>

Except as discussed above, 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 the Latest Practicable Date.

Our Directors confirm that there has not been any material change in our indebtedness since February 28, 2025 and up to the date of this Document. 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 material 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.

FINANCIAL INFORMATION

CAPITAL EXPENDITURES

The following table sets forth our capital expenditures for the years indicated:

	For the Year Ended December 31,	
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>
Payment for the purchase of property, plant and equipment	617	876
Payment for the purchase of intangible assets	—	207
Total	<u>617</u>	<u>1,083</u>

Our historical capital expenditures during the Track Record Period primarily included purchases of equipment and intangible assets. We funded our capital expenditure requirements during the Track Record Period mainly from equity financing. We plan to fund our planned capital expenditures using our cash at bank and the net [REDACTED] received from the [REDACTED]. Please refer to the section headed “Future Plans and Use of [REDACTED]” in this Document for more details. We may reallocate the fund to be utilized on capital expenditure based on our ongoing business needs.

COMMITMENTS

As of December 31, 2023 and 2024, we did not have any material commitments.

CONTINGENT LIABILITIES

As of December 31, 2023 and 2024, we did not have any contingent liabilities. We confirm that as of the Latest Practicable Date, there had been no material changes or arrangements to our contingent liabilities.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet transactions.

FINANCIAL INFORMATION

RELATED PARTY TRANSACTIONS

During the Track Record Period, we had transactions with the related parties in accordance with the terms agreed with the counterparties. Details of our transactions with related parties during the Track Record Period are set out in Note 26 to the Accountants’ Report included in Appendix I to this Document. Our Directors confirm that all material related party transactions during the Track Record Period were conducted on an arm’s length basis, and would not distort our results of operations over the Track Record Period or make our historical results over the Track Record Period not reflective of our expectations for our future performance.

KEY FINANCIAL RATIOS

The table below sets forth the current ratio of our Group as of the dates indicated:

	As of December 31,	
	2023	2024
Current Ratio ⁽¹⁾	<u>2.09</u>	<u>1.21</u>

Note:

(1) Current ratio equals current assets divided by current liabilities as of the dates indicated.

MARKET RISK DISCLOSURE

Exposure to credit, liquidity, interest rate and currency risks arises in the normal course of our business. Our exposures to these risks and the financial risk management policies and practices used by us to manage these risks are described below.

Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in a financial loss. Our credit risk is primarily attributable to other receivables. Our exposure to credit risk arising from cash and cash equivalents and negotiable certificate of deposits with banks is limited because the counterparties are state-owned banks or reputable banks in the PRC, which we considered to have low credit risks. Management has a credit policy in place and the exposure to credit risk is monitored on an ongoing basis.

Management has assessed that during the Track Record Period, other receivables have not had a significant increase in credit risk since initial recognition. Thus, a 12-month expected credit loss approach that results from possible default event within 12 months of each reporting date is adopted by management. The management of the Company expect the occurrence of losses from non-performance by counterparties of other receivables to be remote and a loss allowance provision for other receivables to be immaterial.

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Liquidity Risk

Our policy is to regularly monitor our liquidity requirements and our compliance with lending covenants, to ensure that we maintain sufficient reserves of cash and readily realisable marketable securities and adequate committed lines of funding from major financial institutions to meet our liquidity requirements in the short and longer term. For further details, see Note 24 to the Accountant’s Report set out in Appendix I to this Document.

Interest Rate Risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates.

We are primarily exposed to fair value interest rate risk in relation to negotiable certificate of deposits with banks, fixed rate interest-bearing borrowings and lease liabilities, and cash flow risk in relation to variable-rate bank balances. We currently do not have an interest rate hedging policy to mitigate interest rate risk; nevertheless, the management monitors interest rate exposure and will consider hedging significant interest rate risk should the need arise.

Our interest-bearing financial instruments at variable rates as of December 31, 2023 and 2024 were cash and cash equivalents, and the cash flow interest risk arising from a change in market interest rates is not considered significant.

DIVIDEND

We have never declared or paid any dividends on our ordinary shares or any other securities. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business and we do not intend to declare or pay any dividends in the foreseeable future. [REDACTED] should not purchase our ordinary shares with the expectation of receiving cash dividends. Any future determination to pay dividends will be made at the discretion of our Shareholders’ meeting subject to our Articles of Association and the PRC Company Law, and may be based on a number of factors, including our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors may deem relevant. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. Regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits as determined in accordance with its articles of association and the accounting standards and regulations in China.

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As confirmed by our PRC Legal Adviser, according to the PRC law, any future net profit that we make will have to be first applied to make up for our historically accumulated losses, after which we will be obliged to allocate 10% of our net 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 net profit to our statutory common reserve fund as described above.

DISTRIBUTABLE RESERVES

As of December 31, 2024, our Company did not have any distributable reserves.

[REDACTED] INCURRED AND TO BE INCURRED

Our [REDACTED] expenses represent professional fees, [REDACTED] and other fees incurred in connection with the [REDACTED]. Based on an [REDACTED] of HK\$[REDACTED] per Share, we estimated that the total [REDACTED] expenses for the [REDACTED] are approximately HK\$[REDACTED], accounting for approximately [REDACTED]% of the gross [REDACTED] from the [REDACTED], of which approximately HK\$[REDACTED] is expected to be charged to our consolidated statements of profit or loss and other comprehensive income, and approximately HK\$[REDACTED] is expected to be accounted for as a deduction from equity upon the completion of [REDACTED]. The above expenses comprise of (i) [REDACTED] expenses, including [REDACTED] and other expenses, of HK\$[REDACTED]; and (ii) [REDACTED] expenses of HK\$[REDACTED], including (a) fee paid and payable to legal advisors and reporting accountants of HK\$[REDACTED], and (b) other fees and expenses of HK\$[REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

UNAUDITED [REDACTED] STATEMENT OF ADJUSTED NET TANGIBLE ASSETS

[REDACTED]

FINANCIAL INFORMATION

[REDACTED]

FINANCIAL INFORMATION

SUBSEQUENT EVENTS

Subsequent events are set out in Note 28 to the Accountants’ Report included in Appendix I to this Document.

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that, up to the date of this Document, there has been no material adverse change in our financial or trading position since December 31, 2024 and there has been no event since December 31, 2024 which would materially affect the information shown in our consolidated financial statements included in the Accountants’ Report in Appendix I to this Document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors confirm that, as of the Latest Practicable Date, there was no circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

FUTURE PLANS AND USE OF [REDACTED]

FUTURE PLANS

For further details of our future plans, please see the section headed “Business — Strategies” in this Document.

USE OF [REDACTED]

We estimate that the aggregate net [REDACTED] to our Company from the [REDACTED] will be approximately HK\$[REDACTED], after deducting [REDACTED] fees and estimated expenses in connection with the [REDACTED] payable by us and based on an [REDACTED] of HK\$[REDACTED] per H Share.

We intend to apply such net [REDACTED] from the [REDACTED] for the following purposes:

- (i) approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) to fund the commercialization and indication expansion of our Core Product PB-119, which includes:
 - approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund the commercialization, clinical and regulatory cost of PB-119 for the treatment of T2DM. We expect to receive the NDA approval from the NMPA and commercially launch PB-119 for the treatment of T2DM in China in 2025. Upon receiving the NDA approval of PB-119, we plan to initiate two more Phase III clinical trials in 2026 for combination therapies of PB-119 with either basal insulin (PB119-303) or with SGLT-2 inhibitor (PB119-304), and one Phase III clinical trial (PB119-305) in 2026 for PB-119 monotherapy. For further details, please see the section headed “Business — Core Product — Core Product PB-119, a near-commercialized, long-acting GLP-1 receptor agonist — Commercialization and Clinical Development Plan” in this Document. While we have conducted extensive and long-term clinical trials for PB-119 with comprehensive and reliable data, we may also consider conducting head-to-head clinical studies of PB-119 in the future against then-major competing products on the market to demonstrate the comparative advantages of PB-119;
 - approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund the clinical and regulatory cost of a long-term, multicenter, randomized, double-blind, placebo-controlled Phase III clinical trial (PB119-305) for PB-119 to evaluate its effects on cardiovascular outcomes in T2DM patients. We expect to complete the Phase III clinical trial with the application of net [REDACTED];

FUTURE PLANS AND USE OF [REDACTED]

- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund the clinical and regulatory cost of a multicenter, randomized, double-blind, parallel, placebo-controlled Phase III clinical trial (PB119-303) on combination therapies of PB-119 with basal insulin to evaluate the efficacy and safety of PB-119 in T2DM patients with poor glycemic control treated with insulin glargine (with or without metformin). We expect to complete the Phase III clinical trial with the application of net [REDACTED] aligned with the expected R&D expenses of the clinical trial;
- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund the clinical and regulatory cost of a multicenter, randomized, double-blind, parallel, placebo-controlled Phase III clinical trial (PB119-304) on combination therapies of PB-119 with SGLT-2 inhibitor to evaluate the efficacy and safety of PB-119 in T2DM patients with poor glycemic control after dapagliflozin monotherapy. We expect to complete the Phase III clinical trial with the application of net [REDACTED] aligned with the expected R&D expenses of the clinical trial;
- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund our efforts to enhance our brand awareness and industry impact for the commercialization of PB-119 for the treatment of T2DM in China, as well as costs associated with applicable post-marketing studies of PB-119 after its launch;
- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund the clinical cost and regulatory cost of PB-119 for the treatment of obesity. In June 2021, the NMPA approved our IND application of PB-119 for the treatment of obesity in China. We finalized the clinical trial protocol in February 2024 and received the approval from the NMPA to commence the clinical trial in April 2024. We are initiating a Phase Ib/IIa clinical trial of PB-119 in Chinese obese participants, and we completed participant enrollment in June 2024. Subject to the Phase Ib/IIa clinical trial results, we intend to further advance the clinical development of PB-119 for the treatment of obesity in China by conducting potential Phase II and/or Phase III clinical trials in accordance with the plan that we will formulate. Taking into account its development status in China, we may also expand the clinical development of PB-119 in other jurisdictions. We expect to complete the clinical development of PB-119 for the treatment of obesity in China with the application of net [REDACTED] aligned with the expected R&D expenses of the clinical trials;

FUTURE PLANS AND USE OF [REDACTED]

- (ii) approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) to fund further development of our key product PB-718, which includes:
- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund the clinical and regulatory cost of PB-718 for the treatment of overweight or obesity. We completed the participant follow-up of the Phase Ib/IIa clinical trial of PB-718 for the treatment of obesity in China in April 2024 and we plan to subsequently commence a Phase IIb clinical trial in China. We expect to commence a Phase III clinical trial of PB-718 in China in 2026. We also plan to communicate with the FDA and the EMA regarding the plans for conducting a Phase III MRCT of PB-718 for the treatment of obesity and we expect to commence the Phase III MRCT in the first quarter of 2027. For further details, please see the section headed “Business — Clinical-Stage Products — PB-718, a long-acting GLP-1/GCG dual receptor agonist — Clinical Development Plan” in this Document. We expect to complete the Phase IIb and Phase III clinical trials in China with the application of net [REDACTED] aligned with the expected R&D expenses of the clinical trials;
 - approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used to fund the clinical and regulatory cost of PB-718 for the treatment of NASH. We plan to submit an IND application to the NMPA in the second half of 2025 and commence a Phase II clinical trial of PB-718 for the treatment of NASH in China after obtaining the IND. We may also conduct Phase II and Phase III clinical trials of PB-718 for NASH in the United States. For further details, please see the section headed “Business — Clinical-Stage Products — PB-718, a long-acting GLP-1/GCG dual receptor agonist — Clinical Development Plan” in this Document. We expect to complete the Phase II clinical trial in China with the application of net [REDACTED] aligned with the expected R&D expenses of the clinical trial;
- (iii) approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) to fund ongoing and planned research and development of our other pipeline product candidates:
- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be invested in ongoing research and development of PB-1902. We plan to commence the Phase II clinical trial in China to evaluate the efficacy and safety of PB-1902 for the treatment of patients with cancer pain and OIC in 2025. We expect to complete this Phase II clinical trial in 2027. For further details, please see the section headed “Business — Clinical-Stage Products — PB-1902, a potential first-in-class oral selective opioid receptor antagonist for the treatment of OIC — Clinical Development Plan” in this Document. We expect to complete the Phase II clinical trial with the application of net [REDACTED] aligned with the expected R&D expenses of the clinical trial;

FUTURE PLANS AND USE OF [REDACTED]

- approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be invested in ongoing research and development of PB-722. In May 2023, the NMPA approved our IND application to conduct Phase I clinical trial of PB-722 for the treatment of congenital hyperinsulinemia in China. We plan to initiate a randomized, double-blind, placebo-controlled, dose-escalating Phase I clinical trial to test the safety, tolerability, PK and PD profiles of PB-722 single dose subcutaneous injection in China in 2026. We also expect to commence a Phase II clinical trial for PB-722 in 2027. For further details, please see the section headed “Business — Clinical-Stage Products — PB-722, a long-acting GCG receptor agonist for the treatment of congenital hyperinsulinemia — Clinical Development Plan” in this Document. We expect to complete the Phase I clinical trial with the application of net [REDACTED] aligned with the expected R&D expenses of the clinical trial;
 - approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be invested in ongoing research and development of PB-2301. We plan to advance PB-2301 to clinical development for the treatment of T2DM, NASH and obesity and submit the IND applications to the NMPA in 2026 and initiate the Phase I clinical trials after obtaining the IND. For further details, please see the section headed “Business — Selected Preclinical-Stage Products” in this Document. We expect to complete the Phase I clinical trials with the application of net [REDACTED] aligned with the expected R&D expenses of the clinical trials;
 - approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be invested in ongoing research and development of PB-2309. We plan to advance PB-2309 to clinical development for the treatment of T2DM, NASH and obesity and submit the IND applications to the NMPA in 2025 and initiate the Phase I clinical trials in as early as 2026. For further details, please see the section headed “Business — Selected Preclinical-Stage Products” in this Document. We expect to complete the Phase I clinical trials with the application of net [REDACTED] aligned with the expected R&D expenses of the clinical trials;
- (iv) approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used for business development activities and enhancing our overseas presence. For instance, we presented the results of Phase III clinical trials for PB-119 during The 19th Xiangya International Diabetes Immunology Forum in April 2024 in order to further increase the awareness of the clinical benefits of our Core Product. We intend to continue engaging similar activities for brand awareness and business development purposes. We plan to further participate in and organize a variety of academic and marketing promotion campaigns, in order to strengthen our connections with experts, physicians and patients, and to further establish our brand recognition and increase the awareness of our drug products. With respect to enhancing our overseas presence, we attended and will continue to attend

FUTURE PLANS AND USE OF [REDACTED]

international academic and industry conferences, such as forums hosted by the American Diabetes Association. We also plan to seek local collaboration in the United States for the Phase III clinical development and future commercialization of our Core Product PB-119, and we intend to collaborate with local partners to explore other overseas markets, such as the “Belt and Road Initiative” countries, to market PB-119 and potentially other pipeline products. In addition, we plan to capture the underlying value of our assets through collaborations including but not limited to licensing opportunities, especially of assets with proven efficacy and safety profiles, validated mechanism of action, large addressable medical needs and co-development partnerships, which strategy shall complement and diversify our pipeline to increase our competitiveness;

- (v) approximately HK\$[REDACTED] (or approximately [REDACTED]% of the net [REDACTED]) will be used for our working capital and other general corporate purposes.

To the extent that our net [REDACTED] are not sufficient to fund the purposes set out above, we intend to fund the balance through a variety of means, including cash generated from operations, bank loans and other borrowings.

If the net [REDACTED] of the [REDACTED] are not immediately applied to the above purposes, we will only deposit those net [REDACTED] into short-term interest-bearing accounts at licensed commercial banks and/or other authorized financial institutions (as defined under the Securities and Futures Ordinance or applicable laws and regulations in other jurisdictions).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

APPENDIX I

ACCOUNTANTS’ REPORT

The following is the text of a report set out on pages I – 1 to I – [●], received from the Company’s reporting accountants, KPMG, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this Document.

[Letterhead of KPMG]

ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF PEGBIO CO., LTD. AND CHINA INTERNATIONAL CAPITAL CORPORATION HONG KONG SECURITIES LIMITED

Introduction

We report on the historical financial information of PegBio Co., Ltd. (the “Company”) and its subsidiaries (together, the “Group”) set out on pages I – [4] to I – [●], which comprises the consolidated statements of financial position of the Group and the statements of financial position of the Company as at 31 December 2023 and 2024, and the consolidated statements of profit or loss and other comprehensive income, the consolidated statements of changes in equity and the consolidated statements of cash flows, for the years ended 31 December 2023 and 2024 (the “Relevant Periods”), 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 – [●] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [●] (the “Document”) in connection with the initial [REDACTED] of shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited.

Directors’ responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation and presentation set out in Note 1 to the Historical Financial Information, and for such internal control as the directors of the Company determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountants’ responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 “Accountants’ Reports on Historical Financial Information in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

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Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation and presentation set out in Note 1 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purpose of the accountants’ report, a true and fair view of the Company’s and the Group’s financial position as at 31 December 2023 and 2024, and of the Group’s financial performance and cash flows for the Relevant Periods in accordance with the basis of preparation and presentation set out in Note 1 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I – [3] have been made.

Dividends

We refer to Note 23(c) to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

Certified Public Accountants

8th Floor, Prince’s Building
10 Chater Road
Central, Hong Kong

APPENDIX I**ACCOUNTANTS’ REPORT**

HISTORICAL FINANCIAL INFORMATION

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The consolidated financial statements of the Group for the Relevant Periods, on which the Historical Financial Information is based, were audited by KPMG Huazhen LLP Suzhou Branch (畢馬威華振會計師事務所(特殊普通合夥)蘇州分所) in accordance with Hong Kong Standards on Auditing issued by the HKICPA (the “Underlying Financial Statements”).

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

(Expressed in Renminbi)

	Note	Year ended 31 December	
		2023	2024
		RMB'000	RMB'000
Other net income	4	14,635	7,007
Selling and marketing expenses		—	(7,150)
Research and development expenses		(236,731)	(95,427)
Administrative expenses		(55,358)	(185,282)
Loss from operations		277,454	(280,852)
Finance costs	5(a)	(1,727)	(2,499)
Loss before taxation	5	(279,181)	(283,351)
Income tax	6	—	—
Loss for the year		<u>(279,181)</u>	<u>(283,351)</u>
Other comprehensive income for the year (after tax and other adjustments)		—	—
Total comprehensive income for the year		<u>(279,181)</u>	<u>(283,351)</u>
Attributable to:			
Equity shareholders of the Company		(278,999)	(283,158)
Non-controlling interests		(182)	(193)
Loss and total comprehensive income for the year		<u>(279,181)</u>	<u>(283,351)</u>
Loss per share			
Basic and diluted (RMB)	9	<u>(0.77)</u>	<u>(0.77)</u>

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CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

(Expressed in Renminbi)

	Note	At 31 December 2023 RMB’000	At 31 December 2024 RMB’000
Non-current assets			
Property, plant and equipment	10	3,692	3,572
Right-of-use assets	11	3,256	1,527
Intangible assets	12	975	863
Other non-current assets	13	14,651	22,101
		<u>22,574</u>	<u>28,063</u>
Current assets			
Prepayments and other receivables	15	5,254	8,247
Financial assets at fair value through profit or loss (“FVPL”)	16	263,078	153,655
Cash and cash equivalents	17	77,147	28,392
		<u>345,479</u>	<u>190,294</u>
Current liabilities			
Trade and other payables	18	97,793	56,394
Interest-bearing borrowings	19	65,775	100,003
Lease liabilities	20	1,419	1,269
		<u>164,987</u>	<u>157,666</u>
Net current assets		<u>180,492</u>	<u>32,628</u>
Total assets less current liabilities		<u>203,066</u>	<u>60,691</u>
Non-current liabilities			
Lease liabilities	20	1,713	221
Deferred income	21	6,000	3,000
		<u>7,713</u>	<u>3,221</u>
NET ASSETS		<u>195,353</u>	<u>57,470</u>
CAPITAL AND RESERVES			
Share capital	23	366,672	366,672
Reserves		(176,792)	(314,482)
Total equity attributable to equity shareholders of the Company		<u>189,880</u>	<u>52,190</u>
Non-controlling interests		<u>5,473</u>	<u>5,280</u>
TOTAL EQUITY		<u>195,353</u>	<u>57,470</u>

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ACCOUNTANTS’ REPORT

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

(Expressed in Renminbi)

	Note	At 31 December 2023 RMB'000	At 31 December 2024 RMB'000
Non-current assets			
Property, plant and equipment	10	3,692	3,572
Right-of-use assets	11	3,256	1,527
Intangible assets	12	975	863
Other non-current assets	13	14,651	22,101
Investments in subsidiaries	14	6,476	6,476
		<u>29,050</u>	<u>34,539</u>
Current assets			
Prepayments and other receivables	15	5,254	8,247
Financial assets at FVPL	16	247,313	138,522
Cash and cash equivalents	17	77,125	28,360
		<u>329,692</u>	<u>175,129</u>
Current liabilities			
Trade and other payables	18	97,541	56,215
Interest-bearing borrowings	19	65,775	100,003
Lease liabilities	20	1,419	1,269
		<u>164,735</u>	<u>157,487</u>
Net current assets		<u>164,957</u>	<u>17,642</u>
Total assets less current liabilities		194,007	52,181
Non-current liabilities			
Lease liabilities	20	1,713	221
Deferred income	21	6,000	3,000
		<u>7,713</u>	<u>3,221</u>
NET ASSETS		<u>186,294</u>	<u>48,960</u>
CAPITAL AND RESERVES			
Share capital	23	366,672	366,672
Reserves		(180,378)	(317,712)
TOTAL EQUITY		<u>186,294</u>	<u>48,960</u>

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(Expressed in Renminbi)

	Note	Attributable to equity shareholders of the Company				Non- controlling interests	Total
		Share capital	Capital reserve	Accumulated losses	Subtotal		
		RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Balance at 1 January 2023		354,510	517,554	(572,098)	299,966	5,655	305,621
Changes in equity for 2023:							
Total comprehensive income for the year		–	–	(278,999)	(278,999)	(182)	(279,181)
Capital contributions by investors	23(b)	12,162	121,638	–	133,800	–	133,800
Equity-settled share-based payments	22	–	35,113	–	35,113	–	35,113
Balance at 31 December 2023 and 1 January 2024		366,672	674,305	(851,097)	189,880	5,473	195,353
Changes in equity for 2024:							
Total comprehensive income for the year		–	–	(283,158)	(283,158)	(193)	(283,351)
Equity-settled share-based payments	22	–	145,468	–	145,468	–	145,468
Balance at 31 December 2024		<u>366,672</u>	<u>819,773</u>	<u>(1,134,255)</u>	<u>52,190</u>	<u>5,280</u>	<u>57,470</u>

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Expressed in Renminbi)

		Year ended 31 December	
	Note	2023	2024
		RMB'000	RMB'000
Operating activities			
Cash used in operations	17(b)	(233,283)	(183,442)
Income tax paid		—	—
Net cash used in operating activities		<u>(233,283)</u>	<u>(183,442)</u>
Investing activities			
Payment for the purchase of property, plant and equipment		(617)	(876)
Payment for the purchase of intangible assets		—	(207)
Proceeds from sale of land use right		25,490	—
Payment for purchase of financial assets measured at FVPL		(518,420)	(10,142)
Proceeds from redemptions of financial assets measured at FVPL		595,169	125,578
Net cash generated from investing activities		<u>101,622</u>	<u>114,353</u>
Financing activities			
Proceeds from interest-bearing borrowings	17(c)	50,000	91,510
Interest paid for interest-bearing borrowings	17(c)	(1,389)	(2,142)
Payment for interest-bearing borrowings	17(c)	(31,708)	(65,956)
Payment for capital element of leases liabilities . .	17(c)	(2,064)	(1,287)
Payment for interest element of leases liabilities . .	17(c)	(128)	(107)
Payment for [REDACTED] expenses		[REDACTED]	[REDACTED]
Capital contributions from investors	23(b)	133,800	—
Net cash generated from financing activities		<u>148,511</u>	<u>20,334</u>
Net increase/(decrease) in cash and cash equivalents			
Effects of foreign exchange rate changes		1	—
Cash and cash equivalents at the beginning of the year		<u>60,296</u>	<u>77,147</u>
Cash and cash equivalents at the ending of the year		<u>77,147</u>	<u>28,392</u>

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ACCOUNTANTS’ REPORT

NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1 BASIS OF PREPARATION AND PRESENTATION OF HISTORICAL FINANCIAL INFORMATION

PegBio Co., Ltd.* (派格生物醫藥(杭州)股份有限公司) (formerly known as PegBio Co., Ltd. (派格生物醫藥(蘇州)股份有限公司)) (the “Company”) was established in Suzhou, Jiangsu Province, the People’s Republic of China (the “PRC”) in May 2008 as a company with limited liability. Upon the approval by the Company’s board meeting, the Company was converted from a company with limited liability into a joint stock company with limited liability in December 2020. The Company changed its registered address to Hangzhou, Zhejiang Province in February 2025.

The Company and its subsidiaries (together, “the Group”) are principally engaged in research and development of therapies in chronic disease.

The financial statements of the Company and the subsidiaries of the Group for which there are statutory requirements were prepared in accordance with the relevant accounting rules and regulations applicable to entities in the countries in which they were incorporated and/or established. The statutory financial statements of the Company for the year ended 31 December 2023 were prepared in accordance with the Accounting Standards for Business Enterprises issued by the Ministry of Finance of the PRC and audited by Jiangsu Welsen Certified Public Accountants Co., Ltd.* (江蘇華星會計師事務所有限公司) [The statutory financial statements of the Company for the year ended 31 December 2024 has not been issued as at the date of this report.]

As at 31 December 2024, the Company has direct or indirect interests in the following subsidiaries, both of which are private and limited liability companies:

Company name	Place and date of incorporation/ establishment	Particulars of registered and paid-up capital	Proportion of ownership interest		Principal activities
			Directly held by the Company	Indirectly held by the Company	
Shanghai Hanmai Biomedical Technology Co., Ltd.* 上海瀚邁生物醫藥科技有限公司 (“Shanghai Hanmai”) (i)	The PRC 26 June 2017	RMB5,000,000	64.77%	–	Research and development of drugs
Shanghai Maiji Biomedical Technology Co., Ltd.* 上海邁跡生物醫藥科技有限公司 (“Shanghai Maiji”) (i)	The PRC 26 June 2017	RMB5,000,000	64.77%	–	Research and development of drugs

Notes:

(i) No audited financial statements have been prepared.

* The English translation of all above companies is for reference only. The official names of the companies established in the PRC are in Chinese.

All companies comprising the Group have adopted 31 December as their financial year end date.

The Historical Financial Information has been prepared in accordance with all applicable Hong Kong Financial Reporting Standards (“HKFRSs”) which collectively includes all applicable individual Hong Kong Financial Reporting Standards, Hong Kong Accounting Standards (the “HKASs”) and Interpretations issued by the Hong Kong Institute of Certified Public Accountants (the “HKICPA”). Further details of the material accounting policy information adopted are set out in Note 2.

The HKICPA has issued a number of new and revised HKFRSs. For the purpose of preparing this Historical Financial Information, the Group has adopted all applicable new and revised HKFRSs to the Relevant Periods, except for any new standards or interpretations that are not yet effective for the Relevant Periods. The revised and new accounting standards and interpretations issued but not yet effective for the Relevant Periods are set out in Note 27.

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The Historical Financial Information also complies with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

The accounting policies set out below have been applied consistently to all periods presented in the Historical Financial Information.

The Historical Financial Information are presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

2 MATERIAL ACCOUNTING POLICY INFORMATION

(a) Basis of measurement

The measurement basis used in the preparation of the Historical Financial Information is the historical cost basis except that the financial assets and liabilities are stated at their fair value as explained in the accounting policies as set out in Note 2(d).

(b) Use of estimates and judgements

The preparation of Historical Financial Information in conformity with HKFRSs requires management to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets, liabilities, income and expenses. The estimates and associated assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis of making the judgements about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

Judgements made by management in the application of HKFRSs that have significant effect on the Historical Financial Information and major sources of estimation uncertainty are discussed in Note 3.

(c) Subsidiaries and non-controlling interests

Subsidiaries are entities controlled by the Group. The Group controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. The financial statements of subsidiaries are included in the Historical Financial Information from the date on which control commences until the date on which control ceases.

Intra-group balances and transactions, and any unrealised income and expenses (except for foreign currency transaction gains or losses) arising from intra-group transactions are eliminated. Unrealised losses resulting from intra-group transactions are eliminated in the same way as unrealised gains, but only to the extent that there is no evidence of impairment.

For each business combination, the Group can elect to measure any non-controlling interests (“NCI”) either at fair value or at the NCI’s proportionate share of the subsidiary’s net identifiable assets. NCI are presented in the consolidated statement of financial position within equity, separately from equity attributable to the equity shareholders of the Company. NCI in the results of the Group are presented on the face of the consolidated statement of profit or loss and other comprehensive income as an allocation of the total profit or loss and total comprehensive income for the year between NCI and the equity shareholder of the Company.

Changes in the Group’s interests in a subsidiary that do not result in a loss of control are accounted for as equity transactions.

When the Group loses control of a subsidiary, it derecognises the assets and liabilities of the subsidiary, and any related NCI and other components of equity. Any resulting gain or loss is recognised in profit or loss. Any interest retained in that former subsidiary is measured at fair value when control is lost.

In the Company’s statement of financial position, an investment in a subsidiary is stated at cost less impairment losses (see Note 2(h)(ii)).

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ACCOUNTANTS’ REPORT

(d) Other investments in securities

The Group’s policies for investments in securities, other than investments in subsidiaries, associates and joint ventures, are set out below.

Investments in securities are recognised/derecognised on the date the Group commits to purchase/sell the investment. The investments are initially stated at fair value plus directly attributable transaction costs, except for those investments measured at FVPL for which transaction costs are recognised directly in profit or loss. For an explanation of how the Group determines fair value of financial instruments, see Note 24(d). These investments are subsequently accounted for as follows, depending on their classification.

(i) *Non-equity investments*

Non-equity investments are classified into one of the following measurement categories:

- amortised cost, if the investment is held for the collection of contractual cash flows which represent solely payments of principal and interest. Expected credit losses, interest income calculated using the effective interest method (see Note 2(q)(i)), foreign exchange gains and losses are recognised in profit or loss. Any gain or loss on derecognition is recognised in profit or loss.
- fair value through other comprehensive income (“FVOCI”) – recycling, if the contractual cash flows of the investment comprise solely payments of principal and interest and the investment is held within a business model whose objective is achieved by both the collection of contractual cash flows and sale. Expected credit losses, interest income (calculated using the effective interest method) and foreign exchange gains and losses are recognised in profit or loss and computed in the same manner as if the financial asset was measured at amortised cost. The difference between the fair value and the amortised cost is recognised in other comprehensive income (“OCI”). When the investment is derecognised, the amount accumulated in OCI is recycled from equity to profit or loss.
- FVPL if the investment does not meet the criteria for being measured at amortised cost or FVOCI (recycling). Changes in the fair value of the investment (including interest) are recognised in profit or loss.

(e) Property, plant and equipment

Property, plant and equipment, including right-of-use assets arising from leases of underlying plant and equipment (see Note 2(g)), are stated at cost less accumulated depreciation and impairment losses (see Note 2(h)(ii)).

Any gain or loss on disposal of an item of property, plant and equipment is recognised in profit or loss.

Depreciation is calculated to write off the cost of items of property, plant and equipment, less their estimated residual values, if any, using the straight line method over their estimated useful lives, and is generally recognised in profit or loss.

The estimated useful lives for the current and comparative periods are as follows:

Vehicle.	5 years
Equipment	3 – 10 years
Leasehold improvements.	Shorter of useful lives or lease term
Right-of-use assets	Over the lease term

Depreciation methods, useful lives and residual values are reviewed at each reporting date and adjusted if appropriate.

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(f) Intangible assets

Expenditure on research activities is recognised in profit or loss as incurred. Development expenditure is capitalised only if the expenditure can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable and the Group intends to and has sufficient resources to complete development and to use or sell the resulting asset. Otherwise, it is recognised in profit or loss as incurred. Capitalised development expenditure is subsequently measured at cost less accumulated amortisation and any accumulated impairment losses.

Other intangible assets, including patents and trademarks, that are acquired by the Group and have finite useful lives are measured at cost less accumulated amortisation and any accumulated impairment losses (see Note 2(h)(ii)).

Expenditure on internally generated goodwill and brands, is recognised in profit or loss as incurred.

Amortisation is calculated to write off the cost of intangible assets less their estimated residual values using the straight line method over their estimated useful lives, if any, and is generally recognised in profit or loss.

The estimated useful lives for the current and comparative periods are as follows:

Software 5 years

Amortisation methods, useful lives and residual values are reviewed at each reporting date and adjusted if appropriate

(g) Leased assets

At inception of a contract, the Group assesses whether the contract is, or contains, a lease. This is the case if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Control is conveyed where the customer has both the right to direct the use of the identified asset and to obtain substantially all of the economic benefits from that use.

(i) *As a lessee*

Where the contract contains lease component(s) and non-lease component(s), the Group has elected not to separate non-lease components and accounts for each lease component and any associated non-lease components as a single lease component for all leases.

At the lease commencement date, the Group recognises a right-of-use asset and a lease liability, except for leases that have a short lease term of 12 months or less and leases of low-value items. When the Group enters into a lease in respect of a low-value item, the Group decides whether to capitalise the lease on a lease-by-lease basis. If not capitalised, the associated lease payments are recognised in profit or loss on a systematic basis over the lease term.

Where the lease is capitalised, the lease liability is initially recognised at the present value of the lease payments payable over the lease term, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, using a relevant incremental borrowing rate. After initial recognition, the lease liability is measured at amortised cost and interest expense is recognised using the effective interest method. Variable lease payments that do not depend on an index or rate are not included in the measurement of the lease liability, and are charged to profit or loss as incurred.

The right-of-use asset recognised when a lease is capitalised is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentives received. The right-of-use asset is subsequently stated at cost less accumulated depreciation and impairment losses (see Notes 2(e) and 2(h)(ii)). Depreciation is calculated using the straight line method over the unexpired term of lease.

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Refundable rental deposits are accounted for separately from the right-of-use assets in accordance with the accounting policy applicable to investments in non-equity securities carried at amortised cost (see Notes 2(d)(i), 2(q)(i) and 2(h)(i)). Any excess of the nominal value over the initial fair value of the deposits is accounted for as additional lease payments made and is included in the cost of right-of-use assets.

The lease liability is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in the Group’s estimate of the amount expected to be payable under a residual value guarantee, or if the Group changes its assessment of whether it will exercise a purchase, extension or termination option. When the lease liability is remeasured in this way, a corresponding adjustment is made to the carrying amount of the right-of-use asset, or is recorded in profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

The lease liability is also remeasured when there is a lease modification, which means a change in the scope of a lease or the consideration for a lease that is not originally provided for in the lease contract, if such modification is not accounted for as a separate lease. In this case the lease liability is remeasured based on the revised lease payments and lease term using a revised discount rate at the effective date of the modification.

In the consolidated statement of financial position, the current portion of long-term lease liabilities is determined as the present value of contractual payments that are due to be settled within twelve months after the reporting period.

(h) Credit losses and impairment of assets

(i) Credit losses from financial instruments

The Group recognises a loss allowance for expected credit losses (“ECL”s) on financial assets measured at amortised cost (including cash and cash equivalents and other receivables).

Measurement of ECLs

ECLs are a probability-weighted estimate of credit losses. Generally, credit losses are measured as the present value of all expected cash shortfalls between the contractual and expected amounts.

The expected cash shortfalls are discounted using the following rates if the effect is material:

- fixed-rate financial assets and other receivables: effective interest rate determined at initial recognition or an approximation thereof; and
- variable-rate financial assets: current effective interest rate.

The maximum period considered when estimating ECLs is the maximum contractual period over which the Group is exposed to credit risk.

ECLs are measured on either of the following bases:

- 12-month ECLs: these are the portion of ECLs that result from default events that are possible within the 12 months after the reporting date (or a shorter period if the expected life of the instrument is less than 12 months); and
- lifetime ECLs: these are the ECLs that result from all possible default events over the expected lives of the items to which the ECL model applies.

The Group measures loss allowances at an amount equal to lifetime ECLs, except for the following, which are measured at 12-months ECLs:

- financial instruments that are determined to have low credit risk at the reporting date; and
- other financial instruments for which credit risk (i.e. the risk of default occurring over the expected life of the financial instrument) has not increased significantly since initial recognition.

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Significant increases in credit risk

When determining whether the credit risk of a financial instrument (including a loan commitment) has increased significantly since initial recognition and when measuring ECLs, the group considers reasonable and supportable information that is relevant and available without undue cost or effort. This includes both quantitative and qualitative information and analysis, based on the group’s historical experience and informed credit assessment, that includes forward-looking information.

The Group assumes that the credit risk on a financial asset has increased significantly if it is more than 30 days past due.

The Group considers a financial asset to be in default when (i) the debtor is unlikely to pay its credit obligations to the Group in full, without recourse by the Group to actions such as realising security (if any is held); or (ii) the financial asset is 90 days past due.

ECLs are remeasured at each reporting date to reflect changes in the financial instrument’s credit risk since initial recognition. Any change in the ECL amount is recognised as an impairment gain or loss in profit or loss. The Group recognises an impairment gain or loss for all financial instruments with a corresponding adjustment to their carrying amount through a loss allowance account.

Credit-impaired financial assets

At each reporting date, the Group assesses whether a financial asset is credit-impaired. A financial asset is credit-impaired when one or more events that have a detrimental impact on the estimated future cash flows of the financial asset have occurred.

Evidence that a financial asset is credit-impaired includes the following observable events:

- significant financial difficulties of the debtor;
- a breach of contract, such as a default or past due;
- the restructuring of a loan or advance by the Group on terms that the Group would not consider otherwise;
- it is probable that the debtor will enter bankruptcy or other financial reorganisation; or
- the disappearance of an active market for a security because of financial difficulties of the issuer.

Write-off policy

The gross carrying amount of a financial asset is written off to the extent that there is no realistic prospect of recovery. This is generally the case when the Group determines that the debtor does not have assets or sources of income that could generate sufficient cash flows to repay the amounts subject to the write-off.

Subsequent recoveries of an asset that was previously written off are recognised as a reversal of impairment in profit or loss in the period in which the recovery occurs.

(ii) Impairment of other non-current assets

At each reporting date, the Group reviews the carrying amounts of its non-financial assets (other than inventories and deferred tax assets) to determine whether there is any indication of impairment. If any such indication exists, then the asset’s recoverable amount is estimated.

For impairment testing, assets are grouped together into the smallest group of assets that generates cash inflows from continuing use that are largely independent of the cash inflows of other assets or cash-generating units (“CGU”s).

The recoverable amount of an asset or CGU is the greater of its value in use and its fair value less costs of disposal. Value in use is based on the estimated future cash flows, discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset or CGU.

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An impairment loss is recognised if the carrying amount of an asset or CGU exceeds its recoverable amount. Impairment losses are recognised in profit or loss. They are allocated first to reduce the carrying amount of any goodwill allocated to the CGU, and then to reduce the carrying amounts of the other assets in the CGU on a pro rata basis.

An impairment loss in respect of goodwill is not reversed. For other assets, an impairment loss is reversed only to the extent that the resulting carrying amount does not exceed the carrying amount that would have been determined, net of depreciation or amortisation, if no impairment loss had been recognised.

(i) Inventories

Inventories are measured at the lower of cost and net realisable value as follows:

Cost is calculated using the weighted average cost formula and comprises all costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

(j) Receivables

A receivable is recognised when the Group has an unconditional right to receive consideration and only the passage of time is required before payment of that consideration is due.

All receivables are initially measured at fair value plus transaction costs and subsequently stated at amortised cost (see Note 2(h)(i)).

Payment made in advance of receiving the related services is recognised as prepayment.

(k) Cash and cash equivalents

Cash and cash equivalents comprise cash at bank and on hand, demand deposits with banks and other financial institutions, and short-term, highly liquid investments that are readily convertible into known amounts of cash and which are subject to an insignificant risk of changes in value, having been within three months of maturity at acquisition. Cash and cash equivalents are assessed for ECL (see Note 2(h)(i)).

(l) Trade and other payables

Trade and other payables are initially recognised at fair value. Subsequent to initial recognition, trade and other payables are stated at amortised cost unless the effect of discounting would be immaterial, in which case they are stated at invoice amounts.

(m) Interest-bearing borrowings

Interest-bearing borrowings are measured initially at fair value less transaction costs. Subsequently, these borrowings are stated at amortised cost using the effective interest method. Interest expense is recognised in accordance with Note 2(s).

(n) Employee benefits

(i) Short term employee benefits and contributions to defined contribution retirement plans

Short-term employee benefits are expensed as the related service is provided. A liability is recognised for the amount expected to be paid if the Group has a present legal or constructive obligation to pay this amount as a result of past service provided by the employee and the obligation can be estimated reliably.

Obligations for contributions to defined contribution retirement plans are expensed as the related service is provided.

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(ii) Share-based payments

The fair value of share-based payment awards granted to employees is recognised as an employee cost with a corresponding increase in a reserve within equity. The fair value is measured at grant date by reference to the market price or the valuer’s valuation of the underlying shares. Where the employees have to meet vesting conditions before becoming unconditionally entitled to the shares, the total estimated fair value of the shares is spread over the vesting period, taking into account the probability that the shares will vest.

During the vesting period, the number of equity-settled share-based payments award that is expected to vest is reviewed. Any resulting adjustment to the cumulative fair value recognised in prior years is charged/credited to the profit or loss for the year of the review, unless the original employee expenses qualify for recognition as an asset, with a corresponding adjustment to the capital reserve. On vesting date, the amount recognised as an expense is adjusted to reflect the actual number of equity-settled share-based payments award that vest (with a corresponding adjustment to the capital reserve), except where forfeiture is only due to not achieving vesting conditions that relate to the market price of the Company’s shares. The equity amount is recognised in the capital reserve until either the equity-settled share-based payments award is exercised (when it is included in the amount recognised in share capital for the shares issued) or the equity-settled share-based payments award expires (when it is released directly to retained profits).

When the terms or conditions of equity-settled share-based payment awards with employees are modified to reduce the vesting period, the grant-date fair value is recognised as expenses over the modified vesting period. The cumulative expenses up to the modification date are trued up to what would have been based on the modified vesting period, and the true-up adjustment is recognised immediately in the expenses.

When the terms or conditions of equity-settled share-based payment awards are modified to reduce the number of equity instruments granted to employees, the reduction is accounted for as a cancellation of that portion of the awards.

When the equity-settled share-based payment awards granted to employees are cancelled during the vesting period, the amount of the grant-date fair value that otherwise would have been recognised for services received over the remainder of the vesting period is recognised immediately in the expenses as if vesting were accelerated on the date of cancellation.

(iii) Termination benefits

Termination benefits are expensed at the earlier of when the Group can no longer withdraw the offer of those benefits and when the Group recognises costs for a restructuring.

(o) Income tax

Income tax expense comprises current tax and deferred tax. It is recognised in profit or loss except to the extent that it relates to a business combination, or items recognised directly in equity or in OCI.

Current tax comprises the estimated tax payable or receivable on the taxable income or loss for the year and any adjustments to the tax payable or receivable in respect of previous years. The amount of current tax payable or receivable is the best estimate of the tax amount expected to be paid or received that reflects any uncertainty related to income taxes. It is measured using tax rates enacted or substantively enacted at the reporting date. Current tax also includes any tax arising from dividends.

Current tax assets and liabilities are offset only if certain criteria are met.

Deferred tax is recognised in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is not recognised for:

- temporary differences on the initial recognition of assets or liabilities in a transaction that is not a business combination and that affects neither accounting nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences;
- temporary differences related to investment in subsidiaries, associates and joint venture to the extent that the Group is able to control the timing of the reversal of the temporary differences and it is probable that they will not reverse in the foreseeable future;

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- taxable temporary differences arising on the initial recognition of goodwill; and
- those related to the income taxes arising from tax laws enacted or substantively enacted to implement the Pillar Two model rules published by the Organisation for Economic Co-operation and Development.

The Group recognised deferred tax assets and deferred tax liabilities separately in relation to its lease liabilities and right-of-use assets.

Deferred tax assets are recognised for unused tax losses, unused tax credits and deductible temporary differences to the extent that it is probable that future taxable profits will be available against which they can be used. Future taxable profits are determined based on the reversal of relevant taxable temporary differences. If the amount of taxable temporary differences is insufficient to recognise a deferred tax asset in full, then future taxable profits, adjusted for reversals of existing temporary differences, are considered, based on the business plans for individual subsidiaries in the Group. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realised; such reductions are reversed when the probability of future taxable profits improves.

Deferred tax assets and liabilities are offset only if certain criteria are met.

(p) Provisions and contingent liabilities

Generally provisions are determined by discounting the expected future cash flows at a pre-tax rate that reflects current market assessment of the time value of money and the risks specific to the liability.

A provision for warranties is recognised when the underlying products or services are sold, based on historical warranty data and a weighting of possible outcomes against their associated probabilities.

A provision for onerous contracts is measured at the present value of the lower of the expected cost of terminating the contract and the expected net cost of continuing with the contract, which is determined based on the incremental costs of fulfilling the obligation under that contract and an allocation of other costs directly related to fulfilling that contract. Before a provision is established, the Group recognises any impairment loss on the assets associated with that contract.

Where it is not probable that an outflow of economic benefits will be required, or the amount cannot be estimated reliably, the obligation is disclosed as a contingent liability, unless the probability of outflow of economic benefits is remote. Possible obligations, whose existence will only be confirmed by the occurrence or non-occurrence of one or more future events are also disclosed as contingent liabilities unless the probability of outflow of economic benefits is remote.

(q) Other income

(i) Interest income

Interest income is recognised using the effective interest method. The “effective interest rate” is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to the gross carrying amount of the financial asset. In calculating interest income, the effective interest rate is applied to the gross carrying amount of the asset (when the asset is not credit-impaired). However, for financial assets that have become credit-impaired subsequent to initial recognition, interest income is calculated by applying the effective interest rate to the amortised cost of the financial asset. If the asset is no longer credit-impaired, then the calculation of interest income reverts to the gross basis.

(ii) Government grants

Government grants are recognised in the statement of financial position initially when there is reasonable assurance that they will be received and that the Group will comply with the conditions attaching to them. Grants that compensate the Group for expenses incurred are recognised as income in profit or loss on a systematic basis in the same periods in which the expenses are incurred.

Grants that compensate the Group for the cost of an asset are recognised as deferred income and subsequently recognised in profit or loss over the useful life of the asset.

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(r) Translation of foreign currencies

Transactions in foreign currencies are translated into the respective functional currencies of Group companies at the exchange rates at the dates of the transactions.

Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rate at the reporting date. Non-monetary assets and liabilities that are measured at fair value in a foreign currency are translated into the functional currency at the exchange rate when the fair value was determined. Non-monetary assets and liabilities that are measured based on historical cost in a foreign currency are translated at the exchange rate at the date of the transaction. Foreign currency differences are generally recognised in profit or loss.

(s) Borrowing costs

Borrowing costs that are directly attributable to the acquisition, construction or production of an asset which necessarily takes a substantial period of time to get ready for its intended use or sale are capitalised as part of the cost of that asset. Other borrowing costs are expensed in the period in which they are incurred.

The capitalisation of borrowing costs as part of the cost of a qualifying asset commences when expenditure for the asset is being incurred, borrowing costs are being incurred and activities that are necessary to prepare the asset for its intended use or sale are in progress. Capitalisation of borrowing costs is suspended or ceases when substantially all the activities necessary to prepare the qualifying asset for its intended use or sale are interrupted or complete.

(t) Related parties

- (a) A person, or a close member of that person’s family, is related to the Group if that person:
 - (i) has control or joint control over the Group;
 - (ii) has significant influence over the Group; or
 - (iii) is a member of the key management personnel of the Group or the Group’s parent.
- (b) An entity is related to the Group if any of the following conditions applies:
 - (i) The entity and the Group are members of the same group (which means that each parent, subsidiary and fellow subsidiary is related to the others).
 - (ii) One entity is an associate or joint venture of the other entity (or an associate or joint venture of a member of a group of which the other entity is a member).
 - (iii) Both entities are joint ventures of the same third party.
 - (iv) One entity is a joint venture of a third entity and the other entity is an associate of the third entity.
 - (v) The entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group.
 - (vi) The entity is controlled or jointly controlled by a person identified in (a).
 - (vii) A person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity).
 - (viii) The entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the Group’s parent.

Close members of the family of a person are those family members who may be expected to influence, or be influenced by, that person in their dealings with the entity.

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(u) Segment reporting

Operating segments, and the amounts of each segment item reported in the Historical Financial Information, are identified from the financial information provided regularly to the Group’s most senior executive management for the purposes of allocating resources to, and assessing the performance of, the Group’s various lines of business and geographical locations.

Individually material operating segments are not aggregated for financial reporting purposes unless the segments have similar economic characteristics and are similar in respect of the nature of products and services, the nature of production processes, the type or class of customers, the methods used to distribute the products or provide the services, and the nature of the regulatory environment. Operating segments which are not individually material may be aggregated if they share a majority of these criteria.

For the purpose of resource allocation and performance assessment, the Group’s most senior executive management, being the chief operating decision maker, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole and hence. During the Relevant Periods, the Group has only one reportable segment which is engaged in the research and development of drugs.

3 ACCOUNTING JUDGEMENT AND ESTIMATES

(a) Critical accounting judgement in applying the Group’s accounting policies

In the process of applying the Group’s accounting policies, management has made the following accounting judgements:

(i) *Research and development expenses*

Development expenses incurred on the Group’s pipelines are 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, the Group’s intention to complete and the Group’s ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and the ability to measure reliably the expenditure during the development. Development expenses which do not meet these criteria are expensed when incurred. Management will assess the progress of each of the research and development projects and determine the criteria met for capitalisation. All development expenses were expensed when incurred during the Relevant Periods.

(b) *Key sources of estimation uncertainty*

Notes 22 and 24(d) contains information about the assumptions and risk factors relating to fair value of equity-settled share-based transactions and other financial assets. Other key sources of estimation uncertainty are as follows:

(i) *Recognition of deferred tax assets*

Deferred tax assets in respect of tax losses carried forward and deductible temporary differences are recognised and measured based on the expected manner of realisation or settlement of the carrying amount of the relevant assets and liabilities, using tax rates enacted or substantively enacted at the end of each reporting date. In determining the carrying amounts of deferred tax assets, expected taxable profits are estimated which involves a number of assumptions relating to the operating environment of the Group and require a significant level of judgement exercised by the directors of the Company. Any change in such assumptions and judgement would affect the carrying amounts of deferred tax assets to be recognised and hence the net profit in future years.

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4 OTHER NET INCOME

	Year ended 31 December	
	2023	2024
	RMB'000	RMB'000
Net realised and unrealised gain on financial instruments		
carried at FVPL	6,325	6,013
Government grants	2,806	267
Interest income on bank deposits	5,285	802
Others	219	(75)
	<u>14,635</u>	<u>7,007</u>

5 LOSS BEFORE TAXATION

Loss before taxation is arrived at after charging/(crediting):

(a) Finance costs

	Year ended 31 December	
	2023	2024
	RMB'000	RMB'000
Interest on interest-bearing borrowings	1,599	2,392
Interest on lease liabilities	128	107
	<u>1,727</u>	<u>2,499</u>

(b) Staff costs

	Year ended 31 December	
	2023	2024
	RMB'000	RMB'000
Salaries, wages and other benefits	42,770	36,173
Contributions to defined contribution retirement plan (i)	2,906	2,615
Equity-settled share-based payment expenses (Note 22)	35,113	145,468
	<u>80,789</u>	<u>184,256</u>

(c) Other items

	Year ended 31 December	
	2023	2024
	RMB'000	RMB'000
Depreciation of property, plant and equipment (Note 10)	1,296	829
Depreciation of right-of-use assets (Note 11)	2,144	1,374
Amortisation of intangible assets (Note 12)	308	295
Reversal of impairment loss on other receivables	(64)	—*
Auditors’ remuneration	—	3,198
Research and development expenses (ii)	236,731	95,427
[REDACTED] expenses in connection with the		
[REDACTED] of shares of the Company on the Main		
Board of The Stock Exchange of Hong Kong Limited (iii) .	[REDACTED]	[REDACTED]

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* less than RMB1,000

- (i) Pursuant to the relevant labor rules and regulations in the PRC, the Company and its subsidiaries in the PRC to participate in defined contribution retirement benefit schemes (the “Schemes”) organised by the local government authorities whereby the Company and its subsidiaries in the PRC are required to make contributions to the Schemes based on certain percentages of the eligible employee’s salaries. The local government authorities are responsible for the entire pension obligations payable to the retired employees.

The Group has no other material obligation for the payment of retirement benefits associated with the scheme beyond the annual contributions described above.

- (ii) During the years ended 31 December 2023 and 2024, research and development expenses include staff costs, depreciation and amortisation expenses of RMB37,640,000 and RMB46,061,000 respectively, in which the respective amounts are also disclosed separately above.
- (iii) During the years ended 31 December 2023 and 2024, the Group recognised auditors’ remuneration in respect of [REDACTED] of nil and RMB3,198,000 respectively, which is also included in the [REDACTED] expenses disclosed separately above.

6 INCOME TAX IN THE CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

(a) Taxation in the consolidated statements of profit or loss and other comprehensive income:

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

(i) The PRC

The Company’s subsidiaries established and operated in the PRC are subject to the PRC corporate income tax at the rate of 25%.

According to the tax incentive policies promulgated by the State Tax Bureau of the PRC in September 2022, an additional 100% of qualified research and development expenses incurred for the years ended 31 December 2023 and 2024 is allowed to be deducted from taxable income.

(b) Reconciliation between tax expense and accounting profit at applicable tax rates:

	Year ended 31 December	
	2023	2024
	RMB'000	RMB'000
Loss before taxation	(279,181)	(283,351)
Notional tax on loss before taxation, calculated at the rates applicable to losses in the jurisdictions concerned	(69,795)	(70,838)
Effect of non-deductible expenses	257	288
Effect of share-based payment expenses	8,778	36,367
Effect of deferred tax assets in respect of temporary differences and tax losses not recognised	104,322	48,538
Tax effect of super deduction for research and development expenses (Note 6(a)(i))	(43,562)	(14,355)
Actual tax expense	—	—

(c) Deferred tax assets not recognised:

Deferred tax assets have not been recognised in respect of these losses and deductible temporary differences as they have arisen in the Company and its subsidiaries that have been loss-making for years and it is not considered probable that taxable profits in foreseeable future will be available against which the tax losses can be utilised.

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7 DIRECTORS’ EMOLUMENTS

Directors’ emoluments disclosed pursuant to section 383(1) of the Hong Kong Companies Ordinance and Part 2 of the Companies (Disclosure of Information about Benefits of Directors) Regulation are as follows:

Year ended 31 December 2023							
Directors' fees	Salaries, allowances and benefits in kind	Discretionary bonuses	Retirement scheme contributions	Sub-Total	Equity-settled share-based payments [#]	Total	
RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	
Executive directors							
Michael Min Xu (Chairman)	–	2,304	960	46	3,310	23,608	26,918
Xiaojun Wang (王小軍)	–	870	354	81	1,305	3,116	4,421
Non-executive directors							
Hongkai Li (李宏凱)	–	–	–	–	–	–	–
Ting Zhai (翟婷)	–	–	–	–	–	–	–
Yuhong Xu (徐宇虹)	–	–	–	–	–	–	–
Xiangjun Zhou	–	–	–	–	–	–	–
Independent non-executive directors							
Jiancun Zhang	100	–	–	–	100	–	100
Yangyang Chen (陳秧秧)	100	–	–	–	100	–	100
Jiang Chang (常江) (ii)	100	–	–	–	100	–	100
Supervisors							
Mengjiao Wang (王夢嬌)	–	139	54	26	219	234	453
Zheng Wu (吳正) (i)	–	–	–	–	–	–	–
Yongjun Kong (孔勇軍)	–	–	–	–	–	–	–
	<u>300</u>	<u>3,313</u>	<u>1,368</u>	<u>153</u>	<u>5,134</u>	<u>26,958</u>	<u>32,092</u>

Year ended 31 December 2024						
Directors' fees	Salaries, allowances and benefits in kind	Discretionary bonuses	Retirement scheme contributions	Sub-Total	Equity-settled share-based payments [#]	Total
RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Executive directors						
Michael Min Xu (Chairman)	–	2,328	657	47	3,032	110,017
Xiaojun Wang (王小軍)	–	894	255	84	1,233	11,118
Non-executive directors						
Hongkai Li (李宏凱)	–	–	–	–	–	–
Ting Zhai (翟婷)	–	–	–	–	–	–
Yuhong Xu (徐宇虹)	–	–	–	–	–	–
Xiangjun Zhou	–	–	–	–	–	–
Independent non-executive directors						
Jiancun Zhang	100	–	–	100	–	100
Yangyang Chen (陳秧秧)	100	–	–	100	–	100
Jiang Chang (常江) (ii)	–	–	–	–	–	–
Xinpeng Fan (范新鵬) (iii)	214	–	–	214	–	214
Supervisors						
Mengjiao Wang (王夢嬌)	–	144	58	27	889	1,118
Zheng Wu (吳正) (i)	–	–	–	–	–	–
Yongjun Kong (孔勇軍)	–	–	–	–	–	–
Dong Li (李東) (iii)	–	–	–	–	–	–
	414	3,366	970	158	4,908	122,667

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Notes:

- (i) Zheng Wu (吳正) retired in February 2024.
- (ii) Jiang Chang (常江) retired in February 2024.
- (iii) Xinpeng Fan (范新鵬) and Dong Li (李東) were appointed as an independent non-executive director and a supervisor of the Company, respectively in February 2024.
- (iv) For the years ended 31 December 2023 and 2024, no director of the Company has waived or agreed to waive any emoluments and no amounts were paid or payable by the Group to the directors of the Company as an inducement to join or upon joining the Group or as compensation for loss of any office in connection with the management of the affairs of any member of the Group.
- # These represent the estimated value of the RSUs (Note 22) granted to the directors of the Company under the Company’s restricted share unit scheme. The value of these RSUs is measured according to the Group’s accounting policy for share-based payment transactions as set out in Note 2(n)(ii). The details of the RSUs, including the principal arrangements are disclosed in Note 22.

8 INDIVIDUALS WITH HIGHEST EMOLUMENTS

For the five individuals with the highest emoluments of the Group for the years ended 31 December 2023 and 2024, 2 and 2 are directors whose emoluments are disclosed in Note 7 and the emoluments in respect of the remaining, 3 and 3 individuals during the Relevant Periods are as follows:

	Year ended 31 December	
	2023	2024
	RMB'000	RMB'000
Salaries, allowance and benefits in kind	3,534	1,828
Discretionary bonuses	1,309	128
Retirement scheme contributions	155	133
Equity-settled share-based payments.	2,962	17,768
	<u>7,960</u>	<u>19,857</u>

The emoluments of the above individuals with the highest emoluments are within the following bands:

	Year ended 31 December	
	2023	2024
HKD2,000,001 – HKD2,500,000	2	–
HKD3,000,001 – HKD3,500,000	–	1
HKD4,000,001 – HKD4,500,000	1	–
HKD5,000,001 – HKD5,500,000	–	1
HKD13,000,001 – HKD13,500,000	–	1
	<u>3</u>	<u>3</u>

For the years ended 31 December 2023 and 2024, no amounts were paid or payable by the Group to the above non-director highest paid individuals as an inducement to join or upon joining the Group or as compensation for loss of any office in connection with the management of the affairs of any member of the Group.

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9 LOSS PER SHARE

The calculation of the basic and diluted loss per share during the Relevant Periods is based on the loss for the year attributable to equity shareholders of the Company divided by the weighted average number of shares, calculated as follows:

	Year ended 31 December	
	2023	2024
	RMB'000	RMB'000
Loss for the year attribute to equity shareholders of the Company	278,999	283,158

(i) Weighted average number of shares

	Year ended 31 December	
	2023	2024
	'000	'000
Issued shares at the beginning of the year	354,510	366,672
Effect of capital contributions by investors (Note 23(b))	7,095	–
Weighted average number of shares at the end of the year for the purposes of basic loss per share	361,605	366,672

(ii) Diluted loss per share

For the years ended 31 December 2023 and 2024, the Company did not have any outstanding ordinary shares or potential ordinary shares with potential dilution effects. Therefore, diluted loss per share is the same as basic loss per share.

10 PROPERTY, PLANT AND EQUIPMENT

The Group and the Company

	Vehicle	Equipment	Leasehold improvements	Total
	RMB'000	RMB'000	RMB'000	RMB'000
Cost:				
At 1 January 2023.	1,359	10,413	6,236	18,008
Additions	–	546	–	546
Disposals	–	(2)	–	(2)
At 31 December 2023 and 1 January 2024	1,359	10,957	6,236	18,552
Additions	–	775	–	775
Disposals	–	(678)	–	(678)
At 31 December 2024	1,359	11,054	6,236	18,649
Accumulated depreciation:				
At 1 January 2023.	(1,019)	(6,387)	(6,160)	(13,566)
Charge for the year	(88)	(1,132)	(76)	(1,296)
Written back on disposals	–	2	–	2
At 31 December 2023 and 1 January 2024	(1,107)	(7,517)	(6,236)	(14,860)
Charge for the year	(88)	(741)	–	(829)
Written back on disposals	–	612	–	612
At 31 December 2024	(1,195)	(7,646)	(6,236)	(15,077)
Net book value:				
At 31 December 2023	252	3,440	–	3,692
At 31 December 2024	164	3,408	–	3,572

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11 RIGHT-OF-USE ASSETS

The Group has obtained the right to use certain office buildings through tenancy agreements during the Relevant Periods. The leases typically run for an initial period of 3 years. Some leases include an option to renew the lease when all terms are renegotiated. None of the leases includes variable lease payments. The analysis of the net book value of right-of-use assets by class of underlying asset is presented below:

The Group and the Company

	Office building	Land use right	Total
	RMB'000	RMB'000	RMB'000
Cost:			
At 1 January 2023 and 1 January 2024	4,437	26,255	30,692
Additions	6,803	–	6,803
Disposals	(7,125)	(26,255)	(33,380)
At 31 December 2023, 1 January 2024 and 31 December 2024	4,115	–	4,115
Additions	362	–	362
Disposals	(1,133)	–	(1,133)
At 31 December 2024	3,344	–	3,344
Accumulated depreciation:			
At 1 January 2023	(3,718)	(1,168)	(4,886)
Charge for the year	(1,853)	(291)	(2,144)
Written back on disposals	4,712	1,459	6,171
At 31 December 2023 and 1 January 2024	(859)	–	(859)
Charge for the year	(1,374)	–	(1,374)
Written back on disposals	416	–	416
At 31 December 2024	(1,817)	–	(1,817)
Net book value:			
At 31 December 2023	3,256	–	3,256
At 31 December 2024	1,527	–	1,527

In 2021, the Company obtained land use rights located in Suzhou, the PRC. During the year ended 31 December 2023, the Company disposed such land use right to the government at a consideration of RMB25,490,000 resulting in a gain on disposal of RMB694,000.

The analysis of expense items in relation to leases recognised in profit or loss is as follows:

	Year ended 31 December	
	2023	2024
	RMB'000	RMB'000
Depreciation charge of right-of-use assets by class of underlying asset: (Note 5(c))		
Land use right	291	–
Properties leased for own use	1,853	1,374
	2,144	1,374
Interest on lease liabilities (Note 17(c)).	128	107
Expense relating to short-term leases	285	298

The total cash outflow for leases and the maturity analysis of lease liabilities are set out in Notes 17(d) and 24(b), respectively.

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12 INTANGIBLE ASSETS

The Group and the Company

	Software
	<i>RMB'000</i>
Cost:	
At 1 January 2023, 31 December 2023 and 1 January 2024	1,711
Additions	183
31 December 2024	<u>1,894</u>
Accumulated amortisation:	
At 1 January 2023.	(428)
Charge for the year	(308)
At 31 December 2023	(736)
Charge for the year	(295)
31 December 2024	<u>(1,031)</u>
Net book value:	
At 31 December 2023	<u>975</u>
At 31 December 2024	<u>863</u>

13 OTHER NON-CURRENT ASSETS

The Group and the Company

	At 31 December	
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>
Value-added tax recoverable.	<u>14,651</u>	<u>22,101</u>

As at 31 December 2023 and 2024, value-added tax recoverable amounting to RMB14,651,000 and RMB22,101,000, respectively were recognised as other non-current assets as they are expected to be deducted from future value-added tax payables arising on the Group’s revenue which are not expected to be generated within the next 12 months from the end of each of the reporting period.

14 INVESTMENTS IN SUBSIDIARIES

The Company

	At 31 December	
	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>
Unlisted, at cost		
Shanghai Hanmai	3,238	3,238
Shanghai Maiji.	<u>3,238</u>	<u>3,238</u>
	<u>6,476</u>	<u>6,476</u>

Details of the subsidiaries are set out in Note 1.

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15 PREPAYMENTS AND OTHER RECEIVABLES

The Group and the Company

	At 31 December	
	2023	2024
	RMB'000	RMB'000
Prepayments to suppliers	5,204	2,886
Prepayments for [REDACTED] expenses	[REDACTED]	[REDACTED]
Other debtors and deposits	50	3,362
	<u>[REDACTED]</u>	<u>[REDACTED]</u>

All the prepayments and other receivables are expected to be recovered or recognised as expenses within one year.

16 FINANCIAL ASSETS AT FVPL

The Group

	At 31 December	
	2023	2024
	RMB'000	RMB'000
Negotiable certificate of deposits with banks	247,313	138,522
Wealth management products	15,765	15,133
	<u>263,078</u>	<u>153,655</u>

The Company

	At 31 December	
	2023	2024
	RMB'000	RMB'000
Negotiable certificate of deposits with banks	<u>247,313</u>	<u>138,522</u>

During the years ended 31 December 2023 and 2024, the Group invested in certain negotiable certificate of deposits with banks in the PRC. The negotiable certificate of deposits were transferable and carried at fixed interest rate ranged from 3.1% to 3.2% per annum. The directors of the Company determine such negotiable certificate of deposits are mainly for the purpose of short-term fund management, which will be sold in the secondary market within one year, depending on the cash needs. Therefore, the negotiable certificate of deposits are classified as current financial assets at FVPL.

The maturity date of wealth management products is within 1 year from each reporting date or redeemable on demand.

Valuation techniques and significant assumptions for determining the fair values of these financial assets are set out in Note 24(d).

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17 CASH AND CASH EQUIVALENTS AND OTHER CASH FLOW INFORMATION

(a) Cash and cash equivalents comprise:

The Group

	At 31 December	
	2023	2024
	RMB'000	RMB'000
Cash at banks	<u>77,147</u>	<u>28,392</u>

The Company

	At 31 December	
	2023	2024
	RMB'000	RMB'000
Cash at banks	<u>77,125</u>	<u>28,360</u>

(b) Reconciliation of loss before taxation to cash used in operations:

	Note	Year ended 31 December	
		2023	2024
		RMB'000	RMB'000
Loss before taxation		(279,181)	(283,351)
Adjustments for:			
Depreciation of property, plant and equipment	5(c)	1,296	829
Amortisation of intangible assets	5(c)	308	295
Depreciation of right-of-use assets	5(c)	2,144	1,374
Finance costs	5(a)	1,727	2,499
Net realised and unrealised gain on financial instruments carried at FVPL	4	(6,325)	(6,013)
Loss on disposal of property, plant and equipment		–	66
Gain on disposal of land use right	II	(694)	–
Reversal of impairment loss on trade and other receivables	5(c)	(64)	–
Equity-settled share-based payment expenses	5(b)	35,113	145,468
Operating loss before changes in working capital		<u>(245,676)</u>	<u>(138,833)</u>
Changes in working capital:			
Decrease/(increase) in prepayments and other receivables		4,869	(994)
Increase in other non-current assets		(12,514)	(7,325)
Increase/(decrease) in trade and other payables		20,164	(33,290)
Decrease in deferred income		(126)	(3,000)
Cash used in operations		<u>(233,283)</u>	<u>(183,442)</u>

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(c) Reconciliation of liabilities arising from financing activities

The table below details changes in the Group’s liabilities from financing activities, including both cash and non-cash changes. Liabilities arising from financing activities are liabilities for which cash flows were, or future cash flows will be, classified in the Group’s consolidated cash flow statement as cash flows from financing activities.

	Interest-bearing borrowings	Leases liabilities	Total
	RMB'000 (Note 19)	RMB'000 (Note 20)	RMB'000
At 1 January 2023	23,349	806	24,155
Changes from financing cash flows:			
Proceeds from interest-bearing borrowings	50,000	–	50,000
Repayment of interest-bearing borrowings	(31,708)	–	(31,708)
Interest paid for interest-bearing borrowings	(1,389)	–	(1,389)
Payment for capital element of lease liabilities	–	(2,064)	(2,064)
Payment for interest element of lease liabilities	–	(128)	(128)
Total changes from financing cash flows	16,903	(2,192)	14,711
Other changes:			
Payment using the letter of credit facilities issued by the bank (Note 24(b))	23,924	–	23,924
Termination of the lease contracts	–	(2,413)	(2,413)
Increase in lease liabilities from entering into new leases during the year	–	6,803	6,803
Interest expense (Note 5(a))	1,599	128	1,727
	25,523	4,518	30,041
At 31 December 2023	65,775	3,132	68,907

	Interest-bearing borrowings	Leases liabilities	Total
	RMB'000 (Note 19)	RMB'000 (Note 20)	RMB'000
At 1 January 2024	65,775	3,132	68,907
Changes from financing cash flows:			
Proceeds from interest-bearing borrowings	91,510	–	91,510
Repayment of interest-bearing borrowings	(65,956)	–	(65,956)
Interest paid for interest-bearing borrowings	(2,142)	–	(2,142)
Payment for capital element of lease liabilities	–	(1,287)	(1,287)
Payment for interest element of lease liabilities	–	(107)	(107)
Total changes from financing cash flows	23,412	(1,394)	22,018
Other changes:			
Payment using the letter of credit facilities issued by the bank (Note 24(b))	8,424	–	8,424
Termination of the lease contracts	–	(717)	(717)
Increase in lease liabilities from entering into new leases during the year	–	362	362
Interest expense (Note 5(a))	2,392	107	2,499
	10,816	(248)	10,568
At 31 December 2024	100,003	1,490	101,493

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(d) Total cash outflow for leases

Amounts included in the cash flow statement for leases comprise the following:

	Year ended 31 December	
	2023	2024
	RMB'000	RMB'000
Within operating cash flows	285	298
Within financing cash flows	2,192	1,394
	<u>2,477</u>	<u>1,692</u>

18 TRADE AND OTHER PAYABLES

The Group

	At 31 December	
	2023	2024
	RMB'000	RMB'000
Trade payables	90,613	35,123
Accrued payroll	6,340	3,958
Tax payables	806	429
Other payables and accruals	34	16,884
	<u>97,793</u>	<u>56,394</u>

The Company

	At 31 December	
	2023	2024
	RMB'000	RMB'000
Trade payables	90,395	34,977
Accrued payroll	6,310	3,928
Tax payables	802	426
Other payables and accruals	34	16,884
	<u>97,541</u>	<u>56,215</u>

All of trade and other payables are expected to be settled within one year or are repayable on demand.

As at 31 December 2024, other payables and accruals primarily comprise unpaid professional service fee relating to the [REDACTED] and accrued compensation costs in connection with the relocation of the Company.

As at the end of each of the reporting period, the ageing analysis of trade payables based on the invoice date, is as follows:

The Group

	At 31 December	
	2023	2024
	RMB'000	RMB'000
Within 1 year	90,423	34,933
Over 1 year	190	190
	<u>90,613</u>	<u>35,123</u>

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The Company

	At 31 December	
	2023	2024
	RMB'000	RMB'000
Within 1 year.	90,205	34,787
Over 1 year.	190	190
	<u>90,395</u>	<u>34,977</u>

19 INTEREST-BEARING BORROWINGS

The Group and the Company

	At 31 December	
	2023	2024
	RMB'000	RMB'000
Bank loans	50,047	91,582
Trade finance loans (Note 24(b)).	15,728	8,421
	<u>65,775</u>	<u>100,003</u>

As at 31 December 2023 and 2024, all of the above interest-bearing borrowings are unsecured and carried at amortised cost. All these interest-bearing borrowings are to be settled within one year.

20 LEASE LIABILITIES

The following table shows the remaining contractual maturities of the Group and the Company’s lease liabilities at the end of each of the Relevant Periods.

The Group and the Company

	At 31 December	
	2023	2024
	RMB'000	RMB'000
Within 1 year.	1,419	1,269
After 1 year but within 2 years.	1,497	221
After 2 years but within 5 years	216	–
	<u>1,713</u>	<u>221</u>
	<u>3,132</u>	<u>1,490</u>

21 DEFERRED INCOME

The Group and the Company

	At 31 December	
	2023	2024
	RMB'000	RMB'000
Government grants	6,000	3,000

Deferred income represented the subsidies received from the government for the encouragement of research and development projects which did not meet the conditions attaching to the subsidies or compensated for the costs of assets.

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22 EQUITY-SETTLED SHARE-BASED TRANSACTIONS

Restricted share unit scheme

Pursuant to a written shareholders’ resolution of the Company passed on 27 March 2021, a restricted share unit (the “RSU”) scheme (“the Scheme”) was adopted for purpose of providing incentives to eligible employees of the Group. The participant of the RSU Scheme invested in the Company by the way of acquiring share capital of the Company from the existing shareholder through an employee share purchase platform (the “Platform”).

The Scheme contains certain service conditions and non-market performance conditions. The RSUs shall vest upon the completion of [REDACTED] (“[REDACTED]”) of the Company and if the Company still incurred loss when the [REDACTED] completed, these RSUs shall vest upon the 3 fiscal years after the completion of [REDACTED] of the Company. If employments relationship of the grantees are terminated before the RSUs become vested, these employee have to transfer out their equity interests to the person designed by the general partner of the Platform at the initial purchase price paid by the grantees. Such term is a non-market condition and represents an implicit service period that runs until the end of the full 3 fiscal years after the [REDACTED]. Management of the Group estimate the implicit service period at the end of each reporting period. Equity-settled share-based payment expenses are recognised over the expected service period on a true-up basis.

In 2021, RSUs, representing 29,175,230 shares of the Company were granted to the eligible employees, including the directors of the Company at a subscription price of RMB1.00 per RSU. The grants in 2024 (representing 11,436,194 shares of the Company) were in relation to the re-allocation of the RSUs and forfeited RSUs as disclosed in the following notes. The terms and conditions of the RSUs granted in 2024, are consistent with the Scheme.

Set out below are details of the movements of RSUs during the Relevant Periods:

	For the year ended 31 December	
	2023	2024
	<i>Number of underlying shares of the Company</i>	<i>Number of underlying shares of the Company</i>
At the beginning of the year/period	25,883,199	25,244,458
Granted	–	11,460,030
Forfeited (i)	(638,741)	(201,601)
Cancelled (ii).	–	(7,327,657)
At the end of the year/period	<u>25,244,458</u>	<u>29,175,230</u>

Pursuant to a resolution passed at the shareholders’ meeting of the Company in February 2024, certain terms and conditions of the Scheme was modified. The implicit service period was changed from the full 3 fiscal years after the completion of an [REDACTED] to 12 months following the completion date of the [REDACTED]. As such modification resulted in a reduction of service period in relation to the RSUs granted before 31 December 2023, the Group uses the modified vesting period when applying the requirements of the modified grant-date method. In the period of the change, the Group shall calculate the cumulative amount to be recognised in equity at the reporting date based on the new vesting conditions.

Notes:

- (i) During the Relevant Periods, certain grantees terminated their employment relationships, and they transferred all their equity interests in the Platform to the general partner or the person designed by the general partner, which were treated as the forfeited RSUs. These forfeited equity interests in the Platform were temporarily held by the general partner and then granted to Michael Min Xu (“Dr. Xu”, an executive directors of the Company) in accordance with the terms and conditions of the Scheme in 2024.

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- (ii) In December 2023, Dr. Xu entered into a capital increase agreement with the Platform, pursuant to which, Dr. Xu agreed to subscribe for additional capital of the Platform amounting to RMB270,000 (the “Capital Increase”). The capital of the Platform increased from RMB30,000 to RMB300,000. The total number of underlying shares of the Company available to the Scheme, being 29,175,230 shares (the “Underlying Shares”), remained unchanged before and after the Capital Increase, as the scale and design of the Scheme was intact. However, the entitlements of each participant in the Scheme (i.e. their relative interests in the Underlying Shares upon vesting) changed as a result of the reallocation of RSUs on the Platform.

The Scheme participants other than Dr. Xu who indirectly held 9,023,030 Underlying Shares of the Company through the Platform prior to the Capital Increase. The reallocation of entitlements to the Underlying Shares among all the participants was on a fully pro-rata basis and the other Scheme participants’ interests were diluted by 90% (representing a potential reduction of 8,120,727 Underlying Shares) in comparison to their previous holdings. Simultaneously, in February 2024, Dr. Xu also transferred certain capital of the Platform (representing 793,070 Underlying Shares) to several existing Scheme participants (the “Transfer”). In connection with the net effects of the Capital Increase and the Transfer, the number of Underlying Shares granted to the existing Scheme participants other than Dr. Xu (being 7,327,657 Underlying Shares) was reduced. This reduction is a non-beneficial modification with those employees, and is treated as a cancellation of the related portion of RSUs. In accordance with the Group’s accounting policies set out in Note 2(n)(ii), the unrecognised amount of grant-date fair value of RMB31,830,000 for the cancelled awards that would otherwise be recognised for services received is recognised in the profit or loss immediately as if vesting were accelerated on the date of cancellation during the year ended 31 December 2024.

Fair value of RSUs

The fair value of services received in return for RSUs granted is measured at the difference between (i) the fair value of RSUs granted and (ii) the considerations paid by the employees.

For the grants in 2021, the fair value of the RSUs were determined with reference to the fair value of shares of the Company in equity financing transaction with external investors close to the grant date.

For the grants in 2024, the fair value of RSUs was calculated based on the fair value of underlying ordinary shares as at the grant date. Management of the Company used the income approach to determine the fair value of the underlying shares of the Company and adopted the discounted cash flow to determine the fair value of the underlying shares. The risk-free interest rate based on the yield of Chinese government bonds with maturity of 10 years. Weighted average cost of capital was estimated based on selected comparable companies.

As at 31 December 2023 and 2024, the implicit service period from the grant date, estimated by management was 81 months and 60 months, respectively.

During the years ended 31 December 2023 and 2024, expenses in relation to the RSUs of RMB35,113,000 and RMB145,468,000 were charged into profit or loss, respectively.

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23 CAPITAL, RESERVES AND DIVIDENDS

(a) Movements in components of equity

The reconciliation between the opening and closing balances of each component of the Group’s consolidated equity is set out in the consolidated statement of changes in equity. Details of the changes in the Company’s individual components of equity between the beginning and the end of each year are set out below:

The Company

	<i>Note</i>	<u>Share capital</u>	<u>Capital reserve</u>	<u>Accumulated losses</u>	<u>Total</u>
		<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Balance at 1 January 2023		354,510	485,176	(543,640)	296,046
Changes in equity for 2023:					
Total comprehensive income for the year		—	—	(278,665)	(278,665)
Capital contributions by investors	23(b)	12,162	121,638	—	133,800
Equity-settled share-based payments	22	—	35,113	—	35,113
Balance at 31 December 2023 and 1 January 2024		366,672	641,927	(822,305)	186,294
Changes in equity for 2024:					
Total comprehensive income for the year		—	—	(282,802)	(282,802)
Equity-settled share-based payments	22	—	145,468	—	145,468
Balance at 31 December 2024		<u>366,672</u>	<u>787,395</u>	<u>(1,105,107)</u>	<u>48,960</u>

(b) Share capital

In June 2023, the Company entered into agreements with several investors, pursuant to which, the investors agreed to inject a total of RMB133,800,000 into the Company as a consideration for the subscription of the Company’s newly issued 12,162,000 shares with a nominal value of RMB1.00 each. The difference between the consideration and the amount of share capital, being RMB121,638,000 was recorded in capital reserve.

(c) Dividends

No dividends were declared or paid by the Company or any of its subsidiaries during the Relevant Periods.

(d) Nature and purpose of reserves

The capital reserve primarily comprises the following:

- The portion of the grant date fair value of unvested shares granted to employees of the Group that has been recognised in accordance with the accounting policy adopted for share-based payments in Note 2(n)(ii).
- The difference between the consideration received and the par value of the issued shares of the Company.

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(e) Capital management

The Group’s objectives in the aspect of managing capital are to safeguard the Group’s ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

The Group actively and regularly reviews and manages its capital structure to make adjustments to the capital structure in light of changes in economic conditions.

Neither the Company nor any of its subsidiaries are subject to externally imposed capital requirements.

24 FINANCIAL RISK MANAGEMENT AND FAIR VALUES OF FINANCIAL INSTRUMENTS

Exposure to credit, liquidity, and interest rate arises in the normal course of the Group’s business. The Group’s exposure to these risks and the financial risk management policies and practices used by the Group to manage these risks are described below.

(a) Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in a financial loss to the Group. The Group’s credit risk is primarily attributable to other receivables. The Group’s exposure to credit risk arising from cash and cash equivalents and negotiable certificate of deposits with banks is limited because the counterparties are state-owned banks or reputable banks in the PRC, which the Group considered to have low credit risks. Management has a credit policy in place and the exposure to credit risk is monitored on an ongoing basis.

Management has assessed that during the Relevant Periods, other receivables have not had a significant increase in credit risk since initial recognition. Thus, a 12-month expected credit loss approach that results from possible default event within 12 months of each reporting date is adopted by management. The management of the Company expect the occurrence of losses from non-performance by counterparties of other receivables to be remote and a loss allowance provision for other receivables to be immaterial.

(b) Liquidity risk

The Group’s policy is to regularly monitor its liquidity requirements and its compliance with lending covenants, to ensure that it maintains sufficient reserves of cash and readily realisable marketable securities and adequate committed lines of funding from major financial institutions to meet its liquidity requirements in the short and longer term.

The following tables show the remaining contractual maturities as of the end of the reporting period of the Group’s non-derivative financial liabilities, which are based on contractual undiscounted cash flows (including interest payments computed using contractual rates or, if floating, based on rates current as at the end of each of the reporting period) and the earliest date the Group can be required to pay:

As at 31 December 2023						
Contractual undiscounted cash outflow						
	Within 1 year or on demand	More than 1 year but less than 2 years	More than 2 years but less than 5 years	More than 5 years	Total	Carrying amount
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Lease liabilities	1,542	1,542	337	—	3,421	3,132
Interest-bearing borrowings	66,711	—	—	—	66,711	65,775
Trade and other payables	90,647	—	—	—	90,647	90,647
	<u>158,900</u>	<u>1,542</u>	<u>337</u>	<u>—</u>	<u>160,779</u>	<u>159,554</u>

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As at 31 December 2024

	Contractual undiscounted cash outflow					Carrying amount
	Within 1 year or on demand	More than 1 year but less than 2 years	More than 2 years but less than 5 years	More than 5 years	Total	
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Lease liabilities	1,303	233	–	–	1,536	1,490
Interest-bearing borrowings	101,146	–	–	–	101,146	100,003
Trade and other payables	50,210	–	–	–	50,210	50,210
	<u>152,659</u>	<u>233</u>	<u>–</u>	<u>–</u>	<u>152,892</u>	<u>151,703</u>

- (i) As disclosed in Note 19, the Group had supplier financing arrangements. In 2022, the Group entered into supplier finance arrangements (the “Supplier Financing Arrangement”) with a supplier (the “Supplier”, which is also a shareholder of the Company) and a bank (the “Bank”), pursuant to which, the Bank will settle the trade payables to the Supplier in favour of the Company under a letter of credit facilities which is guaranteed by the Company. The Company should repay these amounts to the Bank upon the maturity within 1 year after the respective draw down. The original credit term with the Supplier is 30 days after the invoice date.

During the years ended 31 December 2023 and 2024, the total loans drawn down under the letter of credit facilities were RMB23,924,000 and RMB8,424,000, respectively. As at 31 December 2023 and 2024, the amount due to the bank under the Supplier Finance Arrangement amounted to RMB15,728,000 and RMB8,421,000, respectively, which were included in trade finance loans. Non-cash changes in the carrying amounts of the financial liability is set out in Note 17(c).

(c) Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates.

The Group is primarily exposed to fair value interest rate risk in relation to negotiable certificate of deposits with banks (Note 16), fixed rate interest-bearing borrowings (Note 19) and lease liabilities (Note 20) and cash flow risk in relation to variable-rate bank balances (Note 17). The Group currently does not have an interest rate hedging policy to mitigate interest rate risk; nevertheless, the management monitors interest rate exposure and will consider hedging significant interest rate risk should the need arise.

The Group’s interest-bearing financial instruments at variable rates as at 31 December 2023 and 2024 are cash and cash equivalents, and the cash flow interest risk arising from a change in market interest rates is not considered significant.

(d) Fair value measurement

(i) Financial assets and liabilities measured at fair value

Fair value hierarchy

The following table presents the fair value of the Group’s financial instruments measured at the end of the reporting period on a recurring basis, categorised into the three-level fair value hierarchy as defined in HKFRS 13, *Fair value measurement*. The level into which a fair value measurement is classified is determined with reference to the observability and significance of the inputs used in the valuation technique as follows:

- Level 1 valuations: Fair value measured using only Level 1 inputs i.e. unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date
- Level 2 valuations: Fair value measured using Level 2 inputs i.e. observable inputs which fail to meet Level 1, and not using significant unobservable inputs. Unobservable inputs are inputs for which market data are not available
- Level 3 valuations: Fair value measured using significant unobservable inputs

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The Group has a team performing valuations for the financial instruments categories into Level 3 of the fair value hierarchy. The team reports directly to the chief financial officer. Valuation assessment with analysis of changes in fair value measurement is prepared by the team at each reporting date and is reviewed and approved by the chief financial officer.

	Fair value at 31 December 2023	Fair value measurements as at 31 December 2023 categorised into		
		Level 1	Level 2	Level 3
	RMB'000	RMB'000	RMB'000	RMB'000

Recurring fair value measurement

Financial assets:

– Wealth management products	15,765	–	–	15,765
– Negotiable certificate of deposits with banks	247,313	–	–	247,313

	Fair value at 31 December 2024	Fair value measurements as at 31 December 2024 categorised into		
		Level 1	Level 2	Level 3
	RMB'000	RMB'000	RMB'000	RMB'000

Recurring fair value measurement

Financial assets:

– Wealth management products	15,133	–	–	15,133
– Negotiable certificate of deposits with banks	138,522	–	–	138,522

During the Relevant Periods, there were no transfers between Level 1 and Level 2, or transfers into or out of Level 3. The Group’s policy is to recognise transfers between levels of fair value hierarchy as at the end of each of the reporting period in which they occur.

Information about Level 3 fair value measurements

The fair values of wealth management products and negotiable certificate of deposits with banks have been estimated using a discounted cash flow valuation model based on assumptions that are not supported by observable market prices or rates. The valuation requires the directors of the Company to make estimates about the expected future cash flows including expected future interest return on maturity of the wealth management products. The directors of the Company believe that the estimated fair values resulting from the valuation technique are reasonable, and that they were the most appropriate values at the end of each of the reporting period.

Below is a summary of significant unobservable inputs to the valuation of these financial assets at FVPL together with a quantitative sensitivity analysis at the end of each of the reporting period:

31 December 2023

	Valuation techniques	Significant unobservable inputs	Range	Sensitivity of fair value to the input
Wealth management products	Discounted cash flow method	Interest return rate	1.94% – 4.2%	0.5% increase/(decrease) in interest return rate would result in increase/(decrease) in fair value by RMB345,000
Negotiable certificate of deposits with banks	Discounted cash flow method	Interest return rate	3.1% – 3.2%	0.5% increase/(decrease) in interest return rate would result in increase/(decrease) in fair value by RMB614,000

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ACCOUNTANTS’ REPORT

31 December 2024

	Valuation techniques	Significant unobservable inputs	Range	Sensitivity of fair value to the input
Wealth management products	Discounted cash flow method	Interest return rate	2.56% – 2.70%	0.5% increase/(decrease) in interest return rate would result in increase/(decrease) in fair value by RMB74,000
Negotiable certificate of deposits with banks	Discounted cash flow method	Interest return rate	3.1% – 3.2%	0.5% increase/(decrease) in interest return rate would result in increase/(decrease) in fair value by RMB772,000

The movement during the year in the balance of these Level 3 fair value measurements are as follows:

	For the year ended 31 December	
	2023	2024
	RMB'000	RMB'000
At the beginning of the year	333,502	263,078
Purchase	518,420	10,142
Changes in fair value recognised in profit or loss during the year (<i>Note 4</i>).	6,325	6,013
Redemption	(595,169)	(125,578)
At the end of the year	<u>263,078</u>	<u>153,655</u>

(ii) **Fair value of financial assets and liabilities carried at other than fair value**

The carrying amounts of the Group’s financial instruments carried at cost or amortised cost were not materially different from their fair values as at 31 December 2023 and 2024.

25 COMMITMENT

As of 31 December 2023 and 2024, the Group did not have any material commitments.

26 MATERIAL RELATED PARTY TRANSACTIONS

(a) **Key management personnel remuneration**

Remuneration for key management personnel of the Group, including amounts paid to the Company’s directors as disclosed in Note 7 and certain of the highest paid employees as disclosed in Note 8, is as follows:

	Year ended 31 December	
	2023	2024
	RMB'000	RMB'000
Salaries, wages and other benefits	6,277	5,936
Contributions to defined contribution retirement plan	199	205
Equity-settled share-based payment expenses	<u>26,958</u>	<u>118,406</u>
	<u>33,434</u>	<u>124,547</u>

Total remuneration is included in “staff costs” (see Note 5(b)).

APPENDIX I

ACCOUNTANTS’ REPORT

(b) Other material related party transactions

During the Relevant Periods, the directors of the Company are of the view that the followings are related parties of the Group:

Name of party	Relationship
Dr. Xu	Chairman and executive director of the Company
Shenzhen Yuanxing Gene Technology Co., Ltd. (“Yuanxing Gene”) (深圳源興基因技術有限公司)	Legal representative and chairman of the board of directors of Yuanxing Gene is a non-executive director of the Company
Hangzhou HighField Biopharmaceuticals, Inc. (“HighField”) (杭州高田生物醫藥有限公司)	Legal representative and chairman of the board of directors of HighField is a non-executive director of the Company

Transactions with related parties

	Year ended 31 December	
	2023	2024
	RMB'000	RMB'000
Service fee charged by Yuanxing Gene	—	1,915
Service fee charged by HighField	—	283

Balances with related parties

	At 31 December	
	2023	2024
	RMB'000	RMB'000
Trade related prepayment to Yuanxing Gene	136	—
Trade related payable to Yuanxing Gene	—	814
Trade related payable to HighField	—	142

27 POSSIBLE IMPACT OF AMENDMENTS, NEW STANDARDS AND INTERPRETATIONS ISSUED BUT NOT YET EFFECTIVE FOR THE RELEVANT PERIODS

Up to the date of this report, the HKICPA has issued a number of amendments, new standards and interpretations, which are not yet effective for the Relevant Periods and which have not been adopted in the Historical Financial Information. These developments include:

	Effective for accounting periods beginning on or after
Amendments to HKAS 21, <i>Lack of Exchangeability</i>	1 January 2025
Amendments to HKFRS 10 and HKAS 28, <i>Sale or contribution of assets between an investor and its associate or joint venture</i>	To be determined
Amendments to HKFRS 9 and HKFRS 7: <i>Amendments to the Classification and Measurement of Financial Instruments</i>	1 January 2026
Annual Improvements to HKFRSs – Volume 11	1 January 2026
HKFRS 18 <i>Presentation and Disclosure in Financial Statements</i>	1 January 2027
HKFRS 19, <i>Subsidiaries without Public Accountability: Disclosures</i>	1 January 2027

The Group is in the process of making an assessment of what the impact of these amendments, new standards and interpretations are expected to be in the period of initial application. So far the Group has concluded that their adoption is unlikely to have a significant impact on the consolidated financial statements of the Group.

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ACCOUNTANTS’ REPORT

28 NON-ADJUSTING EVENTS AFTER THE RELEVANT PERIODS

[As mentioned in Note 1, in February 2025, the Company changes its registered address to Hangzhou, Zhejiang Province. In connection with the relocation, the Company entered into a new office lease agreement, of which, the lease period is from February 2025 to February 2031 with a total lease payment of approximately RMB11 million.]

SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Company or any of its subsidiaries in respect of any period subsequent to 31 December 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 III

SUMMARY OF ARTICLES OF ASSOCIATION

SUMMARY OF ARTICLES OF ASSOCIATION

This appendix sets out an overview of the principal provisions of the Articles of Association of PegBio Co., Ltd. (the “**Articles of Association**”). As the main objective of this appendix is to provide prospective [REDACTED] with an overview of the Articles of Association, it may not contain all the information that may be important to prospective [REDACTED].

DIRECTORS

Power to Allot and Issue Shares

There is no provision in the Articles of Association empowering the Board to allot and issue Shares. Any such allotment or issue is subject to the formalities prescribed by applicable laws and administrative regulations.

Power to Dispose of Assets of the Issuer or Any of Its Subsidiaries

The Board shall lay down strict procedures to inspect and decide on the approval limit for foreign investment, acquisition or sale of assets, mortgage of assets, provision of external guarantees, entrusted assets management, connected transactions and external donations. For major investment projects, the Board shall organize the relevant experts and professional to conduct assessment and report it to the general meeting for approval.

Compensation or Payments for Loss of Office

Unless otherwise stipulated by laws, administrative regulations and the securities regulatory rules of the place where the Shares of the Company are listed, the Shareholders shall have power by an ordinary resolution at the general meeting to remove any Director prior to expiration of his/her term of office, which shall come into effect from the date on which such resolution is made. Where a director is removed prior to expiration of his/her term of office without reasonable cause, the director’s right to claim damages under any contract shall not be affected.

Loans to Directors

There is no provision in the Articles of Association for loans to the Directors.

Financial Assistance for Purchase of Shares in Issuer or Any of Its Subsidiaries

The Company shall not provide gifts, loans, guarantees or other financial assistance for others to acquire the shares of the Company or its parent company, except when the Company implements an employee stock ownership plan.

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SUMMARY OF ARTICLES OF ASSOCIATION

For the interests of the Company, with a resolution made in the Shareholders' meeting or a resolution made by the Board pursuant to the Articles of Association or with the authorization of the Shareholders' meeting, the Company may provide financial assistance for others to acquire shares of the Company or its parent company, but the cumulative amount of financial assistance shall not exceed 10% of the issued share capital. Resolutions of the Board shall be passed by two-thirds or more of all the Directors.

Where otherwise provided by laws, administrative regulations, departmental rules, or securities regulatory rules of the place where the Company's shares are listed, such provisions shall apply.

Disclosure of Interests in Contracts with the Issuer or Any of Its Subsidiaries

Directors shall not enter into contracts or conduct transactions with the Company directly or indirectly without a report on matters relating to the conclusion of such contract or transactions to the Board or the Shareholders' meeting, which has been approved by the Board or the Shareholders' meeting in accordance with the provisions of the Articles of Association.

Remuneration

The general meeting shall exercise its functions and powers in accordance with laws to decide on matters of remuneration for Directors (not being representatives of employees) and such decisions shall be adopted by way of ordinary resolutions.

The remuneration of Directors is determined based on a combination of factors including performance of major duties, time commitment, annual performance appraisal results, remuneration rates of directors of similar enterprises and employment conditions of other positions in the Company. The remuneration plan or proposal for Directors proposed by the Remuneration and Appraisal Committee shall not be implemented until it is submitted to the Shareholders' meeting for consideration and approval after being approved by the Board.

Retirement, Appointment and Removal

The Board shall consist of 9 Directors, including 1 chairman. At any time, the Board shall have at least one-third independent non-executive Directors, the number of whom shall not be less than three, and at least one of whom shall have appropriate accounting or related financial management expertise or appropriate professional qualifications that meet regulatory requirements.

Directors shall be elected or replaced by the general meeting and may be removed by the general meeting before the expiration of their term of office. The term of office of the Directors shall be three years, and the Directors shall be eligible for re-election upon expiration of their term of office.

APPENDIX III

SUMMARY OF ARTICLES OF ASSOCIATION

The term of office of a Director shall commence from his accession till the expiry of the term of the current session of the Board. Where the election of Directors fails to be timely conducted upon expiry of the term of office of the former Directors, or the resignation of any Director during his/her term of office results in the number of board members less than the quorum, the former Directors shall, prior to the accession of the newly elected Directors, perform their duties as Directors in accordance with laws, administrative regulations, departmental rules and the Articles of Association.

If a Director resigns, he/she shall notify the Company in writing, and the Board will disclose the relevant information within 2 days. The resignation takes effect on the date the Company receives the notice, but the Director shall continue to perform his/her duties under the circumstances prescribed in the preceding paragraph.

Any Director appointed by the Board to fill a casual vacancy or as an addition to the Board shall hold office only until the first annual general meeting of the Company after his appointment and shall be eligible for re-election at the meeting. Unless otherwise stipulated by laws, administrative regulations and the securities regulatory rules of the place where the Shares of the Company are listed, the Shareholders shall have power by an ordinary resolution at the general meeting to remove any Director before the expiration of his/her term of office, which shall come into effect from the date on which such resolution is made.

Directors of the Company shall be natural persons. A person shall be disqualified from being a Director of the Company in each of the following circumstances: (1) a person who does not have or who has limited capacity for civil conduct; (2) a person who has been convicted of and sentenced for offences relating to corruption, bribery, trespass to assets, misappropriation of assets or disrupting the order of the socialist market economy or who has been deprived of his/her political rights as a result of him/her having committed an offence and, in each case, a period of 5 years has not elapsed since the completion of the term of the sentence or deprivation; or a period of 2 years has not elapsed since the expiration of the probation period for suspended sentence; (3) a person who was a Director or factory manager or manager of a company or enterprise which had become insolvent and liquidated and who incurred personal liability for the insolvency of that company or enterprise, and a period of 3 years has not elapsed since the date of completion of insolvent liquidation of that company or enterprise; (4) a person who was a legal representative of a company or enterprise which had its business license revoked or was ordered to close down on the grounds of contravention of law, and who incurred personal liability thereof, and a period of 3 years has not elapsed since the date of revocation of the business license or closure of that company or enterprise; (5) a person is listed as a dishonest party by the People's Court due to failure to repay his/her relatively large amount of debts when due; (6) a person who has been forbidden by the CSRC with a penalty to access the securities market and who is still in the period of penalty; (7) other circumstances stipulated by laws, administrative regulations, departmental rules and the securities regulatory rules of the place where the Shares of the Company are listed. Where the Company elects or appoints any Director by violating the provisions in this Article, such elections, appointments or hiring shall be deemed invalid. Where any Director, during his/her term of office, is under any of the circumstances as mentioned in this Article, the Company shall remove him/her from his/her post.

APPENDIX III

SUMMARY OF ARTICLES OF ASSOCIATION

Borrowing Powers

The Board formulates proposals for the issuance and listing of bonds or other securities of the Company, and the decision on the issue of corporate bonds shall be adopted at the general meeting. The Shareholders’ meeting may authorize the Board to make resolutions on the issuance of corporate bonds.

AMENDMENTS TO CONSTITUTIONAL DOCUMENTS

Amendments to the Articles of Association shall be adopted by special resolutions at the general meeting.

Amendments shall be made to the Articles of Association by the Company in any of the following circumstances: (1) after an amendment of the Company Law, relevant laws, administrative regulations or the Hong Kong Listing Rules, and there is any conflict between the provisions of the Articles of Association and those of the amended laws, administrative regulations or the Hong Kong Listing Rules; (2) there are changes in the particulars of the Company which are different from that set out in the Articles of Association; (3) a resolution of the general meeting is passed to amend the Articles of Association.

Amendments to the Articles of Association adopted by a resolution of the general meeting which are subject to approvals from relevant competent authority shall be submitted to the competent authority for approval; if there is any change relating to the registered particulars of the Company, application shall be made for change in registration in accordance with laws.

VARIATION OF RIGHTS OF EXISTING SHARES OR CLASSES OF SHARES

There is no provision in the Articles of Association relating to the variation of rights of existing Shares or classes of Shares.

SPECIAL RESOLUTIONS-MAJORITY REQUIRED

Resolutions of the general meeting are divided into ordinary resolutions and special resolutions.

Ordinary resolutions made by the general meeting shall be passed by more than half of the voting rights held by Shareholders (including their proxies) attending the general meeting.

Special resolutions made by the general meeting shall be passed by two-thirds of the voting rights held by Shareholders (including their proxies) attending the general meeting.

APPENDIX III

SUMMARY OF ARTICLES OF ASSOCIATION

The following matters shall be adopted by an ordinary resolution at the general meeting: (1) working reports of the Board and the Supervisory Committee; (2) proposals made by the Board on profit distribution and loss recovery; (3) appointment and removal of members of the Board and the Supervisory Committee and their remunerations and methods of payment; (4) annual budgets and final accounts of the Company; (5) the annual report of the Company; (6) other circumstances except for those which shall be adopted by special resolutions as stipulated by laws, administrative regulations, the securities regulatory rules of the place where the Shares of the Company are listed or the Articles of Association.

The following matters shall be adopted by a special resolution at the general meeting: (1) increase or reduction of the registered capital of the Company; (2) division, spin-off, merger, dissolution, liquidation of the Company; (3) amendments to the Articles of Association; (4) matters in relation to purchase or sale of material assets or provision of guarantees to others with an amount of more than 30% of the audited total assets of the Company for the most recent period within one year; (5) equity incentive plan; (6) other circumstances stipulated by laws, administrative regulations, the securities regulatory rules of the place where the Shares of the Company are listed or the Articles of Association, and other circumstances adopted by ordinary resolutions at the general meeting as having a significant impact on the Company and requiring approval by way of special resolutions.

VOTING RIGHTS (GENERALLY, THE RIGHT ON A POLL)

If Shareholders (including their proxies) attend the general meeting and exercise voting rights based on the number of voting Shares which they represent, each Share held shall have one vote. When a poll is taken, Shareholders (including their proxies) entitled to two or more votes need not cast all their votes in the same way (for or against or abstaining from voting).

No voting rights shall be attached to the Shares held by the Company, and such Shares shall not be counted among the total number of voting Shares held by the Shareholders present at the general meeting.

Shareholders who purchase the voting Shares of the Company in violation of Clause 1 and Clause 2 of Article 63 of the Securities Law shall not exercise the voting right of the Shares that exceed the prescribed ratio within 36 months after purchasing them, and such number shall not be counted among the total number of voting Shares held by the Shareholders present at the general meeting.

If a Shareholder is required not to exercise or abstain from voting on a resolution, or is restricted to vote only for or against a resolution in accordance with laws, administrative regulations or the securities regulatory rules of the place where the Shares of the Company are listed, such Shareholder or his/her proxy shall abstain from voting or casting a vote in accordance with such requirements and in case of any violation of the aforesaid requirements or restrictions, votes cast by such Shareholder or his/her proxy thereof shall not be adopted.

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SUMMARY OF ARTICLES OF ASSOCIATION

Where the securities regulatory authorities and/or the stock exchange(s) of the place where the Shares of the Company are listed establishes a mechanism for public solicitation of Shareholders’ voting rights, the Board, independent non-executive Directors and Shareholders holding more than 1% of voting Shares of the Company or investor protection institutions established in accordance with laws, administrative regulations or provisions of the securities regulatory authorities of the place where the Shares of the Company are listed may publicly solicit Shareholders’ voting rights. Information including the specific voting preference shall be fully disclosed to the Shareholders from whom voting rights are being solicited. Solicitation of shareholders’ voting rights by way of compensation or in a disguised form of compensation is prohibited. Except for stipulated in laws, administrative regulations and the securities regulatory rules of the place where the Shares of the Company are listed, the Company shall not impose any minimum Shareholding restrictions on the solicitation of voting rights.

When the general meeting considers matters relating to a connected transaction (as defined in the Hong Kong Listing Rules), the Shareholders who constitute connected persons (as defined in the Hong Kong Listing Rules) (the “**Connected Shareholders**”) shall not participate in the vote, and the number of voting Shares represented by them shall not be counted in the total number of valid voting Shares. An announcement on the resolution of the general meeting shall fully disclose the voting by the unconnected Shareholders.

REQUIREMENTS RELATING TO ANNUAL GENERAL MEETINGS

The general meeting shall consist of all shareholders. The general meeting is the organ of authority of the Company, which exercises the following functions and powers in accordance with laws: (i) to decide on the operational objectives and investment plans of the Company; (ii) to elect and replace the Directors and Supervisors (not being representative(s) of employees) and to decide on the matters relating to the remuneration of Directors and Supervisors; (iii) to consider and approve the reports of the Board; (iv) to consider and approve the reports of the Supervisory Committee; (v) to consider and approve the annual financial budgets and final accounts of the Company; (vi) to consider and approve the profit distribution proposals and loss recovery proposals of the Company; (vii) to decide on any increase or reduction of the registered capital of the Company; (viii) to decide on the issue of corporate bonds; (ix) to decide on merger, division, dissolution and liquidation of the Company or change of its corporate form; (x) to amend the Articles of Association; (xi) Resolutions on the appointment and removal of the accounting firm and the determination of their remuneration; (xii) to consider and approve the guarantees which shall be approved by the general meeting as required by the Articles of Association; (xiii) to review matters in relation to purchase or sale of material assets by the Company (including its controlling subsidiaries) with an amount of more than 30% of the audited total assets of the Company for the most recent period within one year; (xiv) To consider and approve the material transactions and connected transactions which shall be considered and approved at the general meeting according to laws, administrative regulations, the securities regulatory rules of the place where the Shares of the Company are listed and the Articles of Association; (xv) to consider and approve the changes in the use of proceeds; (xvi) to consider and approve the equity incentive plan and the employee stock ownership plan; and (xvii) to consider other matters that shall be decided by the general meeting as required by laws, administrative regulations, departmental rules, securities regulatory rules of the place where the Shares of the Company are listed or the Articles of Association.

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SUMMARY OF ARTICLES OF ASSOCIATION

Shareholders’ meetings are classified into annual general meetings and extraordinary general meetings. The Shareholders’ meeting shall convene an annual general meeting once a year, which shall be held within six months after the end of the previous fiscal year.

ACCOUNTS AND AUDIT

Financial and Accounting Policy

The Company shall establish its financial and accounting system in accordance with laws, administrative regulations and requirements of relevant regulatory departments of the PRC. Where the securities regulatory authorities of the place where the Shares of the Company are listed have any other provisions, such provisions shall prevail.

The Company shall prepare, publish, distribute, report, disclose, place and announce the Company’s annual and interim reports in accordance with the relevant laws, administrative regulations, regulatory rules of the place where the Shares of the Company are listed, as well as the regulations of the relevant regulatory authorities, such as the securities regulatory authorities of the place where the Shares of Company are listed, and the stock exchange of the place where the Shares of Company are listed.

The Company shall not establish account books other than the statutory account books. The funds of the Company shall not be deposited in any personal account.

Appointment and Dismissal of Accountants

The Company shall an engage accounting firm that is qualified under the Securities Law to audit its financial statements, verify its net assets, and provide other relevant consulting services. The accounting firm shall serve a term of one year and the engagement can be renewed.

The engagement and removal of an accounting firm responsible for the Company’s audit services shall be subject to the approval of the general meeting, prior to which the Board shall not appoint any accounting firm.

The Company shall provide true and complete accounting vouchers, accounting books, financial statements and other accounting materials to the engaged accounting firm, without any refusal, concealment or misrepresentation.

When the Company dismisses or does not renew the engagement of an accounting firm, it shall give 15 days’ advance notice to such accounting firm. The accounting firm may present its views when the dismissal of the accounting firm is voted at the general meeting. If the accounting firm proposes to resign, it shall make a representation to the general meeting as to whether the Company has any irregularity.

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SUMMARY OF ARTICLES OF ASSOCIATION

NOTICE AND AGENDA OF THE MEETINGS

The Company shall convene an extraordinary general meeting within two months from the occurrence of any of the following events: (I) the number of Directors falls short of the minimum number required by the Company Law or is no more than two-thirds of the number required by the Articles of Association; (II) the unrecovered losses of the Company amount to one-third of its total share capital; (III) Shareholders severally or jointly holding more than 10% of Shares of the Company make a request to hold such meeting; (IV) the Board considers it necessary; (V) the Supervisory Committee proposes to hold such meeting; and (VI) other circumstances stipulated by laws, administrative regulations, departmental rules, the regulatory rules of the place where the Shares of the Company are listed or the Articles of Association.

A general meeting shall be convened by the Board in accordance with laws. Where the Board of Directors is incapable of performing or does not perform its duties of convening the shareholders' meeting, the Supervisory Committee shall convene and preside over such meeting in a timely manner. In case the Supervisory Committee fails to convene and preside over such meeting, shareholders alone or in aggregate holding more than ten percent of the Company's shares for more than 90 days consecutively may unilaterally convene and preside over such meeting.

Independent non-executive Directors shall have the right to propose to the Board to convene an extraordinary general meeting. The Board shall, in accordance with laws, administrative regulations, the securities regulatory rules of the place where the Shares of the Company are listed and the Articles of Association, give a written reply to independent non-executive Directors on whether or not it agrees to convene such extraordinary general meeting within ten days after receipt of the proposal. If the Board agrees to convene such meeting, a notice for convening such meeting shall be given within 5 days after the Board resolution is passed. If the Board disagrees to convene such meeting, a written explanation shall be given and an announcement shall be made pursuant to the securities regulatory rules of the place where the Shares of the Company are listed. Where the securities regulatory authorities of the place where the Shares of the Company are listed have any other provisions, such provisions shall prevail.

The Supervisory Committee shall have the right to propose to the Board in writing to convene an extraordinary general meeting. The Board shall, in accordance with laws, administrative regulations, the securities regulatory rules of the place where the Shares of the Company are listed and the Articles of Association, give a written reply to the Supervisory Committee on whether or not it agrees to convene such extraordinary general meeting within ten days after receipt of the proposal. If the Board agrees to convene such meeting, a notice for convening such meeting shall be given within 5 days after the Board resolution is passed and any changes to the original proposal contained in the notice shall be subject to approval of the Supervisory Committee. If the Board disagrees to convene such meeting or fails to give any reply within 10 days after receipt of the proposal, it shall be deemed to be unable to perform or fail to perform the duty of convening the extraordinary general meeting, in which case the Supervisory Committee may convene and preside over the meeting by itself.

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Shareholders severally or jointly holding more than 10% of Shares of the Company shall have the right to make a request to the Board in writing to convene an extraordinary general meeting. The Board shall, in accordance with laws, administrative regulations, the securities regulatory rules of the place where the Shares of the Company are listed and the Articles of Association, give a written reply to the Shareholders on whether or not it agrees to convene such extraordinary general meeting within ten days after receipt of the request. If the Board agrees to convene such meeting, a notice for convening such meeting shall be given within 5 days after the Board resolution is passed and any changes to the original request contained in the notice shall be subject to the approval of relevant Directors. Where laws, administrative regulations, departmental rules and the securities regulatory authorities of the place where the Shares of the Company are listed have any other provisions, such provisions shall prevail. If the Board disagrees to convene such meeting or fails to give any reply within 10 days after receipt of the request, Shareholders severally or jointly holding more than 10% of Shares of the Company shall have the right to propose to the Supervisory Committee in writing to convene the extraordinary general meeting. If the Supervisory Committee agrees to convene such meeting, a notice for convening such meeting shall be given within 5 days after receipt of the request and any changes to the original request contained in the notice shall be subject to the approval of relevant Shareholders. Where the laws, administrative regulations, departmental rules and provisions of the securities regulatory authorities in the place(s) where the Company's shares are listed contain any other provisions, such provisions shall prevail. If the Supervisory Committee fails to serve any notice of the meeting within the prescribed period, it shall be deemed not to convene and preside over the meeting, in which case Shareholders severally or jointly holding more than 10% of Shares of the Company for more than 90 consecutive days may convene and preside over the meeting by themselves.

Where the Company convenes a general meeting, the Board, the Supervisory Committee and Shareholders severally or jointly holding more than 1% of Shares of the Company shall have the right to put forward proposals to the Company.

Shareholders severally or jointly holding more than 1% of Shares of the Company may submit written provisional proposals to the convener 10 days before the general meeting. The provisional proposals should have clear topics and specific resolutions. The convener shall issue a supplemental notice of the Shareholders' general meeting by way of announcement to inform other Shareholders within 2 days upon receipt of the proposals, and the supplemental notice shall include the contents thereof. The provisional proposals should be submitted to the Shareholders' general meeting for consideration, provided that the provisional proposals violate laws, administrative regulations, the securities regulatory rules of the place where the Company's shares are listed or the Articles of Association, or do not fall within the scope of the power of the Shareholders' general meeting. Unless otherwise provided by laws, administrative regulations, or the securities regulatory rules of the place where the Company's shares are listed, the Company shall not increase the shareholding ratio of Shareholders who submit provisional proposals.

Save as specified in the preceding paragraph, the convener shall not change the proposals set out in the notice of the general meeting or add any new proposal after the said notice is served.

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SUMMARY OF ARTICLES OF ASSOCIATION

Proposals not set out in the notice of the general meeting or not complying with the Articles of Association shall not be voted on or resolved at the general meeting.

Where the laws, administrative regulations, departmental rules and provisions of the securities regulatory authorities in the place(s) where the Company’s shares are listed contain any other provisions, such provisions shall prevail.

The convener shall notify the Shareholders by announcement at least 21 days prior to the convening of the annual general meetings, or at least 15 days prior to the convening of the extraordinary general meetings. Regarding the calculation of the notice period, the date of the meeting shall not be included, but the date on which the notice is given shall be included. Where laws, administrative regulations or the securities regulatory authorities of the place where the Shares of the Company are listed have any other provisions, such provisions shall prevail.

Transfer of Shares

Shares held by Shareholders of the Company may be transferred in accordance with the laws and regulations, regulatory documents and the relevant provisions of the securities regulatory authorities of the places where the shares of the Company are listed.

All H shares shall be transferred by an instrument in writing in any usual or common form or any other form which the Board accepts (including the prescribed form or transfer form as required by the Hong Kong Stock Exchange from time to time). If the transferor or the transferee of the shares transferred is a recognized clearing house (the “recognized clearing house”) as defined by the relevant regulations of the laws of Hong Kong in effect from time to time or the agent thereof, the instrument of transfer in writing may be executed by hand or by machine imprinted signatures. All transfer instruments shall be kept at the legal address of the Company or any address specified by the Board from time to time.

Shares already issued by the Company before [REDACTED] shall not be transferred within one year from the date of the Company’s Shares [REDACTED] on the stock exchange. Where the laws, administrative regulations, or relevant regulatory authorities such as regulatory authorities of the securities regulatory authorities in the place(s) where the Company’s shares are listed contain any other provisions in respect of the transfer of shares of the Company held by the shareholders or actual controllers of the Company, such provisions shall prevail.

Directors, Supervisors and senior management of the Company shall report to the Company about their shareholdings and changes thereof, and Shares transferred each year during their terms of office as determined at the time of their assumption of office shall not exceed 25% of the total number of Shares they held in the Company; Shares they held in the Company shall not be transferred within one year after Shares of the Company are listed. The aforesaid persons shall not transfer their Shares in the Company within half a year after they terminate service with the Company.

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Where the securities regulatory authorities of the place where the Shares of the Company are listed have any other provisions in respect of restrictions on transfer of overseas listed shares, such provisions shall prevail.

POWER OF THE ISSUER TO ACQUIRE ITS OWN SHARES

The Company may not acquire its own shares other than for one of the following purposes: (I) reducing its registered capital; (II) merging with other company holding its Shares; (III) using Shares for the employee stock ownership plan or as equity incentives; (IV) acquiring its own Shares at the request of its Shareholders who vote in the general meeting against a resolution regarding a merger or division; (V) using Shares for converting convertible corporate bonds issued by the Company; (VI) safeguarding corporate value and the interests of Shareholders as the Company deems necessary; (VII) other circumstances stipulated by laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Shares of the Company are listed.

The Company that acquires its own shares shall perform its information disclosure obligation in accordance with the relevant laws, administrative regulations, or the securities regulatory rules of the place where the Company's shares are listed.

When the Company acquires its own Shares, it may conduct by way of open and concentrated transactions, or in other manner permitted by laws, administrative regulations and the securities regulatory authorities of the place where the Shares of the Company are listed. Where the Company acquires its own Shares under circumstances as mentioned in items (III), (V) or (VI) above, it shall be conducted by way of open and concentrated transactions.

Where the Company acquires its own Shares under circumstances as mentioned in items (I) and (II) above, it shall be subject to approval at the general meeting; where the Company acquires its own Shares under circumstances as mentioned in items (III), (V) and (VI) above, it shall, pursuant to the Articles of Association or the authorization of the general meeting, be subject to a resolution of a Board meeting at which more than two-thirds of Directors are present.

If the Company acquires its own Shares in accordance with the above provisions, the Shares acquired under the circumstance of item (I) shall be cancelled within ten days from the date of acquisition; the Shares acquired under the circumstances of items (II) and (IV) shall be transferred or cancelled within six months; the aggregate number of Shares held by the Company shall not exceed 10% of the total issued Shares of the Company, and shall be transferred or cancelled within three years in the circumstances set out in items (III), (V) and (VI).

Where laws, regulations, regulatory documents and the securities regulatory authorities of the place where the Shares of the Company are listed have any other provisions in respect of matters involving share repurchase mentioned above, such provisions shall prevail.

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POWER OF ANY OF THE ISSUER’S SUBSIDIARIES TO OWN SHARES OF ITS PARENT COMPANY

A controlled subsidiary of the Company is not allowed to acquire the shares of the Company. If the controlled subsidiary of the Company holds the shares of the Company due to company mergers, exercise of pledge rights, etc., it is not allowed to exercise the voting rights corresponding to the shares held by it, and the relevant shares of the Company shall be disposed of in a timely manner.

DIVIDENDS AND OTHER METHODS OF DISTRIBUTION

Shareholders of the Company shall have the right to receive dividends and other forms of distribution in proportion to their respective shareholdings.

When the Company distributes its profit after tax for a year, it shall allocate 10% of the profits to its statutory reserve. No further allocations will be required when the balance of the Company’s statutory reserve is more than 50% of its registered capital. If the statutory reserve is insufficient to make up for the losses for the previous year, the profits for the current year shall be used to make up for the losses before any allocation to the statutory reserve in accordance with the preceding paragraph. After allocation to the statutory reserve, subject to the approval by a resolution of the general meeting, the profit after tax may also be appropriated to the discretionary reserve. After making up for the losses and making allocations to the statutory reserve, the Company shall distribute any remaining profits after tax to the Shareholders in proportion to their respective shareholdings, unless otherwise specified in the Articles of Association.

If the Company distributes profits to the Shareholders in violation of the provisions of the Company Law or the Articles of Association, the Shareholders shall return to the Company the profits distributed in breach of the said provisions; if it causes losses to the Company, the Shareholders and the 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 Company will actively distribute its profits in cash when there is sufficient capital for its normal production and operation. The Company may also distribute the profits by dividend based on various genuine and reasonable factors such as the cash flow position, business growth and net asset value per share of the Company.

Cash dividends and other payments payable by the Company to holders of unlisted domestic Shares shall be paid in RMB, whereas those to holders of overseas listed Shares shall be denominated and declared in RMB and paid in foreign currency or RMB. As for the foreign currency needed by the Company for payment of cash dividends and other payments to holders of overseas listed Shares, it shall be handled in accordance with applicable regulations on foreign exchange control of the PRC.

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The Company shall, in principle, distribute profits in cash at least once a year, provided that the closing balance of its accumulated undistributed profits and the distributable profits for the current period are positive, the cash flow is sufficient for its normal operation and sustainable development, and sufficient allocations have been made to its statutory reserve and discretionary reserve. The Company’s accumulated profit distributed in cash in the last three years shall not be less than 30% of the average annual distributable profit achieved in the last three years.

Where the Company has sound operation, and the Board considers that the stock price of the Company does not reflect its share capital size and share dividend is favorable to Shareholders of the Company as a whole, provided that the above conditions of dividend distribution in cash are fully satisfied, the Company may propose dividend distribution in shares. The Company’s share dividend distribution shall not exceed the range of accumulated distributable profits.

The Company shall, in principle, distribute profits once a year, provided that the profit distribution conditions are satisfied. The Company will actively distribute dividends in cash if the conditions for cash dividends are met. The Board of the Company may conditionally propose interim cash distribution based on the actual operating conditions of the Company. If the Company meets the conditions for cash dividend distribution, the Company shall distribute dividends in cash; while implementing the aforementioned cash dividend distribution, the Company may also distribute dividends in shares.

The distribution of the dividends (or Shares) shall be completed within two months after a resolution has been adopted on the profit distribution plan at the general meeting, or after the Board of the Company formulates a specific plan in accordance with the conditions and the cap of the interim dividend for the next year considered and approved at the annual general meeting. Where the laws, administrative regulations, departmental rules and provisions of the securities regulatory authorities in the place(s) where the Company’s shares are listed contain any other provisions, such provisions shall prevail.

The profits of the Company may be distributed in cash, by shares, a combination of cash and shares or in other manner permitted by laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Shares of the Company are listed. Compared to share dividends, the Company shall give priority to cash dividends for profit distribution. Cash dividend policy is aimed at valuing the reasonable investment returns paid to the investors and benefiting the long-term development of the Company.

The Company may not to distribute profits when any of the following situations occurs: (I) the Company plans to or has actually made significant capital expenditure including but not limited to R&D investment, plant construction, etc.; (II) the Company has decided not to distribute profits after making a comprehensive judgement, taking into consideration of its own profit and financial conditions, operations, capital expenditures, subsequent development needs and other factors deemed relevant by the Company.

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The Company shall appoint receiving agents for the holders of overseas [REDACTED] shares in Hong Kong. The receiving agents shall receive on behalf of such Shareholders the dividends declared and all other payments payable by the Company in respect of their overseas listed shares and make payment to such Shareholders. The appointment of receiving agents by the Company shall be in compliance with the securities regulatory rules of the place where the Shares of the Company are listed, as well as the relevant regulations of the stock exchange. The receiving agents appointed for the holders of overseas [REDACTED] shares in Hong Kong shall be a company registered as a trust company under the Trustee Ordinance of Hong Kong.

PROXY

Any Shareholder entitled to attend and vote at the general meeting shall be entitled to attend the meeting in person, or appoint one or more other persons (who may not be Shareholders) as his/her proxy to attend and vote on his/her behalf. If a proxy has been appointed to attend the meeting, the appointer shall be deemed to be present in person at the meeting.

Individual Shareholders attending the meeting in person shall present their identity cards or any other valid certificates or documents or stock account cards for identification. Proxies attending the meeting shall present their personal identity cards and the power of attorney from the Shareholder.

Institutional Shareholders shall attend the meeting by their legal representatives (principals) or their proxies. If the legal representative (principal) attends the meeting, he or she shall produce his/her own ID card and a valid proof of his or her legal representative (principal) status. If a proxy has been appointed to attend the meeting, such a proxy shall produce his/her own ID cards and the power of attorney issued by the legal representative (principal) of institutional Shareholder according to law (except for recognised clearing house or its nominee) or a proxy form signed for its duly authorised proxy. If a proxy has been appointed by the institutional Shareholder to attend the meeting, such Shareholder shall be deemed to be present in person at the meeting.

Where a Shareholder who appoints proxy is a recognised clearing house (or its nominee) as defined by the relevant provisions in Hong Kong that come into effect from time to time, it may authorise corporate representative(s) or one or more persons as it deems fit to act as its proxy(ies) or representative(s) at any general meeting or meeting of creditors, provided that, if more than one person are authorised, the letter of authorization or power of attorney shall specify the number and class of Shares in respect of which each person is authorised, and shall be signed by an authorised officer of the recognised clearing house. The person so authorised may attend the meeting and exercise the statutory rights (including the right to speak and vote) equal to that of other Shareholders on behalf of the recognised clearing house (or its nominees) without presenting evidence of their shareholding, notarised authorization and/or further evidence of their duly authorization or producing letter of authorization signed by the appointor or its legal representative, as if such person were an individual Shareholder of the Company.

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The power of attorney issued by a Shareholder to appoint another person to attend a general meeting shall contain the following information: (I) the name of the proxy; (II) whether the proxy has the right to vote; (III) matters and authority for which the proxy is to act; (IV) instructions to vote for, against or abstain from voting on each matter to be considered on the agenda of the general meeting, respectively; (V) the date of issuance and expiration date of the power of attorney; and (VI) the signature (or seal) of the appointer or its agent authorised in writing. If the appointer is an institutional Shareholder, the seal of the institutional Shareholder or the signature of its directors, duly authorised agent or officer shall be affixed. If the securities regulatory rules of the place where the Shares of the Company are listed have specific provisions on power of attorney, such provisions shall prevail.

If the power of attorney for voting by proxy is signed by another person authorised by the appointer, the authorization letter or other document authorizing the signatory shall be notarised. The notarised authorization letter or other authorization document together with the power of attorney for proxy voting shall be deposited at domicile of the Company or such other place as specified in the notice of the meeting at least 24 hours prior to the meeting where such proxy is required to be voted, or 24 hours before the time appointed for the taking of the poll.

CALLS ON SHARES AND FORFEITURE OF SHARES

There is no provision for calls on Shares and forfeiture of Shares under the Articles of Association.

INSPECTION OF REGISTER

The Company shall make a register of Shareholders based on the vouchers provided by securities registries. The register of Shareholders shall be the sufficient evidence proving the Shareholders' holding of the Company's Shares. The Shareholders enjoy rights and assume obligations as per the Shares they hold; the same class of Shares represents the same rights and the same obligations.

Shareholders of the Company are entitled to inspect and copy the register of Shareholders. Where the securities regulatory rules of the place where the Shares of the Company are listed have any other provisions, such provisions shall prevail.

The Company shall make a complete duplicate of the register of members and meeting minutes of Shareholders' meeting available for free inspection by Shareholders at the Company's Hong Kong address as required by the Hong Kong Listing Rules, but the Company may close the register on terms equivalent to the Companies Ordinance (Chapter 632 of the Laws of Hong Kong). Where Shareholders request for inspection of the relevant information or demand for materials mentioned above, they shall provide with the Company written documents evidencing the class and number of Shares of the Company held by them. The Company shall verify the identity of the Shareholders and provide information requested by such Shareholders. If laws, administrative regulations or relevant provisions of the securities regulatory authorities of the place where the Company's shares are listed otherwise provide for Shareholders' access to and duplication of relevant materials, such provisions shall prevail.

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QUORUM FOR SHAREHOLDERS' GENERAL MEETING AND CLASS MEETING

There is no provision for quorum for general meeting and class meeting under the Articles of Association.

RIGHTS OF MINORITY SHAREHOLDERS IN RELATION TO FRAUD OR OPPRESSION

If Directors and senior management personnel cause losses to the Company for violation of the requirements of laws, administrative regulations or the Articles of Association during the performance of their duties, Shareholders who hold more than 1%, individually or jointly, of the Company's Shares for more than 180 days continuously, may request the Supervisory Committee in written form to file a suit in the People's Court; if the Supervisors cause losses to the Company for violation of the requirements of laws, administrative regulations or the Articles of Association during the performance of their duties, aforementioned Shareholders can request the Board in written form to file a suit in the People's Court. If the Supervisory Committee or the Board causes irreparable losses to the Company's interests as it refuses to file a suit after receiving the written request from Shareholders as set out in the preceding sentence, or fails to file a suit within 30 days since the date of receiving the request, or does not file a suit immediately in case of emergency, the Shareholders as mentioned in the preceding sentence have the right to bring a suit directly to the People's Court in their own name for the interests of the Company. If others infringe on the legitimate rights and interests of the Company and cause losses to it, the Shareholders who hold more than 1%, individually or jointly, of the Company's Shares for more than 180 days continuously can bring a suit to the People's Court as per the regulations as set out in the two preceding sentences.

In the event of a Director or senior management violates the laws, administrative regulations or the Articles of Association, thereby damaging the interest of Shareholders, Shareholders may file an action in the People's Court.

When any Shareholder of the Company abuses the Shareholders' rights and incurs losses to the Company or other Shareholders, such Shareholder shall be liable for the damages. Where Shareholders of the Company abuse the status of the Company as an independent legal entity and the limited liability of Shareholders for the purposes of evading debts, thereby materially impairing the interests of the creditors of the Company, such Shareholders shall be jointly and severally liable for the debts owed by the Company; If the Company's shareholders use two or more companies they control to commit the aforementioned acts, each company shall bear joint and several liability for the debts of any company.

The controlling Shareholders, actual controllers, Directors, Supervisors and senior management of the Company shall not take advantage of the related relationship to damage the interest of the Company; any losses caused to the Company as a result of such violation shall be compensated.

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The controlling Shareholders and actual controllers of the Company are obliged to act in good faith to the Company and the public Shareholders of the Company. The controlling Shareholders shall exercise their rights as capital contributors in strict accordance with the law. The controlling Shareholders shall not impair the lawful rights and interest of the Company and the public Shareholders by means of the distribution of profits, reorganization of assets, external investment, misappropriation of assets, loan, or guarantee, nor make use of their controlling position to impair the interests of the Company or the public Shareholders.

PROCEDURES ON LIQUIDATION

The Company shall be dissolved for any of the following reasons: (I) the expiration of the business period or other reasons for dissolution specified in the Articles of Association; (II) the general meeting adopts a resolution to dissolve the Company; (III) dissolution is required due to the merger or division of the Company; (IV) the Company's business license is revoked, or it is ordered to close down or wind up in accordance with laws; (V) where the Company gets into serious trouble in operation and management and its continuation may cause substantial losses to the interests of Shareholders, and no solution can be found through any other channel, Shareholders holding more than 10% of the voting rights of the Company may request the People's Court to dissolve the Company. If the Company has any grounds for dissolution specified in the preceding paragraph, it shall publicize the grounds for dissolution within ten days.

If the Company is dissolved under the circumstances (I), (II), (IV) and (V) of preceding paragraph, the Company shall be liquidated. Directors, as liquidation obligors, shall establish a liquidation group within 15 days from the date of the cause of dissolution occurred to carry out the liquidation. The liquidation committee shall consist of Directors, unless it is otherwise provided for in the Articles of Association or another person is elected by resolution of the Shareholders' general meeting. The Company shall be liquidated in accordance with the provisions of the Articles of Association. In case no such committee is established within the required timeframe or such committee does not carry out liquidation after the establishment, the interested person may make an application to the People's Court for appointing relevant persons to form the liquidation committee for liquidation. The People's Court shall accept the application and promptly organize a liquidation committee for liquidation.

Where the Company is liquidated pursuant to the provisions of (4) above, the department or company registration authority that makes the decision to revoke its business license, order its closure or revocation may apply to the People's Court to appoint relevant personnel to form a liquidation committee for liquidation.

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The liquidation group shall perform the following duties during the liquidation: (I) to check the assets of the Company and prepare a balance sheet and a checklist of assets; (II) to notify the creditors by notice or announcement; (III) to deal with the outstanding affairs of the Company in connection with liquidation; (IV) to settle outstanding taxes and taxes arising in the course of liquidation; (V) to settle all creditors' rights and debts; (VI) to allocate the residual assets of the Company after the settlement of debts; and (VII) to represent the Company in any civil proceedings.

The liquidation group shall notify the creditors within 10 days from the date of the establishment and publish an announcement within 60 days of its establishment. The creditors shall report their claims to the liquidation group within 30 days after receiving the notice, or within 45 days from the date of the announcement if they do not receive the notice. Creditors declaring their creditors' rights shall state the relevant information relating to the creditors' rights and provide supporting materials. The liquidation team shall register the creditors' rights. The liquidation group shall not repay any debts of the Company during the period for declaration of creditors' rights.

After sorting the Company's assets and preparing the balance sheet and checklist of assets, the liquidation group shall prepare a liquidation plan and submit the plan to the general meeting or the People's Court for confirmation.

The remaining assets of the Company after payment of liquidation expenses, wages, social insurance contribution, statutory compensation, taxes and debts of the Company shall be distributed to Shareholders according to the proportions of their shareholdings.

During the liquidation period, the Company shall continue to exist but shall not engage in any operation activities not relating to liquidation. The Company's assets shall not be distributed to the Shareholders before repayment of the Company's debts in full in accordance with the preceding paragraph.

After checking the assets of the Company and preparing the balance sheet and checklist of assets, if the liquidation group discovers that the Company does not have sufficient assets to settle its debts, the liquidation group shall apply to the People's Court for bankruptcy liquidation. After the People's Court accepts the bankruptcy petition, the liquidating group shall hand over the liquidating matters to the bankruptcy administrator designated by the People's Court.

Upon the completion of the liquidation, the liquidation group shall prepare a liquidation report, report it to the general meeting or the People's Court for confirmation and submit it to the company registration authority to apply for deregistration of the Company and announce the termination of the Company.

Where the Company is declared bankrupt according to laws, the Company shall implement bankruptcy liquidation according to laws relating to bankruptcy of enterprises.

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OTHER PROVISIONS MATERIAL TO THE COMPANY OR ITS SHAREHOLDERS

General Provisions

The Company is a joint stock company with perpetual existence.

All assets of the Company shall be divided into equal Shares. The Shareholders’ liabilities to the Company are limited to the Shares subscribed by them. The liabilities of the Company to the Company’s debts shall only be limited to all its property.

The Articles of Association shall become a legally binding document governing the organization and conduct of the Company, and the rights and obligations between the Company and its Shareholders and among Shareholders since its effective date, and shall constitute a legally binding document governing on the Company, its Shareholders, Directors, Supervisors, senior management members. According to the Articles of Association, Shareholders may sue other Shareholders, Directors, Supervisors, the general manager and other senior management of the Company and the Company. The Company may sue Shareholders, Directors, Supervisors, the general manager and other senior management.

Shares

Issuance of Shares

The capital of the Company is divided into Shares. The Shares of the Company shall be in the form of share certificates. The share certificates of the Company shall be in registered form. In addition to the information required by the Company Law, the information to be set out in the share certificates of the Company shall also include other information required by the stock exchange where the Shares of the Company are listed.

The Company shall issue shares under the open, fair and just principles, and each share of the same class shall carry the same rights.

All Shares issued by the Company shall be denominated in RMB, with each Share having an equal par value.

Increase and Reduction of Shares

Capital Increase

In accordance with the laws and regulations, the Company may increase the registered capital by the following ways upon approval by resolutions of the general meeting according to the operation and development needs of the Company: (I) public offering of shares; (II) non-public offering of shares; (III) offering of bonus shares to existing Shareholders; (IV) capitalization of provident fund into share capital; (V) other form specified in laws, administrative regulations and approved by relevant securities regulatory authorities such as the securities regulatory authority of the place where the Company’s Shares are listed.

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If the Company is to increase its capital by an offering of new Shares, it shall do so by the procedure provided for in relevant state laws, administrative regulations and the securities regulatory rules of the place where the Shares of the Company are listed after such increase has been approved in accordance with the Articles of Association.

Capital Reduction

The Company may reduce its registered capital. The reduction in the registered capital shall be made in accordance with the procedures set out in the Company Law, other related provisions and the Articles of Association.

A company which reduces its registered capital shall formulate a balance sheet and a checklist of assets. The Company shall notify the creditors within 10 days upon the passing of the resolution about the reduction in the registered capital and publish an announcement within 30 days. The creditors shall be entitled to require the Company to pay off the debts or to provide corresponding security within 30 days of the receipt of the notice, or within 45 days upon the date of the announcement if they do not receive the notice.

The registered capital of the Company after the capital reduction shall not be lower than the statutory minimum level required by laws. Where a company reduces its registered capital, its shares shall be reduced in proportion to the proportion of shares held by its shareholders, unless it is otherwise provided for by laws or the articles of association of the company.

Rights and Obligations of Shareholders

Shareholders of the Company shall have the following rights: (I) the rights to receive dividends and other forms of distribution in proportion to the number of Shares held by them; (II) the rights to request, convene, chair, attend or appoint proxy to attend general meetings and exercise corresponding voting rights in accordance with laws; (III) the rights to supervise the operation of the Company and to put forward proposals and raise inquiries; (IV) the rights to transfer, donate, or pledge Shares held by them in accordance with laws, administrative regulations, relevant regulations of the securities regulatory rules of the place where the Shares of the Company are listed and the Articles of Association; (V) to inspect and copy the Articles of Association, register of members, record of bondholders, minutes of general meetings, resolutions of meetings of the Board, resolutions of meetings of the Supervisory Committee and financial reports. Where the securities regulatory rules of the place where the Shares of the Company are listed have any other provisions, such provisions shall prevail. The Company shall make a complete duplicate of the register of members and meeting minutes of Shareholders' meeting available for free inspection by Shareholders at the Company's Hong Kong address as required by the Hong Kong Listing Rules, but the Company may close the register on terms equivalent to the Companies Ordinance (Chapter 632 of the Laws of Hong Kong); (VI) to participate in the distribution of the residual assets of the Company in proportion to their shareholdings in the event of the termination or liquidation of the Company; (VII) to request the Company to purchase their Shares for the Shareholders who object to the resolution on merger or division made by the general meetings; and (VIII) to enjoy other rights stipulated by laws, administrative regulations, departmental rules, securities regulatory rules of the place where the Shares of the Company are listed or the Articles of Association. A company shall regularly disclose to its shareholders the information on the remuneration received by its directors, supervisors and senior management from the company.

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Shareholders of the Company shall have the following obligations: (I) to comply with laws, administrative regulations, the securities regulatory rules of the place where the Shares of the Company are listed and the Articles of Association, exercise Shareholders' rights in accordance with laws, administrative regulations, securities regulatory rules of the place where the Shares of the Company are listed, and the Articles of Association; (II) to pay subscription monies according to the number of Shares subscribed and the method of subscription; (III) not to withdraw the Shares unless required by laws and regulations; (IV) not to abuse their Shareholders' rights to jeopardize the interests of the Company or other Shareholders.

When any Shareholder of the Company abuses the Shareholders' rights and incurs losses to the Company or other Shareholders, such Shareholder shall be liable for the damages; (V) not to abuse the status of the Company as an independent legal entity and the limited liability of Shareholders for the purposes of evading debts, thereby jeopardizing the interests of any creditors of the Company; where Shareholders of the Company abuse the status of the Company as an independent legal entity and the limited liability of Shareholders for the purposes of evading debts, thereby materially impairing the interests of the creditors of the Company, such Shareholders shall be jointly and severally liable for the debts owed by the Company; where a Shareholder of the Company uses two or more companies controlled by him/her to commit the foregoing acts, all companies shall be jointly and severally liable for the debts owed by any company; (VI) other obligations imposed by the laws, administrative regulations, the regulatory rules of the place where the Shares of the Company are listed and the Articles of Association.

Directors and the Board

Board

The Company shall have the Board, which shall be accountable to the Shareholders' general meeting.

The Board shall exercise the following powers: (1) to convene Shareholders' general meeting and report on its work to the Shareholders' general meeting; (2) to implement the resolutions of the Shareholders' general meeting; (3) to decide on our Company's operational plans and investment proposals; (4) to formulate proposals for our Company's annual financial budgets and final accounts; (5) to formulate our Company's profit distribution proposals and loss recovery proposals; (6) to formulate proposals for the increase or reduction of registered capital, issue of bonds or other securities and listing of our Company; (7) to formulate proposals for material acquisition, repurchase of our Company's Shares or merger, division, dissolution and change of corporate form of our Company; (8) to decide on external investment, acquisition or disposal of assets, assets security, external guarantee, entrusted wealth management, connected transactions and external donations of our Company within the scope authorised by the Shareholders' general meeting and in accordance with the securities regulatory rules of the place where the Company's shares are listed; (9) to decide on the setup of our Company's internal management organs; (10) to decide on appointment or dismissal of our Company's general manager, secretary of the Board and other senior management, and to

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decide on their remuneration, rewards and punishments; to decide on appointment or dismissal of our Company’s deputy general manager, Chief Financial Officer and other senior management based on the general manager’s recommendation, and to decide on their remuneration, rewards and punishments; (11) to formulate our Company’s basic management system; (12) to formulate proposals for amendment to the Articles of Association; (13) to manage Company’s information disclosure; (14) to propose to hire or replace an accounting firm auditing for the Company to the Shareholders’ general meeting; (15) to listen to the work report of the general manager of the Company and check the work of the general manager; (16) to formulate and review the corporate governance policies and practices of the Company; (17) to review and monitor the training and continuous professional development of Directors and senior management; (18) to review and monitor the Company’s policies and practices on compliance with legal and regulatory requirements; (19) to formulate, review and monitor the code of conduct and compliance manual (if any) applicable to employees and Directors; (20) to review the Company’s compliance with the Corporate Governance Code under the Hong Kong Listing Rules and disclosure in the Corporate Governance Report; (21) other powers as provided by laws, administrative regulations, departmental rules, securities regulatory rules of the place where the shares of the Company are listed and the Articles of Association or permitted by the Shareholders’ general meeting.

Matters which are beyond authorization of the Shareholders’ general meeting shall be submitted to the Shareholders’ general meeting for consideration.

Meetings of the Board 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. If the relevant laws, administrative regulations or the Articles of Association of the Company provide otherwise, such provisions shall prevail.

Directors’ Responsibilities

Directors shall comply with the laws, administrative regulations and the Articles of Association, and shall fulfill faithful obligations to the Company as follows: (1) not to abuse his/her position to accept bribes or other illegal income or misappropriate the properties of the Company; (2) not to misappropriate the funds of the Company; (3) not to set up accounts in his/her own name or in the name of any other person for the purpose of depositing any of the assets or funds of the Company; (4) not to lend funds of the Company to any other person or use the property of the Company to provide guarantee for any other person without the consent of the Shareholders’ general meeting or the Board in contravention of the provisions of the Articles of Association; (5) not to enter into contracts or conduct transactions with the Company directly or indirectly without a report on matters relating to the conclusion of such contracts or transactions to the Board or the Shareholders’ meeting, which has been approved by the Board or the Shareholders’ meeting in accordance with the provisions of the Articles of Association; (6) not to abuse his/her position to seize business opportunities for himself/herself or for other persons which should otherwise belong to the Company, except under any of the following circumstances: (1) reported to the Board or the shareholders’ meeting, and approved by the Board or the Shareholders’ meeting in accordance with the provisions of the Articles of

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Association; (2) the Company cannot take advantage of business opportunities according to the laws, administrative regulations, the regulatory rules of the place where the Shares of the Company are listed and the Articles of Association; (7) not to operate a business similar to that of the Company on his or her own or for others without reporting to the Board or the Shareholders' Meeting and approved by the Board or the shareholders' meeting in accordance with the Articles of Association; (8) not to misappropriate commissions derived from transactions entered into by the Company and other parties; (9) not to disclose confidential information of the Company without authorization; (10) not to damage the interests of the Company by taking advantage of his/her connections with the Company; and (11) other faithful obligations as required by the laws, administrative regulations, departmental rules, the regulatory rules of the place where the Shares of the Company are listed and the Articles of Association. Income gained by Directors in violation of this provision shall belong to the Company; if any losses are caused to the Company thereby, Directors shall bear the appropriate liabilities for damages. Directors shall take measures to avoid conflicts between their own interests and those of the Company, and shall not use their powers to seek improper benefits.

Directors shall, in accordance with applicable laws, administrative regulations and the Articles of Association, perform their duties with all the reasonable care normally expected of a manager in the best interests of the Company, and perform the following responsibilities of diligence to the Company that they: (1) shall exercise the rights conferred by the Company with due discretion, care and diligence to ensure the business operations of the Company comply with the state's laws, administrative regulations and economic policies, not going beyond the scope of business specified in the Company's business license; (2) shall treat all Shareholders fairly; (3) shall stay abreast of the operations and management of businesses of the Company; (4) shall provide signatory confirmation for the periodic reports of the Company and ensure that the information disclosed by the Company is true, accurate, and complete; (5) shall truthfully provide relevant information and data to the Supervisory Committee, and shall not obstruct the Supervisory Committee or Supervisors from performing their duties; (6) shall perform other responsibilities of diligence stipulated by laws, administrative regulations, departmental rules, securities regulatory rules of the place where the shares of the Company are listed and the Articles of Association.

On a Director's resignation becoming effective or expiration of the tenure of his/her office, the Director shall complete all handover procedures, and his/her faithful obligations to the Company and the Shareholders shall not cease immediately after the termination of tenure and are still effective within one year after the termination of tenure. His/her obligation to keep the Company's business secrets (including core technologies, etc.) confidential will remain valid after the termination of tenure until the business secrets become public information, and he/she shall not use the Company's business secrets in his/her possession to engage in business that is the same as or similar to that of the Company. The duration of other faithful obligations shall be determined based on the principle of fairness, taking into account factors such as the nature of the matter, its importance to the Company, the time of its impact on the Company, and the relationship with the Director.

APPENDIX III

SUMMARY OF ARTICLES OF ASSOCIATION

Directors shall ensure that he/she has sufficient time and energy to participate in the affairs of the Company, and prudently assesses the risks and benefits that may arise from matters concerned.

Director who contravenes any laws, administrative regulations, departmental rules or the Articles of Association in the performance of his/her duties resulting in any loss to the Company shall be liable to the Company for compensation. If a Director causes damage to others in the performance of his duties, the Company shall be liable for compensation; if a Director commits intentional or gross negligence, the Company shall also be liable for compensation.

Directors shall safeguard the interests of the Company and all Shareholders, and shall not prejudice the interests of the Company for the interest of beneficial controllers, Shareholders, employees, himself/herself or other third parties. Directors shall actively promote the regulated operation of the Company, supervise Company to fulfill information disclosure obligation, timely rectify and report the irregularities of the Company and support the Company to fulfil its social responsibilities. Directors shall keep Company's business secrets, and shall not disclose material information that has not yet been made public or use inside information to obtain unlawful benefits. Directors shall focus on matters such as the operating condition of the Company and timely report relevant issues and risks to the Board, and shall not claim exemption from liability on the grounds that they are not familiar with the Company's business or do not understand the relevant matters.

Independent non-executive Directors

The Company has independent non-executive Directors and the issues including conditions of appointment, nomination and election procedures, tenure of office, resignation and power of the independent non-executive Directors are implemented in accordance with the relevant provisions of the laws, administrative regulations, departmental rules, securities regulatory rules of the place where the shares of the Company are listed and relevant authorities such as securities regulatory authorities of the place where the shares of the Company are listed.

The Board shall consist of nine Directors and shall have one chairman. At all times, at least one-third of the members of the Board shall be independent non-executive Directors, and the total number of independent non-executive Directors shall be not less than three, at least one of whom shall have appropriate accounting or related financial management expertise or appropriate professional qualifications in line with regulatory requirements.

Independent non-executive Directors shall faithfully perform their duties and safeguard the interests of the Company, with particular attention to ensuring that the legitimate rights and interests of public Shareholders are not jeopardized, so as to ensure that the interests of all Shareholders are adequately represented.

APPENDIX III

SUMMARY OF ARTICLES OF ASSOCIATION

Board Secretary

The Company shall have a secretary to the Board, who is responsible for the preparation of Shareholders' general meeting and meetings of the Board, the keeping of documentation as well as the management of Shareholders' information, handling the matters relating to information disclosure and other matters. The secretary to the Board shall comply with relevant provisions of laws, administrative regulations, departmental rules and securities regulatory rules of the place where the Company's shares are listed and the Articles of Association.

Supervisory Committee

The Company shall have a Supervisory Committee. The Supervisory Committee shall consist of three Supervisors and shall have one chairman. The chairman of the Supervisory Committee shall be elected by more than half of all Supervisors.

The Supervisory Committee shall consist of Shareholder representatives and an appropriate proportion of the Company's employee representatives and the percentage of employee representatives shall not be less than one-third. The employee representatives of the Supervisory Committee shall be elected by employees of the Company at the employee representatives' meeting, the employee meeting or otherwise democratically.

The Supervisory Committee shall exercise the following powers: (1) to review the regular reports of the Company prepared by the Board and to execute written confirmation opinions; (2) to examine the financial affairs of the Company; (3) to supervise the Directors and senior management in their performance of their duties and to propose the dismissal of Directors and senior management who have violated laws, administrative regulations, the Articles of Association or the resolutions of the Shareholders' general meetings; (4) to demand rectification from a Director or senior management when the acts of such persons are detrimental to the interests of the Company; (5) to propose the convening of extraordinary general meetings and to summon and preside over Shareholders' general meetings when the Board fails to perform the duty of summoning and presiding over Shareholders' general meetings under the Company Law and Articles of Association; (6) to submit proposals to the Shareholders' general meeting; (7) to initiate proceedings against Directors and senior management in accordance with the provisions of Article 189 of the Company Law; (8) to investigate any irregularities identified in the operation of the Company and, when necessary, to engage professional institutions such as accounting firms and law firms to assist its work at the expense of the Company; and (9) to exercise other powers provided by laws, administrative regulations, departmental rules, and the Articles of Association.

Resolutions of the Supervisory Committee shall be passed by more than half of all Supervisors.

APPENDIX III

SUMMARY OF ARTICLES OF ASSOCIATION

General Manager and Other Senior Management

The Company shall have one general manager who shall be appointed or dismissed by the Board. The Company shall have several deputy general managers, who shall be appointed or dismissed by the Board. The general manager, deputy general managers (appointed according to the needs of the Company), the secretary to the Board and the Chief Financial Officer of the Company are senior management of the Company.

The general manager shall be accountable to the Board and exercise the following powers according to the provisions of the Articles of Association and the authorization of the Board: (1) to be in charge of the production, operation and management of the Company, organize the implementation of the resolutions of the Board and report to the Board; (2) to organize the implementation of the Company's annual business plan and investment plan; (3) to draft plans for the establishment of the Company's internal management bodies; (4) to draft the basic management system of the Company; (5) to formulate the specific rules and regulations of the Company; (6) to propose to the Board to appoint or dismiss deputy general managers, Chief Financial Officer and other senior management of the Company; (7) to appoint or dismiss management personnel other than those required to be appointed or dismissed by the Board; and (8) to exercise other powers conferred by the Articles of Association or the Board.

The general manager is to attend Board meetings.

In accordance with the provisions of laws, administrative regulations and the Articles of Association, the general manager is responsible for making decisions on matters not considered and decided by the Shareholders' general meeting and the Board of the Company. The Company's daily operation matters are decided by the general manager.

The deputy general manager and Chief Financial Officer shall be nominated by the general manager and appointed and dismissed by the Board. The general manager shall submit the detailed information of the candidates to the Board when nominating the deputy general manager and Chief Financial Officer. The deputy general manager and Chief Financial Officer are responsible to the general manager and carry out their work under the unified leadership of the general manager. Their powers are reasonably determined by the general manager's office meeting.

Senior Management who contravenes any laws, administrative regulations, departmental rules or the Articles of Association in the performance of his/her duties resulting in any loss to the Company shall be liable to the Company for compensation. If a senior manager causes damage to others in the performance of his duties, the Company shall be liable for compensation; if a senior manager commits intentional or gross negligence, the Company shall also be liable for compensation.

The senior management of the Company shall faithfully perform his/her duties and safeguard the best interests of the Company and all Shareholders. The senior management of the Company shall be liable for compensation in accordance with the law if he/she has caused damage to the interests of the Company and the public Shareholders due to their failure of performing their duties faithfully or the breach of their fiduciary duties.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

FURTHER INFORMATION ABOUT OUR COMPANY

Establishment of our Company

Our Company was established as a limited liability company in the PRC on May 13, 2008 and was converted into a joint stock limited company with limited liability on December 30, 2020 under the laws of the PRC. As of the Latest Practicable Date, the registered share capital of our Company is RMB366,672,032.

Our Company has established a place of business in Hong Kong at 46/F, Hopewell Centre, 183 Queen’s Road East, Wanchai, Hong Kong and has been registered as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance on January 26, 2024. Ms. Yuen Mui CHAN (陳婉梅), one of our joint company secretaries, has been appointed as the authorized representative in Hong Kong and our agent for the acceptance of service of process in Hong Kong whose correspondence address is the same as our place of business in Hong Kong.

As we are established in the PRC, our corporate structure and Articles of Association are subject to the relevant laws and regulations of the PRC. A summary of the relevant provisions of our Articles of Association is set out in “Summary of Articles of Association” in Appendix III. A summary of certain relevant aspects of the laws and regulations of the PRC is set out in “Regulatory Overview — Overview of Laws and Regulations in the PRC”.

Changes in Share Capital of Our Company

Save as disclosed in the section headed “History, Development and Corporate Structure — Corporate Development and Major Shareholding Changes” and “History, Development and Corporate Structure — [REDACTED] Investments”, there has been no other alteration in the share capital of our Company during the two years immediately preceding the date of this Document.

Changes in Share Capital of Our Subsidiaries

A summary of the corporate information and the particulars of our subsidiaries are set out in the Accountants’ Report in Appendix I.

On January 21, 2025, PegBio Suzhou was established with an registered capital of RMB1,000,000.

There had been no other alterations of share capital of our subsidiaries within the two years preceding the date of this Document.

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Resolutions of our Shareholders

Pursuant to a general meeting held on February 14, 2024, among other things, our Shareholders resolved that:

- (a) the issuance by our Company of the H Shares of nominal value of RMB1.00 each and such H Shares being [REDACTED] on the Hong Kong Stock Exchange;
- (b) the number of H Shares to be issued shall not be more than 25% of the total issued share capital of our Company as enlarged by the [REDACTED];
- (c) subject to our obtaining the formal written authorization from the relevant Shareholders and the completion of filing procedure with the CSRC, upon completion of the [REDACTED], [REDACTED] Unlisted Shares in aggregate will be converted into H Shares on a one-for-one basis;
- (d) subject to the completion of the [REDACTED], the conditional adoption of the Articles of Association which shall become effective on the [REDACTED], and authorization to the Board to amend the Articles of Association in accordance with the requirements of the relevant laws and regulations and the Listing Rules;
- (e) authorization of the Board to handle matters relating to, among other things, the [REDACTED], the issue and [REDACTED] of the H Shares;
- (f) subject to the completion of the [REDACTED], the granting of a general mandate to the Board to repurchase H Shares issued on the Stock Exchange at any time within a period commencing from the [REDACTED] and up to the date of the conclusion of the next annual general meeting of the Shareholders to be held after the [REDACTED] or the date on which the Shareholders pass a resolution to revoke or change such mandate, whichever is earlier, upon such terms and conditions and for such purposes as the Board in their absolute discretion deem fit, and to make necessary amendments to the Articles of Association, provided that, the number of Shares to be repurchased shall not exceed 10% of the number of the total issued H Shares as at the [REDACTED];
- (g) 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 to be held after the [REDACTED] or the date on which the Shareholders pass a resolution to revoke or change such mandate, whichever is earlier, upon such terms and conditions and for such purposes as the Board in their absolute discretion deem fit, and to make necessary amendments to the Articles of Association, provided that, the number of Shares to be issued shall not exceed 20% of the number of the Shares in issue as at the [REDACTED]; and

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- (h) subject to the completion of the [REDACTED], the conditional adoption of the Articles of Association, which shall become effective on the [REDACTED] and the authorization of the Board to amend the Articles of Association in accordance with relevant laws and regulations and upon the request from the Stock Exchange and relevant PRC regulatory authorities.

Explanatory Statement on Repurchase of Our Own Securities

The following paragraphs include, among others, certain information required by the Stock Exchange to be included in this Document concerning the repurchase of our own securities.

(a) Reasons for repurchase

The Board considered that the repurchase of the Shares would be beneficial to and in the best interests of the Company and its Shareholders as a whole. It can strengthen the [REDACTED] confidence in the Company and promote a positive effect on maintaining the Company’s reputation in the capital market. Such repurchases will only be made when the Board believes that such repurchases will benefit the Company and its Shareholder as a whole.

(b) Exercise of the general mandate to repurchase Shares

Subject to the passing of the special resolution approving the grant of the general mandate to repurchase Shares at annual general meetings, the Board will be granted general mandate to repurchase Shares until the end of the relevant period. The general mandate to repurchase Shares would expire on the earlier of:

- (i) the conclusion of the next annual general meeting of the Company to be held after the [REDACTED] of which time it shall lapse unless, by special resolutions passed at that meeting, the authority is renewed, either conditionally or subject to conditions; or
- (ii) the revocation or variation of the mandate under the resolution by a special resolution at any general meeting of the Company.

Furthermore, we need to complete registration and approval procedures with relevant government authorities for the actual grant of the repurchase mandate to the Board, as applicable. The exercise in full of the general mandate to repurchase H Shares (on the basis of [REDACTED] H Shares in issue as of the [REDACTED] and no H Shares will be allotted and issued or repurchased by the Company on or prior to the date of the next annual general meeting to be held after the [REDACTED]) would result in a maximum of [REDACTED] H Shares being repurchased by the Company during the relevant period, being the maximum of 10% of the H Shares in issue as of the [REDACTED].

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(c) Source of funds

In repurchasing its Shares, the Company intends to apply funds from the Company’s internal resources (which may include surplus funds and retained profits) legally available for such purpose in accordance with the Articles of Association and the applicable laws, rules and regulations of the PRC.

The Company is empowered by its Articles of Association to repurchase its Shares. Any shares to be repurchased will be cancelled or kept as treasury shares if allowed by the Articles of Association and applicable laws and regulations. The Company may not purchase securities on the Stock Exchange for a consideration other than cash or for settlement otherwise than in accordance with the [REDACTED] rules of the Stock Exchange from time to time.

(d) Suspension of repurchase

A [REDACTED] company shall not repurchase its shares on the Stock Exchange at any time after inside information has come to its knowledge until the information is made publicly available. In particular, during the period of one month immediately preceding the earlier of: (i) the date of the board meeting (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of the company’s results for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules); and (ii) the deadline for the issuer to announce its results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules), until the date of the results announcement, the company may not repurchase its shares on the Stock Exchange unless there are exceptional circumstances.

(e) Close associates and core connected persons

None of our Directors or, to the best of their knowledge having made all reasonable inquiries, any of their close associates have a present intention, in the event the general mandate to repurchase Shares is approved, to sell any Shares to our Company.

No core connected person of our Company has notified our Company that they have a present intention to sell Shares to our Company, or have undertaken to do so, if the general mandate to repurchase Shares is approved.

A [REDACTED] company shall not knowingly purchase its shares on the Stock Exchange from a core connected person (namely a director, supervisor, chief executive or substantial shareholder of the company or any of its subsidiaries, or a close associate of any of them), and a core connected person shall not knowingly sell their interest in shares of the company to it.

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(f) Status of repurchased Shares

Any shares to be repurchased will be cancelled or kept as treasury shares, subject to the Articles of Association, the Listing Rules and any other applicable laws and regulations.

(g) Takeover implications

If, as a result of any repurchase of Shares, a Shareholder’s proportionate interest in the voting rights of our Company increases, such increase will be treated as an acquisition for the purposes of the Takeovers Code. Accordingly, a Shareholder or a group of Shareholders acting in concert could obtain or consolidate control of our Company and become obliged to make a mandatory offer in accordance with Rule 26 of the Takeovers Code.

Save as aforesaid, our Directors are not aware of any consequences which would arise under the Takeovers Code as a consequence of any repurchases pursuant to the general mandate to repurchase Shares.

(h) General

If the general mandate to repurchase Shares were to be carried out in full at any time, there may be a material and adverse impact on our working capital or gearing position (as compared with the position disclosed in our most recent published audited accounts). However, our Directors do not propose to exercise the general mandate to repurchase Shares to such an extent as would have a material and adverse effect on our working capital or gearing position.

Our Directors have undertaken to the Stock Exchange that they will exercise the general mandate to repurchase Shares in accordance with the Listing Rules and the applicable laws in the PRC.

FURTHER INFORMATION ABOUT OUR BUSINESS

Summary of Material Contract

We have entered into the following contract (not being contracts entered into in the ordinary course of business) within the two years immediately preceding the date of this Document that is or may be material:

(a) [REDACTED].

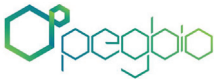
Intellectual Property Rights

As of the Latest Practicable Date, our Group has registered, or has applied for the registration of the following intellectual property rights which were material to our Group’s business.

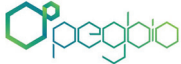
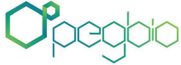
APPENDIX IV STATUTORY AND GENERAL INFORMATION

Trademarks

As of the Latest Practicable Date, we have registered the following trademarks which we consider to be or may be material to our business:

No.	Trademark	Registration Number	Owner	Date of Registration	Place of Registration
1. . . .	派达康	71951082	The Company	November 21, 2023	PRC
2. . . .	派格生医	60665224	The Company	August 21, 2022	PRC
3. . . .	派格生医	60662640	The Company	November 14, 2023	PRC
4. . . .	派格生科	60656788	The Company	July 21, 2022	PRC
5. . . .	派格生科	60655118	The Company	July 21, 2022	PRC
6. . . .	派格生科	60649441	The Company	November 14, 2023	PRC
7. . . .	派格生医	60646531	The Company	August 14, 2022	PRC
8. . . .	派达通	56570489	The Company	December 21, 2021	PRC
9. . . .	派达灵	56561698	The Company	December 14, 2021	PRC
10. . .	派达多	56560743	The Company	December 14, 2021	PRC
11. . .	派达康	56539185	The Company	December 14, 2021	PRC
12. . .	HECTOR	54387339	The Company	October 14, 2021	PRC
13. . .		54205404	The Company	October 28, 2021	PRC
14. . .	派格	54204549	The Company	October 7, 2021	PRC
15. . .	派格聚诺	54202204	The Company	October 7, 2021	PRC
16. . .	PEGBIO	54200024	The Company	October 7, 2021	PRC
17. . .	PEGBIO	54199210	The Company	November 7, 2022	PRC
18. . .	PEGBIO	54199183	The Company	October 7, 2021	PRC
19. . .		54199131	The Company	October 28, 2021	PRC

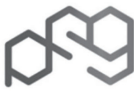
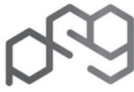
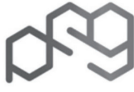
APPENDIX IV STATUTORY AND GENERAL INFORMATION

No.	Trademark	Registration Number	Owner	Date of Registration	Place of Registration
20...	PEGBIO	54198785	The Company	January 21, 2022	PRC
21...	PEGBIO	54198653	The Company	October 7, 2021	PRC
22...	派格	54198648	The Company	October 7, 2021	PRC
23...		54197239	The Company	February 14, 2022	PRC
24...	PEGBIO	54197229	The Company	December 28, 2021	PRC
25...	派格聚诺	54195215	The Company	October 7, 2021	PRC
26...	派格	54194553	The Company	October 7, 2021	PRC
27...		54194167	The Company	November 7, 2022	PRC
28...	派格聚诺	54192492	The Company	October 7, 2021	PRC
29...	派格聚诺	54190941	The Company	October 7, 2021	PRC
30...	PEGBIO	54190142	The Company	October 7, 2021	PRC
31...		54188505	The Company	October 28, 2021	PRC
32...		54187578	The Company	October 21, 2021	PRC
33...	PEGBIO	54186873	The Company	October 7, 2021	PRC
34...	派格聚诺	54176583	The Company	October 7, 2021	PRC
35...		54173814	The Company	October 21, 2021	PRC
36...	派达净	72382905	The Company	January 7, 2024	PRC
37...	派达静	72391973	The Company	January 7, 2024	PRC
38...	派达美	72387986	The Company	January 7, 2024	PRC
39...	派达平	72370651	The Company	January 7, 2024	PRC
40...	派达舒	72386471	The Company	January 7, 2024	PRC
41...	派达泰	72382848	The Company	January 7, 2024	PRC

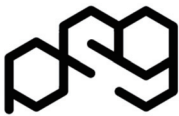
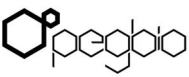
APPENDIX IV STATUTORY AND GENERAL INFORMATION

No.	Trademark	Registration Number	Owner	Date of Registration	Place of Registration
42. . .	派达欣	72392890	The Company	January 7, 2024	PRC
43. . .	派达新	72379247	The Company	January 7, 2024	PRC
44. . .	派格达	72374594	The Company	January 7, 2024	PRC
45. . .	派格静	72379756	The Company	January 7, 2024	PRC
46. . .	派全泰	72363293	The Company	January 7, 2024	PRC
47. . .	派格宁	72371796	The Company	January 7, 2024	PRC
48. . .	派格泰	72386502	The Company	January 7, 2024	PRC
49. . .	派格欣	72394779	The Company	January 7, 2024	PRC
50. . .	派格优	72394903	The Company	January 7, 2024	PRC
51. . .	派各安	72385997	The Company	January 7, 2024	PRC
52. . .	派各达	72371807	The Company	January 7, 2024	PRC
53. . .	派各静	72377931	The Company	January 7, 2024	PRC
54. . .	派各康	72370171	The Company	January 7, 2024	PRC
55. . .	派各宁	72386026	The Company	January 7, 2024	PRC
56. . .	派各平	72383596	The Company	January 7, 2024	PRC
57. . .	派各泰	72394964	The Company	January 7, 2024	PRC
58. . .	派各欣	72378423	The Company	January 7, 2024	PRC
59. . .	派各优	72379822	The Company	January 7, 2024	PRC
60. . .	派全安	72392662	The Company	January 7, 2024	PRC
61. . .	派全达	72392249	The Company	January 7, 2024	PRC
62. . .	派全静	72392173	The Company	January 7, 2024	PRC
63. . .	派全宁	72384479	The Company	January 7, 2024	PRC

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No.	Trademark	Registration Number	Owner	Date of Registration	Place of Registration
64. . .	派全平	72376256	The Company	January 7, 2024	PRC
65. . .	派各泰	72380943	The Company	January 7, 2024	PRC
66. . .	派全欣	72367656	The Company	January 7, 2024	PRC
67. . .	派全优	72367786	The Company	January 7, 2024	PRC
68. . .	派锐达	72384916	The Company	January 7, 2024	PRC
69. . .	派唐安	72382825	The Company	January 7, 2024	PRC
70. . .	派唐净	72389785	The Company	January 7, 2024	PRC
71. . .	派易安	72376592	The Company	January 7, 2024	PRC
72. . .	派易达	72381092	The Company	January 7, 2024	PRC
73. . .	派易静	72385171	The Company	January 7, 2024	PRC
74. . .	派易平	72391302	The Company	January 7, 2024	PRC
75. . .	派易泰	72378445	The Company	January 7, 2024	PRC
76. . .	派易欣	72376574	The Company	January 7, 2024	PRC
77. . .	派易优	72380985	The Company	January 7, 2024	PRC
78. . .		73536297	The Company	February 21, 2024	PRC
79. . .		73540990	The Company	February 21, 2024	PRC
80. . .		73536075	The Company	February 21, 2024	PRC
81. . .		73521843A	The Company	March 14, 2024	PRC
82. . .		73536100	The Company	February 21, 2024	PRC

APPENDIX IV STATUTORY AND GENERAL INFORMATION

No.	Trademark	Registration Number	Owner	Date of Registration	Place of Registration
83 ..		73527896	The Company	February 21, 2024	PRC
84 ..		73536123	The Company	February 21, 2024	PRC
85 ..		73526824	The Company	February 21, 2024	PRC
86 ..		73530264	The Company	February 21, 2024	PRC
87 ..		73526048	The Company	February 21, 2024	PRC
88 ..	PEGCREAT	76035154	The Company	June 21, 2024	PRC
89 ..	PEGCREATX	76025906	The Company	June 21, 2024	PRC
90 ..	PEG-X	76025914	The Company	June 21, 2024	PRC
91 ..	PEIGNITE	76017926	The Company	July 7, 2024	PRC
92 ..	PEIGNITEX	76011596	The Company	July 7, 2024	PRC
93 ..	(A) 	306435081	The Company	December 22, 2023	Hong Kong
	(B) 				
94 ..	(A) 	306435090	The Company	December 22, 2023	Hong Kong
	(B) 				

APPENDIX IV STATUTORY AND GENERAL INFORMATION

Patents

For material patents and patent applications of our Group as of the Latest Practicable Date, see paragraph headed “Business — Intellectual Property” for more details.

Copyrights

As of the Latest Practicable Date, we have the following copyrights which we consider to be or may be material to our Group’s business:

No.	Copyright Name	Registration Number	Registered Owner	Place of Registration
1. . . .	Enterprise LOGO of “Pegbio” (“派格生物”企業LOGO)	國作登字-2022-F-10197269	The Company	PRC

Domain Names

As of the Latest Practicable Date, we have registered the following internet domain names which we consider to be or may be material to our business:

No.	Domain Name	Registered Owner	Registration Date	Expiry Date
1. . . .	pegbio.com	the Company	May 26, 2008	May 26, 2028

Save as the above, as of the Latest Practicable Date, there were no other intellectual property rights which were material to our business.

FURTHER INFORMATION ABOUT OUR DIRECTORS, SUPERVISORS, SENIOR MANAGEMENT AND SUBSTANTIAL SHAREHOLDERS

Interests and short positions of our Directors, Supervisors and chief executive of our Company in the Shares, underlying Shares and debentures of our Company and our associated corporations

Save as disclosed in the section headed “Substantial Shareholders” and below, immediately following the completion of the [REDACTED], so far as our Directors are aware, none of our Directors, Supervisors and chief executive has any interests and short positions in our Shares, underlying Shares or debentures of our Company or any of our associated corporations (within the meaning of Part XV of the SFO) (i) which will have to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions in which they are taken or deemed to have under such provisions of the SFO), or (ii) which will be required, pursuant to section 352 of the SFO, to be entered

APPENDIX IV STATUTORY AND GENERAL INFORMATION

in the register referred to therein, or (iii) which will be required to be notified to us and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers contained in the Listing Rules:

Name	Capacity/Nature of interest	Number of Shares ⁽¹⁾	Approximate percentage of shareholding in the Unlisted Shares/ H Shares immediately after completion of the [REDACTED] ⁽²⁾	Approximate percentage of shareholding in the total Share capital immediately after completion of the [REDACTED] ⁽²⁾
Dr. Michael Min XU ⁽³⁾	Beneficial owner	[REDACTED]	[REDACTED]%	[REDACTED]%
		[REDACTED]	[REDACTED]%	[REDACTED]%
	Interest in controlled corporation	[REDACTED]	[REDACTED]%	[REDACTED]%
Ms. Xiaojun WANG (王小軍) ⁽³⁾	Interest in controlled corporation	[REDACTED]	[REDACTED]%	[REDACTED]%
Dr. Xiangjun ZHOU	Beneficial owner	[REDACTED]	[REDACTED]%	[REDACTED]%
Dr. Yuhong XU (徐宇虹)	Beneficial owner	[REDACTED]	[REDACTED]%	[REDACTED]%

Notes:

1. The letter “L” denotes the person’s long position in the Shares.
2. The calculation is based on the total number of [REDACTED] Unlisted Shares and [REDACTED] H Shares in issue immediately after completion of the [REDACTED] since [REDACTED] Unlisted Shares will be converted into H Shares and [REDACTED] H Shares will be issued pursuant to the [REDACTED].
3. Shanghai Sujie was established in the PRC as a limited partnership, of which Ms. Xiaojun WANG (王小軍) is acting as the sole general partner, and Dr. Michael Min XU owns approximately 93.10% interest as a limited partner as of the Latest Practicable Date. As such, Ms. Xiaojun WANG (王小軍) and Dr. Michael Min XU are deemed to be interested in the Shares held by Shanghai Sujie under the SFO.

Interests of the substantial shareholders in the Shares

Save as disclosed in “Substantial Shareholders”, immediately following the completion of the [REDACTED], our Directors are not aware of any other person (not being a Director, Supervisor or chief executive of our Company) who will have an interest or short position in our Shares or the underlying Shares which would fall to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or who is, directly or indirectly, interested in 10% or more of the issued voting shares of our Company.

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Interests of the substantial shareholders in other members of our Group

So far as the Directors are aware, the following persons (other than our Company, and any subsidiaries of our Group) are entitled to exercise, or control the exercise of, 10% or more of voting power at the general meetings of other members of our Group:

Name of the subsidiary	Name of the shareholder	Percentage of interest in the subsidiary
Shanghai Hanmai	Beijing Agile Way Consulting Co., Ltd. (北京敏捷之道諮詢有限公司) (the “Beijing Agile”) ⁽¹⁾	15.38%
	Mei HE ⁽²⁾	11.38%
Shanghai Maiji	Beijing Agile ⁽¹⁾	15.38%
	Mei HE ⁽²⁾	11.38%

Notes:

- (1) To the best knowledge of our Directors, Beijing Agile is controlled by Mr. Jian CHEN (陳儉) and is an Independent Third Party.
- (2) To the best knowledge of our Directors, Mei HE is the general manager of Shanghai Hanmai and Shanghai Maiji, which are insignificant subsidiaries of the Company.

Particulars of Directors’ and Supervisors’ Service Contracts

Each of the Directors and Supervisors [has] entered into a service contract or a letter of appointment with our Company.

Save as disclosed above, we have not entered into, and do not propose to enter into any service contracts with any of our Directors or Supervisors in their respective capacities as Directors or Supervisors (excluding agreements expiring or determinable by any member of our Group within one year without payment of compensation other than statutory compensation).

Remuneration of Directors and Supervisors

Save as disclosed in “Directors, Supervisors and Senior Management” and Note 7 to the Accountants’ Report set out in Appendix I for the two financial years ended December 31, 2023 and 2024, none of our Directors or Supervisors received other remunerations of benefits in kind from us.

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Disclaimers

Save as disclosed in this Document:

- (a) none of our Directors, Supervisors or our chief executive has any interest or short position in our Shares, underlying Shares or debentures of our Company or any of our associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO, or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required to be notified to us and the Stock Exchange pursuant to Model Code for Securities Transactions by Directors of Listed Issuers once the H Shares are [REDACTED] on the Stock Exchange;
- (b) none of our Directors or Supervisors is aware of any person (not being a Director, Supervisor or chief executive of our Company) who will, immediately following the completion of the [REDACTED] and the conversion of Unlisted Shares into H Shares, have an interest or short position in our Shares or underlying Shares which would fall to be disclosed to us under the provisions of Divisions 2 and 3 of Part XV of the SFO or who is interested, directly or indirectly, in 10% or more of the issued voting shares of any member of our Group;
- (c) none of our Directors, their respective close associates (as defined under the Listing Rules) or Shareholders who own more than 5% of the number of issued shares of our Company have any interests in the five largest suppliers of our Group, and all of our five largest suppliers in each year/period during the Track Record Period are Independent Third Parties; and
- (d) none of our Directors, Supervisors or any of the parties listed in “Qualifications of Experts” in this Appendix is:
 - i. interested in our promotion, or in any assets which have been, within two years immediately preceding the date of this Document, acquired or disposed of by or leased to us, or are proposed to be acquired or disposed of by or leased to any member of our Group; or
 - ii. materially interested in any contract or arrangement subsisting at the date of this Document which is significant in relation to our business.

[REDACTED] EQUITY INCENTIVE PLAN

The following is a summary of the principle terms of the [REDACTED] Equity Incentive Plan, which was adopted by the Company on March 27, 2021 and took effect on the adoption date, as amended from time to time. The [REDACTED] Equity Incentive Plan does not involve the grant of new Shares or awards by the Company after the [REDACTED].

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Purpose

The main purpose of the [REDACTED] Equity Incentive Plan is to improve the incentive mechanism of the Group, further enhance the work enthusiasm and creativity of the participants thereto (the “**Eligible Participants**”), promote the continued growth of the performance of the Group, and bring economic benefits to the Eligible Participants while enhancing the value of the Group, so as to realize the common development of the Eligible Participants and the Group.

Eligible Participants

The Eligible Participants include employees of the Group who have contributed to the development of the Group, and other participants recommended by the chairman of the Board and determined by the Board in compliance with laws, regulations, regulatory rules, the Articles of Association and the rules of the [REDACTED] Equity Incentive Plan.

Administration

The Board shall act as the scheme administrator of the [REDACTED] Equity Incentive Plan, and shall be responsible for, among others,

- setting and adjusting the conditions for granting awards;
- obtaining the list of proposed grantees recommended by the chairman of the Board and proposed number of awards, and conducting assessment for the proposed grantees;
- determining the identities of the grantees and the corresponding amount of awards to be granted;
- arranging execution of the grant agreements, the partnership agreements of the Equity Incentive Platform and other relevant documents;
- maintaining a grantee list for internal record;
- determining the transferees, methods and prices for the transfer of or withdrawal from holding the partnership interests of the Equity Incentive Platform held by the grantees in accordance with the laws and regulations and the [REDACTED] Equity Incentive Plan;
- interpreting and amending the [REDACTED] Equity Incentive Plan; and
- other matters that the Board shall be responsible for under the [REDACTED] Equity Incentive Plan.

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The voting rights attached to the Shares in the Company held by the Equity Incentive Platform underlying the awards, all of which have been granted and vested as of the Latest Practicable Date, reside with the general partner of the Equity Incentive Platform.

Form of Awards under the [REDACTED] Equity Incentive Plan

The grantees shall subscribe for partnership interests of the Equity Incentive Platform as partners according to the amount of awards granted under the [REDACTED] Equity Incentive Plan as approved by the Board, and make the corresponding capital contributions in accordance with the arrangements of the Board, thereby holding indirect interests in the Shares.

Total Number of the Shares underlying the Awards

Grantees are indirectly interested in a total of 29,175,230 Shares, representing approximately 7.96% of the share capital of our Company as of the Latest Practicable Date, through holding partnership interests in our Equity Incentive Platform.

As of the Latest Practicable Date, all awards, corresponding to a total of 29,175,230 Shares, have been granted and vested under the [REDACTED] Equity Incentive Plan, and no further awards will be granted thereunder after the [REDACTED].

Term

The [REDACTED] Equity Incentive Plan shall take effective from the date of being approved at the Shareholders’ general meeting. The Board is authorized to review and approve the implementation, amendment and termination of the [REDACTED] Equity Incentive Plan.

Grant of Awards

The Board shall determine the grantees and the allocation of awards after considering, among others, the Company’s operating conditions, and the Eligible Participant’s performance appraisal, position, time in office, length of service, remuneration in the particular position, the value of services provided and the contribution to the Group. The chairman of the Board is responsible for informing the grantees and the Company to execute the grant agreements.

Grantees must subscribe for the partnership interests of our Equity Incentive Platform in cash, and should ensure that their source of funds is genuine and lawful. All contribution payments shall be made fully and timely.

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Transfer Restrictions

Prior to the [REDACTED] of the Company, except as otherwise stipulated in the [REDACTED] Equity Incentive Plan, the grantees shall not directly or indirectly dispose the partnership interests held in our Equity Incentive Platform, including but not limited to, transferring such partnership interests to any third party, requesting the Equity Incentive Platform to repurchase such partnership interests, placing any encumbrances (such as pledges) on such partnership interests, conducting any transactions with such partnership interests as the consideration or means of payment (such as debt settlement, capital contribution, exchange).

Save as otherwise allowed in the [REDACTED] Equity Incentive Plan, the grantees shall not dispose any of the partnership interests held in our Equity Incentive Platform within 12 months following the date of [REDACTED] of the Company, and shall not directly or indirectly transfer any of the partnership interests held in our Equity Incentive Platform without the prior written consent of the chairman of the Board (the “**Awards Lock-up Period**”).

In addition, save as otherwise allowed in the [REDACTED] Equity Incentive Plan and with the written consent of the chairman of the Board, the grantees shall not reduce or transfer any of the partnership interests held in our Equity Incentive Platform, or directly or indirectly dispose any of the partnership interests held in our Equity Incentive Platform, until his awards are released. The dividend distribution by our Equity Incentive Platform to the grantees shall be decided by the general partner of our Equity Incentive Platform, and the grantees have no right to distributions of our Equity Incentive Platform for their unreleased awards. The awards granted under the [REDACTED] Equity Incentive Plan shall be released as follows upon the confirmation of the chairman of the Board:

- 100% of the total number of awards granted to a grantee who has served or been employed by the Group for more than 5 years (inclusive) shall be released on the grant date;
- 80% of the total number of awards granted to a grantee who has served or been employed by the Group for more than 4 years (inclusive) but less than 5 years shall be released on the grant date, and the remaining awards shall be released on the date when the performance targets set to such grantee (the “**Performance Targets**”) are appraised and deemed as being satisfied in the second year;
- 60% of the total number of awards granted to a grantee who has served or been employed by the Group for more than 3 years (inclusive) but less than 4 years shall be released on the grant date, and the remaining awards shall be released on the dates when the Performance Targets are appraised and deemed as being satisfied in the subsequent years (with 20% released each year);

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- 40% of the total number of awards granted to a grantee who has served or been employed by the Group for more than 2 years (inclusive) but less than 3 years shall be released on the grant date, and the remaining awards shall be released on the dates when the Performance Targets are appraised and deemed as being satisfied in the subsequent years (with 20% released each year);
- 20% of the total number of awards granted to a grantee who has served or been employed by the Group for more than 1 year (inclusive) but less than 2 years shall be released on the grant date, and the remaining awards shall be released on the dates when the Performance Targets are appraised and deemed as being satisfied in the subsequent years (with 20% released each year);
- the awards granted to a grantee who has served or been employed by the Group for less than 1 year shall be released on the dates when the Performance Targets are appraised and deemed as being satisfied in the subsequent years (with 20% released each year); and
- if the Performance Targets are not satisfied in certain year, the corresponding proportion of the awards may be released on the date when the Performance Targets are appraised and deemed as being satisfied in the next year.

The Performance Targets shall be determined by the Board in consultation with the employees of the Company at the beginning of each assessment period taking into account among others: (i) work progress, satisfaction of business counterparts and other targets which ought to be reached by the respective grantee during the relevant period, (ii) accuracy and timeliness with which the grantee ought to complete his work and the sufficiency of his use of resources during the relevant period, (iii) the grantee’s protectiveness, team work, and contribution to team goals during the relevant period, and (iv) the grantee’s growth during the relevant period, taking into account of the training participated in, self-improvement efforts made, and improvements in skills achieved.

Clawback Mechanism

If the Performance Targets are not satisfied in the consequent two years, the partnership interests in our Equity Incentive Platform underlying the unreleased awards shall be transferred to the chairman of the Board or the party designated by the chairman of the Board, or repurchased by the Equity Incentive Platform, at the price that the grantee paid for subscription of such partnership interests (“**Clawed Back**”).

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In case of the termination of the grantee’s employment or service with the Group due to the grantee’s unilateral termination of employment or service with the Group or refusal to renewal such employment or service relationship with adverse impact on the company, incompetency for work, seriously violation of the relevant rules and regulations of the Group, unsatisfactory performance during the probation period, violation of the agreements with the Group, causation of direct or indirect, material and reputational losses to the Group or the Equity Incentive Platform due to intentional or gross negligence, being suspected of a crime and investigated or held criminally responsible by the judicial authorities, establishing labor relations with other employers without the Group’s consent or other behaviors that conflict with interests of the Group, or fault entitling the Group to terminate his labor relationship in accordance with the Labor Contract Law and other laws and regulations (the “**Causes**”): (i) the awards of the grantee shall be Clawed Back in case of any Cause before the [REDACTED] of the Company or during the Awards Lock-up Period, (ii) the unreleased awards of the grantee shall be Clawed Back, whereas the released awards shall be sold (“**Disposed**”) to the chairman of the Board or the party designated by the chairman of the Board or our Equity Incentive Platform at the average closing price of the Shares in the twenty (20) [REDACTED] days before the signing of the transfer agreement in case of any Cause after the Awards Lock-up Period.

In case of termination of employment or service with the Group due to the grantee’s retirement, death or declared death or missing according to law, being unable to perform his duty due to incapability, injury or sickness, becoming a person without capacity for civil conduct or with limited capacity for civil conduct, consensus with the Group on such termination, being terminated of the labor/service relationship with the Group which is not attributable to the grantee, or other circumstances determined by the Board (the “**Incidents**”): (i) the awards of the grantee shall be Clawed Back in case of any Incident before the [REDACTED] of the Company, (ii) the unreleased awards shall be Clawed Back, whereas the released awards could be kept with the approval of the chairman of the Board, in case of any Incident after the [REDACTED] of the Company but during the Awards Lock-up Period, (iii) the unreleased awards shall be Clawed Back, whereas the released awards shall be Disposed, in case of any Incident after the Awards Lock-up Period.

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Details of the Grantees

As of the Latest Practicable Date, the awards corresponding to a total of 29,175,230 Shares, representing approximately 7.96% of our total issued Shares, have been granted to a total of 21 Eligible Participants under the [REDACTED] Equity Incentive Plan. As of the Latest Practicable Date, all partnership interests in the Equity Incentive Platform have been subscribed by and fully paid up by the grantees. As of the Latest Practicable Date, the relevant registrations [had] been completed. The details of the awards are set out below:

Name	Position	Approximate partnership interests in Shanghai Sujie as of the Latest Practicable Date	Approximate number of Shares corresponding to awards granted to the grantees ⁽¹⁾	Approximate shareholding percentage corresponding to awards in the total number of Shares immediately prior to the [REDACTED] ⁽²⁾
Directors				
Dr. Michael Min XU	Chairman of the Board, executive Director and general manager	93.10%	27,161,458	[REDACTED]%
Ms. Xiaojun WANG (王小軍).	Executive Director and chief financial officer	3.11%	907,252	[REDACTED]%
Subtotal of Directors		96.21%	28,068,710	[REDACTED]%
Supervisor				
Ms. Mengjiao WANG (王夢嬌).	Chairlady of the Supervisory Committee, and the employee representative Supervisor	0.06%	16,046	[REDACTED]%
Senior Management (other than Directors)				
Mr. Yifeng HUANG (黃一峰).	Secretary of Board and joint company secretary	0.41%	120,007	[REDACTED]%
Other Grantees				
17 employees	–	3.33%	970,465	[REDACTED]%
Total		100.00%	29,175,230	[REDACTED]%

Notes:

- (1) For illustrating the indirect interests of grantees in the Shares, the number of Shares are presented and calculated by multiplying their respective percentage of partnership interests in Shanghai Sujie by the total number of Shares held by Shanghai Sujie.
- (2) All the Unlisted Shares held by Shanghai Sujie will be converted into H Shares, subject to the relevant regulatory approvals and registration.

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As no further awards will be granted after the date of this Document and the 29,175,230 Shares corresponding to the awards granted under the [REDACTED] Equity Incentive Plan have been issued to the Equity Incentive Platform as of the date of this Document, the [REDACTED] Equity Incentive Plan will not cause any dilution of the shareholding of our Shareholders after the [REDACTED].

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 under the laws of the PRC.

Litigation

As of the Latest Practicable Date, we were not engaged in any litigation, arbitration or claim of material importance and no litigation, arbitration or claim of material importance was known to our Directors to be pending or threatened by or against any member of our Group, that would have a material and adverse effect on our Group’s results of operations or financial conditions, taken as a whole.

Preliminary Expenses

As of the Latest Practicable Date, our Company has not incurred any material preliminary expenses.

Promoter

The promoters of the Company are all of the 49 then Shareholders as of December 30, 2020 immediately before our conversion into a joint stock limited liability company. Within the two years immediately preceding the date of this Document, no cash, securities or other benefit has been paid, allotted or given or is proposed to be paid, allotted or given to the promoters in connection with the [REDACTED] and the related transactions described in this Document.

Taxation of Holders of H Shares

The sale, purchase and transfer of H Shares registered with our Hong Kong branch register of members will be subject to Hong Kong stamp duty. The current rate charged on each of the purchaser and seller is 0.1% of the consideration of or, if higher, of the fair value of our Shares being sold or transferred.

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No Material Adverse Change

Our Directors confirm that up to the date of this Document, there has been no material adverse change in our financial, operational or trading positions or prospects since December 31, 2024, being the end of the period reported on as set out in the Accountants’ Report included in Appendix I to this Document.

Qualifications of Experts

The qualifications of the experts (as defined under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance) who have given their opinion and/or advice in this Document are as follows:

Name	Qualification
China International Capital Corporation Hong Kong Securities Limited	A corporation licensed 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) of the regulated activities as defined under the SFO
KPMG	Certified Public Accountants, and Public Interest Entity Auditor registered in accordance with the Accounting and Financial Reporting Council Ordinance
JunHe LLP	PRC legal adviser
China Insights Industry Consultancy Limited	Independent industry consultant

As of the Latest Practicable Date, none of the experts named above had any shareholding interest in our Company or any of our subsidiaries or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group.

Consents of Experts

Each of the experts as referred to “— Qualifications of Experts” in this Appendix has given and has not withdrawn their respective written consents to the issue of this Document with the inclusion of their reports and/or letters (as the case may be) and the references to their names included in the form and context in which they are respective included.

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Sole Sponsor’s Independence

Sole Sponsors satisfies the independence criteria applicable to the sponsor set out in Rule 3A.07 of the Listing Rules.

Pursuant to the engagement letter entered into between the Company and the Sole Sponsor, the Sole Sponsor’s fees payable by us to the Sole Sponsor in respect of its service as the sponsor in connection with the [REDACTED] on the Stock Exchange is [REDACTED].

Binding Effect

This Document shall have the effect, if an application is made in pursuance of it, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

Bilingual Document

The English and Chinese language versions of this Document are being published separately, in reliance upon the exemption provided under section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

Miscellaneous

Save as otherwise disclosed in this Document:

- (a) within the two years preceding the date of this Document: (i) we have not issued nor agreed to issue any share or loan capital fully or partly paid either for cash or for a consideration other than cash; and (ii) no [REDACTED], discounts, brokerage fee or other special terms have been granted in connection with the issue or sale of any shares of our Company;
- (b) no share or loan capital of our Company is under option or is agreed conditionally or unconditionally to be put under option;
- (c) we have not issued nor agreed to issue any founder shares, management shares or deferred shares;
- (d) there are no arrangements under which future dividends are waived or agreed to be waived;
- (e) there are no procedures for the exercise of any right of pre-emption or transferability of subscription rights;

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- (f) there are no contracts for hire or hire purchase of plant to or by us for a period of over one year which are substantial in relation to our business;
- (g) 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;
- (h) there are no restrictions affecting the remittance of profits or repatriation of capital by us into Hong Kong from outside Hong Kong;
- (i) no part of the equity or debt securities of our Company, if any, is currently [REDACTED] on or dealt in on any stock exchange or trading system, and no such [REDACTED] or permission to [REDACTED] on any stock exchange other than the Hong Kong Stock Exchange is currently being or agreed to be sought;
- (j) our Company has no outstanding convertible debt securities or debentures;
- (k) our Company is a joint stock limited company and is subject to the PRC Company Law; and
- (l) our Company has adopted a code of conduct regarding Directors’ and Supervisors’ securities transactions on terms as required under the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix C3 to the Hong Kong Listing Rules.

**APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES
IN HONG KONG AND AVAILABLE ON DISPLAY**

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG

The documents attached to a copy of this Document and delivered to the Registrar of Companies in Hong Kong for registration were:

- (a) a copy of the material contract referred to in “Appendix IV — Statutory and General Information — Further Information about our Business — Summary of Material Contract”; and
- (b) the written consents referred to in “Appendix IV — Statutory and General Information — Other Information — Consents of Experts”.

DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be published on the Stock Exchange’s website at www.hkexnews.hk and the Company’s website at <http://www.pegbio.com> during a period of 14 days from the date of this Document:

- (a) the Articles of Association;
- (b) the audited consolidated financial statements of our Group for the two years ended December 31, 2023 and 2024;
- (c) the Accountants’ Report from KPMG, the text of which is set out in Appendix I;
- (d) the report from KPMG on the unaudited [REDACTED] financial information of our Group, the text of which is set out in Appendix II;
- (e) the material contract referred to in “Appendix IV — Statutory and General Information — Further Information about our Business — Summary of Material Contract”;
- (f) the written consents referred to in “Appendix IV — Statutory and General Information — Other Information — Consents of Experts”;
- (g) the service contracts and letters of appointment referred to in “Appendix IV — Statutory and General Information — Further Information about our Directors, Supervisors, Senior Management and Substantial Shareholders — Particulars of Directors’ and Supervisors’ Service Contracts”;
- (h) the legal opinions issued by JunHe LLP, our PRC Legal Adviser, in respect of, among other things, the general corporate matters and property interests of our Group under the PRC law;

**APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES
IN HONG KONG AND AVAILABLE ON DISPLAY**

- (i) the industry report issued by China Insights Industry Consultancy Limited referred to in “Industry Overview”; and
- (j) a copy of the following PRC laws, together with unofficial English translations:
 - (i) the PRC Company Law;
 - (ii) the PRC Securities Law; and
 - (iii) the Overseas Listing Trial Measures.