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Application Proof of

B&K CORPORATION LIMITED*

華芒生物科技（青島）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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B&K CORPORATION LIMITED*

華芒生物科技（青島）股份有限公司

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

[REDACTED]

Number of [REDACTED] under the [REDACTED] : [REDACTED] H Shares (Subject to the [REDACTED])
Number of [REDACTED] : [REDACTED] H Shares (subject to [REDACTED])
Number of [REDACTED] : [REDACTED] H Shares (Subject to the [REDACTED] and [REDACTED])
[REDACTED] : Not more than HK\$[REDACTED] per H Share, plus brokerage of 1.0%, SFC transaction levy of 0.0027%, AFRC transaction levy of 0.00015%, and Hong Kong Stock Exchange trading fee of 0.00565% (payable in full on application in Hong Kong dollars and subject to refund)
Nominal value : RMB1.00 per H Share
[REDACTED] : [•]

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Prior to making an investment decision, prospective investors should carefully consider all of the information set out in this document, in particular, the risk factors set out in the section headed “Risk Factors.” Pursuant to the termination provisions contained in the [REDACTED] in respect of the [REDACTED], the [REDACTED], on behalf of the [REDACTED], have the right in certain circumstances, in their absolute discretion, to terminate the obligations of the [REDACTED] pursuant to the [REDACTED] at any time prior to 8:00 a.m. on the [REDACTED] Date. Further details of the terms of the termination provisions are set out in the section headed “[REDACTED]”

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IMPORTANT

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EXPECTED TIMETABLE

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EXPECTED TIMETABLE

[REDACTED]

EXPECTED TIMETABLE

[REDACTED]

EXPECTED TIMETABLE

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SUMMARY

This summary aims to give you an overview of the information contained in this document. As it is a summary, it does not contain all the information that may be important to you. You should read the whole document before you decide to invest in the [REDACTED]. There are risks associated with any investment. Some of the particular risks in investing in the [REDACTED] are set out in “Risk Factors” in this document. You should read that section carefully in full before you decide to invest in the [REDACTED]. 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 on the basis that we are unable to meet the requirements under Rule 8.05(1), (2) or (3) of the Listing Rules.

OVERVIEW

Founded in 2012, we are a China-based innovative biopharmaceutical company committed to developing breakthrough therapies with an emphasis on protein drugs for indications with unmet medical needs and large market opportunities. We primarily focus on the discovery, development and commercialization of multifunctional therapies for wound healing, currently platelet-derived growth factor (“PDGF”) drugs. Our Core Products, namely Pro-101-1 and Pro-101-2, are recombinant human platelet-derived growth factor-BB (“rhPDGF-BB”) drugs. Pro-101-1 is the most advanced PDGF drug candidate in terms of clinical development progress for the treatment of thermal burns in China, and has the potential to be the first commercialized PDGF product in China for this indication, according to the Frost & Sullivan report. Meanwhile, with respect to Pro-101-2, we are one of the leading biopharmaceutical companies with the potential to first achieve commercialization of PDGF drugs in diabetic foot ulcer (“DFUs”) in China, according to the same source. PDGF is one of the growth factors secreted by platelets after injury. It promotes the development of new blood vessels, regulation of inflammation, and stimulation of cell proliferation and migration, among other things, which eventually leads to wound closure and healing. PDGF drugs have been clinically used as growth factor therapeutic products in DFUs for more than 20 years mainly in the U.S. PDGF is the sole recombinant growth factor that has received approval from the FDA for topical use, specifically in treating DFUs. PDGF drugs have demonstrated notable efficacy with a favorable safety profile in treating DFUs across multiple clinical studies over the years. Meanwhile, as of the Latest Practicable Date, due to the high barriers in research and development and production of PDGF drugs, there were no PDGF drugs commercially available in China.

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

OUR PIPELINE

Our pipeline consisted of ten candidates with substantial market potential covering a wide range of indications, including two Core Products, namely Pro-101-1 and Pro-101-2, currently undergoing the Phase II & IIb clinical trials for two indications in China, respectively, as of the Latest Practicable Date. The following chart summarizes our pipeline and the development status of each pipeline candidate as of the same date:

SUMMARY

Candidate	Mechanism/Target	Indication	Form	Clinical Trial Region	Development Phase				Upcoming Milestone	Competent or Regulatory Authorities	Commercial Rights	Self-developed or Co-developed
					Pre-Clinical	Phase I	Phase II IIa	Phase II IIb				
★ Pro-101-1		Thermal burns	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	Expected to complete Phase IIb in 2025Q2 and initiate Phase III in 2025Q3	NMPA	Global	Self-developed
					U.S.	Phase I	Phase II IIa	Phase II IIb				
★ Pro-101-2		DFUs	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	Expected to complete Phase II in 2027Q2 and initiate Phase III in 2027Q3	NMPA	Global	Co-developed with the Institute of Biengineering of AMMS®
					China	Phase I	Phase II IIa	Phase II IIb				
Pro-101-3	PDGF receptor	Fresh wounds	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	Self-developed
		Pressure ulcers	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	
		Radiation ulcers	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	
		Photodermatitis	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2026	NMPA	Global	
		Alopecia	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2026	NMPA	Global	
		Hemorrhoids	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2026	NMPA	Global	
		Fresh wounds	Spray	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2028	NMPA	Global	
		Photodermatitis	Spray	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2028	NMPA	Global	
		Dry eye syndrome	Eye drops	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	
		Corneal injury	Eye drops	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	
Pro-104		Alopecia	Medical devices	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2029	NMPA	Global	Self-developed
					China	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2027			
Pro-105		Gastric ulcers	Oral	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2027	NMPA	Global	Self-developed
					China	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2027			
Mes-201 (mRNA)	TSA	Solid tumor	Injection	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2027	NMPA	Global	Self-developed
Oli-101 (ASO)	IneRNA	Brain glioma	Injection	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2028	NMPA	Global	Self-developed
Oli-201 (ASO)	IneRNA	TNBC	Injection	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2029	NMPA	Global	Self-developed

★ Core Products

SUMMARY

Notes:

1. Phase I clinical trial data of Pro-101-2 for the indication of DFUs are shared with indications of thermal burns and fresh wounds.
2. We submitted a pre-IND communication application to the FDA in December 2021 with respect to Pro-101-1 for thermal burns. In lieu of a meeting, the FDA provided written responses in February 2022. The FDA replied that whether the Phase I clinical trial of Pro-101-2 in the treatment of DFUs and our current nonclinical studies are sufficient to support the initiation of the US IND-opening trial will be determined after the FDA’s review of the complete initial IND submission, including the product quality and nonclinical components. The FDA also provided useful guidance on CMC process and the design of our Phase II clinical trial of Pro-101-1 in the treatment of thermal burns. As we are currently focusing on the development of Pro-101-1 in China, we expect to submit the IND filing to the FDA in the first quarter of 2026.
3. Even though the Phase II clinical trial of Pro-101-2 for DFUs began in February 2022, we expect to complete the same in the second quarter of 2027, mainly because we had made registration of new product specification and certain revision to the existing clinical trial protocol since we entered the Phase II clinical trial of Pro-101-2 in DFUs. We expect to initiate the patient enrollment process in the second quarter of 2024. In particular, the revision in the clinical trial protocol is mainly related to our intention to rely on the clinical evidence obtained from immunogenicity studies in the Phase IIa clinical trial of Pro-101-1 in thermal burns, as the enrollment process of thermal burn patients is faster than that of DFU patients. Such revision has been confirmed by the CDE in October 2023.
4. In December 2021, we submitted application materials for a pre-IND meeting with the CDE to discuss the IND application, the plan to directly conduct Phase Ib clinical trial based on the results of the Phase I clinical trial of Pro-101-2 in the treatment of DFUs and the design of the Phase Ib clinical trial. In lieu of a meeting, the CDE provided written responses in March 2022. The CDE provided useful guidance on the design of the Phase Ib clinical trial of Pro-101-3 in the treatment of fresh wounds and suggested that whether additional safety studies are necessary should depend on the mechanism of action (“MOA”), dosage, administration timing and systemic/local exposure of the result of Pro-101-2 in the treatment of DFUs. Meanwhile, as we believe conducting studies to evaluate the safety, tolerability, pharmacokinetics and immunogenicity of Pro-101-1 on thermal burn patients can render more representative results compared to subjects in other indications, we have decided to conduct the Phase IIa clinical trial of Pro-101-1 in thermal burns first. Then, depending on the actual results, we plan to share the relevant results of pharmacokinetics and immunogenicity of Pro-101-1 with clinical studies of Pro-101-3 in fresh wounds, and directly proceed with the Phase II clinical trial on the efficacy and safety of Pro-101-3 in fresh wounds. We have completed the Phase IIa clinical trial of Pro-101-1 in thermal burns in May 2023 and entered the Phase IIb clinical trial in December 2023. We plan to submit the IND application for Pro-101-3 in fresh wounds to the NMPA in the first quarter of 2025 based on the Phase IIa and Phase IIb clinical trial results of the Pro-101-1 in thermal burns and the Phase I clinical trial results of the Pro-101-2 in DFUs. We expect to directly initiate the Phase II clinical trial of Pro-101-3 in fresh wounds upon obtaining the IND approval from the NMPA.
5. Both the Company and the Institute of Bioengineering of AMMS are holders of the relevant patents. Nevertheless, according to its written confirmation dated October 8, 2023, the Institute of Bioengineering of AMMS acknowledged that the rights to own, commercialize and use such patents belong exclusively to the Company. We cooperated with the Institute of Bioengineering of AMMS in pre-clinical development of Pro-101-2 for DFUs, which we have independently researched and developed after the IND approval. For details on our arrangements with the Institute of Bioengineering of AMMS, see “Business — Collaboration, Licensing and Transfer Arrangements — Collaboration with the Institute of Bioengineering of AMMS and JinBang.”

SUMMARY

Core Products

Our Core Products comprise Pro-101-1 and Pro-101-2 which are PDGF candidates for the treatment of thermal burns and DFUs, respectively. The active substance of our Core Products is rhPDGF-BB, which is a form of PDGF-BB manufactured in laboratories using recombinant DNA technology and used for clinical treatments. We acquired the PDGF-related technology, patents and know-how in relation to the treatment of DFUs at a pre-clinical stage in 2013 and have been independently developing PDGF candidates for the treatment of other indications since then. As of the Latest Practicable Date, we had entered the Phase IIb clinical trial of Pro-101-1 in thermal burns and the Phase II clinical trial of Pro-101-2 in DFUs. We completed the Phase I clinical trial of Pro-101-2 in DFUs in October 2021 in China. As Pro-101-2 demonstrated a favorable safety and tolerability profile in the Phase I clinical trial in DFUs, we applied for NMPA approval to directly commence the Phase II clinical trial of Pro-101-1 in thermal burns based on such clinical results and received the approval in June 2022. We completed the Phase IIa clinical trial of Pro-101-1 in thermal burns in May 2023, and commenced the Phase IIb clinical trial in December 2023. For details of our Core Products, see “Business — Our Candidates — PDGF.”

Other Product Candidates

In addition to our Core Products, we are developing PDGF candidates for several other indications in multiple dosage forms, as well as one pre-clinical mRNA candidate and two pre-clinical ASO candidates in our pipeline. In particular, our PDGF candidates other than the Core Products are currently being developed for a broad spectrum of wound healing indications comprising fresh wounds, pressure ulcers, radiation ulcers, dry eye syndrome, corneal injury, photodermatitis, alopecia, hemorrhoids and gastric ulcers. Meanwhile, we are developing an mRNA candidate targeting solid tumors, and two ASO candidates targeting brain glioma and triple-negative breast cancer (“TNBC”). As of the Latest Practicable Date, we were intensively researching the continuous optimization of PDGF in application, developing new PDGF formulations and expanding PDGF indications. At the same time, we were conducting pre-clinical biological, cytological and pharmacological researches on mRNA and ASO molecules.

BUSINESS MODEL

Our business model primarily consists of pipeline candidate development. Our future success will substantially depend on the success of our pipeline candidate development business, comprising research and development and subsequent commercialization upon receipt of marketing authorization of our pipeline candidates. Under pipeline candidate development, we plan to employ a strategic marketing model to increase our market penetration, to promote our products

SUMMARY

and to achieve geographical and channel coverage. To complement our internal efforts, we may also collaborate with third parties on the clinical development, commercialization and marketing of our candidates to better capture market opportunities. See “Business — Commercialization.”

TECHNOLOGY PLATFORMS

We have established systematic and well-integrated biomolecular therapeutic drug development platforms, including a protein/polypeptide pharmaceutical platform and a nucleic acid pharmaceutical platform. Our protein/polypeptide pharmaceutical platform is fortified by a combination of innovative technologies, including eukaryotic expression technology, prokaryotic expression technology and recombinant DNA technology. Meanwhile, our nucleic acid pharmaceutical platform is underpinned by mRNA molecular design technology and LNP delivery technology. In particular, the protein/polypeptide pharmaceutical platform is integral to the advancement of our product portfolio, particularly that of our Core Products. Its capabilities in both prokaryotic and eukaryotic expression technologies have been instrumental in the creation and refinement of recombinant proteins and peptide drugs. For details of our technology platforms, see “Business — Research and Development — Our Research and Development Platforms.”

COMPETITION

There are currently no PDGF products in the China biopharmaceutical market. One of our Core Products, Pro-101-1, is the most advanced PDGF drug candidate in terms of clinical development progress for the treatment of thermal burns in China, and has the potential to be the first commercialized PDGF product in China for this indication, according to the Frost & Sullivan report. Meanwhile, with respect to the other Core Product, Pro-101-2, we are one of the leading biopharmaceutical companies with the potential to first achieve commercialization of PDGF drugs in DFUs in China, according to the same source. However, the pharmaceutical industry is highly competitive and subject to rapid and significant changes. While we believe that our strong research and development capability, integrated research and development platform and seasoned leadership team provide us with competitive advantages, we encounter competition from international and China-based biopharmaceutical companies and specialty pharmaceutical and biotechnology companies of various sizes, as well as academic institutions and research institutions. Any candidates that we successfully develop and commercialize will compete with existing drugs and products or any new drugs or products that may become available in the future.

SUMMARY

According to the Frost & Sullivan report, there were three PDGF drug pipelines in China as of the Latest Practicable Date, comprising one pipeline focusing on the treatment of skin ulceration of lower extremity in chronic diabetes, especially DFUs, one pipeline focusing on the treatment of DFUs and one pipeline focusing on the treatment of thermal burns. As of the same date, no PDGF drugs had been approved in China. All of the PDGF pipelines are based on the isoform of PDGF-BB. The PDGF-BB drug candidate of Tasly Pharmaceutical entered Phase III clinical trial in 2014 and as of the Latest Practicable Date, there had been no further update in relation to the status of Tasly Pharmaceutical’s drug pipeline. The other two PDGF-BB pipelines belong to us, which have entered Phase II clinical trial in February 2022 for DFUs and Phase IIb clinical trial for thermal burns in December 2023, respectively. According to the Frost & Sullivan report, one of our Company’s Core Products, Pro-101-1, is the most advanced PDGF drug candidate in terms of clinical development progress for the treatment of thermal burns in China, and has the potential to be the first commercialized PDGF product in China for this indication.

OUR STRENGTHS

We believe the following competitive strengths have contributed to our success and distinguished us from our competitors: (i) leading innovative biopharmaceutical company of PDGF drugs in China in a vast wound healing market of blue ocean opportunities with a significantly unmet medical need; (ii) strong competitive edge achieved in PDGF drugs via breakthroughs of multi-dimensional barriers in research and development and production; (iii) favorable clinical data of our Core Products demonstrating satisfactory efficacy and safety profiles based on years of research in PDGF drugs, which can enhance the certainty of commercialization of such candidates; (iv) capabilities to continually develop new products of significance, as bolstered by a distinguished research and development team and well-established methodical technology platforms encompassing core areas such as protein/polypeptide and mRNA; and (v) seasoned management team and strong support from Shareholders. For details, see “Business — Our Strengths.”

OUR STRATEGIES

We plan to pursue the following opportunities and execute our key strategies accordingly: (i) continually advance the research and development of our Core Products to reach commercialization; (ii) rapidly establish production and commercialization systems of Core Products and well-rounded comprehensive capabilities encompassing research, manufacture and sales; (iii) further enhance our research and development capabilities and collaborations, and continually upgrade and launch product pipelines of huge potential leveraging our core technology platforms; and (iv) continue to explore potential business development opportunities overseas, deepen international development strategy and reinforce global partnerships. For details, see “Business — Our Strategies.”

SUMMARY

RESEARCH AND DEVELOPMENT

We focus on utilizing our systematic and well-integrated biomacromolecule therapeutic drug development platforms to develop innovative biopharmaceutical drugs for a wide variety of diseases, including thermal burns, DFUs, pressure ulcers, hemorrhoids, photodermatitis, radiation ulcers, fresh wounds, gastric ulcers, dry eye syndrome, corneal injury and alopecia. We believe research and development is critical to our future growth and our ability to remain competitive in the global biopharmaceutical market. We are dedicated to building an innovative product pipeline with a focus on PDGF- and RNA-based therapeutics by leveraging our in-house research and development capabilities, which span internal discovery, CMC, pre-clinical and clinical development.

We incurred research and development expenses of approximately RMB34.8 million and RMB39.9 million in 2022 and 2023, respectively, accounting for 44.1% and 48.7%, respectively, of our total operating expenses in the same years. We incurred research and development expenses of RMB26.8 million and RMB33.3 million attributable to our Core Products in 2022 and 2023, respectively, accounting for 33.9% and 40.6% of our total operating expenses in the same years, respectively. For details, see “Business — Research and Development.”

INTELLECTUAL PROPERTY

We have a comprehensive portfolio of patents to protect our candidates and technologies. As of the Latest Practicable Date, we owned 13 issued patents and 19 pending patent applications. Our issued patents and any patents to be issued from our pending patent applications are scheduled to expire on various dates from July 2024 through January 2044, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other governmental fees.

With regard to our PDGF candidates, as of the Latest Practicable Date, we owned 3 issued patent and filed 12 patent applications in China. The expected expirations for the issued patents and any patents that may issue from the pending patent application range from July 2024 to January 2044, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees. As of the Latest Practicable Date, with respect to our Core Products, we had one issued patent, which will expire in July 2024, and we had filed seven patent applications, currently under review. For details of such expiration and its impact on the development and commercialization of our Core Products, see “Risk Factors — Risks Relating to Our Intellectual Property Rights — Even if we are able to obtain patent protection for our candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or

SUMMARY

identical to ours and compete directly against us after the expiration of our patent rights, if any, and it would have a material adverse effect on our ability to successfully commercialize any product or technology” and “Business — Intellectual Property Rights.”

With regard to Mes-201, as of the Latest Practicable Date, we owned 4 issued patents and filed 6 patent applications in China. The expected expirations for the issued patents and any patents that may issue from the pending patent application range from May 2042 to November 2042, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fee. For details, see “Business — Intellectual Property Rights.”

SUPPLIERS

Our suppliers are primarily reputable CROs, CMOs, CDMOs and research and medical institutions, as well as providers of raw materials for biological products and housing rental services. We collaborate with CROs, CMOs, CDMOs and research and medical institutions on pre-clinical and clinical trials in China. We primarily procure raw materials, equipment, research and development services and other professional services from our suppliers to support the development and manufacturing of our candidates. We select our suppliers by taking into account a number of factors, including their qualifications, industry reputation, cost competitiveness and compliance with relevant laws and regulations. In 2022 and 2023, our purchases from our five largest suppliers in the aggregate accounted for 34.1% and 50.4% of our total purchases, respectively, while purchases from our largest supplier in each year accounted for 10.9% and 17.3% of our total purchases, respectively. For details, see “Business — Suppliers.”

MANUFACTURING

We currently work with qualified CMOs and CDMOs to manufacture product candidates for pre-clinical and clinical supply. We also cooperate with CDMOs in the refinement of product candidates. We have adopted procedures to ensure that the production qualifications, facilities and processes of our CMOs and CDMOs comply with the relevant regulatory requirements and our internal guidelines.

As of the Latest Practicable Date, we were exploring effective strategies to initiate the large-scale production of our product candidates upon commercialization. Options under consideration include leasing production facilities, constructing our own manufacturing sites, and collaborating with CMOs to ensure GMP-compliant production of such candidates, including the fermentation, crude extraction and purification of bulk solutions, as well as formulation, filling and packaging of dosages. We will ascertain in due course the most appropriate option for the Company in light of subsequent developments and the interests of the Shareholders. To ensure a

SUMMARY

reliable supply of our products and to accommodate potential growth in business demand, we may consider implementing a hybrid manufacturing model, which would integrate our internal manufacturing capabilities with those of CMOs. In addition, we expect such approach to support our clinical trials in China, and potentially to support our clinical trials globally in the future. The facilities are expected to be equipped with systems and equipment from leading, highly reputable manufacturers and suppliers of the industry. For details, see “Business — Manufacturing and Quality Control.”

OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li, through the Concert Party Agreement, were collectively interested in approximately 66.99% of our total issued share capital, comprising (i) 19.54% of our total issued share capital directly held by Ms. Jia; (ii) 17.98% of our total issued share capital directly held by Mr. Wang; (iii) 17.47% of our total issued share capital directly held by Ms. Zhang; and (iv) 12.00% of our total issued share capital directly held by Mr. Li. Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li will continue to control in aggregate approximately [REDACTED]% of our total issued share capital. Therefore, Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li will remain as a group of our Controlling Shareholders upon [REDACTED]. See “Relationship with Our Controlling Shareholders.”

PRE-[REDACTED] INVESTMENTS

We have completed the Pre-[REDACTED] Investments raising over RMB400 million in 2021 and 2023. Our Pre-[REDACTED] Investors include Mr. Zhang Hong, CDH Investors and Qingdao Hitech, among which CDH Investors being our Sophisticated Investor, will hold approximately [REDACTED]% of the total issued Shares of the Company upon the completion of the [REDACTED] (assuming the [REDACTED] has not been exercised). We utilize the proceeds from the Pre-[REDACTED] Investments to finance our research and development activities and fund our daily operations. For details, see “History, Development and Corporate Structure — Pre-[REDACTED] Investments.”

SUMMARY OF KEY FINANCIAL INFORMATION

The following tables set forth summary financial data from our consolidated financial information for the Track Record Period, extracted from Appendix I to this document. The summary financial data set forth below should be read together with our consolidated financial statements and the accompanying notes, as well as “Financial Information.”

SUMMARY

Summary of Results of Operations

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

	Year ended December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Revenue	—	472 ⁽¹⁾
Cost of sales	—	(255)
Gross Profit	—	217
Other income and gains	1,002	271
Administrative expenses	(44,223)	(42,117)
Research and development expenses	(34,818)	(39,915)
Other expenses	(32)	(62)
Finance costs	(7,855)	(23,582)
Loss before tax	(85,926)	(105,188)
Income tax expense	—	—
Loss for the year	(85,926)	(105,188)
Total Comprehensive Loss for the Year	(85,926)	(105,188)

Note:

- (1) Our revenue in 2023 was generated from the provision of research services to a single customer in relation to a project on medical devices for wound healing. Such business is not part of our core business. For details, see “Financial Information — Description of Major Components of Our Results of Operations — Revenue.”

For details, see “Financial Information — Description of Major Components of Our Results of Operations.”

SUMMARY

Summary of Consolidated Statements of Financial Position

The following table sets out selected data from our consolidated balance sheet as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Total non-current assets	18,986	18,185
Total current assets	16,725	244,904
Total assets	35,711	263,089
Total non-current liabilities	82,581	383,231
Total current liabilities	8,068	11,732
Total liabilities	90,649	394,963
Net current assets	8,657	233,172
Net liabilities	(54,938)	(131,874)
Equity attributable to owners of the parent:		
Paid-in capital	82,715	91,806
Deficits	(137,653)	(223,680)
Total deficit	(54,938)	(131,874)

Our net current assets increased from RMB8.7 million as of December 31, 2022 to RMB233.2 million as of December 31, 2023, mainly because our total current assets increased significantly from RMB16.7 million as of December 31, 2022 to RMB244.9 million as of December 31, 2023, primarily due to an increase in cash and cash equivalents as a result of our Pre-[REDACTED] Investment in 2023. Such increase was partially offset by an increase of our total current liabilities from RMB8.1 million as of December 31, 2022 to RMB11.7 million as of December 31, 2023, primarily due to an increase in trade payables in relation to the payables for purchasing research services from CROs and CDMOs.

Our total non-current liabilities increased from RMB82.6 million as of December 31, 2022 to RMB383.2 million as of December 31, 2023, mainly due to a large increase in other financial liabilities primarily related to the redemption liabilities from the Pre-[REDACTED] Investment in 2023. We had a net liability position as of December 31, 2022 and 2023, which increased from RMB54.9 million to RMB131.9 million. Pursuant to the supplemental agreement to the shareholders agreement dated February 23, 2024 entered into between us and the Shareholders, the redemption right granted to the Pre-[REDACTED] Investors has been terminated on the date of such supplemental agreement. See “History, Development and Corporate Structure

SUMMARY

— Pre-[REDACTED] Investments.” As such, the financial instruments issued to Pre-[REDACTED] Investors have been reclassified from other financial liabilities to equity, which reversed our net liability position to a net asset position since the termination of the redemption right. For details, see “Financial Information — Discussion of Certain Key Balance Sheet Items.”

Summary of Consolidated Statements of Cash Flows

The following table sets out our cash flows for the years indicated:

	Year ended December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Operating cash flows before movements in working capital . .	(47,526)	(60,637)
Movements in working capital	1,873	1,540
Interest received	726	237
Net cash flows used in operating activities	(44,927)	(58,860)
Net cash flows used in investing activities	(3,434)	(3,123)
Net cash flows (used in)/from financing activities	(3,245)	287,729
Net (decrease)/increase in cash and cash equivalents	(51,606)	225,746
Cash and cash equivalents at the beginning of the year	67,370	15,765
Effects of foreign exchange rate changes, net	1	1
Cash and cash equivalents at the end of the year	15,765	241,512

For details, see “Financial Information — Liquidity and Capital Resources — Cash Flow.”

Working Capital

While we had net operating cash outflows and net losses during the Track Record Period, we believe our liquidity requirements will be satisfied by using funds from a combination of our cash and cash equivalents, net [REDACTED] from the [REDACTED] and other funds raised from the capital markets from time to time. As of December 31, 2023, we had cash and cash equivalents of RMB241.5 million. We currently do not have any plans for material external debt financing. Taking into account the above, together with the estimated net [REDACTED] from the [REDACTED], our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs, including research and development expenses, administrative expenses, finance costs and other expenses for at least the next 12 months from the date of this document.

Our cash burn rate refers to the average monthly aggregate amount of (i) net cash used in operating activities; (ii) capital expenditures; and (iii) lease payments. Assuming that the average cash burn rate going forward of [REDACTED] times the level in 2023, we estimate that our total cash balance as of December 31, 2023 will be able to maintain our financial viability for approximately [REDACTED] months or, if taking into account the estimated net [REDACTED] (based on the mid-point of the indicative [REDACTED] of HK\$[REDACTED] per [REDACTED] and assuming the

SUMMARY

[REDACTED] is not exercised) from the [REDACTED], for at least [REDACTED] months. Our Directors and our management team 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 Ratio

The following table sets out our key financial ratio as of the dates indicated:

	As of December 31,	
	2022	2023
Current ratio ⁽¹⁾	2.1	20.9

Note:

- (1) Represents current assets divided by current liabilities as of the same date.

For details, see “Financial Information — Key Financial Ratio.”

[REDACTED] STATISTICS

The statistics in the following table are based on the assumptions that [REDACTED] H Shares are issued pursuant to the [REDACTED], [REDACTED] H Shares are converted from Unlisted Shares and the [REDACTED] is not exercised:

	Based on an [REDACTED] of HK\$[REDACTED]	Based on an [REDACTED] of HK\$[REDACTED]
Market capitalization of our H Shares ⁽¹⁾	HK\$[REDACTED]	HK\$[REDACTED]
Unaudited [REDACTED] adjusted consolidated net tangible assets per Share ⁽²⁾	HK\$[REDACTED] (RMB[REDACTED])	HK\$[REDACTED] (RMB[REDACTED])

Notes:

- (1) The calculation of market capitalization is based on [REDACTED] H Shares will be issued pursuant to the [REDACTED] and [REDACTED] Unlisted Shares will be converted into H Shares (without taking into account H Shares that may be issued upon the exercise of the [REDACTED]).
- (2) The unaudited [REDACTED] adjusted consolidated net tangible assets per Share as of December 31, 2023 is calculated after making the adjustments referred to in Appendix II to this document and on the basis that [REDACTED] Shares are expected to be in issue immediately upon completion of the [REDACTED].

For the calculation of the unaudited [REDACTED] adjusted consolidated net tangible assets per Share attributable to our Shareholders, see “Unaudited [REDACTED] Financial Information” in Appendix II to this document.

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DIVIDEND

No dividend was paid or declared by our Company or other entities comprising our Group during the Track Record Period.

Any future declarations and payments of dividends will be at the absolute discretion of our Directors and will depend on our actual and expected results of operations, cash flow and financial position, general business conditions and business strategies, expected working capital requirements and future expansion plans, legal, regulatory and other contractual restrictions, and other factors which our Directors consider relevant. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. According to relevant PRC laws, 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. As a result, we may not have sufficient or any distributable profits to make dividend contributions to our Shareholders, even if we become profitable. As of December 31, 2023, we did not have any pre-determined dividend payout ratio.

USE OF [REDACTED]

Assuming that the [REDACTED] is not exercised, after deducting the [REDACTED] and other estimated [REDACTED] paid and payable by us in connection with the [REDACTED], and assuming an [REDACTED] of HK\$[REDACTED] per Share (being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED]), we estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] million from the [REDACTED]. We intend to use the [REDACTED] from the [REDACTED] for the purposes and in the amounts set forth below:

- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for carrying out the continual clinical development of our Core Products, Pro-101-1 and Pro-101-2.
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for payment of the expenses of third-parties’ services, R&D personnel costs and raw materials costs of the continual pre-clinical research and development of our PDGF products other than the Core Products for other indications, such as fresh wounds, pressure ulcers and radiation ulcers.
- approximately [REDACTED]% of the net [REDACTED] or HK\$[REDACTED] million, will be used for payment of the expenses of third-parties’ services, R&D personnel costs and raw materials costs of pre-clinical research and development activities of our Mes-201, Oli-101 and Oli-201.

SUMMARY

- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for enhancing our research and development capabilities by purchasing specialized equipment and instruments related to our research and development and quality control activities. Such purchases are expected to enhance our research and development capabilities, accelerate the progress of drug discovery, and enable us to more effectively navigate complex medical innovation pathways, as well as to strengthen our quality control capabilities to ensure that our products meet the stringent safety and efficacy standards required by the relevant industries and jurisdictions.
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, as working capital and for general corporate uses.

For 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 “Risk Factors” in this document. Some of the major risks we face include: (i) Our business and financial prospects depend substantially on the success of our clinical-stage and pre-clinical-stage candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our candidates, or if we experience significant delays or cost overruns in doing any of the foregoing, our business and competitive position could be materially and adversely affected; (ii) Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may encounter unexpected difficulties executing our clinical trials. Results of earlier studies and trials may not be predictive of later-stage clinical trial results; (iii) If our 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 candidates; (iv) If we encounter difficulties in enrolling patients for our clinical trials, our clinical development activities could be delayed or otherwise materially and adversely affected; and (v) We may not be able to enhance our proprietary research and development platforms or develop new platforms as expected to advance the development of innovative biopharmaceutical products. For details, see “Risk Factors.”

SUMMARY

[REDACTED]

[REDACTED] represent professional fees, [REDACTED] and other fees incurred in connection with the [REDACTED]. We expect to incur [REDACTED] of approximately RMB[REDACTED] million (HK\$[REDACTED] million), comprising: (i) [REDACTED] fees of RMB[REDACTED] million (HK\$[REDACTED] million); and (ii) non-[REDACTED]-related expenses of RMB[REDACTED] million (HK\$[REDACTED] million), which are further categorized into: (a) fees and expenses of legal advisors and accountants of RMB[REDACTED] million (HK\$[REDACTED] million); and (b) other fees and expenses of RMB[REDACTED] million (HK\$[REDACTED] million), assuming the [REDACTED] is not exercised and based on the [REDACTED] of HK\$[REDACTED] per [REDACTED] (being the mid-point of the [REDACTED] range), approximately RMB[REDACTED] million (HK\$[REDACTED] million) of which has been charged to our consolidated statements of profit or loss (including RMB[REDACTED] million (HK\$[REDACTED] million) charged during the Track Record Period), approximately RMB[REDACTED] million (HK\$[REDACTED] million) of which is expected to be charged to our consolidated statements of profit or loss, and approximately RMB[REDACTED] million (HK\$[REDACTED] million) of which is expected to be capitalized and will be deducted from equity upon the completion of the [REDACTED]. The [REDACTED] are expected to represent approximately [REDACTED]% of the gross [REDACTED] of the [REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED] (being the mid-point of the indicative [REDACTED] range) and that the [REDACTED] is not exercised. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

RECENT DEVELOPMENTS

Since December 2023, when we completed the enrollment of the first patient for the Phase IIb clinical trial of Pro-101-1 in thermal burns, we have been proactively facilitating the patient enrollment process. The current enrollment status is in progress and within our expectations. We expect to complete the Phase IIb clinical trial of Pro-101-1 in the second quarter of 2025.

NO MATERIAL ADVERSE CHANGE

Our Directors have confirmed that up to the date of this document there has been no material adverse change in our financial or trading position or prospects since December 31, 2023 (being the date of our latest audited financial statements) and there has been no event since December 31, 2023 which would materially affect the information shown 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 “Glossary of Technical Terms” in this document.

“Accountants’ Report”	the accountants’ report of our Company prepared by Ernst & Young, details of which are set forth in Appendix I to this document
“affiliate”	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
“AMMS”	Academy of Military Medical Sciences of the People’s Liberation Army Academy of Military Sciences (中國人民解放軍軍事科學院軍事醫學研究院), or its predecessor, the People’s Liberation Army Academy of Military Medical Sciences (中國人民解放軍軍事醫學科學院)
“Articles of Association” or “Articles”	the articles of association of our Company, conditionally adopted on April 1, 2024 with effect from the [REDACTED] Date, and as amended from time to time, a summary of which is set out in Appendix III to this document
“Audit Committee”	the audit committee of the Board
“Board” or “Board of Directors”	the Board of Directors of our Company
“Beijing Huarene Biotechnology”	Beijing Huarene Biotechnology Hongkong Company Limited (香港華人生物技術有限公司), a private company limited by shares incorporated under the laws of Hong Kong on August 8, 2022 and is wholly owned by the Company
“Business day” or “business day”	a day on which banks in Hong Kong are generally open for normal banking business to the public and which is not a Saturday, Sunday or public holiday in Hong Kong

DEFINITIONS

[REDACTED]

“CCDC”	Chinese Center for Disease Control and Prevention (中國疾病預防控制中心)
“CDE”	the Center for Drug Evaluation of NMPA (國家藥品監督管理局藥品審評中心), a division of the NMPA mainly responsible for review and approval of IND and BLA
“CDH Investors”	Qingdao CDH and Jiaxing CDH
“China,” “Mainland China” or “PRC”	the People’s Republic of China, but for the purpose of this document and for geographical reference only and except where the context requires, references in this document to “China,” “Mainland China” and the “PRC” do not include Hong Kong, Macau and Taiwan Province
“CNIPA”	China National Intellectual Property Administration
“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Companies (Winding up and Miscellaneous Provisions) Ordinance”	the Companies (Winding up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Compliance Advisor”	has the meaning ascribed to it under the Listing Rules
“Concert Party Agreement”	the concert party agreement dated April 16, 2024 entered into among Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li
“Controlling Shareholder(s)”	has the meaning ascribed to it under the Listing Rules, and unless the context otherwise requires, refers to Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li, details of which are set out in “Relationship with our Controlling Shareholders”

DEFINITIONS

“Conversion of Unlisted Shares into H Shares”	the conversion of [REDACTED] Unlisted Shares in aggregate held by [REDACTED] existing Shareholders into H Shares upon the completion of the [REDACTED]. Such conversion of Unlisted Shares into H Shares [has been filed] with the CSRC on [•], 2024 and an application for H Shares to be [REDACTED] on the Hong Kong Stock Exchange has been made to the [REDACTED] Committee
“Core Products”	have the meaning ascribed to it in Chapter 18A of the Listing Rules; for the purpose of this document, our Core Products refer to Pro-101-1 and Pro-101-2, the active substance of which is a recombinant human platelet-derived growth factor BB secreted and expressed by adopting pMEX9K vector and <i>Pichia pastoris</i> expression system; previously known as TPG, a topical PDGF-BB gel used in clinical trials for thermal burns and DFUs and pre-clinical studies for other indications. It is a homodimer composed of two identical peptide chains through multiple pairs of disulfide bonds
“Corporate Governance Code”	the Corporate Governance Code in Appendix C1 to the Listing Rules
“CSDC”	China Securities Depository and Clearing Corporation Limited (中國證券登記結算有限責任公司)
“CSDC (Hong Kong)”	China Securities Depository and Clearing (Hong Kong) Company Limited
“CSRC”	China Securities Regulatory Commission (中國證券監督管理委員會), a regulatory body responsible for the supervision and regulation of the PRC national securities markets
	[REDACTED]
“Director(s)” or “our Directors”	the director(s) of our Company
“EIT Law”	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

DEFINITIONS

[REDACTED]

“EU”	European Union, a supranational organization that currently comprises 27 member states that are located primarily in Europe
“EMA”	the European Medicines Agency, the EU agency responsible for evaluating and granting centralized approval for market authorization valid in all EU, European Economic Area states, and European Free Trade Association states
“Employees Shareholding Platforms”	Qingdao Huaren and Hainan Huaren
“Exchange Participant(s)”	a person: (a) who, in accordance with the Listing Rules, may trade on or through the Hong Kong Stock Exchange; and (b) whose name is entered in a list, register or roll kept by the Hong Kong Stock Exchange as a person who may trade on or through the Hong Kong Stock Exchange
“Extreme Conditions”	the occurrence of “extreme conditions” as announced by any governmental authority of Hong Kong due to serious disruption of public transport services, extensive flooding, major landslides, large-scale power outage or any other adverse conditions before Typhoon Signal No. 8 or above is replaced with Typhoon Signal No. 3 or below
“FDA”	the United States Food and Drug Administration, a federal agency of the Department of Health and Human Services

[REDACTED]

“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., our industry consultant, which is an Independent Third Party
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DEFINITIONS

“Frost & Sullivan report” an independent market research report commissioned by us and prepared by Frost & Sullivan for the purpose of this document

“GDP” gross domestic product

[REDACTED]

“GLOBOCAN” an online database providing global cancer statistics and estimates of incidence and mortality in 185 countries for 36 types of cancer, and for all cancer sites combined

[REDACTED]

“Guide for New Listing Applicants” the Guide for New Listing Applicants issued by the Stock Exchange, as amended, supplemented or otherwise modified from time to time

“Hainan Huaren” Hainan Huaren Gongying Corporate Management Consultancy Partnership (Limited Partnership) (海南華人共贏企業管理諮詢合夥企業(有限合夥)), a limited partnership established under the laws of the PRC on April 25, 2021, one of our Employee Shareholding Platforms

“Hainan Huaren Biotechnology” Hainan Huaren Biotechnology Co., Ltd. (海南華人生物技術有限公司), a limited liability company incorporated under the laws of the PRC on March 6, 2022 and is wholly owned by the Company

“H Share(s)” overseas [REDACTED] foreign shares in the share capital of our Company with nominal value of RMB1.00 each, which are to be [REDACTED] for and [REDACTED] in HK dollars and are to be [REDACTED] on the Hong Kong Stock Exchange

[REDACTED]

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

DEFINITIONS

[REDACTED]

“Hong Kong”

the Hong Kong Special Administrative Region of the PRC;

[REDACTED]

DEFINITIONS

[REDACTED]

“Huaren Yihai Biotechnology”	Huaren Yihai Biotechnology (Beijing) Co., Ltd. (華仁益海生物科技(北京)有限公司), a limited liability company incorporated under the laws of the PRC on July 21, 2023 and is wholly owned by the Company
“IFRS”	International Financial Reporting Standards, which include standards, amendments and interpretations promulgated by the International Accounting Standards Board and the International Accounting Standards and interpretation issued by the International Accounting Standards Committee
“Independent Third Party(ies)”	any entity or person who is not a connected person of our Company within the meaning ascribed thereto under the Listing Rules

[REDACTED]

DEFINITIONS

[REDACTED]

“Jiaxing CDH”

Jiaxing CDH Zhaoyun Equity Investment Partnership (Limited Partnership) (嘉興鼎暉兆筠股權投資合夥企業(有限合夥)), a limited partnership established under the laws of the PRC on July 14, 2021 and one of our Pre-[REDACTED] Investors

“JinBang”

Beijing JinBang Biological Engineering Co., Ltd. (北京勁邦生物科技有限公司), formerly a company engaged in the science promotion and application services, which has been deregistered in July 2020; for details on our arrangement with the Institute of Bioengineering of AMMS and JinBang, see “Business — Collaboration, Licensing and Transfer Arrangements — Collaboration with the Institute of Bioengineering of AMMS and JinBang”

[REDACTED]

DEFINITIONS

[REDACTED]

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

“Latest Practicable Date” April 22, 2024, being the latest practicable date for the purpose of ascertaining certain information in this document prior to its publication

[REDACTED]

“Listing Committee” the Listing Committee of the Stock Exchange

[REDACTED]

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

“Macau” the Macau Special Administrative Region of the PRC

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

“Mr. Li” Mr. Li Gewei (李葛衛), one of our Controlling Shareholders

“Mr. Wang” Mr. Wang Kelong (王軻龍), the president of our Company, an executive Director, the vice chairperson of the Board, one of our Controlling Shareholders and the son of Ms. Jia

“Ms. Jia” Ms. Jia Lijia (賈麗加), the founder of our Company, an executive Director, the chairperson of the Board, one of our Controlling Shareholders and the mother of Mr. Wang

DEFINITIONS

“Ms. Zhang”	Ms. Zhang Hongbo (張紅波), one of our Controlling Shareholders
“NCBI”	National Center for Biotechnology Information
“NHC”	National Health Commission of the PRC
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局)
“Nomination Committee”	the nomination committee of the Board
“NSFC”	National Natural Science Foundation of China (國家自然科學基金委員會)

[REDACTED]

“our Company” or “the Company”	B&K Corporation Limited (華芒生物科技(青島)股份有限公司), a limited liability company established under the laws of the PRC on April 24, 2012 and converted into a joint stock limited liability company in the PRC on April 1, 2024, and if the context requires, including its predecessors
“our Group,” “we” or “us”	our Company and its subsidiaries (or our Company and any one or more of its subsidiaries, as the context may require)

[REDACTED]

DEFINITIONS

[REDACTED]

“PBOC”	the People’s Bank of China (中國人民銀行), the central bank of the PRC
“PCT”	Patent Cooperation Treaty, an international patent law treaty, which provides a unified procedure for filing patent applications (known as PCT applications) to protect inventions in each of its contracting states
“PRC Company Law”	the Company Law of the PRC (中華人民共和國公司法), as amended, supplemented or otherwise modified from time to time
“PRC Legal Advisor”	Commerce & Finance Law Offices, our legal advisor as to PRC laws and PRC intellectual property law
“PRC Securities Law”	the Securities Law of the PRC (中華人民共和國證券法), as amended, supplemented or otherwise modified from time to time
“Pre-[REDACTED] Investment(s)”	the Pre-[REDACTED] Investments in our Company undertaken by the Pre-[REDACTED] Investors, details of which are set out in “History, Development and Corporate Structure”
“Pre-[REDACTED] Investor(s)”	the investors of Pre-[REDACTED] Investments

DEFINITIONS

[REDACTED]

“Qingdao CDH”	Qingdao CDH Shuangbai Equity Investment Partnership (Limited Partnership) (青島鼎暉雙百股權投資合夥企業(有限合夥)), a limited partnership established under the laws of the PRC on December 2, 2019 and one of our Pre-[REDACTED] Investors
“Qingdao Hitech”	Qingdao Hitech Industry Development Co., Ltd. (青島高科產業發展有限公司), a limited liability company established under the laws of the PRC on June 26, 2001 and one of our Pre-[REDACTED] Investors
“Qingdao Huaren “	Qingdao Huaren Gongchuang Corporate Management Consultancy Partnership (Limited Partnership) (青島華苙共創企業管理諮詢合夥企業(有限合夥)), a limited partnership established under the laws of the PRC on November 30, 2020, one of our Employee Shareholding Platforms
“Regulation S”	Regulation S under the U.S. Securities Act
“Remuneration Committee”	the remuneration committee of the Board
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“R&D”	research and development

DEFINITIONS

“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)
“SAIC”	the State Administration of Market Regulation of the PRC (國家市場監督管理總局)
“Securities and Futures Ordinance” or “SFO”	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Series A Financing”	one of the Pre-[REDACTED] Investments in our Company, the details of which are set out in “History, Development and Corporate Structure — Major Corporate Development of our Company — 9. Series A Financing”
“Series B Financing”	one of the Pre-[REDACTED] Investments in our Company, the details of which are set out in “History, Development and Corporate Structure — Major Corporate Development of our Company — 10. Series B Financing”
“Series Pre-A Financing”	one of the Pre-[REDACTED] Investments in our Company, the details of which are set out in “History, Development and Corporate Structure — Major Corporate Development of our Company — 8. Series Pre-A Financing”
“SFC”	the Securities and Futures Commission of Hong Kong
“Share(s)”	shares in the share capital of our Company, with a nominal value of RMB1.00 each, comprising our Unlisted Shares and H Shares
“Shareholders”	holders of our Shares
“Sophisticated Investor(s)”	has the meaning given to it under paragraph 10 of Chapter 2.3 of the Guide for New Listing Applicants
“STA”	the State Taxation Administration (國家稅務總局)
	[REDACTED]
“State Council”	State Council of the PRC (中華人民共和國國務院)
“Stock Exchange”	the Stock Exchange of Hong Kong Limited

DEFINITIONS

“subsidiary(ies)”	has the meaning ascribed thereto in section 15 of the Companies Ordinance
“Supervisor(s)”	supervisor(s) of our Company
“Supervisory Committee”	the supervisory committee of our Company
“Takeovers Code”	the Codes on Takeovers and Mergers and Share Buybacks issued by the SFC, as amended, supplemented or otherwise modified from time to time
“Track Record Period”	the period comprising the years ended December 31, 2022 and 2023
“U.S. dollars”, “US\$” or “USD”	United States dollars, the lawful currency of the United States
“U.S. Securities Act”	the United States Securities Act of 1933, as amended and supplemented or otherwise modified from time to time, and the rules and regulations promulgated thereunder
“UN”	United Nations
	<p style="text-align: center;">[REDACTED]</p>
“United States” 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) in the share capital of our Company, with a nominal value of RMB1.00 each, which are not [REDACTED] on any stock exchange
“USPTO”	United States Patent and Trademark Office
“VAT”	value added tax

DEFINITIONS

“WHO” World Health Organization

“%” per cent

In this document, the terms “associate,” “close associate,” “connected person,” “core connected person,” “connected transaction,” “controlling shareholder” and “substantial shareholder” shall have the meanings given to such terms in the Hong Kong Listing Rules, unless the context otherwise requires.

Unless otherwise expressly stated or the context otherwise requires, all data in this document is as of the date of this document.

The English names of the PRC entities, PRC laws or regulations, and the PRC governmental authorities referred to in this document are translations from their Chinese names and are for identification purposes. If there is any inconsistency, the Chinese names shall prevail.

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

GLOSSARY OF TECHNICAL TERMS

This glossary contains explanations of certain technical terms used in this document in connection with our Company and our business. Such terminology and meanings may not correspond to standard industry meanings or usages of those terms.

“AE”	adverse events, any untoward medical occurrences in a patient or clinical investigation subject administered with a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment
“ADR”	adverse reaction, any unexpected or dangerous reaction to a drug
“API”	active pharmaceutical ingredient, a substance used in a finished pharmaceutical product, which is intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings
“ASO”	antisense oligonucleotide, small nucleic acid drugs comprised of single-stranded nucleic acid used to treat rare or refractory infectious diseases, cancers and genetic diseases at the gene level
“BLA”	biologics license application, a request for permission to introduce, or deliver for introduction, a biologic product for commercialization in a specific jurisdiction
“CAGR”	compound annual growth rate
“CDMO”	contract development and manufacturing organization, a pharmaceutical company that develops and manufactures drugs for other pharmaceutical companies on a contractual basis

GLOSSARY OF TECHNICAL TERMS

“cGMP”	current good manufacturing practice, a system that stipulates minimum requirements for the methods, facilities, and controls used in manufacturing, processing and packing of a drug product to make sure that a product is safe for use, and that it has the ingredients and strength it claims to have
“CMC”	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
“CMO(s)”	a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
“COVID-19”	coronavirus disease 2019, an infectious disease caused by the most recently discovered coronavirus (severe acute respiratory syndrome coronavirus 2, SARS-CoV-2), which no longer constitutes a public health emergency of international concern since May 2023
“CRO(s)”	contract research organization, a company that provides support to pharmaceutical companies by providing a range of professional research services on a contract basis
“DFU”	diabetic foot ulcer, an open sore or wound that occurs in approximately 25% of patients with diabetes in China, and is commonly located on the bottom of the foot
“DNA”	deoxyribonucleic acid, a polymer composed of two polynucleotide chains that coil around each other to form a double helix carrying genetic instructions for the development, functioning, growth and reproduction of all known organisms and many viruses

GLOSSARY OF TECHNICAL TERMS

“DS” or “drug substance”	an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient
“ECG”	electrocardiogram, a simple test that can be used to check heart’s rhythm and electrical activity
“FAS”	full analysis set, the set of subjects derived from the set of all randomized subjects by minimal and justified elimination of subjects
“G0/G1 phase”	the preparatory stage of the cell cycle, where cells grow and synthesize RNA and proteins in preparation for DNA replication
“GCP”	good clinical practice
“GMP”	good manufacturing practice
“H index”	a metric for evaluating the cumulative impact of an author’s scholarly output and performance, calculated by counting the number of publications for which an author has been cited by other authors at least that same number of times
“ <i>in vitro</i> ”	Latin for “within the glass”, studies using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells or biological molecules
“ <i>in vivo</i> ”	Latin for “within the living”, studies <i>in vivo</i> are those in which the effects of various biological or chemical substances are tested on whole, living organisms including animals, humans and plants, as opposed to a partial or dead organism, or those done <i>in vitro</i>

GLOSSARY OF TECHNICAL TERMS

“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China or the U.S.
“KOL”	key opinion leader, influencers and trusted persons who have expert product knowledge and influence in a respective field and are an important part of burgeoning industries and businesses in China, including biotech/pharmaceutical industries
“lncRNA(s)”	long non-coding RNA, a type of RNA, generally defined as transcripts more than 200 nucleotides that are not translated into protein
“LNP”	lipid nanoparticles, which are spherical vesicles made of ionizable lipids positively charged at low pH (enabling RNA complexation) and neutral at physiological pH (reducing potential toxic effects, as compared with positively charged lipids, such as liposomes), and designed to carry and protect genetic material or drugs until they reach their target cells and facilitate the absorption and release of the therapeutic substance into the cells
“MOA”	mechanism of action, which refers to the specific biochemical interaction through which a drug substance produces its pharmacological effect
“mRNA”	messenger ribonucleic acid, a single-stranded molecule of RNA that corresponds to the genetic sequence of a gene, and is read by a ribosome in the process of synthesizing a protein
“NDA”	new drug application, the vehicle through which drug sponsors formally propose that the competent authority approves a new pharmaceutical for sale and marketing

GLOSSARY OF TECHNICAL TERMS

“NOAEL”	no-observed-adverse-effect level, the level of exposure of an organism, found by experiment or observation, at which there is no biologically or statistically significant increase in the frequency or severity of any adverse effects (e.g., alteration of morphology, functional capacity, growth, development or life span) in the exposed population when compared to its appropriate control
“PDGF”	platelet-derived growth factor, which is a type of growth factors secreted by platelets after injury that stimulates cell proliferation and angiogenesis, or where the context requires, PDGF-BB, or rhPDGF-BB
“PDGF receptor”	platelet-derived growth factor receptor, a type of cell surface receptor that, when bound by PDGF, activates a series of intracellular signaling pathways. These pathways are involved in regulating a variety of biological processes including cell proliferation, differentiation, migration, and survival
“PDGF-BB”	platelet-derived growth factor BB, which is one of the five dimeric isoforms of platelet-derived growth factor
“PDX model”	patient-derived xenograft model, a model of cancer where the tissue or cells from a patient’s tumor are implanted into an immunodeficient or humanized mouse to evaluate the natural growth of cancer, its monitoring, and corresponding treatment for the original patient
“Phase I clinical trial”	study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
“Phase I/II clinical trial”	study that combines Phase I and Phase II clinical trials into one trial. The clinical trial design may adaptively use data from all previous patients to make decisions and select the best dose for each new cohort

GLOSSARY OF TECHNICAL TERMS

“Phase II clinical trial”	study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance and optimal dosage
“Phase IIa clinical trial”	usually pilot study designed to demonstrate clinical efficacy or biological activity
“Phase IIb clinical trial”	study that determines the optimal dose at which the drug shows biological activity with minimal adverse reactions
“Phase III clinical trial”	study in which a drug is administered to an expanded patient population generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the labeling of the product
“placebo”	a substance or treatment with no active therapeutic effect, commonly used in clinical trials as the administered substance for the control group
“PNP”	polypeptide nanoparticle, which is composed of a branched Histidine Lysine polymer
“PPS”	per protocol set, the subset of subjects who complied with the protocol sufficiently to ensure that these data would be likely to exhibit the effects of treatment according to the underlying scientific model
“pre-clinical studies”	studies or programs 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
“primary endpoint”	the specific key measurement upon which a clinical study is designed to assess the effect of the drugs being investigated
“RGA”	reporter gene assay

GLOSSARY OF TECHNICAL TERMS

“rhPDGF-BB”	recombinant human platelet-derived growth factor BB, which is a clinically utilized version of PDGF-BB
“RNA”	ribonucleic acid, a polymeric molecule essential in various biological roles in coding, decoding, regulation and expression of genes
“RTCA”	real-time, label-free cellular analysis
“S phase”	the DNA synthesis stage of the cell cycle, during which cells replicate their DNA, resulting in two identical copies of each chromosome
“SA”	streptavidin, a 66.0 (tetramer) kDa protein purified from the bacterium <i>Streptomyces avidinii</i> . Streptavidin is used extensively in molecular biology and bionanotechnology due to the streptavidin-biotin complex’s resistance to organic solvents, denaturants (e.g. guanidinium chloride), detergents (e.g. SDS, Triton X-100), proteolytic enzymes, and extremes of temperature and pH
“SAE”	serious adverse events, any untoward medical occurrence in human drug trials that at any dose: results in death; is life threatening; requires inpatient hospitalization or causes prolongation of existing hospitalization; results in persistent or significant disability/incapacity; may have caused a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage
“SCI”	Science Citation Index
“secondary endpoint”	with respect to a clinical study or trial, the secondary objective that was obtained
“solid tumor”	an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them

GLOSSARY OF TECHNICAL TERMS

“STZ”	streptozotocin, a naturally occurring alkylating antineoplastic agent that is particularly toxic to the insulin-producing beta cells of the pancreas in mammals
“TMZ”	temozolomide, an oral alkylating agent for the treatment of newly diagnosed glioblastoma multiforme and refractory anaplastic astrocytoma
“TNBC”	triple-negative breast cancer, broadly refers to any breast cancer that does not express the genes for estrogen receptor, progesterone receptor and HER2/neu
“TSA”	tumor-specific antigen, a protein or other molecule that is found only on cancer cells and not on normal cells, which can be used as possible targets for targeted therapy or for immunotherapy to help boost the body’s immune system to kill more cancer cells
“VEGF”	vascular endothelial growth factor, originally known as vascular permeability factor (VPF), is a signal protein produced by many cells that stimulates the formation of blood vessels
“wound healing rate”	absolute area healed as of a given day as a percentage of the initial area of wound
“WST”	a water-soluble reducing tetrazolium salt

FORWARD-LOOKING STATEMENTS

This document includes forward-looking statements. All statements other than statements of historical facts contained in this document, including, without limitation, those regarding our future financial position, our strategy, plans, objectives, goals, targets and future developments in the markets where we participate or are seeking to participate, and any statements preceded by, followed by or that include the words “believe,” “expect,” “estimate,” “predict,” “aim,” “intend,” “will,” “may,” “plan,” “consider,” “anticipate,” “seek,” “should,” “could,” “would,” “continue,” or similar expressions or the negative thereof, are forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors, some of which are beyond our control, which 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. These forward-looking statements are based on numerous assumptions regarding our present and future business strategies and the environment in which we will operate in the future. Important factors that could cause our actual performance or achievements to differ materially from those in the forward-looking statements include, among other things, the following:

- general political and economic conditions, including those related to the PRC;
- our ability to successfully implement our business plans and strategies;
- future developments, trends and conditions in the industries and markets in which we operate or into which we intend to expand;
- our business operations and prospects;
- our capital expenditure plans;
- the actions and developments of our competitors;
- our financial condition and performance;
- capital market developments;
- our dividend policy;
- any changes in the laws, rules and regulations of the central and local governments in the PRC and other relevant jurisdictions and the rules, regulations and policies of the relevant governmental authorities relating to all aspects of our business and our business plans;

FORWARD-LOOKING STATEMENTS

- various business opportunities that we may pursue; and
- changes or volatility in interest rates, foreign exchange rates, equity prices or other rates or prices, including those pertaining to the PRC and Hong Kong and the industry and markets in which we operate.

Additional factors that could cause actual performance or achievements to differ materially include, but are not limited to, those discussed in “Risk Factors” and elsewhere in this document. We caution you not to place undue reliance on these forward-looking statements, which reflect our management’s view only as of the date of this document. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this document might not occur. All forward-looking statements contained in this document are qualified by reference to the cautionary statements set out in this section.

RISK FACTORS

An investment in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an investment in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In any such case, the market price of our Shares could decline, and you may lose all or part of your investment. 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. There are unique challenges, risks and uncertainties associated with investing in companies such as ours, which may cause you to lose all or part of your investment.

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, 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.

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

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

RISK FACTORS

RISKS RELATING TO THE RESEARCH AND DEVELOPMENT OF OUR CANDIDATES

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

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

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

- favorable safety and efficacy data from our pre-clinical studies and clinical trials;
- successful enrollment of patients in, and completion of, clinical trials as well as completion of pre-clinical studies;
- sufficient supplies of drug products that are either used in combination or in comparison with our candidates in clinical trials;
- the performance by CROs or other third parties we engage to conduct clinical trials and their compliance with our protocols and applicable laws without damaging or compromising integrity of the resulting data;
- the capabilities and competence of our collaborators;
- sufficient resources to acquire or discover additional candidates and successful identification of potential candidates based on our research or business development methodology or search criteria and process;
- receipt of regulatory approvals;
- strong commercial manufacturing capabilities;
- successful launch of commercial sales of our candidates, if and when approved;

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- the obtaining and maintenance of favorable reimbursement from third-party payers for drugs, if and when approved;
- competition with other candidates and drugs;
- the obtaining, maintenance and enforcement of patents, trademarks, trade secrets and other intellectual property protections and regulatory exclusivity for our candidates;
- successful defense against any claims brought by third parties that we have or may have infringed, misappropriated or otherwise violated any intellectual property of any such third party; and
- the continued acceptable safety profile of our candidates following regulatory approval.

Some of our candidates represent a novel approach to therapeutic needs compared with more commonly used medical methods, and therefore carry inherent development risks that could result in delays and cost overruns in clinical development, regulatory approvals or commercialization. Any modification to the protocols related to the demonstration of safety or efficacy of our candidates may delay the clinical program, regulatory approvals or commercialization, and we may be required to supplement, modify, or withdraw and refile our applications for regulatory approvals. In addition, potential patients and their doctors may be inclined to use conventional standard-of-care treatments rather than any novel approach. Given the novelty of our candidates, a substantial amount of education and training may need to be provided to patients and medical personnel. This may have a material adverse effect on potential revenue generated from our candidates, which in turn may materially and adversely affect our competitive position, business, financial condition and results of operations.

As of the Latest Practicable Date, we had ten candidates for various indications that were in different phases of pre-clinical and clinical development. If we do not achieve one or more of the aforementioned factors as expected in a timely manner or at all, we could experience significant delays or difficulties in obtaining approvals for, and commercializing, our candidates, which would have a material adverse effect on our business, financial condition and results of operations. In addition, among our candidates, one of our Core Products, Pro-101-2, has demonstrated favorable results in the pre-clinical studies and encouraging safety and tolerability profile in the Phase I clinical trial for the treatment of DFUs. Accordingly, we received approval to directly initiate clinical trials for Pro-101-1 in thermal burns, and plan to directly initiate clinical trials for Pro-101-3 in fresh wounds, based on the existing research data of Pro-101-2 for the treatment of DFUs. If Pro-101-2 for the treatment of DFUs fails to demonstrate the efficacy and safety results

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that we expect during further research and development, it could negatively affect the clinical trials of Pro-101-2 for the treatment of DFUs, thermal burns and fresh wounds, which will have a material adverse effect on our business and financial condition.

Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may encounter unexpected difficulties executing our clinical trials. Results of earlier studies and trials may not be predictive of later-stage clinical trial results.

Clinical trials are capital-intensive and may demand years of effort to complete, while their outcomes are inherently uncertain and may not be favorable. A new candidate for a particular indication may take from 10 to 15 years from pre-clinical studies to launch. In 2022 and 2023, our research and development expenses were RMB34.8 million and RMB39.9 million, respectively, representing 40.5% and 37.9% of our total loss, respectively. We may encounter unexpected difficulties while executing our clinical trials, such as long wait times for regulatory approvals, complexities of analytical testing technology, shortages of material supplies and outbreaks of epidemics, which may result in changes to our current clinical development plans. See “— Risks Relating to Our Operations — We may be subject to disasters, health epidemics or pandemics, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition and results of operations.” Failure can occur at any time or stage during the clinical trial process, which would result in a material and adverse effect on our business, financial condition and results of operations.

The results of pre-clinical studies and early clinical trials may not be predictive of the success of later-phase clinical trials, and favorable initial or interim results of a clinical trial do not necessarily indicate the success of final results. Candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. It is common that various aspects of the development programs, such as manufacturing and formulation, are altered along the entire research and development stage in an effort to optimize processes and results, and there can be no assurance that such alterations would help achieve the intended objectives.

There may be significant variability in safety or efficacy results among different trials of the same candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in size and demographics of the enrolled patients (such as genetic differences and patient adherence to the dosage regimen) and the dropout rate among enrolled patients in clinical trials. Differences in the number of clinical trial sites and countries involved may also lead to variability between earlier and later-phase clinical trials. Therefore, the results of

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planned clinical trials or other future clinical trials could be significantly different and other than as predicted, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our candidates.

If our 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 candidates.

Before obtaining regulatory approvals for the commercialization of our candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our candidates in humans. If the results of clinical trials of our 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 candidates would be delayed or denied;
- we may be required to conduct additional clinical trials or other testing of our candidates beyond our current development plan;
- 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 side 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 candidates;
- we may be unable to obtain reimbursement coverage for use of the drug from relevant health administrative authorities, private health insurers and other organizations; and

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- conditional regulatory approval of our candidates may require us to conduct confirmatory studies to verify the predicted clinical benefit and additional safety studies. The results from such studies may not support the clinical benefit, which would result in the approval being withdrawn.

Having expended a significant amount of capital to progress our candidates, if such candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in future clinical trials, we would not be able to realize any revenue on such candidates if they then or ultimately fail to receive regulatory approvals due to unsatisfactory clinical trial results, thereby materially and adversely affecting our business, financial condition, results of operations and prospects.

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

The successful and timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who opt to participate and remain in the clinical trials until the end of the trial. We may experience difficulties in patient enrollment for our clinical trials for a variety of reasons, including:

- the design of the trial;
- the size and demographics of the patient population;
- the size of the study population required for analysis of the trial's primary endpoints;
- the patient eligibility criteria defined in the protocol;
- our ability to obtain and maintain patient consents;
- our resources to facilitate timely subject enrollment in clinical trials;
- patients' and clinicians' perceptions of the potential advantages and side effects of the candidate being studied compared with other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- the availability of approved therapies that are similar in mechanism to our candidates;

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- the outbreaks of epidemics or pandemics. See “— Risks Relating to Our Operations — We may be subject to disasters, health epidemics or pandemics, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition and results of operations”;
- the availability of patients and their proximity to trial sites;
- the selection of quality clinical trial sites and investigators with the appropriate competencies and experience; and
- the selection, contracting and performance of third-party suppliers.

In addition, our clinical trials may compete with other clinical trials for candidates that are in the same therapeutic areas as our candidates. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead choose to enroll in a trial being conducted by one of our competitors. For example, according to the Frost & Sullivan report, as of the Latest Practicable Date, there were three PDGF drug pipelines in China, two of which belong to us while the other one belongs to Tasly Pharmaceutical. The PDGF-BB drug candidate of Tasly Pharmaceutical entered Phase III clinical trial in 2014 and as of the Latest Practicable Date, there had been no further update in relation to the status of Tasly Pharmaceutical’s drug pipeline. We have commenced the patient enrollment process for the Phase IIb clinical trial of Pro-101-1 in thermal burns since December 2023, and expect to commence the patient enrollment process for the Phase II clinical trial of Pro-101-2 in DFUs in the second quarter of 2024. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct certain clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, thereby hindering the completion of these trials and adversely affecting our ability to advance the development of our candidates.

We may not be able to enhance our proprietary research and development platforms or develop new platforms as expected to advance the development of innovative biopharmaceutical products.

As of the Latest Practicable Date, we had established two major research and development platforms comprising a protein/peptide pharmaceutical platform and a nucleic acid pharmaceutical platform. We have devoted, and will continue to devote, significant resources to the building and enhancement of our proprietary research and development platforms. In addition, we may develop new platforms to supplement our existing technologies. There can be no assurance that we will be

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able to continually enhance our proprietary research and development platforms or develop new platforms as expected. As a result, we may not be able to further expand the reach of our product pipeline or enhance the efficacy of our candidates as expected, which may materially and adversely affect our business, results of operations and prospects.

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

Although we mainly focus on the continued clinical testing, potential approvals and commercialization of our existing product candidates, the success of our business depends in part upon our ability to discover, identify, in-license, develop or commercialize additional product candidates. There can be no assurance that we will be successful in identifying potential candidates. Although we have developed proprietary research and development platforms, which we believe enable us to design, evaluate and select optimal candidates and continue to expand our pipeline, there can be no assurance that we will be successful in identifying, discovering, developing or in-licensing potential candidates in the future. Potential candidates that we identify may be shown to have side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approvals. Some of such potential candidates may be technically challenging to develop and manufacture. We have also pursued collaboration with third parties in the discovery and development of potential candidates. However, there can be no assurance that such collaboration will be able to deliver the expected results.

Research programs to pursue the development of our candidates for additional indications and to identify new candidates and drug targets require substantial technical, financial and human resources. Our research programs may show promising results in identifying potential indications and/or candidates at an initial stage yet fail to yield favorable results for clinical development.

We may fail to discover, identify or in-license new candidates for clinical development and commercialization for a number of reasons, including those beyond our control. We may not be able to identify new candidates or additional therapeutic opportunities for our candidates or to develop suitable potential candidates through internal research programs. We may invest efforts and resources in potential candidates or other potential programs that ultimately prove to be unsuccessful. Any of the foregoing events will have a material adverse effect on our business, results of operations and prospects.

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The data and information that we gather in our research and development process could be inaccurate or incomplete.

We collect, aggregate, process, and analyze data and information from our pre-clinical studies and clinical programs. Because data in the healthcare industry are fragmented in origin, inconsistent in format, and often incomplete, the overall quality of data collected or accessed in the healthcare industry are often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and we may discover data issues and errors when monitoring and auditing the quality of our data. If we make mistakes in the capture, input, or analysis of these data, our ability to advance the development of our product candidates may be materially harmed.

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

In addition, we rely on third-party collaborators, such as CROs, to monitor, quality control and manage data for some of our ongoing pre-clinical and clinical programs and control only certain aspects of their activities. If any of our CROs or other third-party collaborators does not perform to our standards in terms of data accuracy or completeness, data from those pre-clinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. See “— Risks Relating to Our Reliance on Third Parties — We work with various third parties to develop our candidates and may have limited control over them. 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 candidates, and our business, financial condition and results of operations could be materially and adversely affected.” Moreover, despite the implementation of security measures, our internal computer systems and those of our third-party collaborators are vulnerable to damages from computer viruses and unauthorized access. Failure to manage such risks may materially and adversely affect our research and development process and our business. For details, see “— Risks

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Relating to Our Operations — Our internal computer systems, or those used by our partners or other contractors or consultants, may fail or suffer security breaches or other disruptions, which could adversely affect our business and reputation.”

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

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

RISKS RELATING TO REGULATORY APPROVALS AND GOVERNMENT REGULATIONS

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

The development and commercialization of candidates are heavily regulated in various jurisdictions. While we focus on expanding our business in the PRC, we also consider development opportunities in the U.S. and other jurisdictions. Under the strict regulations of the biopharmaceutical industry, regulatory authorities in various jurisdictions employ similar regulatory strategies which cover the development, approval, manufacturing, marketing, sales and distribution of products, including operations related to data and genetic information processing. However, certain regulatory regimes impose onerous compliance burdens upon companies that expect to expand into the relevant jurisdictions.

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The process of obtaining regulatory approvals and maintaining compliance with applicable laws and regulations may require considerable expenditure of time and financial resources. Failure to comply with the applicable laws and regulations at any time or stage before or after approvals may lead to administrative penalties or judicial sanctions upon an applicant. Such penalties and sanctions may include, among other things, refusal to approve pending applications, withdrawal of an approval, revocation of a license, a hold on clinical trials, voluntary or mandatory recalls of products, the seizure of products, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, and disgorgement of profits. Any of the foregoing events could materially and adversely affect our business, financial condition, results of operations and prospects.

In particular, we are subject to risks associated with obtaining regulatory approvals. Difficulties and failures in doing so may expose us to various harms, either actual or perceived. Granting, and the time in granting, regulatory approvals by the NMPA, the FDA and other comparable regulatory authorities involve various factors, including regulatory officials' discretion. It generally takes several years to obtain regulatory approvals following the commencement of pre-clinical studies and clinical trials. In addition, regulations, approval policies and requirements for clinical data may change during the clinical development process of a candidate and may vary among jurisdictions. There can be no assurance that we will be able to obtain regulatory approvals for our existing candidates or any candidates we may discover, identify, in-license or develop in the future.

In addition, the NMPA, the FDA or comparable regulatory authorities may require more information, including additional analyses, reports, data, non-clinical studies and clinical trials, or questions regarding interpretations of data and results, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development programs. Even if we were to obtain approval, regulatory authorities may approve any of our 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 candidate with an indication that is not desirable for the successful commercialization of that candidate. Any of the foregoing scenarios could materially harm the commercial prospects of our candidates.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Resubmission may impact the costs, timing or successful completion of a clinical trial. The policies of the NMPA, the FDA and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our candidates. If we are slow or unable to adapt to changes in existing requirements or the

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adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

Failure to obtain regulatory approvals as expected in a timely manner, or at all, or failure to obtain regulatory approvals with an ideal scope of indications could have a negative impact on the commercial prospects of our candidates, and may cause reputational damage to us.

We primarily conduct clinical trials for our candidates in China, while the FDA or comparable foreign regulatory authorities may not accept data from such trials.

We primarily conduct clinical trials for our candidates in China. However, we may consider conducting clinical trials for our candidates in other jurisdictions such as the U.S. For example, we expect to submit the IND filing to the FDA in the first quarter of 2026 with respect to Pro-101-1 in thermal burns. The acceptance of trial data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application for marketing approvals on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA’s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming and delay our business plan, and may result in product candidates that we may develop not receiving approval for commercialization in the relevant jurisdiction.

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We may seek approvals from the NMPA, the FDA or other comparable regulatory authorities for an expedited review process for our candidates or for the use of data from registrational trials through accelerated development pathways, failure to obtain which may have a material adverse effect on our business, financial condition, results of operations and prospects.

The NMPA, the FDA and the comparable regulatory authorities in other jurisdictions may allow the use of data from a registrational trial and/or have implemented expedited review programs for candidates, among others, which are innovative drug applications, or which treat a serious or life-threatening condition and provide meaningful therapeutic benefit over available therapies upon a determination that the candidate demonstrates an effect on a surrogate endpoint or intermediate clinical endpoint which is reasonably likely to predict clinical benefit.

There can be no assurance that the regulatory authorities will consider our existing or future candidates as innovative drug applications or agree with our surrogate endpoints or intermediate clinical endpoints, or that we will decide to pursue or submit any additional NDAs or BLAs for accelerated approvals or any other form of expedited development, review or approvals. Similarly, there can be no assurance that, after receiving feedback from the regulatory authorities, we will continue to pursue or apply for accelerated approvals or any other form of expedited development, review or approvals, even if we initially decide to do so. Furthermore, for any submission of an application for accelerated approvals or application under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted for filing, or that any expedited development, review or approvals will be granted on a timely basis, or at all.

Any failure to obtain accelerated approvals or any other form of expedited development, review or approvals for our candidates may result in a longer period of time prior to the commercialization of such candidate, an increase in the development expenses for such candidate and an adverse impact on our competitive position in the market.

In addition, if we obtain accelerated approvals of a candidate based on a surrogate endpoint, we will likely be required to conduct a post-approval clinical outcome trial to confirm the clinical benefit of the candidate. If the post-approval trial is not successful, we may not be able to continue marketing the drug for the relevant indication.

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Our candidates may cause undesirable AEs or have other properties that could delay or affect the granting of regulatory approvals, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval.

Although our candidates have not caused any SAEs for the time being, any AEs that may occur in subsequent phases could cause us or regulatory authorities to interrupt, delay or cease clinical trials and may result in a more restrictive label, delay in or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities, or a significant change in our clinical protocol or our development plan. Our trial results may reveal a high level of severity or prevalence of certain AEs. In such an event, our trials could be suspended or terminated and the NMPA, the FDA or other comparable regulatory authorities could deny approvals, or order us to cease further development, of our candidates for any or all targeted indications. AEs related to our candidates may affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition, results of operations and prospects.

Additionally, if adverse reactions caused by any of our candidates after they receive regulatory approvals have been identified, it may lead to severe negative consequences, including the following:

- we may need to suspend marketing/commercialization of the candidate;
- regulatory authorities may withdraw their approvals of or revoke the licenses for the candidate;
- regulatory authorities may require additional warnings on the label;
- regulatory authorities may require us to implement a risk evaluation and mitigation strategy program, or restrict distribution of our drugs or otherwise impose burdensome implementation requirements on us;
- we may be required to conduct specific post-marketing studies; and
- we could be subject to litigation and held liable for harm caused to patients, and our reputation may suffer.

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Any of the foregoing events could prevent us from achieving or maintaining market acceptance of any candidate that is approved and could materially and adversely affect our business, financial condition, results of operations and prospects. Moreover, potential combination therapy, such as using our candidates together with third-party agents, may involve unique AEs that could be exacerbated compared with AEs from monotherapies.

After we receive regulatory approvals for our candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses and penalties for non-compliance.

If any of our candidates receives regulatory approvals in the future, it will be subject to ongoing and additional regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including the requirements of regulatory authorities in the PRC, the U.S. and other jurisdictions.

Our candidates that have received regulatory approvals may be subject to conditions of approval or limitations on the approved indicated uses for which the drug may be marketed, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the candidate. The NMPA, the FDA or other comparable regulatory authorities may also require a risk evaluation and mitigation strategy program as a condition of approval of our candidates or following approval. If the NMPA, the FDA or other comparable regulatory authorities approve our candidates, we will have to comply with requirements, including submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs, for any clinical trials that we conduct post-approval.

We are required to maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business pursuant to relevant laws and regulations. Any failure to maintain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or bear fines and penalties which could materially and adversely affect our business, financial condition and results of operations. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional approvals, permits, licenses or certificates and there can be no assurance 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 our results of operations and prospects.

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In addition, after a drug is approved by the NMPA, the FDA or a comparable regulatory authority for marketing, there may be a subsequent discovery of problems with respect to our drug products which have not been identified previously, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. Such problems may result in, among other things: restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls; fines, warning letters or holds on our clinical trials; suspension or revocation of existing drug license approvals; and injunctions or the imposition of civil, administrative or criminal penalties. Any of the foregoing may materially and adversely affect our results of operations and prospects.

The NMPA, the FDA and comparable regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA, the FDA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

If we successfully commercialize any of our candidates, such approved products distributed or sold in the biopharmaceutical market may be subject to off-label drug use. 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. Even though the NMPA, the FDA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains the risk that our candidate, upon regulatory approval, is subject to off-label drug use and is prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities. This occurrence may render our candidate, upon regulatory approval, less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand image, commercial operations and financial condition. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our candidates. The illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our candidates, upon regulatory approval, and could have a negative impact on our reputation and business.

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We may be directly or indirectly subject to applicable anti-kickback, false claims laws, doctor payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in the PRC, the U.S. and other jurisdictions, which could, in the event of non-compliance, expose us to administrative sanctions, criminal sanctions, civil penalties, contractual damages, reputational damage and diminished profits and future earnings.

Healthcare providers, doctors and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain the NMPA or the FDA approvals for any of our candidates and begin commercializing those drugs in the PRC or in the U.S., our operations may be subject to various PRC and U.S. federal and state fraud and abuse laws, including the PRC Anti-Unfair Competition Law, PRC Criminal Law, the U.S. Federal Anti-Kickback Statute and the U.S. Federal False Claims Act, and doctor payment transparency laws and regulations which primarily include the U.S. Affordable Care Act and the U.S. Physician Payments Sunshine Act. These laws may impact, among others, our proposed sales, marketing and education programs.

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

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines, exclusion or suspension from federal and state healthcare programs and being debarred from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the Federal False Claims Act as well as under the false-claims laws of several states.

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

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We are subject to registration, review and other requirements of the regulatory authorities for operations related to genetics and data safety.

Going forward, we may enter into agreements with CROs in the PRC and the U.S. for their technical support to assist us with the development of individual candidates, which may be deemed to constitute the import of technology under the regulations. As a result, such transfers are required to be registered with applicable PRC governmental authorities. Although there are no explicit penalties set forth in these regulations for lack of such registration, failure to register an agreement where such registration is required may result in restrictions concerning foreign exchange, banking and taxation matters relating to such agreements. In addition, we are also subject to regulatory supervision over genetics and data-related operations. According to the Administration of Human Genetic Resources (《人類遺傳資源管理條例》) promulgated in May 2019, as amended in March 2024 (to be effective in May 2024), Detailed Rules for the Implementation of the Regulation on the Administration of Human Genetic Resources(《人類遺傳資源管理條例實施細則》) promulgated in May 2023 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. As the laws and regulations of this area are evolving, failure to comply with the relevant requirements may adversely affect our business, results of operations and prospects.

RISKS RELATING TO MANUFACTURING OF OUR CANDIDATES

We are exposed to various supply chain risks, and any price increases or interruptions of such supply may have a material adverse effect on our business.

Our business operations are exposed to various supply chain risks. During the Track Record Period, we relied on third parties to supply technical and other services, materials and equipment. We expect to continue to seek the cooperation with third parties on the supply of such services, materials and equipment for the research, development, manufacturing and commercialization of our candidates. See “Business — Research and Development — Engagement of Third Parties in Research and Development” and “Business — Procurement.”

Currently, the services, materials and equipment are supplied by multiple source suppliers. We have agreements for the supply of services, materials and equipment with suppliers that we believe have sufficient capacity to meet our demands. However, if supplies are interrupted, we may not be able to find alternative supplies in a timely and commercially reasonable manner, or at all. Any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the research and development of our candidates. Moreover, we require a stable supply of materials for our candidates in the course of our research and development activities, and such needs are expected to increase significantly once we enter

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commercial production of drugs upon receipt of marketing approvals. However, there can be no assurance that current suppliers have the capacity to meet our demand. Although we have taken and will continue to take measures to mitigate such risks, including cooperating with more suppliers, there can be no assurance that such measures are or will be effective. Any delay in receiving such materials in the quantities and of the quality that we need could delay the completion of our clinical studies, regulatory approvals of our candidates or our ability to timely meet market demand for our commercialized products, as applicable. Our suppliers may not be able to cater to our growing demands or may reduce or cease their supply of materials to us at any time. We are also exposed to the possibility of price increases, which we may not be able to pass on to customers and may, in turn, lower our profitability.

Our suppliers may also fail to maintain adequate quality of the services, materials and equipment we need. Although we implement quality inspection on the materials, there can be no assurance that we will be able to identify all of the quality issues. Suboptimal or even deficient supplies of services, materials and equipment may hinder the research and development of our candidates, subject us to product liability claims or otherwise have a material adverse effect on our operations.

In addition, there can be no assurance that these third parties will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which, in turn, may result in shortage of the services, materials and equipment supplied to us, and cause delays in clinical trials and regulatory filings, or the recall of our products. The non-compliance of these third parties may also subject us to potential product liability claims, cause us to fail to comply with the continuing regulatory requirements, and incur significant costs to rectify such incidents of non-compliance, which may have a material and adverse effect on our business, financial condition and results of operation.

Our manufacturing capacity may not be able to meet the increasing demand for our existing candidates and future drug products.

We currently work with qualified CMOs and CDMOs to manufacture product candidates for pre-clinical and clinical supply. We also cooperate with CDMOs in research and develop product candidates. As at the Latest Practicable Date, we were exploring effective strategies to initiate the large-scale production of our product candidates upon commercialization. Options under consideration include leasing production facilities, constructing our own manufacturing sites, and collaborating with CMOs to ensure GMP-compliant production of such candidates. If we were to construct our own production facilities, any delays in completing such facilities, or any disruption in the development of new facilities, could reduce or restrict our production capacity. We may also experience various unfavorable events in the course of developing our new manufacturing facilities, such as: unforeseen delays due to construction, land use rights or regulatory issues,

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which could result in loss of business opportunities; and difficulty in finding sufficient numbers of trained and qualified staff. See “Business — Manufacturing and Quality Control — Our Planned Manufacturing Capacities.” Manufacturers of biological drug products often encounter difficulties in production, particularly in scaling up or out, validating the production process and assuring the high reliability of the manufacturing process. If our future manufacturing facilities encounter unanticipated delays and expenses as a result of any of these difficulties, or if construction, regulatory evaluation and/or approvals of new manufacturing facilities are delayed, we may not be able to manufacture sufficient quantities of our candidates, which would limit our development and commercialization activities.

In addition, depending on the size of our future manufacturing facilities, we may not be able to fully utilize them immediately or within a reasonable period of time after we commence operation. During the construction and ramp-up period, there may be significant changes in the biopharmaceutical industry, including, among other things, market demand, product and supply pricing, and customer preferences. Any adverse trends in these respects could result in operational inefficiency and excess capacity in our future manufacturing facilities, thereby having a material adverse effect on our business, financial condition, results of operations and prospects..

We have no experience in manufacturing biopharmaceutical products on a large commercial scale and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.

As of the Latest Practicable Date, all of our products were in the research and development stage. We have limited experience in managing the manufacturing process. The manufacture of biopharmaceutical products is complex, in part due to strict regulatory requirements. If we are unable to identify an appropriate production site or a suitable partner to develop the manufacturing infrastructure, or fail to do so in a timely manner, it may lead to significant delays in the manufacturing of our candidates after we have obtained regulatory and marketing approvals. Investments in constructing or leasing new biologics manufacturing facilities which are in compliance with GMP regulations may result in significant cost for us and in turn would have a material adverse effect on our commercialization plans. We may also fail to attract and retain personnel with the requisite skills and experience for drug manufacturing.

In addition, problems may arise during the manufacturing process for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays in the construction of new manufacturing facilities or expansion of any future manufacturing facilities, changes in manufacturing production sites or limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, physical limitations that could inhibit continuous supply, and the occurrence of natural disasters. If problems arise during the production process of certain future products, a batch or even several related batches of such product may have to be discarded and cause production delays, cost

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increases, lost revenue and damage to customer relationships and our reputation. If problems have not been discovered before the relevant products are released to the market, we may incur additional costs in connection with product recalls and product liability, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

Any failure to perform proper quality control and quality assurance during manufacturing upon commercialization of our product candidates would have a material adverse effect on our business and financial results.

Manufacturing of biopharmaceutical products for commercial sale are subject to applicable laws, regulations and GMP requirements that govern the manufacturing processes and procedures. We intend to adopt stringent quality control standards at every stage of our manufacturing process not only to fulfill the legal requirements but to ensure a high-quality output. Apart, we intend to perform extensive tests throughout the manufacturing processes to ensure the safety and effectiveness of our biopharmaceutical products. However, there can be no assurance that such standards or tests when implemented or carried out will be effective. We may, however, detect instances in which an unreleased product was produced without adherence to our manufacturing procedures or the raw material used in our manufacturing process was not collected to store in accordance with the GMP standards or other regulations, resulting in a determination that the implicated products should be destroyed. In addition, if we fail to comply with relevant quality control requirements under any laws or GMP, we could experience disruptions in manufacturing of our biopharmaceutical products, which could delay or prevent further sales of such products, and may result in material adverse effect on our business and financial results.

Quality issues may also arise during the large volume manufacturing process. If we are unable to maintain the consistent and high-quality manufacturing of our biopharmaceutical products after commercialization during large-volume manufacturing, the sales of our products may be interrupted and adversely impacted. In addition, cross-contamination could result from manufacturing activities at shared equipment and facilities, which are common. Other activities such as diagnosis and research are frequently linked to manufacturing, which may create opportunities for cross-contamination. Furthermore, improper actions during the long-distance transportation, storage and delivery services may also result in contamination. These could have a material adverse effect on our business and financial results.

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RISKS RELATING TO COMMERCIALIZATION OF OUR CANDIDATES

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

Even if our candidates receive regulatory approvals and as innovative candidates, have various advantages compared to traditional therapies, they may nonetheless fail to achieve satisfactory market acceptance by doctors, patients, third-party payers, hospitals or others in the medical community. If our candidates do not achieve an adequate level of acceptance, the commercialization of such candidates may become less successful or profitable than we had expected.

If our candidates are approved but fail to achieve market acceptance among doctors, patients, third-party payers, hospitals or others in the medical community, we will not be able to generate significant revenue or become profitable. Even if our drugs achieve market acceptance, we may not be able to maintain such market acceptance over time if new products or technologies are introduced which are more favorably received or more cost-effective than our drugs or render our drugs obsolete, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

The biopharmaceutical industry in which we operate is highly competitive and rapidly changing. While our principal focus is to develop candidates with the potential to become novel or highly differentiated drugs, we face competition with respect to our current candidates and will face competition with respect to any candidates that we may seek to develop or commercialize in the future. Large multinational pharmaceutical companies, well-established biopharmaceutical companies, specialty pharmaceutical companies, universities and other research institutions have commercialized, are in the process of commercialization, or are pursuing the development of drugs for the treatment of indications for which we are developing our candidates. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. See "Business — Competition." Potential competitors further include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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Even if successfully developed and subsequently approved by the NMPA, the FDA or other comparable regulatory authorities, our candidates may still face competition in various aspects, including safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price and patent status. Many of our competitors have substantially greater financial, technical and other resources, such as more advanced commercial infrastructure, more candidates in late-stage clinical development, more seasoned research and development staff and well-established marketing and manufacturing teams than us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated in our competitors. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or achieve better acceptance in the markets in which we operate or have established a competitive position. For example, the NMPA has accelerated marketing approvals of drugs for diseases with high medical needs and the NMPA may review and approve drugs that have gained regulatory marketing approvals in the U.S., the EU or Japan in the past ten years without requiring further clinical trials in the PRC. This may lead to potential increased competition from drugs that have already obtained approvals in other jurisdictions.

Competition may further intensify as a result of advances in the commercial applicability of technologies and availability of capital for investment in the industry. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective with a lower cost than our candidates, or achieve earlier patent protection, regulatory approvals, product commercialization and market penetration than we do. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability or safety in order to overcome price competition and to be commercially successful. Furthermore, disruptive technologies and medical breakthroughs may further intensify the competition and render our candidates obsolete or noncompetitive. Technologies developed by our competitors may render our potential candidates uneconomical or obsolete, and we may not be successful in marketing our candidates against competitors.

We have limited experience in launching and marketing candidates. If we are unable to effectively build and manage our sales network or benefit from the sales networks of third-party collaborators, we may be unable to generate any revenue.

We currently have no sales, marketing or commercial product distribution capabilities and have limited marketing experience. We intend to develop an in-house marketing team and sales force, which requires significant capital expenditure, management resources and time. We expect to compete with other biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel.

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If we are unable to establish internal sales, marketing and commercial distribution capabilities, we may consider pursuing collaborative arrangements with third parties regarding the sales and marketing of our candidates. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or, if we are able to do so, that such arrangements will provide sufficient and effective sales support. We will also face competition in the search for third parties to assist us with the sales and marketing efforts of our candidates.

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

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

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approvals of the sale price of a drug before marketing. In many countries, the pricing review period commences after marketing or licensing approvals are granted. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approvals are granted. In addition, drug pricing policies are constantly changing in many countries. As a result, we might obtain regulatory approvals for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenue we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more candidates, even if our candidates obtain regulatory approvals.

The successful commercialization of our candidates also depends on the extent to which reimbursement for these candidates and related treatments will be available from relevant health administrative authorities, private health insurers and other organizations. Governmental authorities and third-party payers, such as private health insurers and healthcare organizations, decide which medications they will pay for and stipulate reimbursement levels. With the trend of cost containment in the global healthcare industry, governmental authorities and third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. There is an increasing number of third-party payers requiring companies to provide them with predetermined discounts from list prices and challenging the prices charged for medical products. There can be no assurance as to whether or to what extent reimbursement will be available for any candidate we commercialize. Reimbursement may impact the demand for, or the price of, any candidate for which we obtain regulatory approvals. Obtaining reimbursement for

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our candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a doctor. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any candidate that we have developed.

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

If safety, efficacy, or other issues arise with any medical product that is used in combination with our candidates, we may be unable to market such drug candidate or may experience significant regulatory delays or supply shortages, which could have a material adverse effect on our business.

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

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manufacturing or other issues result in a supply shortage of any component of our combination candidates, we may not be able to complete clinical development of our candidates on our current timeline, or at all.

The market opportunities for our candidates may be smaller than we anticipate, or limited to those patients who are ineligible for or have failed prior treatments, and our estimates of the prevalence of our target patient populations may be inaccurate.

We estimate the incidence and prevalence of target populations for particular diseases based on various third-party sources, such as scientific literature, surveys of clinics, participants foundations or market research, as well as internally generated analysis, and we use such estimates in making decisions regarding our pipeline development strategy, including determining on which candidates to focus our resources for pre-clinical or clinical trials. These estimates may be inaccurate or based on imprecise data. The total addressable market opportunity will depend on, among other things, acceptance of the candidates by the medical community and consumer access, product pricing and reimbursement.

The number of patients in the addressable markets may turn out to be lower than expected, patients may not be amenable to treatment with our candidates, or new candidates may become increasingly difficult to identify or access. Furthermore, new studies may change the estimated incidence or prevalence of the diseases that our candidates target, and the number of addressable patients for our candidates in any case may turn out to be lower than expected. In such cases, even if we obtain significant market share for our candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional diseases. Any of the above unfavorable developments could have a material adverse effect on our business, financial condition and results of operations.

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

Our candidates may be administered in combination with drugs of other biopharmaceutical companies as one regimen. We may also use third-party drugs in our development and clinical trials as controls for our studies. As a result, both the results of our clinical trials and the sales of our drugs may be affected by the availability of these third-party drugs. We generally have no influence over the availability and pricing of such drugs. If other biopharmaceutical companies discontinue these combination drugs, or if these drugs become prohibitively expensive, regimens that use these combination drugs may no longer be prescribed, and we may not be able to introduce or find an alternative drug to be used in combination with our drugs in a timely manner and on commercially reasonable terms, or at all. As a result, demand for our drugs may be lowered, which would in turn materially and adversely affect our business, financial condition, results of operations and prospects.

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Illegal and parallel imports and counterfeit biopharmaceutical products may reduce demand for our future approved candidates and could have a negative impact on our reputation and business.

The illegal importation of similar or competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved candidates and, in turn, may adversely affect our sales and profitability in the PRC and other countries where we commercialize our products. Unauthorized foreign imports of prescription drugs are illegal under the current laws of the PRC. Furthermore, cross-border imports from lower-priced markets into higher-priced markets, which are known as parallel imports, could harm sales of our future drug products and exert commercial pressure on pricing within one or more markets. In addition, competent governmental authorities may expand consumers’ ability to import lower-priced biosimilar products of our future approved products or competing products from outside China or other countries in which we expect to operate, conduct our clinical trials and perform our contractual obligations. Any future legislation or regulations that increase consumer access to lower priced drugs from outside China or other countries in which we expect to operate, conduct our clinical trials and perform our contractual obligations could have a material adverse effect on our business.

Certain drug products distributed or sold may be manufactured without proper licenses or approvals or be fraudulently mislabeled with respect to their contents or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. Relevant governmental authorities may be unable to timely prevent counterfeit pharmaceutical products imitating our products. As counterfeit pharmaceutical products in many cases resemble the authentic pharmaceutical products, yet are generally sold at lower prices, any counterfeiting of our products could reduce the demand for our future approved candidates. In addition, counterfeit pharmaceutical products are unlikely to meet our or our collaborators’ rigorous manufacturing and testing standards, and may even cause health damage to patients. Our reputation and business could suffer as a result of counterfeit pharmaceutical products.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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

Our commercial success depends, to a certain extent, on our ability to protect our technology and candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. See “Business — Intellectual Property Rights.”

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We seek to protect our candidates and technology that we consider commercially important by filing patent applications in the PRC and other relevant jurisdictions, relying on a combination of trade secrets and regulatory protection methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in all jurisdictions in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we may fail to timely identify third-party infringement of our intellectual property rights and take necessary actions to defend and enforce our rights, or at all. Even if we decide to seek patent protection, 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.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been frequently litigated. The issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not be granted with approvals which effectively prevent third parties from commercializing competitive technologies and biosimilar candidates. The patent examination process may require us to narrow the scope of the claims of our pending and future patent applications, which may limit the scope of patent protection that could be obtained. There can be no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being granted with a patent.

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

Our competitors may be able to circumvent our patent issuance by developing similar or alternative technologies or candidates in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our patents may be challenged in the

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courts or patent offices in any jurisdictions. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and candidates, or limit the duration of the patent protection of our technology and candidates.

Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, after March 2013, under the Leahy-Smith America Invents Act ("**Leahy-Smith Act**"), the U.S. transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases are not published at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

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

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

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the U.S. and Europe, and many companies have encountered significant difficulties in registering, protecting and defending such rights in the relevant jurisdictions. Furthermore, the legal systems of certain jurisdictions, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to prevent the infringement of our patents or marketing of competing candidates in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property

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rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, there can be no assurance that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may expect to market our candidates. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

Even if we are able to obtain patent protection for our candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and it would have a material adverse effect on our ability to successfully commercialize any product or technology.

Although various adjustments and extensions may be available, the term of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years for invention in the PRC and generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority in the U.S. As of the Latest Practicable Date, with respect to our Core Products, we had one issued Chinese patent, which is expected to expire in July 2024, and we had filed seven patent applications, currently under review. See “Business — Intellectual Property Rights.” While we have implemented a number of measures such as making patent applications as to our Core Products in unpatented indications and techniques and filing PCT applications to continually protect our intellectual property rights, there can be no assurance as to the effectiveness of such measures. Upon the expiration of our issued patents or patents that may be issued from our pending patent applications, we will not be able to assert such patent rights against potential competitors, which may have an adverse effect on our business, financial condition, results of operations and prospects. Even if we successfully obtain patent protection for an approved candidate, it may face competition from generic or biosimilar products once the relevant patent has expired. The scope of our patent protection may be uncertain, and our current or any future patents may be challenged by competitors and invalidated even after issuance, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product.

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

Our patents and other intellectual property may be subject to further priority disputes or to inventorship disputes and similar proceedings. If we are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, or to modify or cease the development, manufacture and commercialization of one or more of the candidates we may develop, which could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our owned patents or other intellectual property as an inventor or co-inventor. If we are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which we are subject, we may lose valuable intellectual property rights through the loss of one or more of our patents or our patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we are unsuccessful in any inventorship disputes to which we are subject, we may lose valuable intellectual property rights, such as the exclusive ownership of, or exclusive right to use, our patents. If we are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties. Such licenses may not be available on commercially reasonable terms or at all or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to modify or cease the development, manufacture, and commercialization of one or more of our candidates. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing events could result in a material adverse effect on our business, financial condition, results of operations and prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

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

Claims that our candidates or the sale or use of our future products infringe, misappropriate or otherwise violate the patents or other intellectual property rights of third parties could result in substantial legal costs and may lead to unfavorable publicity which may harm our reputation and business, and any unfavorable outcome of such litigation could limit our research and development activities and/or our ability to commercialize our candidates.

Our candidates or the sale or use of our future products could in the future infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights. Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, or with respect to the use or manufacture of the compounds we have developed or are developing. Litigations relating to patents and other intellectual property rights in the biopharmaceutical industry are common, including patent infringement lawsuits. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. Some claimants may have substantially greater resources than us and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. Third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

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

If a third party were to assert claims of patent infringement against us, even if we believe such third-party claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be

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able to block our ability to commercialize the applicable product unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention, or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In addition, defending such claims would cause us to incur substantial expenses and could cause us to pay substantial damages, if we are found to be infringing third-party patent rights. In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial and may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a candidate, or be forced, by court order or otherwise, to modify or cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on commercially acceptable terms.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could be costly and time-consuming, regardless of the outcome. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs.

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 investors regard these announcements, or the announcement of the litigation, as negative, the perceived value of our candidates, future drugs, programs or intellectual property could be diminished. Accordingly, the market price of our Shares may decline. Such announcements could also harm our reputation or the market for our 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, or enter into strategic partnerships that would help us bring our candidates to market.

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Obtaining and maintaining our patent protection depends on compliance with various procedures, 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 CNIPA, the USPTO and other patent agencies in other jurisdictions in several stages over the lifetime of a patent. The CNIPA, the USPTO and other governmental patent agencies also require compliance with a number of procedural, documentary, and other similar provisions during the patent application process. 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.

Changes in patent laws of the PRC, the U.S. or other jurisdictions could reduce the value of patents in general, thereby impairing our ability to protect our candidates and future drugs.

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

In the PRC, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection. For example, the new PRC Patent Law was amended on October 17, 2020 and became effective on June 1, 2021. The new PRC Patent Law will introduce patent extensions to eligible innovative drug patents, and the patents owned by third parties may be extended, which may in turn affect our ability to commercialize our candidates. The new PRC Patent Law enables the patent owners to apply for a patent term extension. The compensation period shall not exceed five years, and the total validity period of patent rights for a new drug shall not exceed 14 years after the new drug is approved for marketing. If we are required to delay commercialization for an extended period of time, technological advances may develop and new

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products may be launched, which may in turn render our products noncompetitive. There can be no assurance that any other changes to PRC intellectual property laws would not have an adverse effect on our intellectual property protection.

Recently enacted U.S. laws have changed the procedures through which patents may be obtained and by which the validity of patents may be challenged. For example, the Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, among other things. Recent U.S. Supreme Court rulings have also changed the law surrounding patent eligibility, 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. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we might obtain in the future, thereby impacting the value of our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial condition, results of operations and prospects.

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

In addition to our issued patents and pending patent applications, we rely on a combination of trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our candidates. We seek to protect our trade secrets and confidential information, in part, by entering into confidentiality agreements with parties that have access to trade secrets or confidential information, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties that have access to them. However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements. Monitoring unauthorized use and disclosure is difficult and we do not know whether the steps we have taken to protect our proprietary rights will be effective. Any of the foregoing parties may breach or violate the terms of their agreements with us and may disclose our proprietary information or otherwise infringe our rights, and we may not be able to obtain adequate remedies for any such breach or violation. We could lose our trade secrets and third parties could use our trade secrets to compete with our candidates and technology. Additionally, there can be no assurance that we have

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entered into all necessary agreements with each party that may have or had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Many of our employees, including our senior management, may have been previously employed at other pharmaceutical or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer or, in the case of consultants and advisors, other companies for which they currently work. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management that are material to the Group, but in the future, litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms, or at all. An inability to incorporate such intellectual property rights would harm our business and may prevent us from successfully commercializing our candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may have an adverse effect on our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our candidates and technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees.

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

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

If our trademarks and trade names are not adequately protected, we may not be able to build brand recognition in our markets of interest which may have an adverse effect on our business.

We currently own issued trademark registrations and have trademark applications pending review, and may file trademark applications as needed in the ordinary course of business, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. In particular, we do not currently own any issued trademark registrations of "B&K," "B&K Corporation," "華芒" or "華芒生物" in Mainland China, and accordingly our use of business names "B&K," "B&K Corporation," "華芒" or "華芒生物" is not adequately protected. In fact, there is a prior registration of the "華芒" trademark held by a third party in Mainland China. To enhance the protection over our brands, we have filed trademark applications in Mainland China and Hong Kong with respect to "B&K," which were under review as of the Latest Practicable Date. Alternatively, we may negotiate with the third party that holds the "華芒" trademark in Mainland China for potential trademark transfer arrangements, which could lead to additional costs to us and thus adversely affect our results of operations and financial condition. We may also apply for new trademarks and operate under such trademarks upon registration, and if we are unable to complete such trademark registrations in a timely manner, our commercialization plans may be adversely affected.

There can be no assurance that any currently pending trademark applications or any trademark applications we may file in the future will be approved. During trademark registration proceedings, we may receive rejections and, although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining

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trademark protection for our primary brands, we may be required to change our brand names, which could materially and adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and, as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, it may have a material adverse effect on our business.

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

Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

The degree of 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. For example:

- others may be able to make products that are similar to any candidates we may develop, or others may develop alternative technologies that are similar to our technologies, while our candidates and technologies are not protected by our intellectual property rights;
- we, our future licensors or current or future collaborators might not have been the first to make the inventions covered by the issued patent that we license or may own in the future;

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- we, our future licensors or current or future collaborators might not have been the first to file patent applications covering certain of our, or their, inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed (if any) intellectual property rights;
- it is possible that our pending patent applications or those that we may file in the future will not lead to issued patents;
- issued patents that we hold rights to may not provide us with a competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- we may obtain patents for certain technologies many years before we commercialize candidates leveraging such technologies, and because patents have a limited life, which may begin to run prior to the commercial sale of the related candidates, the commercial value of our patents may be limited;
- our competitors or other third parties might conduct research and development activities in jurisdictions where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- the validity and scope of any claims relating to copyrights or other intellectual property may involve complex legal and factual questions and analyses and, as a result, the outcome may be highly uncertain;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

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RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

We work with various third parties to develop our candidates and may have limited control over them. 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 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-party CROs, to monitor and manage data for our ongoing pre-clinical and clinical programs. We work with these parties to execute our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable 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, the FDA and other comparable regulatory authorities for all of our candidates 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, the FDA or other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our registration trials must be conducted with products produced under cGMP regulations. Any failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs 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 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 revenue generation ability and have a material adverse effect on our business and prospects.

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Our future revenue is dependent on our ability to work effectively with collaborators to develop our candidates. Our arrangements with collaborators will be critical to the successful commercialization of our 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 our products which could materially and adversely affect our business, financial condition, cash flows and results of operations. In addition, we will rely on third parties to perform certain specification tests on our 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.

More generally, supply chain risks associated with the foregoing third-party service providers and our other suppliers may have a material adverse effect on our business, financial condition, results of operations and prospects. See “— Risks Relating to Manufacturing of Our Candidates — We are exposed to various supply chain risks, and any price increases or interruptions of such supply may have a material adverse effect on our business.”

We entered into collaborations with our partners and may form or seek additional collaborations or strategic alliances or enter into additional licensing arrangements in the future. We may not realize any or all benefits of such alliances or licensing arrangements, and disputes may arise between us and our current or future collaboration partners.

We have in the past formed, and may in the future seek and form, strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our candidates and any future candidates that we may develop. See “Business — Collaboration, Licensing and Transfer Arrangements.” Any of these relationships may require us to incur nonrecurring and other charges, increase our near-and long-term expenditures, issue securities that dilute our existing Shareholders, or disrupt our management and business.

Our future strategic collaboration with partners may involve various risks, including that we may not achieve the revenue and cost synergies expected from the transaction. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and beyond our control. Also, the synergies from our collaboration with partners may be offset by other costs incurred in

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the collaboration, increases in other expenses, operating losses or problems in the business unrelated to our collaboration. As a result, there can be no assurance that expected synergies will be achieved in due course, or at all.

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

During the Track Record Period, we did not experience any material dispute arising from our current collaboration with partners. However, disputes may arise between us and our future collaboration partners. Such disputes may cause delays in or termination of the research, development or commercialization of our candidates, or may result in costly litigation or arbitration that diverts management’s attention and resources. Any cessation or suspension of our collaboration with research partners may increase our costs in research and development, lengthen our new candidates’ development process and lower our efficiency in new products development.

Global markets are an important component of our growth strategy. We have retained rights for the development and commercialization of certain of our candidates globally. If we fail to obtain licenses or enter into collaboration arrangements with third parties in other markets, or if any third-party collaborator is not successful, our revenue-generating growth potential will be adversely affected.

Moreover, international business relationships subject us to additional risks that may materially and adversely affect our ability to attain or sustain profitable operations. For details, see “— Risks Relating to Our Operations — We are subject to the risks of doing business in multiple jurisdictions.

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We may rely on third parties to manufacture our product candidates for clinical development. Our business could be harmed if those third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality levels or prices.

We currently engage third-party CDMOs and CMOs to manufacture product candidates used for our pre-clinical and clinical development. We also cooperate with third-party CDMOs in the refinement of our product candidates.

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, the FDA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our candidates;
- Our third-party manufacturers might be unable to timely manufacture our candidates or produce the quantity and quality required to meet our pre-clinical and clinical needs, if any;
- Manufacturers are subject to ongoing periodic unannounced inspection and other government regulations by the NMPA, the 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 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

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- Our third-party manufacturers may be subject to inclement weather, as well as natural or man-made disasters.

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

RISKS RELATING TO OUR OPERATIONS

The loss of any key members of our senior management team as well as key scientific employees or our inability to attract, retain and motivate highly qualified management, clinical and scientific personnel could delay or prevent the successful development of our candidates and result in a material and adverse effect on our business and results of operations.

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 employees and consultants. The loss of the services of any of these individuals could delay or prevent the successful development of our candidates and our business operations would be impaired.

Although we have not historically experienced difficulties in attracting and retaining qualified employees, we may experience such problems in the future. Competition for qualified employees in the biopharmaceutical industry is intense and the pool of qualified candidates is limited. We may not be able to retain the services of, or attract and retain, experienced management or key clinical and scientific personnel in the future. The departure of one or more of our management or key clinical and scientific personnel, regardless of whether or not they join a competitor or form a competing company, may subject us to risks relating to inability to replace them in a timely manner, which may disrupt our drug development progress and have a material and adverse effect on our business and results of operations. In addition, we will need to hire additional employees as we expand our commercialization team. We may not be able to attract and retain qualified employees on commercially reasonable terms, or at all.

Our reputation is important to our business success. Negative publicity may adversely affect our reputation and business prospect.

Our ability to maintain our reputation depends on a number of factors, some of which are out of our control. We may face negative publicity, claims, disputes and allegations, which may have a material and adverse impact on our reputation, even if untrue or inaccurate. Moreover, any negative publicity, claims, disputes and allegations involving, any conduct of, and any matters affecting the reputation of, other parties, including our Directors, Shareholders, senior

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management, employees and entities that use the “B&K,” “B&K Corporation,” “華芒” or “華芒生物” name, could have a material and adverse impact on our business and reputation. We may be required to spend significant time and incur substantial costs to respond and protect our reputation, and we cannot assure you that we will be able to do so within a reasonable period of time, or at all, in which case our business, results of operations, financial condition and prospects may be materially and adversely affected.

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 things, product liability, environmental matters, breach of contract, employment or labor disputes and infringement of intellectual property rights. As of the Latest Practicable Date, we were not involved in any litigations and legal proceedings that may materially affect our research and development of our candidates, business and results of operations. Any claims, or legal proceedings initiated by us or brought against us, with or without merit, may result in substantial costs and diversion of resources, and could materially harm our reputation. Furthermore, claims, disputes or legal proceedings against us may be due to defective supplies sold to us by our suppliers, who 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.

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

We are exposed to risks relating to product and professional liability as a result of clinical testing and any future commercialization of our candidates in and outside China. For example, we may be sued if our candidates cause, or are perceived to cause, injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing or design, a failure to warn of the inherent dangers in the drugs, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against, or obtain indemnification from our collaborators for, product liability claims, we may incur substantial liabilities or be required to limit commercialization of our candidates. Defending ourselves would require significant expenditures and management resources. Regardless of the merits or eventual outcome, liability claims may result in reputational damage, withdrawal of clinical trial participants and inability to continue clinical trials, initiation of investigations by regulators, costs to defend the related litigation, a diversion of management’s time and our

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resources, substantial monetary awards to trial participants or patients, product recalls, a decrease in demand for our candidates, withdrawals, restrictive labeling and marketing or promotional restrictions.

It is possible that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a product liability claim or a series of claims is brought against us for uninsured liabilities, our assets may not be sufficient to cover such claims and our business operations may be impaired. Should any of the foregoing events occur, our business, financial condition and results of operations would be materially and adversely affected.

If we use hazardous materials in a manner that causes injury, we could be liable for damages.

We are subject to laws and regulations governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials. Our operation involves the use of hazardous materials, including chemicals, and may produce hazardous waste products. We cannot eliminate the risks of contamination or personal injury from these materials. We may incur substantial costs in order to comply with current or future laws and regulations on the use of hazardous materials. These current or future laws and regulations may impose restrictions on our research, development or production activities. Failure to comply with these laws and regulations may also result in substantial fines, penalties or other sanctions.

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

Disasters, health epidemics or pandemics, 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 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 outbreaks of a widespread health epidemic such as swine flu, avian influenza, severe acute respiratory syndrome, SARS, Ebola, Zika and Coronavirus disease, other force majeure events such as power outages, water or fuel shortages, failures, malfunction and breakdown of information technology 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 in the PRC or elsewhere in the world could materially disrupt our business and operations. In particular, it could cause delay of clinical trials, regulatory submissions and required approvals of our candidates, and could cause us to incur additional costs. If our

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employees or employees of our suppliers and other business partners are suspected of being infected with an epidemic disease, our operations may be disrupted because we or our business partners must quarantine some or all of the affected employees or disinfect relevant facilities. If we are not able to effectively develop and commercialize our candidates as a result of protracted clinical trials of enrolled patients, elevated public health safety measures, or failure to recruit patients and conduct patient follow-up, we may not be able to generate revenue from sales of our candidates as planned.

Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. We partially rely on our third-party collaborators for conducting research and development of our candidates, and they may be affected by funding withdrawals. We also rely on third-party manufacturers to produce and process supplies of our candidates. Our ability to obtain supplies of our candidates could be disrupted if the operations of these collaborators or suppliers are affected by disasters, epidemics, business interruptions and other force majeure events. Damage or extended periods of interruption to our operational 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 candidates. 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, cause loss of lives, disrupt our business network and destroy our markets. Any of the foregoing events and other events beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial condition and results of operations.

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

As we seek to advance our product candidates through clinical trials and commercialization, and further commercialization of approved products, we plan to continue to expand our research and development capabilities and build up our manufacturing, marketing and sales capabilities. The success of our growth strategy will depend on, among other things, our ability to advance clinical research and development, enhance our drug development platforms, enhance business development capabilities and commence operations of manufacturing facilities upon commercialization of our candidates. See “Business — Our Strategies.” However, we have limited operational, administrative and financial resources, which may be inadequate to sustain the growth we seek to achieve. In particular, in order to implement our growth strategy, we will need to increase our investment in, among other things, our research and development, marketing and other areas of operations. If we are unable to manage our growth and expansion effectively, our business may be adversely affected.

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Potential acquisition, collaboration or strategic partnership in which we engage in may entail various risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail various risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of additional equity securities and hence the dilution of our existing Shareholders;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel, or failure to otherwise achieve intended synergies in the combined operations;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the assimilation of operations, corporate culture and personnel of the acquired business;
- risks associated with the acquisition of intangible assets, which are subject to amortization and impairment assessment;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and its existing drugs or candidates and regulatory approvals;
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and
- changes in accounting principles relating to the recognition and measurement of our investments that may have a significant impact on our financial results.

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Moreover, we may not be able to identify suitable opportunities for acquisition and strategic partnerships, which may limit our ability to grow or obtain access to technology or products that may be important to the development of our business.

We are subject to the risks of doing business in multiple jurisdictions.

As we operate in the PRC and may expand into overseas markets, our business is subject to risks associated with doing business in multiple jurisdictions. Our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country’s or region’s political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in relevant jurisdictions;
- efforts to develop an international sales, marketing and distribution system, which may increase our expenses and divert our management’s attention from the development of candidates or potentially profitable licensing opportunities;
- the occurrence of economic stagnation or downturn in certain jurisdictions, including those caused by inflation or political instability;
- the burden of complying with a variety of foreign laws, including difficulties in enforcement of contractual provisions;
- inadequate intellectual property protection in certain jurisdictions;
- enforcement of anti-corruption and anti-bribery laws;
- trade-protection measures, import or export licensing requirements and fines, penalties or suspension;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles and greater difficulty in accounts receivable collection;
- the effects of applicable local tax regimes and potentially adverse tax consequences; and
- significant adverse changes in local currency exchange rates.

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We may pursue partnerships with entities in foreign countries and regions, in particular in the U.S. In the event that China or the countries from which we import raw materials impose tariffs or other trade policies affecting the importation of such components or raw materials, we may not be able to obtain a stable supply of necessary components or raw materials at competitive prices, and our business and operations may be materially and adversely affected. We may also sell our products to certain foreign countries or regions in the future. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. It is notable that the U.S. government has recently made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as announcing import tariffs, which have led to other countries, including China and members of the EU, imposing tariffs against the U.S. in response. These trade disputes may escalate and may result in certain types of goods, such as advanced research and development equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even illegal to export. Furthermore, there can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Tensions and political concerns between different countries or regions may therefore adversely affect our business, financial condition, results of operations and prospects.

In addition, we are subject to general geopolitical risks in foreign countries or regions where we may operate in the future, such as political and economic instability and changes in diplomatic and trade relationships. The occurrence of any one or more of these risks of doing business internationally, individually or in the aggregate, could materially and adversely affect our business and results of operations.

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

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. See “Business — Insurance.” We have elected not to maintain certain types of insurance, such as business interruption insurance. Our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by, our manufacturing facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may adversely affect our drug development and overall operations.

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Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, and insider trading.

We may be exposed to fraud, bribery or other misconduct committed by our employees, principal investigators, consultants and commercial partners that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. In particular, our employees and other third parties we engage may have access to medical data treatment records and other personal details of patients enrolled in our clinical trials, along with other personal or sensitive information, when they carry out data monitoring and quality control responsibilities for our clinical programs. Despite that we and such third parties have strict measures to safeguard data privacy and security as well as confidentiality, there can be no assurance that such employees and other third parties will comply with all requirements of privacy laws, information security policies and contractual obligations related to data privacy and security and confidentiality at all time.

During the Track Record Period, we were not aware of any instances of fraud, bribery, or other misconduct involving employees and other third parties that had any material and adverse impact on our business and results of operations. However, there can be no assurance that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct. Any such instances of misconduct committed against our interests, including undetected past acts and future acts, may have a material adverse effect on our business and results of operations.

We are subject to risks associated with leasing properties.

As of the Latest Practicable Date, (i) we leased nine properties in China, comprising four properties with an aggregate gross floor area of approximately 3,577.9 sq.m., which were used for research and development and office space, and five properties used as employee dormitory. The expiration dates of these leases range from May 2024 to October 2026; and (ii) we leased one property in Hong Kong with a gross floor area of approximately 473.0 square feet, which we used for research and development, and the expiration of such lease is in April 2025. As of the same date, the property ownership certificate of one of our leased properties in China used for research and development had not been provided to us by the relevant lessor. Accordingly, such lessor may not be entitled to lease the relevant property to us. If the above defect of this leased property prevents us from continuing the lease so that we are required to move to another location, we can relocate to other comparable alternative premises in the relevant region without any material adverse effect on our business, financial condition and results of operations, given that our primary assets at such leased property are office equipment and research equipment. The relevant lessor also confirmed to indemnify us for any losses that we incurred as a result of such defect.

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Nevertheless, there can be no assurance that we will be able to find proper substitutes in a timely manner and at commercially reasonable terms in the event of such relocation. In addition, as our leases expire, we may fail to negotiate renewals, either on commercially acceptable terms, or at all, which could require us to close such offices or manufacturing facilities. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition. See "Business — Properties."

Pursuant to PRC laws, the lease agreements must be filed with the local branch of the Ministry of Housing and Urban-Rural Development. The filing of such leases will require the cooperation of the lessors. Any failure to register lease agreements as required under PRC laws will not affect the validity and enforceability of the lease agreements, but may subject us to a fine for non-registration which may range from RMB1,000 to RMB10,000 for each non-registration agreement, which may negatively affect our ability to operate our business covered under those leases. As of the Latest Practicable Date, we had not filed our lease agreements for seven properties we leased in China with the local housing administration authorities as required under PRC laws and regulations.

As advised by our PRC Legal Advisor, the foregoing property defects will not have a material and adverse effect on our business operation, or materially jeopardize the proposed [REDACTED]. Nevertheless, there can be no assurance that we will not be penalized by the competent authorities as a result of such defects in our leased properties in the future.

Our internal computer systems, or those used by our partners or other contractors or consultants, may fail or suffer security breaches or other disruptions, which could adversely affect our business and reputation.

Despite the implementation of security measures, our internal computer systems and those of our partners, contractors and consultants are vulnerable to damages from computer viruses and unauthorized access. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification, or intentional or accidental release or loss of information maintained in the information systems and networks of us and our vendors, including personal information of our employees and participants, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, and other cyberattacks. The

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number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes are costly and requires ongoing monitoring and updating, as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with counterparties, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our candidates could be delayed.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We had incurred net losses during the Track Record Period and anticipate that we will continue to incur net losses for the foreseeable future.

Investment in the development of biopharmaceutical products is highly speculative as it requires substantial upfront capital expenditures and involves significant risks that a candidate may fail to demonstrate efficacy or safety to gain regulatory or marketing approvals or become commercially viable. During the Track Record Period, we had financed our operating activities primarily through capital contributions from our Shareholders and private equity financing. While we have other sources of income including government grants, we had not generated any revenue from commercialization of our candidates during the Track Record Period, and had incurred, and will continue to incur, significant research and development expenses and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred net losses since our inception. In 2022 and 2023, our loss for the year was RMB85.9 million and RMB105.2 million, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development expenses and administrative expenses, as well as finance costs.

We expect to continue to incur net losses for the foreseeable future, and also expect that these operating losses will increase as we may carry out certain activities relating to our development, including the following: conducting pre-clinical and clinical trials of our candidates; manufacturing clinical trial materials through CMOs and CDMOs in and outside China; seeking regulatory approvals for our candidates; commercializing our candidates for which we have

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obtained marketing approvals; hiring additional personnel; establishing a commercialization team for any future drug products that have obtained regulatory approvals; seeking to identify additional candidates; obtaining, maintaining, expanding and protecting our intellectual property portfolio; and acquiring or in-licensing other candidates, intellectual property and technologies.

Typically, it takes many years to develop one new drug from the time of its discovery to the time when it becomes available for treating patients. During this process, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown events that may have an adverse effect on our business, financial condition and results of operations. The size of our future operating losses will depend partially on the rate of the future growth of our expenses, our ability to generate revenue and the timing and amount of milestone payments and other payments that we receive from, or pay to, third parties. If any of our candidates fails during clinical trials or does not obtain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital and Shareholders' equity.

We expect to incur significant share-based payments in connection with equity grants to our key management, directors and employees.

To incentivize and maintain our and our subsidiaries' directors, senior management members, core technical personnels and key employees, we have granted and expect to continue to grant employee incentive plans. The Company adopted three employee incentive plans in December 2020, October 2021 and February 2024, respectively. In 2022 and 2023, we recorded share-based payment expenses of RMB24.8 million and RMB14.7 million, respectively. The granting of such plans would increase our share-based payment expenses and thus may adversely affect our financial performance and potentially dilute our shareholding.

We had recorded net cash outflow from operating activities in 2022 and 2023. Even if we consummate the [REDACTED], we may need to obtain additional financing to fund our operations. If we are unable to obtain such financing, we may be unable to complete the development and commercialization of our major candidates.

We had net cash used in operating activities of RMB44.9 million and RMB58.9 million in 2022 and 2023, respectively. We expect our expenses to increase significantly in connection with our ongoing operating activities, particularly as we advance the clinical development of our clinical-stage candidates, continue the research and development of our pre-clinical-stage candidates, initiate additional pre-clinical and clinical trials of, and seek regulatory approvals for, our candidates.

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In addition, if we obtain regulatory approvals for any of our candidates, we expect to incur significant commercialization expenses relating to product manufacturing, marketing, sales and distribution and post-approval commitments to continue monitoring the efficacy and safety data of our future products on the market.

We currently have no drug approved for commercial sale and have not generated any revenue from drug sales. We have incurred operating losses in each year since inception. We expect that we may continue to experience net cash outflows from our operating activities for the foreseeable future. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations through equity offerings, debt financing or other sources. Adequate additional funding may not be available to us on commercially reasonable terms, or at all. If we are unable to raise sufficient capital in a timely manner or on commercially reasonable terms, we could be forced to delay, reduce or terminate our research and development projects or any future commercialization efforts, which could have a material adverse effect on our business, financial condition and results of operations.

We recorded net liabilities as of December 31, 2022 and 2023.

We recorded net liabilities of RMB54.9 million and RMB131.9 million as of December 31, 2022 and 2023, respectively, primarily due to other financial liabilities in relation to redemption liabilities from our Pre-[REDACTED] Investments. Pursuant to the supplemental agreement to the shareholders agreement dated February 23, 2024 entered into between us and the Shareholders, the redemption right granted to the Pre-[REDACTED] Investors has been terminated on the date of such supplemental agreement. See “History, Development and Corporate Structure — Pre-[REDACTED] Investments.” As such, the financial instruments issued to Pre-[REDACTED] Investors have been reclassified from other financial liabilities to equity, which reversed our net liability position to a net asset position since the termination of the redemption right. If we are unable to maintain adequate working capital or obtain sufficient equity or debt financing to meet our capital needs, we may be unable to continue our operations according to our plans and be forced to scale back our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

We had a notable amount of intangible assets. Amortization may adversely affect our results of operations and financial condition.

Our intangible assets represent patents. Our intangible assets decreased from RMB3.0 million as of December 31, 2022 to RMB1.0 million as of December 31, 2023, primarily due to accumulated amortization. See Note 15 in Appendix I to this document. Our intangible assets are with a definite useful life and hence subject to amortization. As we carry a substantial balance of intangible assets, any significant amortization of our intangible assets could have a material adverse effect on our business, financial condition and results of operations.

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

Many factors, encompassing geopolitical, economic and market conditions, significantly influence the regions in which we conduct our operations. These factors include, but are not limited to, the fluidity of international financial markets, fluctuations in debt and equity valuations, variations in interest rates, and the prices of currencies and commodities. Additionally, investor confidence, inflation rates, and the accessibility and expense of capital and credit are pivotal determinants. Recent times have seen a marked deceleration in growth rates amidst pervasive uncertainty within the financial markets. In the past, governments have taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If these actions are not successful, the return of adverse economic conditions may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all.

The tepid pace of economic recovery globally, coupled with an environment characterized by high levels of inflation and interest rates, has exacerbated market instability. Such conditions have the potential to negatively influence global liquidity, amplify market volatility, and escalate the costs of funding in U.S. dollars. Consequently, this could lead to a constriction of financial conditions worldwide and stoke fears of an impending recession. A prolonged period of extremely volatile and unstable market conditions would likely increase our funding costs and could also adversely affect the jurisdictions where we operate, which could in turn materially and adversely affect our ability to raise capital.

Raising additional capital may cause dilution to the interests of our Shareholders or restrict our operations.

We may seek additional funding through a combination of equity offerings, debt financings or other methods. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the value of your investment in our Shares will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could give rise to increased fixed payment obligations and also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, the issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Shares to decline.

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

The change in the value of the Renminbi against the Hong Kong dollar, the U.S. dollar and other currencies may fluctuate and is affected by various factors beyond our control. Substantially all of our costs are denominated in Renminbi and most of our financial assets are also denominated in Renminbi. However, our [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. Any significant change in the exchange rates of the Hong Kong dollar against the Renminbi may materially and adversely affect the value of, and any dividends payable on, our Shares in Hong Kong dollars.

RISKS RELATING TO OUR DOING BUSINESS IN THE PRC

We enjoyed preferential tax treatment and government grants during the Track Record Period. Expiration of, or changes to, these incentives or policies, or our failure to satisfy any condition for these incentives, would have an adverse effect on our results of operations.

During the Track Record Period, we enjoyed preferential tax treatment and government grants. In particular, we benefited from a preferential tax rate of 15% as we were qualified as a High and New Technology Enterprise under the relevant PRC laws and regulations on December 17, 2021 and such qualification will expire on December 16, 2024. Our eligibility to receive these financial incentives in the future depends on our ability to maintain the relevant qualifications. The discontinuation or reduction of financial incentives currently available to us could have a material adverse effect on our business, financial condition and results of operations.

The biopharmaceutical industry in the PRC is highly regulated and such regulations are subject to change, which may affect approvals and commercialization of our candidates.

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

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termination of our business activities in the PRC. We believe our strategies and approach are consistent with the PRC government’s policies, but there can be no assurance that our strategies and approach will remain consistent therewith.

Changes in China’s economic, political and social conditions could adversely affect our business, financial condition, results of operations, cash flows and prospects.

Substantially all of our current businesses, assets and operations are located in the PRC and, as a result, our business, financial condition and results of operations are influenced by the overall economic and regulatory environment in the PRC.

Our performance is affected by China’s economy, which, in turn, is influenced by the global economy. The uncertainties relating to the global economy as well as the political environment in various regions of the world can also possibly impact China’s economy. We are unable to predict all the risks that we face as a result of current economic and regulatory developments and many of these risks are beyond our control. All such factors may materially and adversely affect our business and operations as well as our financial performance.

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 provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in the PRC must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded, at least in part, by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. There can be no assurance that we can always obtain relevant approvals for sending scientific data including the results of our pre-clinical studies or clinical trials conducted within the PRC abroad or to our foreign partners in the PRC. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of candidates may be hindered, which may materially and adversely affect our business, financial condition, results of operations and prospects. If the relevant governmental 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 governmental authorities.

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

Under the applicable PRC tax laws, both the dividends we pay to non-PRC resident individual holders of H shares (“**non-resident individual holders**”), and gains realized through the sale or transfer by other means of H shares by such Shareholders, are subject to PRC individual income tax at a rate of 20%, unless reduced by the applicable tax treaties or arrangements.

Under applicable PRC tax laws, the dividends we pay to, and gains realized through the sale or transfer by other means of H shares by non-PRC resident enterprise holders of H shares (“**non-resident enterprise holders**”), are both subject to PRC enterprise income tax at a rate of 10%, unless reduced by applicable tax treaties or arrangements. Pursuant to the Arrangements 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 Incomes (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) dated August 21, 2006, any non-resident enterprise registered in Hong Kong that holds, directly, at least 25% of the shares of our Company shall pay Enterprise Income Tax for the dividends declared and paid by us at a tax rate of 5% if the Hong Kong non-resident enterprise is the beneficial owner of the equity and certain other conditions are met.

For non-resident individual holders, gains realized through the transfer of properties are normally subject to PRC individual income tax at a rate of 20%. However, according to the Circular of the Ministry of Finance and the State Taxation Administration on Issues Concerning Individual Income Tax Policies (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), income received by individual foreigners from dividends and bonuses of a foreign-invested enterprise are exempt from individual income tax for the time being. According to the Circular Declaring that Individual Income Tax Continues to Be Exempted over Individual Income from Transfer of Shares issued by the MOF and the STA (關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知) effective as of March 30, 1998, income from individuals’ transfer of stocks of listed companies continued to be temporarily exempted from individual income tax. On February 3, 2013, the State Council approved and promulgated the Notice of Suggestions to Deepen the Reform of System of Income Distribution (國務院批轉發展改革委等部門關於深化收入分配制度改革若干意見的通知). On February 8, 2013, the General Office of the State Council promulgated the Circular Concerning Allocation of Key Works to Deepen the Reform of System of Income Distribution (國務院辦公廳關於深化收入分配制度改革重點工作分工的通知). According to these two documents, the PRC government is planning to cancel foreign individuals’ tax exemption for dividends obtained from foreign-invested enterprises, and the Ministry of Finance and the State Taxation Administration should be responsible for making and implementing details of such plan. However, relevant implementation rules or regulations have not been promulgated by the Ministry of Finance and the State Taxation Administration.

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

The remittance of Renminbi into and out of the PRC and PRC government's policies on currency conversion may affect our ability to pay dividends and other obligations, and affect the value of your investment.

The PRC government has promulgated a series of laws and regulations on foreign exchange. We receive all of our revenue in Renminbi. We may convert a portion of our revenue into other currencies to meet our foreign currency obligations, such as payments to certain suppliers. Shortages in the availability of foreign currency may affect our ability to remit sufficient foreign currency, or otherwise satisfy our foreign currency-denominated obligations.

Under the existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior SAFE approval by complying with certain procedural requirements. However, approval from or registration with competent governmental 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. Under the relevant laws and regulations, the government is eligible to take necessary measures to guarantee and control the international balance of payments when serious disequilibrium of balance of payments occurs or is possible to occur or other legal circumstances occur. If the foreign exchange policies prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our Shareholders. Furthermore, there can be no assurance that new regulations will not be promulgated in the future that further regulate the remittance of Renminbi into or out of China.

Investors may experience difficulties in effecting service of legal process and enforcing judgments against us and our Directors, Supervisors and management.

We are a company incorporated under the laws of the PRC and substantially all of our assets and subsidiaries are located in the PRC. The majority of our Directors, Supervisors and senior management reside within the PRC. The assets of these Directors, Supervisors and senior management also may be located within the PRC. As a result, it may not be possible to effect service of process upon most of our Directors, Supervisors and senior management outside the PRC. Moreover, the PRC does not have treaties providing for reciprocal recognition and enforcement of court judgments in the United States, the United Kingdom, Japan or most other countries. In addition, Hong Kong has no arrangement for the reciprocal enforcement of judgments with the United States. Recognition and enforcement of court judgments from other jurisdictions may be difficult or impossible.

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On July 14, 2006, the Supreme People’s Court of the Mainland and the Government of the Hong Kong Special Administrative Region signed an Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters (《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 “**2006 Arrangement**”). Under the 2006 Arrangement, where any designated People’s Court of the PRC or Hong Kong court has made an enforceable final judgment requiring payment of money in a civil and commercial case pursuant to a choice of court agreement, any party concerned may apply to the relevant People’s Court of the PRC or Hong Kong court for recognition and enforcement of the judgment. On January 18, 2019, the Supreme People’s Court of the PRC and the government of the Hong Kong Special Administrative Region signed an 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 “**2019 Arrangement**”), which came into effect on January 29, 2024. The 2019 Arrangement will supersede the 2006 Arrangement and any party concerned may apply to the relevant PRC court or Hong Kong High Court for recognition and enforcement of the effective judgments made on or after the effective date of the 2019 Arrangement in civil and commercial cases. However, the written jurisdiction agreements signed subject to the 2006 Arrangement before the effective date of the 2019 Arrangement remain applicable under the 2006 Arrangement. As the 2019 Arrangement went effective relatively recently, its implementation and interpretation is still evolving.

Although we will be subject to the Listing Rules and the Codes on Takeovers and Mergers and Share Repurchases of Hong Kong upon the [REDACTED] of our H Shares on the Stock Exchange, the holders of H Shares will not be able to bring actions on the basis of violations of the Listing Rules and must rely on the Stock Exchange to enforce its rules. The Listing Rules and the Codes on Takeovers and Mergers and Share Repurchases of Hong Kong do not have the force of law in Hong Kong.

Uncertainties in the interpretation and enforcement of the Measures for Cybersecurity Review or the Regulations on the Administration of Cyber Data Security (Draft for Comments) may adversely affect our business operations and our [REDACTED].

On December 28, 2021, the CAC, jointly with other 12 governmental authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “**Cyber Review Measures**”) which became effective on February 15, 2022. Pursuant to Article 2 of the Cyber Review Measures, critical information infrastructure operators purchasing network product or service and network platform operators conducting data process activities, which affect or may affect national security, shall be subject to the cybersecurity review. Pursuant to the Cyber Review Measures, an network platform operator which possesses personal information of over one million users and intends to “list abroad” shall be subject to cybersecurity review. For more details, see “Regulatory Overview — Regulations in Relation to Company Establishment, Foreign Investment

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and Outbound Investment — Regulations on Data Security.” Any failure or delay in the completion of the cybersecurity review under Cybersecurity Review Measures, or other non-compliance with the relevant cybersecurity laws and regulations, may result in administrative penalties, including fines, a shut-down of our business, as well as reputational damage or legal proceedings or actions against us, which may have material adverse effects on our business, financial condition or results of operations.

As of the Latest Practicable Date, (i) to the best knowledge of our Directors, we had not been determined or identified as a critical information infrastructure operator by any governmental authorities; (ii) to the best knowledge of our Directors, we had not engaged in any data process activities that affect or may affect national security according to the applicable PRC laws; (iii) we had not been involved in any investigations on cybersecurity review made by CAC, and had not received any inquiry, notice, warning or sanctions in this regard, our PRC Legal Advisor is of the view that we have no obligation to proactively apply for cybersecurity review under the Cyber Review Measures at this stage.

However, the Cyber Review Measures provides no further explanation or interpretation for “network platform operator”, and does not stipulate that a network platform operator which intends to list in Hong Kong shall be subject to cybersecurity review. Given that the expression used in the Cyber Review Measures is “list abroad” and Hong Kong is not a country or region outside of the PRC, our PRC Legal Advisor is of the view that we have no obligation to proactively apply for cybersecurity review for our application for our proposed [REDACTED] under the Cyber Review Measures.

Nevertheless, the Cyber Review Measures also grants the member organization of the cybersecurity review mechanism the right to initiate cyber security review without application, if any of them has reason to believe that any internet products, services or data process activities affect or may affect national security. The PRC governmental authorities may have broad discretion in the interpretation of “affect or may affect national security.” If any internet products, services or data process activities of us are deemed to “affect or may affect national security” by the PRC governmental authorities under its broad discretion, we may be subject to cybersecurity review. If we fail to pass such cybersecurity review, our [REDACTED] may be impeded and/or our business operations may be adversely affected.

On November 14, 2021, CAC promulgated the Regulations on the Administration of Cyber Data Security (Draft for Comments) (《網絡數據安全管理條例(徵求意見稿)》) (the “**Draft Cyber Data Regulations**”). The Draft Cyber Data Regulations, among other things, stipulate that data processors shall, in accordance with relevant state provisions, apply for cybersecurity review when carrying out activities including: (i) seeking to be listed in Hong Kong that affect or may affect national security; and (ii) other data processing activities that affect or may affect national security. As of the Latest Practicable Date, the Draft Cyber Data Regulation has not taken effect,

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and it is uncertain as to the definition and interpretation of key terms in such regulations, the standard of review to be adopted and potential consequences. Especially, the Draft Cyber Data Regulation provides no further explanation or interpretation for “affect or may affect national security.”

If we were deemed as a data processor that “affects or may affect national security” by the PRC governmental authorities under its broad discretion, we may be subject to cybersecurity review. 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 severe penalties and/or action by the competent governmental authority.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals. Our operations also produce hazardous waste products. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials or our or third parties’ disposal of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

Any failure to make adequate contributions to various employee benefit plans as required by PRC regulations may subject us to penalties.

Companies operating in China are required to participate in various employee benefit plans, including pension insurance, unemployment insurance, medical insurance, work-related injury insurance, maternity insurance and housing provident fund and contribute to the amounts equal to certain percentage of salaries, including bonuses and allowances, of their employees up to a maximum amount specified by the local government from time to time at locations where they operate their business. As of February 29, 2024, we did not pay the social insurance and/or housing provident funds for several employees, mainly because: (i) we were in the process of going through relevant procedures for some of our newly recruited employees, and such

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procedures have been completed as of the date of this document; (ii) some of them had voluntarily relinquished such payments, despite our efforts to persuade them to comply with the relevant requirements; and (iii) the relevant payments for some employee were made through third-party human resources agencies, due to the employee's own preferences for the location of the relevant payments. As of the Latest Practicable Date, we had not received any notice from the competent authorities ordering rectification or deadline for payment of outstanding fees or administrative penalties in respect of social insurance and housing provident fund, and have not received any reports or complaints from employees. In addition, Ms. Jia and Mr. Wang, two of our Controlling Shareholders, have provided indemnity in favor of our Group in respect of any notice from the competent authorities ordering deadline for payment of administrative penalties in respect of social insurance and housing provident fund after the proposed [REDACTED]. As advised by our PRC Legal Advisor, such non-compliant incidents will not have a material and adverse effect on our business operation, or materially jeopardize the proposed [REDACTED]. However, we cannot assure you that any new laws and regulations or any changes in the implementation of the existing laws and regulations will not require us to pay any contribution shortfall retroactively, thereby adversely affecting our financial condition and results of operations.

RISKS RELATING TO THE [REDACTED]

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

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

In particular, according to the PRC Company Law, all of the Shares in issue as of the date of this document, representing [REDACTED]% of our total issued Shares upon [REDACTED] (assuming the [REDACTED] is not exercised), will be subject to a lock-up period of one year from the [REDACTED]. These may significantly affect the liquidity and [REDACTED] volume of our H Shares in the short term following the [REDACTED].

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The [REDACTED] of our H Shares may be volatile, which could lead to substantial losses to investors. In addition, the market price of our H Shares will be affected following announcements and data releases regarding products and pipeline similar to ours.

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

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

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

In addition, our unlisted shares may be converted into H shares subject to regulatory approvals and compliance with relevant regulatory requirements. Any conversion of our unlisted shares will increase the number of H shares available on the market and may affect the [REDACTED] of our H Shares.

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

We currently expect to retain all future earnings for use in operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the foreseeable future. Any future declarations and payments of dividends will be at the absolute discretion of our Directors and will depend on our actual and expected results of operations, cash flow and financial position, general business conditions and business strategies, expected working capital requirements and future expansion plans, legal, regulatory and other contractual restrictions, and other factors which our Directors consider relevant. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. According to the PRC laws, 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. As a result, there can be no assurance whether, when and in what form we will pay dividends in the future. Subject to any of the above constraints, we may not be able to pay dividends in accordance with our dividend policy. See “Financial Information — Dividend.”

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

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

Certain facts, forecasts and statistics obtained from official government sources in this document relating to the pharmaceutical markets may not be fully reliable.

Certain facts, forecasts and statistics in this document relating to the pharmaceutical markets in and outside China are obtained from official government publications that have not been independently verified by us, the Joint Sponsors, [REDACTED], any of their respective directors, employees, agents or advisors, or any other person or party involved in the [REDACTED], and no representation is given as to its accuracy. However, we cannot guarantee the quality or reliability of these sources. Neither we, the Joint Sponsors, [REDACTED]

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nor our or their respective affiliates or advisors have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

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

This document contains certain statements and information that are forward-looking and uses forward-looking terminology such as "believe," "expect," "estimate," "predict," "aim," "intend," "will," "may," "plan," "consider," "anticipate," "seek," "should," "could," "would," "continue," and other similar expressions. You are cautioned that reliance on any forward-looking statement involves risks and uncertainties and that any or all of those assumptions could prove to be inaccurate and, as a result, the forward-looking statements based on those assumptions could also be incorrect. In light of these and other risks and uncertainties, the inclusion of forward-looking statements in this document should not be regarded as representations or warranties by us that our plans and objectives will be achieved and these forward-looking statements should be considered in light of various important factors, including those set forth in this section. Subject to the requirements of the Listing Rules, we do not intend publicly to update or otherwise revise the forward-looking statements in this document, whether as a result of new information, future events, or otherwise. Accordingly, you should not place undue reliance on any forward-looking information. All forward-looking statements in this document are qualified by reference to this cautionary statement.

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

Subsequent to the date of this document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we

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disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this document only and should not rely on any other information.

A future significant increase or perceived significant increase in the supply of our H Shares in public markets could cause the [REDACTED] of our H Shares to decrease significantly, and/or dilute shareholdings of holders of our H Shares.

The [REDACTED] 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, or the issuance of new shares or other securities, or the perception that such sales or issuances may occur. Future sales, or anticipated sales, of substantial amounts of our securities, including any future offerings, could also materially and adversely affect our ability to raise capital at a specific time and on terms favorable to us. In addition, our Shareholders may experience dilution in their holdings if we [REDACTED] 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.

Our Domestic Shares can be converted into H Shares if the conversion and [REDACTED] of the H Shares is duly completed pursuant to the requisite approval process and the approval from the relevant PRC regulatory authorities, including the CSRC, is obtained. In addition, such conversion and [REDACTED] must, in all aspects, comply with the regulations promulgated by the securities regulatory authority under the State Council and the regulations, requirements and procedures of the Stock Exchange. If a significant number of Domestic Shares are converted into H Shares, the supply of H Shares may be substantially increased, which could have a material and adverse effect on the prevailing market price for our H Shares.

In addition, while investors [REDACTED] shares in the [REDACTED] are not subject to any restrictions on the disposal of the H Shares, they may have existing arrangements or agreement to dispose part or all of the H Shares they hold immediately or within certain period upon completion of the [REDACTED] for legal and regulatory, business and market, or other reasons. Such disposal may occur within a short period or any time or period after the [REDACTED].

Any sale of the H Shares [REDACTED] by such investors pursuant to such arrangement or agreement could adversely affect the [REDACTED] of our H Shares and any sizeable sale could have a material and adverse effect on the [REDACTED] of our H Shares and could cause substantial volatility in the [REDACTED] of our H Shares.

WAIVER AND EXEMPTION

In preparation for the [REDACTED], we have sought the following waiver 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.

MANAGEMENT PRESENCE

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

Our headquarters are based, and our core business and operations are substantially based and conducted in the PRC and most of the Company’s assets are located in the PRC. Further, all of the Company’s executive Directors are based in the PRC, as the Board believes it would be in our best interests for them to be based in places where our Group has significant operations. We consider it practically difficult and commercially unreasonable for us to arrange for two executive Directors to be ordinarily resident in Hong Kong, either by means of relocation of our existing executive Directors or appointment of additional executive Directors. Therefore, our Company does not have, and does not contemplate in the foreseeable future that we will have sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rules 8.12 of the Listing Rules.

Accordingly, pursuant to Rule 19A.15 of the Listing Rules, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver from strict compliance with Rule 8.12 of the Listing Rules subject to the following conditions:

1. we have appointed Dr. ZHAI Junhui (翟俊輝) and Ms. WONG Wai Yee Ella (黃慧兒) as our authorized representatives (“**Authorized Representatives**”), pursuant to Rule 3.05 of the Listing Rules. The Authorized Representatives will act as our Company’s principal channel of communication with the Stock Exchange. The Authorized Representatives will be readily contactable by phone, facsimile and email to promptly deal with enquiries from the Stock Exchange, and will also be available to meet with the Stock Exchange to discuss any matter within a reasonable period of time upon request of the Stock Exchange;

WAIVER AND EXEMPTION

2. when the Stock Exchange wishes to contact our Directors on any matter, each of the Authorized Representatives will have all necessary means to contact all of our Directors (including our independent non-executive Directors) promptly at all times. We have provided the Stock Exchange with the contact details (i.e. mobile phone number, office phone number and email address) of all Directors to facilitate communication with the Stock Exchange;
3. all Directors who do not ordinarily reside in Hong Kong possess or can apply for valid travel documents to visit Hong Kong and can meet with the Stock Exchange within a reasonable period upon the request of the Stock Exchange;
4. we have appointed Orient Capital (Hong Kong) Limited as our compliance advisor (the “**Compliance Advisor**”) upon [REDACTED] pursuant to Rule 3A.19 of the Listing Rules. The Compliance Advisor will, among other things and in addition to the Authorized Representatives, provide our Company with professional advice on continuing obligations under the Listing Rules and act as the additional channel of communication with the Stock Exchange during the period from the [REDACTED] to 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 immediately after the [REDACTED]; and
5. meetings between the Stock Exchange and our Directors could be arranged through our Authorized Representatives or our Company’s Compliance Advisor, or directly with our Directors within a reasonable period. Our Company will inform the Stock Exchange as soon as practicable in respect of any change in the Authorized Representatives, the Directors and/or the Compliance Advisor of our Company in accordance with the Listing Rules.

WAIVER AND EXEMPTION

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 prospectuses 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 prospectus 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 prospectus, 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 prospectus 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 prospectus and (ii) the assets and liabilities of the company of each of the three financial years immediately preceding the issue of the prospectus.

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 compliance with the relevant requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance if, having regard to the circumstances, the SFC considers that the exemption will not prejudice the interests of the investing public and compliance with any or all of such requirements would be irrelevant or unduly burdensome, or is otherwise 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 listing document or such shorter period as may be acceptable to the Stock Exchange be included in the accountants' report to the prospectus.

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. According to Rule 18A.03(3) of the Listing Rules, a biotech company must have been in operation in its current line of business for at least two financial years prior to listing under substantially the same management. Rule

WAIVER AND EXEMPTION

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

In compliance with the above-mentioned requirements under the Listing Rules, the Accountants’ Report set out in Appendix I is currently prepared to cover the years ended December 31, 2022 and 2023, and will cover the two years ended December 31, 2022 and 2023 [and at least the [REDACTED]] in our final document. Accordingly, we have applied to the SFC for a certificate of exemption from strict compliance with the requirements under Section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance and paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule on the following grounds.

- (a) our Company is primarily engaged in research, development and commercialization of multifunctional therapies for wound healing, currently PDGF drugs, 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) as of the Latest Practicable Date, we had not commercialized any products and therefore did not generate any revenue from product sales. Major financing activities conducted by us since our incorporation include our Pre-[REDACTED] Investments, the details of which have been fully disclosed in “History, Development and Corporate Structure” in this document;
- (c) the Accountants’ Report for each of the financial years ended December 31, 2022 and 2023 has been prepared and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules;
- (d) notwithstanding that the financial results set out in this document are only for the years ended December 31, 2022 and 2023 in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and requirements under the Companies (Winding up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements. Therefore, 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 unduly burdensome as this would require additional work to be performed by our Company and the Company’s reporting accountants; and

WAIVER AND EXEMPTION

- (e) the Accountants' Report covering the years ended December 31, 2022 and 2023 (as set out in Appendix I), together with other disclosures in this 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]** public.

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]

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[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
Chairperson of the Board and Executive Director		
Ms. JIA Lijia (賈麗加)	Room 2701, Unit 3, Building 4 Court 1, Qinglin Road Chaoyang District Beijing, PRC	Chinese
Executive Directors		
Mr. WANG Kelong (王軻龍)	Room 2701, Unit 3, Building 4 Court 1, Qinglin Road Chaoyang District Beijing, PRC	Chinese
Dr. ZHAI Junhui (翟俊輝)	Bungalow 383, Court 20 Dongda Street Fengtai District Beijing, PRC	Chinese
Non-executive Directors		
Mr. MIAO Tianxiang (苗天祥)	Room 2001, Building 3 Vanke Xingyuan Chaoyang District Beijing, PRC	Chinese
Ms. LIN Ying (林穎)	Unit 28B, Unit 2, Building 2 Runfu (Phase IV), China Resources City Nanshan District, Shenzhen Guangdong, PRC	Chinese (Hong Kong)
Mr. YUAN Fei (袁飛)	Room 101, Building 3 No. 71 Tuandaoyi Road Shinan District, Qingdao Shandong, PRC	Chinese

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
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Independent non-executive Directors

Mr. FOK Chi Tat Michael (霍志達)	Flat C, 28/F Grand Excelsior 83 Waterloo Road Kowloon Tong Kowloon Hong Kong	Chinese (Hong Kong)
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Mr. LI Jiayan (李嘉焱)	No. 58 Xinwenhua Street Xicheng District Beijing, PRC	Chinese
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Mr. YUE Yichun (岳儀春)	No. 1501,1502, Unit 5, Building 2, Court 288, Chaoyangmen Inner Street Dongcheng District Beijing, PRC	Chinese
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SUPERVISORS

Name	Address	Nationality
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Ms. SONG Bing (宋冰)	House 18, Clover Lodge 14A Wong Keng Tei, Sai Kung New Territories Hong Kong	Chinese (Hong Kong)
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Ms. LIU Yali (劉亞利)	Room 1401, Building 48 Huayan Beili Chaoyang District Beijing, PRC	Chinese
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DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
Ms. CHEN Xuanyu (陳炫宇)	Room 1-2043 Longhu Guanyu, Beijing Guogongzhuang Subway Station Branch I Building 5, Court 18 Guogongzhuangzhongjie Fengtai District Beijing, PRC	Chinese

For further information of the Directors and Supervisors, see “Directors, Supervisors and Senior Management” in this document.

PARTIES INVOLVED IN THE [REDACTED]

Joint Sponsors

Huatai Financial Holdings (Hong Kong) Limited
62/F, The Center,
99 Queen’s Road,
Central, Hong Kong

CITIC Securities (Hong Kong) Limited
18/F, One Pacific Place,
88 Queensway,
Hong Kong

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

Legal Advisors to the Company

As to Hong Kong and U.S. laws

Clifford Chance

27/F, Jardine House

One Connaught Place Central

Hong Kong

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

as to PRC laws and PRC intellectual property law

Commerce & Finance Law Offices

12-14/F, China World Office 2
No.1 Jianguomenwai Avenue
Chaoyang District Beijing
PRC

**Legal Advisors to the Joint Sponsors
and the [REDACTED]**

As to Hong Kong and U.S. laws

DLA Piper Hong Kong

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

As to PRC laws

Jingtian & Gongcheng

34th Floor, Tower 3
China Central Place
77 Jianguo Road
Chaoyang District
Beijing, PRC

Auditor and Reporting Accountant

Ernst & Young

Certified Public Accountants

Registered Public Interest Entity Auditor

27/F, One Taikoo Place
979 King's Road
Quarry Bay
Hong Kong

Industry Consultant

Frost & Sullivan (Beijing) Inc.,

Shanghai Branch Co.

Room 2504
Wheellock Square
1717 Nanjing West Road
Shanghai 200040
PRC

[REDACTED]

CORPORATE INFORMATION

Registered Office	Room 1507, Building 1 Xiexin Center, No. 19 Qinling Road Laoshan District, Qingdao Shandong Province, PRC
Head Office and Principal Place of Business in the PRC	Room 1507, Building 1 Xiexin Center, No. 19 Qinling Road Laoshan District, Qingdao Shandong Province, PRC
Principal Place of Business in Hong Kong	5/F, Manulife Place 348 Kwun Tong Road Kowloon Hong Kong
Company's Website	<u>huarenshengwu.com</u> <i>(information on this website does not form part of this document)</i>
Joint Company Secretaries	Mr. HO Hung Tim Chester (何鴻添) <i>(member of the Hong Kong Institute of Certified Public Accountants)</i> Flat B, 20/F, Block 37 Laguna City 9 South Laguna Street Kowloon Hong Kong Ms. WONG Wai Yee Ella (黃慧兒) <i>(HKFCG, FCG)</i> 5/F, Manulife Place 348 Kwun Tong Road Kowloon, Hong Kong
Authorized Representatives	Dr. ZHAI Junhui (翟俊輝) Room 707, Building 1 Jinweikai Biotechnology Park Court 8, Haiying Road Fengtai District Beijing, PRC

CORPORATE INFORMATION

	<p>Ms. WONG Wai Yee Ella (黃慧兒) 5/F, Manulife Place 348 Kwun Tong Road Kowloon, Hong Kong</p>
Audit Committee	<p>Mr. YUE Yichun (岳儀春) (<i>Chairperson</i>) Mr. FOK Chi Tat Michael (霍志達) Mr. MIAO Tianxiang (苗天祥)</p>
Remuneration Committee	<p>Mr. YUE Yichun (岳儀春) (<i>Chairperson</i>) Mr. LI Jiayan (李嘉焱) Ms. JIA Lijia (賈麗加)</p>
Nomination Committee	<p>Mr. YUE Yichun (岳儀春) (<i>Chairperson</i>) Mr. LI Jiayan (李嘉焱) Ms. JIA Lijia (賈麗加)</p>
Compliance Advisor	<p>Orient Capital (Hong Kong) Limited 28/F–29/F, 100 Queen’s Road Central Central Hong Kong</p>
	<p>[REDACTED]</p>
Principal Bank	<p>Agricultural Bank of China Limited, Qingdao Laoshan Sub-branch No. 242 Hong Kong East Road Qingdao Hi-Tech Industrial Park Laoshan District, Qingdao Shandong Province, PRC</p>

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from an independent industry report prepared by Frost & Sullivan, which was commissioned by us, in connection with the [REDACTED] and from various official government publications and other publicly available publications. We believe that the sources of such information and statistics are appropriate 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 Joint Sponsors, the [REDACTED], any of their respective directors and advisors, or any other persons or parties involved in the [REDACTED], and no representation is given as to its accuracy.

CHINA BIOLOGICS MARKET

Overview

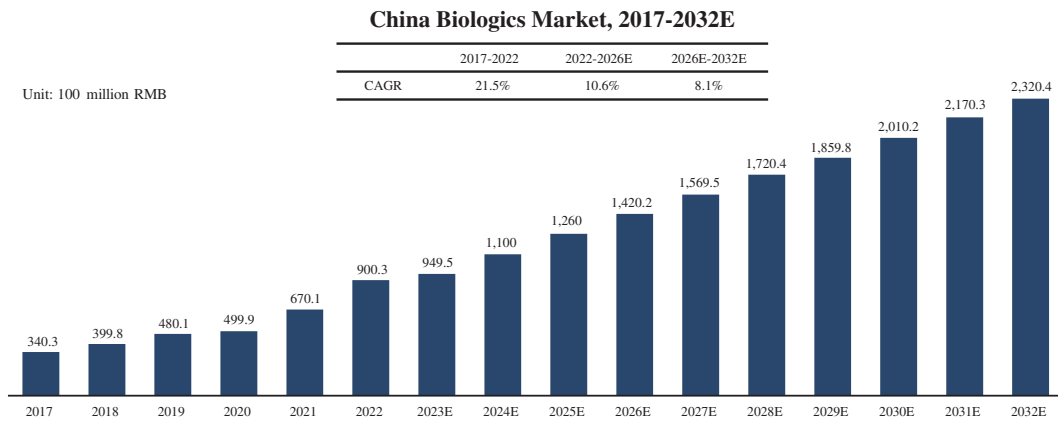
Biologics, pharmaceutical products manufactured using biological methods and sources, are designed to replicate the activities of natural substances such as enzymes, antibodies or hormones. The following chart sets forth details on the major types of biologics:

Antibodies	<ul style="list-style-type: none"> Antibodies therapy is a form of immunotherapy that utilizes antibodies to specifically bind to their targets to treat patients for therapeutic purposes. The most prevalent form of antibody drugs are monoclonal antibodies, which are artificially produced with single specificity through genetic engineering and related techniques.
Recombinant Proteins	<ul style="list-style-type: none"> The vast majority of recombinant protein drugs consist of human proteins or their mutants. Their primary MOA involves compensating for deficiencies in certain functional proteins within the body or enhancing the body's protein function. Typical examples of recombinant protein drugs include peptide hormone drugs and cytokine drugs.
Vaccines	<ul style="list-style-type: none"> A vaccine is a biological product that provides active acquired immunity against specific infectious disease. It typically contains an agent that mimics a disease-causing microorganism and is often derived from weakened or inactivated forms of the microbe, its toxins, or one of its surface proteins.
Cell Therapy	<ul style="list-style-type: none"> Cell therapy represents one of the most cutting-edge fields within biologics. It involves the injection, grafting, or implantation of viable cells into a patient to produce a therapeutic effect. For example, CAR-T cell therapy, a form of cancer therapy, utilizes the patient's own genetically modified white blood cells to target and destroy cancer cells.
Blood and Blood Products	<ul style="list-style-type: none"> Blood and blood products are crucial in the field of biologics. They encompass the therapeutic transplantation or transfusion of blood components, such as plasma, for treatment purposes. Plasma therapy, for example, employs the blood plasma from a patient or donor to treat conditions including immune deficiencies.
Growth Factors	<ul style="list-style-type: none"> Growth factors are natural substances that stimulate cell growth, regulating cellular processes by binding to specific cell receptors and promoting division, differentiation, and development. Their capacity to enhance cell and tissue growth renders them invaluable in medicine, biotechnology, and agriculture.
Gene Therapy	<ul style="list-style-type: none"> Gene therapy is a technique that involves modifying genes within cells to treat or prevent diseases. This approach entails inserting a gene into a patient's cells as an alternative to drugs or surgery. It is currently undergoing trials for conditions such as cancer, genetic disorders, and certain viral infections.
RNA-based Treatments	<ul style="list-style-type: none"> RNA-based treatments utilize RNA to guide protein synthesis in the treatment of diseases. These treatments have played a significant role in the development of mRNA COVID-19 vaccines and hold promise for addressing genetic and infectious diseases and cancer.

Source: literature review, the Frost & Sullivan report

INDUSTRY OVERVIEW

The biologics market in China experienced significant growth from RMB34.0 billion in 2017 to RMB90.0 billion in 2022, at a CAGR of 21.5%, and it is expected to further increase to RMB142.0 billion in 2026 and RMB232.0 billion by 2032, at a CAGR of 10.6% from 2022 to 2026 and 8.1% from 2026 to 2032. The following chart sets forth the historical and forecast size of the biologics market in China by sales amount from 2017 to 2032:



Source: the WHO, the Frost & Sullivan report

Growth Drivers and Future Trends

According to the Frost & Sullivan report, the growth of the biologics market in China has been, and is expected to continually be, driven by: (i) increasing research and development investment; (ii) technology advancement in the application of biotechnology in pharmaceutical science; (iii) better effectiveness of biologics demonstrated in treating some diseases that had no adequate treatments; (iv) increasing population diagnosed with cancer due to an increasing aging population, dietary habits and implementation of early screening; and (v) improvement in patients’ affordability.

Meanwhile, the biologics market in China is expected to expand into new therapeutic areas, including gene therapy and cell therapy. These innovative methods seek to address the underlying causes of a broad spectrum of diseases, ranging from genetic disorders and cancer to neurodegenerative diseases, going beyond mere symptom relief. As these novel treatments demonstrate efficacy and progress, their incorporation into standard medical care is anticipated to increase, thus offering patients more advanced treatment options.

CHINA WOUND HEALING MARKET

Overview

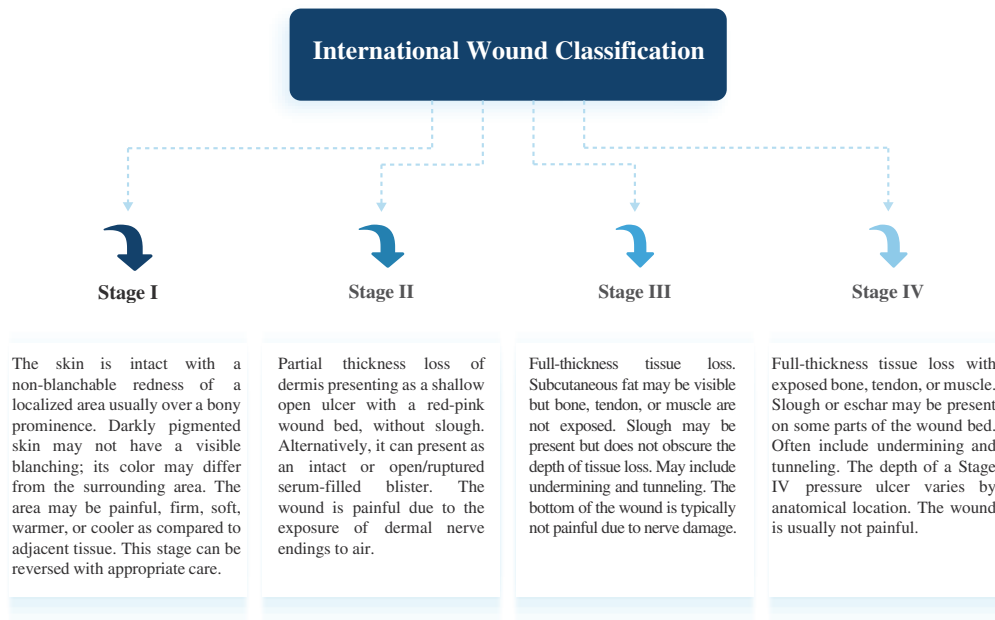
Wound healing is a complex biological process involving the repair and regeneration of skin and tissue after an injury. The aim of this process is to restore the structural integrity and function of the affected area. The efficiency of wound healing may be influenced by various factors, such as the nature of the wound, the individual’s overall health, and any existing underlying health conditions.

INDUSTRY OVERVIEW

There are two primary categories of wound: acute wounds and chronic wounds.

- Acute wounds are injuries that disrupt the integrity of the skin and follow a predictable and timely healing process. Typically resulting from surgery, trauma, or burns, these wounds progress through the normal stages of wound healing, which include hemostasis, inflammation, proliferation and remodeling. The healing duration for acute wounds depends on the wound’s severity and the individual’s overall health. Proper care and management are crucial to prevent infection and ensure optimal healing, thereby minimizing the risk of the wound becoming chronic.
- Chronic wounds, which fail to follow a normal, systematic and timely healing process, are frequently encountered and often subjected to inadequate treatment. On the other hand, fail to progress through a normal, orderly, and timely healing trajectory. These wounds are commonly encountered and are often subject to inadequate treatment, leading to significant morbidity and economic impact. Arterial, DFU and pressure injuries (bedsores and pressure ulcers) are among the most prevalent types of lower extremity chronic wounds. The adoption of effective prevention and management strategies for chronic wounds is of paramount importance.

To establish a standardized framework for assessing and classifying wounds, including the prevalent issue of pressure ulcers, the International Ostomy Association and the National Pressure Ulcer Advisory Panel have jointly established the following international wound classification method:



Source: the NCBI, the WHO, the Frost & Sullivan report

INDUSTRY OVERVIEW

The wound healing market represents a substantial and diverse market, comprising numerous sub-markets dedicated to addressing particular medical requirements and therapeutic objectives, providing treatments for a variety of conditions, including DFUs, thermal burns, pressure ulcers, hemorrhoids, photodermatitis (sunburn), radiation ulcers, fresh wounds, gastric ulcers, dry eye disease, corneal injury, and alopecia. Despite the broad spectrum conditions, which range from external traumas to chronic ailments, the primary objective remains consistent which is to deliver effective solutions that facilitate healing and recovery. As a result, the wound healing market presents a comprehensive selection of drug products and therapies, each designed to address the particular requirements of these diverse conditions.

The wound healing market in China has shown a consistent upward trend in sales amount from 2017 through the projection period extending to 2032. In 2017, the total sales amount associated with wound healing market in China was recorded at RMB79.3 billion, steadily increasing to RMB90.7 billion in 2022, at a CAGR of 2.7% from 2017 to 2022. This growth reflects not only the increasing demand for wound care products and services but also the advancements in medical technologies and treatment methodologies within the market. The market is expected to further increase from RMB90.7 billion to RMB99.9 billion in 2026 and RMB114.5 billion in 2032, at a CAGR of 2.4% from 2022 to 2026 and 2.3% from 2026 to 2032, respectively. The chart below illustrates the wound healing market size in China by sales amount from 2017 to 2032:



Source: GLOBOCAN, the WHO, the Frost & Sullivan report

Note: the statistical approach involves categorizing and counting the number of hospital visits and out-of-hospital cases for both acute and chronic wounds, analyzing the treatment needs for wounds of varying severity, and assessing the costs of treatment and the size of the drug market both inside and outside the hospital, aimed at comprehensively evaluating the overall expenses and market demand for wound healing.

INDUSTRY OVERVIEW

Comparison of Major Therapeutic Products Approved Globally for Wound Healing

The following table sets forth a comparison of therapeutic products approved globally for wound healing:

Classification	Name	MOA	Drug Guide	Sale price <i>(from the U.S. market for reference only)</i>
Advance wound dressing	Aquacel Ag	Aquacel Ag combines hydrofiber technology with silver, providing antimicrobial properties and promoting a moist wound environment conducive to healing.	Aquacel Ag is indicated for use in the management of moderate to heavily exuding wounds, including DFUs, venous leg ulcers, and surgical wounds.	10cm*12cm, US\$77.49/10 gel 5cm*5cm, US\$26.99/10 gel 15cm*15cm, US\$54.59/5 gel
	Duoderm	Duoderm is a hydrocolloid dressing that forms a gel-like consistency when in contact with wound exudate, providing a moist wound environment conducive to healing.	Duoderm is indicated for use in the management of partial and full-thickness wounds, including pressure ulcers, leg ulcers, and superficial burns.	15cm*15cm, US\$25.28/5 gel 10cm*10cm, US\$35.99/10 gel 5cm*10cm, US\$28.50/20 gel
	Mepilex	Mepilex is a soft silicone foam dressing designed to absorb exudate while minimizing trauma to the wound bed during dressing changes, promoting a moist wound environment conducive to healing.	Mepilex is indicated for use in the management of moderate to heavily exuding wounds, including pressure ulcers, DFUs, and surgical wounds.	10cm*10cm, US\$24.48/5 gel 4cm*5cm, US\$17.00/10 gel 15cm*20cm, US\$8.75/1 gel
Wound care biologics	Regranex (becaplermin gel)	Regranex contains recombinant platelet-derived growth factor (PDGF), which stimulates cell proliferation and the formation of granulation tissue, promoting wound healing.	Regranex is indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have adequate blood supply.	US\$1,721.1/15g
	Santyl (collagenase)	Santyl contains collagenase enzymes, which break down necrotic tissue in wounds, facilitating the removal of dead tissue and promoting the formation of healthy granulation tissue.	Santyl is indicated for debriding chronic dermal ulcers such as pressure ulcers and venous stasis ulcers.	US\$250/250g
	Dermagraft	Dermagraft provides a scaffold for cellular ingrowth, promotes tissue regeneration, and accelerates wound closure by delivering viable cells that produce growth factors and cytokines essential for tissue repair.	Dermagraft is indicated for use in the treatment of full-thickness DFUs greater than 6 weeks duration, with adequate blood supply.	US\$1,700/one time
	Apligraf	Apligraf promotes wound healing by providing cells that produce growth factors and cytokines essential for tissue repair and regeneration. It also serves as a scaffold for cellular ingrowth and promotes angiogenesis.	Apligraf is indicated for use in the treatment of non-infected partial and full-thickness skin ulcers, including venous leg ulcers and DFUs.	US\$1,500-2,500/one time

INDUSTRY OVERVIEW

Classification	Name	MOA	Drug Guide	Sale price <i>(from the U.S. market for reference only)</i>
Wound therapy devices	V.A.C. Therapy (Vacuum Assisted Closure)	The negative pressure applied by the V.A.C. Therapy system helps increase blood flow to the wound bed, removes infectious materials and excess exudate, and promotes the formation of granulation tissue, leading to faster wound healing.	V.A.C. Therapy is indicated for the management of a wide range of wound types, including DFUs, pressure ulcers, traumatic wounds, and surgical wounds.	US\$100-500/day
	Hyperbaric Oxygen Therapy (HBOT)	Hyperbaric Oxygen Therapy (HBOT) is a therapeutic approach that involves delivering 100% oxygen at higher-than-normal atmospheric pressure to promote wound healing and tissue repair.	HBOT is indicated for the treatment of various wound types, including DFUs, compromised skin grafts, non-healing wounds caused by radiation injury, and gas gangrene.	US\$250-450/session

Source: the CDE, the Frost & Sullivan report

Growth Drivers and Future Trends

According to the Frost & Sullivan report, the wound healing market in China is expected to experience strong growth in the future, and in addition to general drivers applicable to the biologics market, such as aging population and increasing investment in R&D, such growth is also driven by the following specific factors:

- ***Growth in surgical procedures.*** There has been a significant increase in surgical procedures, due to both acute injuries and the progression of chronic diseases. With the continuous advancement of medical technologies, a broader range of surgical interventions has become possible, driving the demand for trauma and surgical wound healing products.
- ***Increasing prevalence of chronic diseases.*** The increase in chronic diseases, especially diabetes and obesity, has led to an increase in wound healing disorders, such as DFUs. These chronic wounds require specialized products and treatment options, which in turn is driving the growth of the advanced wound healing market.

Entry Barriers

New entrants to the wound healing market mainly face following barriers:

- ***Challenges related to biofilm.*** Biofilm, a slimy protective layer formed by various microorganisms, can develop on the wound surface and resist elimination by antibiotics and the immune system. This issue adds complexity to wound management as it can impede healing and heighten the risk of infection. Consequently, additional investment in research and development is necessary to create products and solutions that can surmount this barrier and enhance wound healing.

INDUSTRY OVERVIEW

- **Stringent clinical data requirements.** To obtain regulatory approval and market acceptance, new wound treatment products and technologies need to provide strong clinical evidence. This requirement can be both time-consuming and expensive, especially concerning clinical trials and data collection, thus creating barriers to introducing new products to market.
- **High initial investment.** The development of new wound treatment products or technologies necessitates substantial initial investment in R&D and clinical trials, presenting a considerable barrier to entry for new market participants.

CHINA GROWTH FACTOR DRUG MARKET

Overview

Growth factors, a group of polypeptides, are important for regulating a variety of cellular processes. They have the capability to stimulate cell proliferation, wound healing, and occasionally cellular differentiation, acting as signaling molecules between cells. Various growth factors are instrumental in promoting the differentiation and maturation of different cell types. For example, epidermal growth factor (EGF) enhances osteogenic differentiation, while fibroblast growth factors (FGF) and vascular endothelial growth factors (VEGF) stimulate blood vessel differentiation (angiogenesis). Among these growth factors, PDGF has been reliably demonstrated to stimulate wound healing, particularly in DFUs, and has historically gained approval from the FDA for its application. The following table sets forth details on the different types of growth factors:

EGF	FGF	NGF
<ul style="list-style-type: none"> • EGF is a single polypeptide consisting of 53 amino acid residues which is involved in regulating cell proliferation. When EGF binds to its receptor, it can activate signaling cascades that produce several effects, including increased cell proliferation, reduced apoptosis, and angiogenesis. 	<ul style="list-style-type: none"> • FGF regulates a plethora of developmental processes, including brain patterning, branching morphogenesis and limb development. Several mitogenic, cytoprotective and angiogenic therapeutic applications of FGF are already being explored. 	<ul style="list-style-type: none"> • NGF is an insulin-like protein, which regulates growth, development and maintenance of sympathetic and embryonic sensory neurons. NGF has proven to possess the ability to enhance peripheral nerve regeneration.
PDGF	VEGF	Others
<ul style="list-style-type: none"> • PDGF is a potent mitogen, chemoattractant, and survival factor for cells of mesenchymal origin (such as fibroblasts, smooth muscle cells, or glial cells). In adult organisms, PDGFs participate in wound healing, regulation of blood vessel tonus, and maintenance of the interstitial fluid pressure. 	<ul style="list-style-type: none"> • VEGF is a chief proangiogenic factor in development, wound healing, and pathogenic processes, such as carcinogenesis and rheumatoid arthritis. By binding to receptors, VEGF initiates multiple signaling pathways affecting cell proliferation, survival, migration, and tissue permeability. 	<ul style="list-style-type: none"> • Transforming growth factor-β (TGF-β) • insulin-like growth factors (IGFs) • Hepatocyte growth factor (HGF)

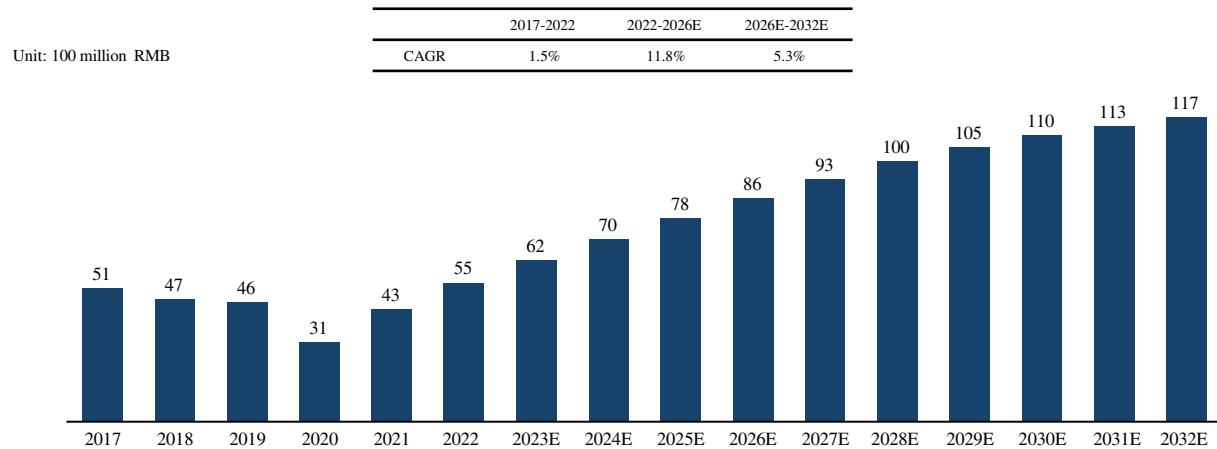
Sources: literature review, the Frost & Sullivan report

The growth factor drug market in China has demonstrated a decreasing trend from 2017 to 2020, mainly impacted by: (i) concerns over side effects from non-human derived growth factor products and stricter regulations in China from 2017 to 2019; and (ii) disrupted logistics and supply chains impacted by the COVID-19 pandemic, resulting in a scarcity of relevant drugs in pharmaceutical sales in 2020. As more human derived growth factor products launched in the market, the growth factor drug market in China bounced back in 2021 and reached RMB5.5 billion in 2022. Driven by increasing demand, expansion of indications and improving household spending power, this market is expected to further increase to RMB8.6 billion in 2026 and

INDUSTRY OVERVIEW

RMB11.7 billion in 2032, growing at a CAGR of 11.8% from 2022 to 2026 and 5.3% from 2026 to 2032, respectively. The following chart sets forth the historical and forecast size of the growth factor drug market in China by sales amount from 2017 to 2032:

Growth Factor Drug Market in China, 2017-2032E



Source: the Frost & Sullivan report

Comparison of Growth Factors

The following table sets forth a comparison of different types of growth factors:

Factor	Full Name	Primary Role in Wound Healing	Notable Advantages	Common Applications	Impact on Wound Healing Speed
EGF	Epidermal Growth Factor	Enhances epithelialization and accelerates wound closure	Promotes rapid epithelial cell growth, used for burns and skin wounds	Burns, skin wounds	High
FGF	Fibroblast Growth Factor	Involved in cell growth, tissue repair and angiogenesis	Broad-spectrum action for acute wound efficacy	Acute wounds, surgical healing	High
NGF	Nerve Growth Factor	Promotes tissue regeneration in specific types of wounds	Focus on neurological aspects, beneficial for nerve-related wounds	Diabetic wounds, nerve cell development	Moderate
PDGF	Platelet-Derived Growth Factor	Stimulates cell proliferation and angiogenesis, efficacy in chronic wounds	Effective in chronic wounds, strong mitogenic properties	Chronic wounds, diabetic ulcers	High
VEGF	Vascular Endothelial Growth Factor	Stimulates angiogenesis (formation of new blood vessels)	Promotes tissue vascularization	Wound healing and tissue engineering	Accelerates tissue regeneration by improving blood supply

Sources: the Frost & Sullivan report

INDUSTRY OVERVIEW

PDGF exists in four isoforms, namely, PDGF-A, -B, -C, and -D. These isoforms can form five dimeric isoforms, details of which are set forth below:

Factor	Full Name	Primary Role in Wound Healing	Notable Advantages	Common Applications	Impact on Wound Healing Speed
PDGF-AA	Platelet-Derived Growth Factor AA	Stimulates cell proliferation and migration	Promotes early tissue repair	Used in chronic wounds and diabetic ulcers	Accelerates early stages of tissue regeneration
PDGF-AB	Platelet-Derived Growth Factor AB	Stimulates both cell proliferation and migration	Versatile in promoting tissue repair and angiogenesis	Promotes wound closure in diverse wound types	Accelerates various aspects of wound healing
PDGF-BB	Platelet-Derived Growth Factor BB	Potent stimulator of cell proliferation and migration	Strongly promotes tissue regeneration and angiogenesis	Widely used in wound healing therapies	Significantly expedites wound closure and improves healing outcomes
PDGF-CC	Platelet-Derived Growth Factor CC	Stimulates cell proliferation, migration, and angiogenesis	Promotes tissue regeneration and blood vessel formation	Used in chronic wounds and ulcers	Accelerates tissue regeneration and vascularization
PDGF-DD	Platelet-Derived Growth Factor DD	Stimulates cell proliferation and migration	Stimulates the production of extracellular matrix components	In the treatment of various types of wounds	Accelerate the wound healing process

Sources: the Frost & Sullivan report

Competitive Landscape

Global Competitive Landscape

The FDA has only approved three growth factor drugs, one of which is a PDGF drug, details of which are set forth below:

Brand Name	Drug	Current Owner	Indication	Route of Administration	Approved Year	Price	Dose per Day	Cost per Day	Safety and Efficacy	Reimbursement Scheme
Oxervate (Cenegelein)	NGF	Dompé farmaceutici SpA	Neurotrophic keratitis	Eye drop	2018	US\$28,156/7*1ml	0.3ml	US\$1,206.7	Oxervate is a medicine for moderate to severe neurotrophic keratitis. Clinical studies have demonstrated that a significantly greater number of patients receiving Oxervate experienced complete corneal healing after an 8-week treatment period.	Covered by the U.S. medical insurance
Keppivance (Palifermin)	rh-KGF/rh-FGF	Biovitrum AB	Oral mucositis	Intravenous bolus injection	2004	US\$3,190.24/5.16mg	3.6mg	US\$2,225.8	Keppivance is a medication aimed at the epithelial cells lining the oral cavity and gastrointestinal tract, proving effective in the treatment of mucosal inflammation following radiation and chemotherapy. However, its safety and efficacy in patients with non-hematologic malignancies have not yet to be established.	/
Regranex (Becaplermin)	rh-PDGF	Smith+Nephew	Diabetic neuropathic ulcers	Smearable gel	1997	US\$1,721.1/15g	0.1g	US\$10.8	Regranex is a human platelet-derived growth factor designed for the treatment of diabetic neuropathic ulcers on the lower extremities, which penetrate into the subcutaneous tissue or subcutaneous tissue and possess an adequate blood supply. It may serve as a complement to, rather than a substitute for, proper ulcer care practices.	Covered by the U.S. medical insurance

Source: the Frost & Sullivan report

Note: ordered by approved year of each drug

INDUSTRY OVERVIEW

The following table sets forth details on the worldwide growth factor drug pipelines:

Drug Candidate	Sponsor	Country of Clinical Trial	Indication	Phase and Status	First Posted Date	Clinical No.
TGF-B and PDGF	St. Antonius Hospital	Holland	Rotator Cuff Rupture/Subacromial Impingement	Completed (III)	July 2010	NCT01510639
anti-PDGF pegylated aptamer	IVERIC bio	America	Age-Related Macular Degeneration	Completed (II)	March 2010	NCT01089517
PDGF Antagonist E10030 and VEGF Antagonist Ranibizumab	National Eye Institute (NEI)	America	Von Hippel -Lindau Syndrome	Completed (I/II)	January 2017	NCT02859441
rh-PDGF-BB	Universidad Autonoma de Nuevo Leon	Mexico	Periodontal Diseases	Recruiting (II)	January 2024	NCT06162832
rh-PDGF	Nova Southeastern University	America	Intrabony Periodontal Defect	Recruiting (I/II)	October 2022	NCT05442034
anti-PDGF pegylated aptamer	IVERIC bio	America	Age-related Macular Degeneration	Completed (I)	December 2007	NCT00569140
Vascular Endothelial Growth Factor (VEGF), Platelet Derived Growth Factor (PDGF), Hepatocyte Growth Factor (HGF)	National Institute of Cardiology, Warsaw, Poland	Poland	Acute Coronary Syndrome	Completed (observational)	January 2007	NCT00844987

Source: the Frost & Sullivan report

Notes:

- (1) Ordered by clinical study phase of each drug pipeline.
- (2) A drug sponsor may submit a NDA to the FDA for review only upon the completion of Phase III clinical trial.

Competitive Landscape in China

The growth factor drug market in China consists of FGF, EGF and NGF drugs, among them FGF drug contributes to the largest market share of 64.5% in 2021, followed by EGF of 19.1% and NGF of 16.3%. Cutaneous wound, ophthalmology and nerve system are main indications of approved growth factor drugs in China, where 64.7% of the market share, mainly EGF and FGF, is for the treatment of cutaneous wound, such as burn wound, chronic wound and fresh wound, among others. As of the Latest Practicable Date, there was no PDGF drug approved by the relevant regulatory authority in China.

INDUSTRY OVERVIEW

The following tables set forth details on the approved growth factor drugs in China:

Approved FGF drugs in China

Brand Name	Drug	Current Owner	Indication	Approved Year	National Health Insurance
Recombinant Bovine Basic Fibroblast Growth Factor For External Use, Liquid (贝复济)	rb-bFGF	Zhuhai Essex	Burn wounds, chronic wounds and fresh wounds	1998	Not included / Class B (by dosage form)
Recombinant Bovine Basic Fibroblast Growth Factor Eye Drops (贝复舒)	rb-bFGF	Zhuhai Essex	Corneal epithelial defect and punctate keratopathy caused by various reasons, recurrent superficial punctate keratopathy, mild to moderate dry eye, bullae keratitis, corneal abrasion, mild to moderate chemical burn, corneal surgery and poor postoperative healing, map (or nutritional) single blistering corneal ulcer, among others	1999	Class B
Recombinant Human Basic Fibroblast Growth Factor Gel (优济复)	rh-bFGF	Beijing SL Pharm	Burn wounds, chronic wounds (including chronic granulation wounds, ulcers and bedsores, among others) and fresh wounds (including trauma, surgical wounds, among others)	2004	Class B
Recombinant Human Acidic Fibroblast Growth Factor For External Use (艾夫吉夫)	rh-aFGF	Shanghai Tenry	Burn wounds, chronic wounds	2006	Class B
Recombinant Human Basic Fibroblast Growth Factor Gel (贝复新)	rb-bFGF	Zhuhai Essex	Burn wounds, chronic wounds and fresh wounds	2006	Class B
Recombinant Human Basic Fibroblast Growth Factor for External Use (蓝扶)	rh-bFGF	Nanhai Longtime Pharmaceutical	Burn wounds, chronic wounds and fresh wounds	2007	Class B

Source: the CDE, the Frost & Sullivan report

Note: ordered by approved year of each drug

Approved EGF drugs in China

Brand Name	Drug	Current Owner	Indication	Approved Year	National Health Insurance
Recombinant Human Epidermal Growth Factor Derivative For External Use, Liquid (金因肽)	rhEGF	Shenzhen Watsin Genetech Ltd	The topical solution is suitable for burn wounds (including shallow II° or deep II° burn wounds), residual small wounds, various chronic ulcer wounds (including vascular, radiation, and diabetic ulcers) and fresh wounds in the donor area, among others	2001	Class B
Human Epidermal Growth Factor For External Use (康合素)	rhEGF	Shanghai Haohai Healthcare	Freeze-dried preparation is suitable for the treatment of burn wounds (including shallow II. and deep II. wounds), residual small wounds, and skin donor area wounds. Suitable for all types of chronic ulcer wounds (including diabetic, vascular, radiation ulcers), among others	2001	Class B
Recombinant Human Epidermal Growth Factor Eye Drops (易贝)	rhEGF	Guilin Pavay	Eye drops, corneal epithelial defects caused by various reasons, including corneal mechanical injury, various corneal surgeries, mild dry eye syndrome with superficial punctate keratopathy, mild chemical burns, among others	2002	Class B
Human Epidermal Growth Factor Gel (易孚)	rhEGF	Guilin Pavay	Human epidermal growth factor gel is suitable for the treatment of skin burn wounds (shallow second degree to deep second degree burn and scald wounds), residual wounds, donor site wounds and chronic ulcer wounds.	2002	Class B
Recombinant Human Epidermal Growth Factor Derivative Eye Drops (金因舒)	rhEGF	Shenzhen Watsin Genetech Ltd	Eye drops, indications are corneal epithelial defects caused by various reasons, including corneal mechanical damage, various corneal surgeries, mild dry eye with superficial punctate keratopathy, mild chemical burns, among others	2004	Class B
Lyophilized Mouse Epidermal Growth Factor (一天)	mEGF	Zhejiang Hawking Pharmaceutical	Lyophilizer for external use, burns, fresh wound surface, ulcers and gangrene due to diabetes or varicose veins, ulcer wound, among others	2007	Not included

Source: the CDE, the Frost & Sullivan report

Note: ordered by approved year of each drug

INDUSTRY OVERVIEW

Approved NGF drugs in China

Brand Name	Drug	Current Owner	Indication	Approved Year	National Health Insurance
Mouse Nerve Growth Factor for Injection (金路捷)	mNGF	Wuhan Hiteck Biological Pharmaceutical	Injection (lyophilized powder for injection), indications are demyelination disease, axonal degeneration. n-hexane toxicity peripheral neuropathy.	2003	Not included
Mouse Nerve Growth Factor for Injection (恩经复)	mNGF	Beijing Sinobioway Biomedicine	Injection (lyophilized powder for injection), indicated for the treatment of n-hexane toxic peripheral neuropathy. This product works by promoting recovery from nerve damage	2003	Not included
Mouse Nerve Growth Factor for Injection (苏敏生)	mNGF	Beijing Staidson Biopharmaceuticals	Injection (lyophilized powder for injection), the indication is that this product can promote the recovery of nerve damage. Used to treat optic nerve damage.	2006	Not included
Mouse Nerve Growth Factor for Injection (丽康东)	mNGF	Zhuhai Livzon	Injections used to treat optic nerve damage. This product works by promoting recovery from nerve damage.	2006	Not included

Source: the CDE, the Frost & Sullivan report

Note: ordered by approved year of each drug

The following tables set forth details on the growth factor drug pipelines in China:

FGF drug pipeline in China

Drug Candidate	Sponsor	Indication	Phase and Status	First Posted Date	Clinical No.
rh-aFGF	Shanghai Tenry	Fresh wounds	In-progress (III)	April 13, 2021	CTR20210692
rh-bFG (external solution)	Nanhai Longtime Pharmaceutical	Class I surgical incision on extremities	In-progress (III)	November 4, 2017	CTR20171134
rh-bFG (external gel)	Nanhai Longtime Pharmaceutical	Chronic wounds including diabetic ulcers, vascular ulcers, bedsores, traumatic ulcers, radioactive ulcers, among others	In-progress (III)	March 19, 2012	CTR20132467
hb-FGF	Yaogu (Wenzhou) Technology Development Co., Ltd.	Deep second degree burns	In-progress (II)	September 12, 2023	CTR20232626

Source: the CDE, the Frost & Sullivan report

Note: ordered by clinical study phase of each pipeline

EGF drug pipeline in China

Drug Candidate	Sponsor	Indication	Phase and Status	First Posted Date	Clinical No.
rh-EGF (injection)	Genetic and Biotechnology Engineering Center/ Huake Pharmaceutical Intellectual Property Consulting Center	DFUs	In-progress (III)	August 7, 2014	CTR20140502
rh-EGF	Guilin Pavay	Moderate xerophthalmia with superficial punctate keratopathy	In-progress (II)	September 18, 2015	CTR20130920
rh-EGF	The Sixth Affiliated Hospital of Sun Yat-sen University	Radiodermatitis	In-progress	January 20, 2019	ChiCTR1900020842
Lyophilized rh-EGF (eye drops)	Institute of Bioengineering of AMMS, PLA/Chengdu Huasun	After corneal transplantation and pterygium excision	In-progress	February 3, 2015	CTR20132246

Source: the CDE, the Frost & Sullivan report

Note: ordered by clinical study phase of each pipeline

INDUSTRY OVERVIEW

NGF drug pipeline in China

Drug Candidate	Sponsor	Indication	Phase and Status	First Posted Date	Clinical No.
rh-NGF	Sichuan Zeha Times Pharmaceutical Co. Ltd.	Optic nerve damage	In-progress (II)	July 10, 2023	CTR20232035
mNGF (injection)	Beijing Staidson Biopharmaceuticals	Refractory DFUs	In-progress (II)	May 4, 2017	CTR20170195
rh-NGF (injection)	Institute of Bioengineering of AMMS, PLA/Sichuan Zeha Times Pharmaceutical Co. Ltd.	Optic nerve injury	Completed (I)	June 22, 2020	CTR20201202
rh-NGF (injection)	Jiangsu Xintrum Pharma	Optic nerve injury	Completed (I)	September 23, 2019	CTR20191810
Recombinant human nerve growth factor eye drops	Chongqing Kerun Biopharmaceutical R&D Co., Ltd.	Neurotrophic keratitis	In-progress (I)	March 15, 2024	CTR20240851
SMR001 (rh-NGF for injection)	Beijing Sinobioway Biomedicine	Xerophthalmia	In-progress (I)	October 10, 2020	CTR20201934

Source: the CDE, the Frost & Sullivan report

Note: ordered by clinical study phase of each pipeline

Other growth factor drug pipelines in China

Drug Candidate	Sponsor	Indication	Phase and Status	First Posted Date	Clinical No.
rh-KGF (freeze-drying)	Shanghai Newsummit Biopharma Co., Ltd.	Superficial second degree burns	In-progress (III)	September 5, 2014	CTR20140592
rh-KGF (freeze-drying)	Chengdu Zhitian Bioengineer Corp.	Treatment of severe oral mucositis in patients with hematopoietic stem cell transplantation	In-progress (I/II)	April 3, 2015	CTR20150028
rh-KGF (eyedrops)	JNU Guangdong Pharmaceutical Engineering Research Center for Gene	Treatment of corneal epithelial defects caused by corneal abrasions, mild and moderate chemical burns, corneal surgery and poor postoperative healing and dry eye	In-progress (I)	March 10, 2021	CTR20210423
PMBT combined with CGF	Xi'an Jiaotong University Stomatological Hospital	Gingival papillary regression	In-progress	September 29, 2020	ChiCTR2000038732

Sources: the CDE, the Frost & Sullivan report

Note: ordered by clinical study phase of each pipeline

For details on PDGF drug pipelines in China, see “— China PDGF-BB Drug Market — Competitive Landscape.”

Growth Drivers and Future Trends

According to the Frost & Sullivan report, the growth of the growth factor drug market has been, and is expected to continually be, driven by: (i) an increase in demand for growth factor drugs in treating open wounds, ophthalmic diseases and regeneration of nervous systems in China; (ii) expansion of indications to cover a wider range of open wounds as well as ophthalmic diseases and potentially esthetic medicine; (iii) encouraging policies that promote research and

INDUSTRY OVERVIEW

development of novel drugs and accelerate review and approval of new drug, which are beneficial to drugs that could better fulfill the clinical demand of patients; and (iv) increasing ability of households to afford drugs with better therapeutic effects such as growth factor drugs.

Meanwhile, this market is evolving with following several key trends shaping its future: (i) leveraging genetic insights and individual patient data, growth factor drugs are expected to be tailored more precisely to the unique requirements of individual patients, thereby enhancing the effectiveness of treatments; (ii) growth factors, traditionally associated with wound healing and tissue regeneration, are now being explored for new therapeutic uses. Research is uncovering potential applications in oncology, for instance, targeting PDGF's role in angiogenesis to inhibit tumor growth; and (iii) there is potential for recombinant growth factors to be administered in combination with other treatments, such as chemotherapy, radiation, or targeted therapies. Such combination therapies could produce synergistic effects, enhancing the clinical outcomes for patients with multifaceted diseases.

CHINA PDGF-BB DRUG MARKET

Overview

PDGF-BB, or platelet-derived growth factor-BB, is a cytokine consisting of two BB subunits forming a homodimer that facilitates cell processes such as proliferation, migration, and tissue repair. It interacts with specific receptors on the cell surface, initiating signals that regulate cellular functions, and is integral to wound healing by activating fibroblasts and other crucial cell types.

In addition to wound healing, PDGF-BB is implicated in diseases such as atherosclerosis and cancer, influencing plaque formation and tumor growth through angiogenesis. Clinically, recombinant human PDGF-BB (rhPDGF-BB) is utilized to treat chronic wounds such as, diabetic ulcers and is being explored as a therapeutic target for cancer and in tissue engineering applications.

The versatile functions of this growth factor offer potential for advancing therapeutic strategies across various medical fields.

MOA

PDGF is integral to the body's healing response following injury, playing a crucial role in wound healing and tissue repair, including skin, bone, tendon, muscle and cornea.

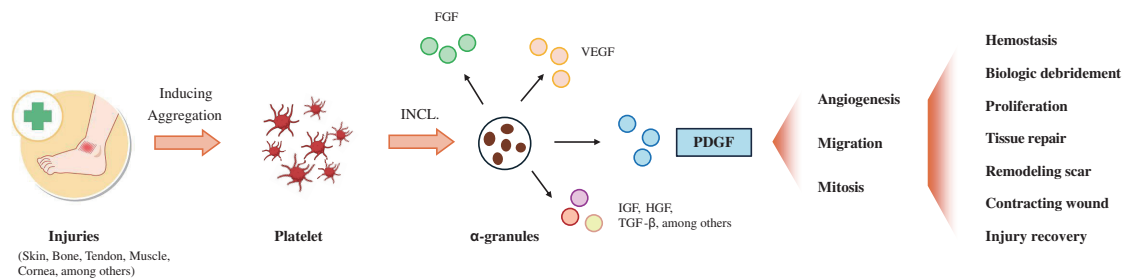
When an injury occurs, platelets gather at the damaged site and release contents from their α -granules, which contain growth factors such as VEGF, Insulin-like Growth Factor (IGF), Hepatocyte Growth Factor (HGF), Transforming Growth Factor-beta (TGF- β) and PDGF itself.

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PDGF specifically drives several critical processes in the healing cascade:

- **Angiogenesis.** The formation of new blood vessels is essential for delivering oxygen and nutrients to the injured area, aiding the healing process.
- **Migration.** PDGF facilitates the movement of cells, such as fibroblasts and endothelial cells, towards the wound site, where they contribute to tissue repair.
- **Mitosis.** PDGF promotes cell division, thereby increasing the number of cells available to repair the damaged tissue.

The following illustration demonstrates the PDGF’s mechanism in wound healing and tissue repair:



Source: the Frost & Sullivan report

Currently, PDGF products are commercially available as hydrogels, with the following advantages: (i) the hydrogel form of PDGF products offers excellent absorption properties. Its active properties ensure that PDGF is readily available to facilitate the wound healing process; and (ii) these products express PDGF-BB, which stimulates adjacent tissues, thereby promoting the growth of granulation tissues, an essential stage in effective wound healing. The mechanism of hydrogel promotes the growth and migration of vascular endothelial cells, thereby boosting angiogenesis. It has demonstrated encouraging outcomes in skin regeneration, notably in the increased deposition of collagen and the thickening of the epidermis.

The PDGF-BB-derived supramolecular hydrogel, which is designed to promote skin wound healing, is in fact a PDGF peptide. This innovative hydrogel has been developed by combining a PDGF epitope with a self-assembling motif to form a stable structure that aids in the healing process. Supramolecular hydrogels are highly effective for wound care, combining the ability to deliver healing agents and maintain ideal moisture levels while absorbing excess fluid. These gels self-assemble in water through noncovalent bonds, offering benefits such as trapping proteins and influencing cell behavior.

Competitive Landscape

PDGF-BB drugs are expected to be applied to a wide range of indications going forward. For example, within the DFUs indication segment, PDGF-BB does not currently encounter direct competition from drugs of a similar class. However, for other indications, it is expected to compete with other growth factors such as EGF and FGF drugs, and related medications.

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The following table sets forth details on the PDGF-BB drug pipeline in China:

Drug Candidate	Sponsor	Indication	Route of Administration	Phase and Status	First Posted Date	Clinical No.
rhPDGF-BB	Tasly Pharmaceutical	Skin ulceration of lower extremity in chronic diabetes	External application	In-progress (III)	January 22, 2014	CTR20132176
rhPDGF-BB	Our Company	Thermal burns	External application	In-progress (IIb)	November 14, 2023	CTR20233683
rhPDGF-BB	Our Company	DFUs	External application	In-progress (II)	March 24, 2022	CTR20220638

Source: the CDE, the Frost & Sullivan report

Note: ordered by clinical study phase of each pipeline.

According to the Frost & Sullivan report, there were three PDGF drug pipelines in China as of the Latest Practicable Date, comprising one pipeline focusing on the treatment of skin ulceration of lower extremity in chronic diabetes, especially DFUs, one pipeline focusing on the treatment of DFUs and one pipeline focusing on the treatment of thermal burns. As of the same date, no PDGF drugs had been approved in China. All of the PDGF pipelines are based on the isoform of PDGF-BB. The PDGF-BB drug candidate of Tasly Pharmaceutical entered Phase III clinical trial in 2014 and as of the Latest Practicable Date, there had been no further update in relation to the status of Tasly Pharmaceutical’s drug pipeline. The other two PDGF-BB pipelines belong to us, which have entered Phase II clinical trial in February 2022 for DFUs and Phase IIb clinical trial for thermal burns in December 2023, respectively. According to the Frost & Sullivan report, one of our Company’s Core Products, Pro-101-1, is the most advanced PDGF drug candidate in terms of clinical development progress for the treatment of thermal burns in China, and has the potential to be the first commercialized PDGF product in China for this indication.

Indications and Corresponding Market Size and Trends

Thermal Burns

Overview

Thermal burns are burns to the skin caused by external heat sources, which raise the temperature of the skin and tissues and cause tissue cell death or charring. Hot metals, scalding liquids, steam, and flames, when coming into contact with the skin, can cause thermal burns. In general, thermal burns can be divided into three degrees: (i) first-degree burns affect only the epidermis, or outer layer of skin, such as a mild sunburn; (ii) second-degree burns involve the epidermis and part of the dermis layer of skin. The burn site appears red, blistered, and may be swollen and painful; and (iii) third-degree burns destroy the epidermis and dermis and may also damage the underlying bones, muscles, and tendons.

There are two treatment methods that should be employed jointly for thermal burn patients to fully recover: burn wound healing and rehabilitation treatment. Among the two treatment methods, measures such as cooling, drug management, nutritional support and rehabilitation are safe and effective in reducing symptoms, preventing infection and promoting healing. Patients should adopt treatment under professional guidance to ensure the best results. Set forth below are details of such two treatment methods:

INDUSTRY OVERVIEW

Burn Wound Healing	Rehabilitation Treatment
Medical	
<ul style="list-style-type: none"> Superficial partial thickness burns and donor sites of split-thickness skin grafts benefit from occlusion for long periods (at least one week). Humid and heat-preserving dressings are preferred. If these are not available, moist dressings should be utilized. Cleansing with gentle washing is the most important component of burn wound cleansing. The beneficial effect of employing antiseptics or antimicrobial agents for cleansing remains uncertain. Raw areas should be dressed with a closed technique. The type (temporary or semi-permanent) and frequency of dressing should be determined based on the wound condition and availability of dressing products. Closed dressing is the standard approach for deep partial thickness and full thickness burns. If early excision is not feasible, deep partial and full thickness burns may be managed with an open dressing technique until the onset of eschar separation. 	<p>Placing the patient in specific positions</p> <ul style="list-style-type: none"> It is essential to place burn patients in specific positions that counteract the forces of contraction to achieve optimal functional outcomes during recovery. This positioning should be implemented consistently throughout the entire healing process. <p>Splinting</p> <ul style="list-style-type: none"> Orthotic and splinting devices should be used to ensure proper positioning of the body surface area when immobilization is warranted or to progressively stretch joints and maintain or promote movement. <p>Maintain joint range of motion (ROM)</p> <ul style="list-style-type: none"> Passive joint ROM practice should be performed at least twice daily for both injured and uninjured joints. During these exercises, doctors must monitor the patient's vital signs closely. As the patient recovers, active joint ROM practice and muscle training should be conducted. In addition, some activities of daily living (ADL) can be incorporated into the regimen. <p>After discharge from hospital</p> <ul style="list-style-type: none"> The first and second years post-discharge represent the most challenging period. Patients need to check up with their doctors regularly.
Surgical	
<ul style="list-style-type: none"> An appropriate surgical plan should be tailored for each major burn patient. The plan is influenced by the extent, site and depth of the burn injury; the general physical condition of the patient; and the resources available to the treating team. Early excision and wound closure represent the standard of care when resources permit. However, a conservative approach to wound debridement is indicated in situations where logistics and resources are limited by the number of patients or available skill sets. 	

Source: ISBI Practice Guidelines for Burn Care, Guidelines for Burn Rehabilitation, the Frost & Sullivan report

Market size

According to the Frost & Sullivan report, the thermal burn prevalence in China increased from 28.0 million people in 2017 to 29.4 million people in 2022, and is expected to increase to 31.0 million people in 2027, at a CAGR of 1.1% from 2022 to 2027, mainly resulting from (i) industrial expansion, especially those involving high-temperature processes such as metalworking, manufacturing and chemical production, heightens the risk of workplace-related thermal burns and (ii) the intensification in urban population density heightens the potential of fires, which may lead to a higher incidence of household thermal burns, as more individuals utilize heating, cooking appliances and electrical equipment in close quarters. The thermal burn prevalence in China is expect to increase from 31.0 million people in 2027 to 32.5 million people in 2032, at a CAGR of 1.0%. The slight slowdown of CAGR from 2027 to 2032 compared to that from 2022 to 2027 primarily reflects the potential impact of effective implementation of safety measures, improved medical treatments, and possibly enhanced public awareness and education about fire safety and burn prevention. The following chart sets forth the historical and forecast thermal burn prevalence in China from 2017 to 2032:



Source: the CDE, the Frost & Sullivan report

INDUSTRY OVERVIEW

Despite the decreasing growth rate of this market, the thermal burn therapy market in China remains stable increase from 2017 to 2032. China has experienced and is expected to continually experience a comparatively high thermal burn prevalence, however, enhanced awareness and improved preventative measures have led to a decline in the growth rate of the thermal burn therapy market in China. Even with this slowdown, the market size remains significant. The thermal burn therapy market in China expanded from RMB1.4 billion in 2017 to RMB1.5 billion in 2022, at a CAGR of 3.2%, and it is projected to reach RMB1.6 billion and RMB1.8 billion in 2026 and 2032, respectively. The following chart sets forth the historical and forecast size of the thermal burn therapy market in China by sales amount from 2017 to 2032:



Source: the Frost & Sullivan report

DFUs

Overview

DFUs are open sores or wounds that occur in patients with diabetes, manifesting as foot ulcers and/or deep tissue destruction. The direct causes include distal lower extremity neuropathy and varying degrees of vascular disease, which are associated with a lack of sensation in the foot, compromised circulation, foot deformities, irritation (such as friction or pressure), trauma and duration of diabetes.

The diabetic foot is characterized by infection, ulceration and gangrene. Ulcers can be classified as neurological, ischemic and neuro-ischemic ulcers according to the etiology. Similarly, gangrene can be classified as wet gangrene, dry gangrene and mixed gangrene. Accurate classification and grading of diabetic foot patients prior to treatment are essential for selecting an appropriate treatment plan and assessing the prognosis.

Common treatments for DFUs include basic treatments such as lowering blood sugar, lowering blood pressure, lowering lipids levels, and nutritional support. According to the condition of the disease, timely and effective application of antibiotics is crucial for controlling infection. In addition, the utilization of vasodilators, antiplatelet drugs and anticoagulants is important to improve the blood supply and micro-circulation in the lower limbs. On the basis of basic treatment and comprehensive care, local debridement and dressing changes, blood supply reconstruction, wound repair and decompression of the affected foot are important steps in promoting the healing of DFUs.

INDUSTRY OVERVIEW

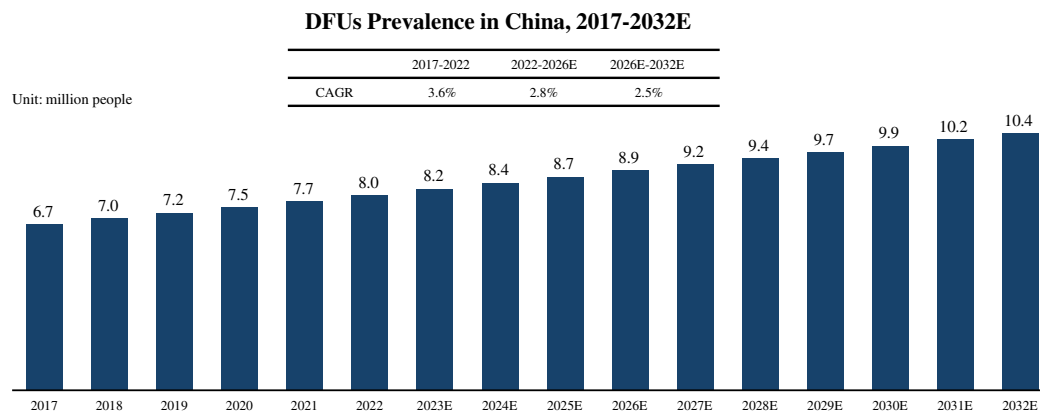
The treatment of DFUs demonstrates good safety and effectiveness through active blood sugar management, appropriate pharmacological treatment and necessary surgical intervention, which can significantly diminish complications and improve patients’ quality of life. Set forth below are details of treatment of DFUs:

Medical Treatment	Drug Therapy
<ul style="list-style-type: none"> • Good metabolic management For diabetic foot patients, blood sugar control should be actively carried out. Insulin is the first choice to control blood sugar. Patients should aim for adequate blood sugar control with glycated hemoglobin levels below 7%, and while simultaneously minimizing the risk of hypoglycaemia. This approach helps to reduce the incidence of foot ulcers and infections, thereby lowering the patient’s risk of amputation. • Lower limb sports rehabilitation treatment For patients with ischemic or neuro-ischemic types whose foot skin is intact, exercise can improve walking distance and walking time in patients with intermittent claudication. 	<ul style="list-style-type: none"> • Vasodilator drug therapy Vasodilators currently used clinically include lipid microsphere alprostadil injection, beraprost sodium, cilostazol, sarpgreglate hydrochloride, buflodil, and pentoxifylline. • Antiplatelet drug therapy In diabetic foot patients, clopidogrel is an indicated antiplatelet drug. Compared with aspirin, antiplatelet therapy with clopidogrel combined with aspirin can significantly reduce all-cause mortality and cardiovascular events, but the risk of severe bleeding mild increase. • Anticoagulant drugs Heparin, low molecular weight heparin and oral anticoagulant drugs.
Vascular Reconstruction Surgery Treatment	
<ul style="list-style-type: none"> • Lower extremity arterial endovascular interventional therapy • Lower extremity arterial bypass grafting • Angiogenesis therapy • Perioperative management 	<p><i>The above pharmacological treatments only delay the progression of mild to moderate ischemic lesions of the lower extremity arteries. Development is the basis of diabetic foot treatment; however, most patients with severe lower limb ischemia cannot achieve the purpose of improving symptoms and limb salvage. Therefore, for patients with severe ischemia who are ineffective in conventional medical treatment, percutaneous interventional treatment or surgical treatment is required.</i></p>

Source: Guidelines for the treatment of diabetic foot in China, the Frost & Sullivan report

Market size

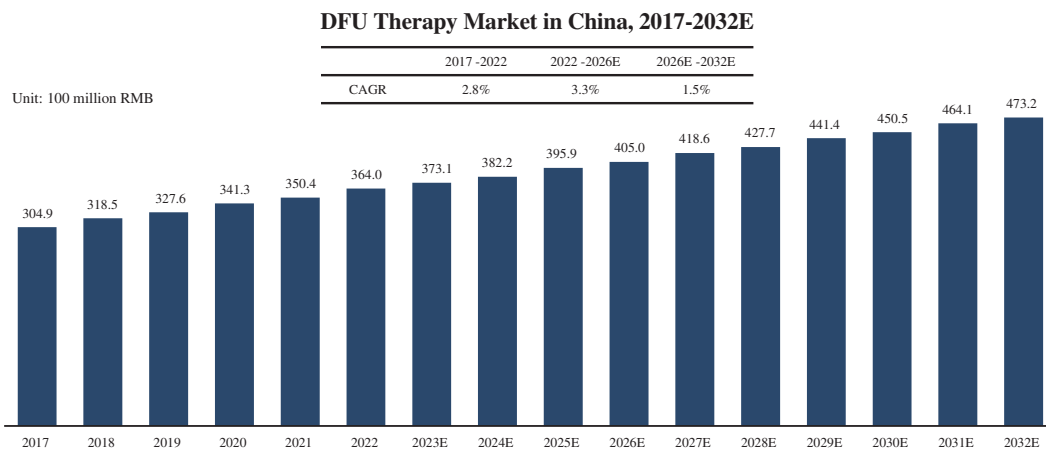
China has a significant of diabetic patients in the world. The prevalence of diabetes in China increased from 118.3 million people in 2017 to approximately 136.8 million people in 2022, mainly driven by unhealthy diets, lack of exercise, and an aging population. It is expected that the prevalence of diabetes in China will reach 151.7 million people in 2026 and 174.0 million people in 2032, at a CAGR of 2.7% and 2.3%, respectively. The increase in the number of diabetic patients has also led to, and is expected to continue to lead to, an increase in the prevalence of DFUs in China. The prevalence of DFUs in China increased from 6.7 million people in 2017 to 8.0 million people in 2022, growing at a CAGR of 3.6%, and is expected to reach 8.9 million people in 2026 and 10.4 million in 2032, at a CAGR of 2.8% from 2022 to 2026 and 2.5% from 2026 to 2032, respectively. The following chart sets forth the historical and forecast DFU prevalence in China from 2017 to 2032:



Source: Guidelines for the treatment of diabetic foot in China, the Frost & Sullivan report

INDUSTRY OVERVIEW

The DFU therapy market has shown steady growth from RMB30.5 billion in 2017 to RMB36.4 billion in 2022, at a CAGR of 2.8%, mainly attributed to a growing diabetic population in China, increased awareness of DFU complications and the introduction of new treatments and therapies. Looking forward, the market is expected to grow from RMB36.4 billion in 2022 to RMB40.5 billion in 2026, at a CAGR of 3.3%, mainly attributed to an increase of public healthcare awareness and an emphasis on preventative approach. Further into the future, the market is expected to increase to RMB47.3 billion in 2032, at a CAGR of 1.5%, indicating a continued but slower pace of growth. The gradual slowing down in the growth rate may reflect a stabilization in the prevalence of diabetes and DFUs or effectiveness in early treatment and prevention strategies. The following chart sets forth the historical and forecast size of the DFU therapy market in China by sales amount from 2017 to 2032:



Source: the Frost & Sullivan report

Fresh Wounds

Overview

Fresh wound is a recent injury to the skin that typically involves a break in the skin’s surface. Such wounds result from damage to healthy tissue, inflicted by a variety of external agents including surgical procedures, physical trauma, thermal exposure, electrical sources, chemical interactions, and cryogenic effects, as well as internal contributors like compromised local blood circulation. This condition is frequently marked by a breach in the skin’s integrity and the subsequent loss of a quantifiable amount of normal tissue. The following sets forth the classification of fresh wound and relevant traditional solutions:

Classification	Symptom Presentation	Traditional Solution
Abrasions	Abrasions refer to minor injuries where only the surface layer of the skin is affected, typically resulting from friction. These wounds usually exhibit scant bleeding.	To manage a wound effectively, commence by cleansing it with mild soap and water to eliminate any debris. Proceed to apply a slender coating of antibiotic cream and cover the area with a sterile dressing. It is imperative to maintain the cleanliness and dryness of the wound.

INDUSTRY OVERVIEW

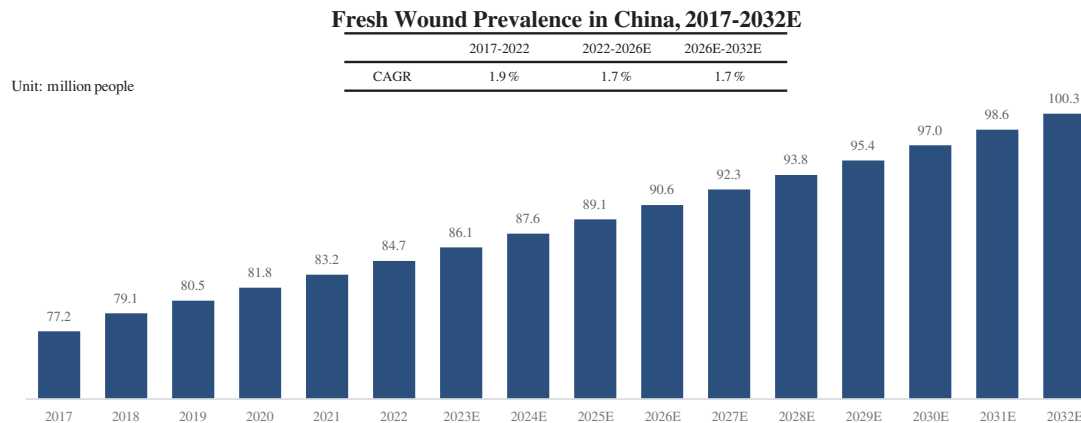
Classification	Symptom Presentation	Traditional Solution
Incisions	Incisions are defined by their clean and linear nature, often the result of contact with sharp instruments such as knives. Owing to their penetrative nature, incisions can lead to considerable bleeding.	In the event of bleeding, exert direct pressure to stem the flow. Once hemorrhage is under control, purify the wound, utilize an antiseptic solution, and secure with a dressing. Deep incisions might necessitate professional medical intervention and potential suturing.
Lacerations	Lacerations are characterized by their jagged and irregular edges, usually inflicted by a tearing action of the skin following blunt trauma.	To halt bleeding, apply firm pressure, then cleanse the affected region with soap and water, followed by an antiseptic application. If the laceration be profound or extensive, it is advisable to seek medical care, as stitching may be required.
Punctures	Puncture wounds are narrow yet deep injuries, commonly inflicted by pointed objects like nails or needles. While they may not result in extensive surface bleeding, their depth makes them susceptible to infection.	If an object be embedded within the wound, do not attempt to extract it. For minor puncture wounds, encourage a small amount of bleeding to help cleanse the wound, then proceed to wash and apply an antiseptic. Dress the wound and remain vigilant for any indications of infection. In cases of serious punctures or when objects remain embedded, professional medical assistance should be sought.
Contusions (Bruises)	Contusions, also known as bruises, are injuries where the skin remains intact, but the underlying tissue suffers damage due to impact or blunt force.	To alleviate swelling and discomfort from a contusion, apply a cold compress. If the bruise be severe or accompanied by a loss of function, a medical evaluation is recommended.

When treating fresh wounds, safety assessment should focus on aseptic procedures to prevent infection, appropriate intervention to promote granulation growth, timely removal of necrotic tissue, and reasonable scar management to ensure safe wound healing. The treatment of a fresh wound involves several distinct but overlapping phases that the body naturally undergoes to heal the damaged tissue: (i) inflammation, which is the immediate response following a wound; (ii) granulation tissue formation, occurring after the initial inflammatory response, focuses on combating bacteria and clearing away dead tissue; (iii) re-formation of the matrix which is a proliferative phase, mainly involves tissue growth and development of granulation tissue; (iv) scar formation, which is the final stage. Following the proliferative phase, the wound begins to heal, and over time, the scar and any scabs present are re-modeled to improve both the appearance and function of the affected area. This re-modeling period can take anywhere from several days to a year, heavily dependent on the wound’s severity.

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Market size

The fresh wound prevalence in China has demonstrated a steady growth trajectory since 2017, starting with 77.2 million people and increasing to 84.7 million people in 2022, at a CAGR of 1.9%, primarily attributable to the aging population and advancements in healthcare. Such prevalence is expected to further increase to 90.6 million people and 100.3 million people in 2026 and 2032, respectively, at a CAGR of 1.7% from 2022 to 2026 and from 2026 to 2032, mainly driven by a sustained increase in the demand for fresh wound treatment, combined with an enhancement in the recognition and adoption of advanced wound care solutions. The following chart sets forth the historical and forecast fresh wound prevalence in China by from 2017 to 2032:



Source: the Frost & Sullivan report

The fresh wound therapy market in China increased from RMB33.6 billion in 2017 to RMB37.4 billion in 2022, at a CAGR of 2.2% from 2017 to 2022, reflecting a steady growth in demand for fresh wound care treatments, primarily due to advancements in drug formulations, increased healthcare expenditure and wider acceptance of innovative wound healing products. Subsequently, the market’s growth rate is expected to slightly increase to a CAGR of 2.3% from RMB37.4 billion in 2022 to RMB40.9 billion in 2026, primarily driven by increasing cases of diseases and conditions affecting wound healing capabilities, increasing surgical cases and growth in global prevalence of chronic diseases. The growth rate is expected to slightly slow down to a CAGR of 2.2% from RMB40.9 billion in 2026 to RMB46.6 billion in 2032, mainly due to the maturation of existing product offerings and economic variables that could limit healthcare spending, resulting in increased competitive intensity and increased pricing pressure. The following table sets forth the historical and forecast size of the fresh wound therapy market in China by sales amount from 2017 to 2032:



Source: the Frost & Sullivan report

INDUSTRY OVERVIEW

Pressure Ulcers

Overview

Pressure ulcers are injuries to the skin and underlying tissue resulting from sustained pressure on a specific part of the body. This pressure disrupts the blood supply to the affected area of skin. Blood contains oxygen and other essential nutrients required to maintain healthy tissue. In the absence of a continuous blood supply, tissue sustains damage and will ultimately perish. The disrupted blood supply also means that infection-fighting white blood cells no longer reach the skin. Once an ulcer has formed, it is at risk of becoming infected by bacteria. While they can occur in anyone, pressure ulcers typically affect individuals who are bedridden or who remain seated in a chair or wheelchair for extended durations.

Treatment of pressure ulcers can be an extensive and complex process. It is essential to classify the ulcers by their severity to devise an appropriate treatment strategy. A complete treatment plan includes the close wound monitoring, pain assessment and management and any additional supportive healing. However, each treatment option must be tailored to the patient’s individual circumstances and implemented under the supervision of a medical professional to minimize any potential risks. Common medications used in the treatment of pressure ulcers include wound dressings, biological dressings and growth factors. The table below sets forth details of wound dressings, biological dressings and growth factors.

Wound Dressings	<p>Advanced Wound Dressings for Category/Stage I and II Pressure Injuries</p> <ul style="list-style-type: none"> Use hydrocolloid, hydrogel and polymeric membrane dressings for non-infected Category/Stage II pressure injuries. <p>Advanced Wound Dressings for Full Thickness Pressure Injuries</p> <ul style="list-style-type: none"> Use hydrogel dressings for non-infected Category/Stage III and IV pressure injuries with minimal exudate. Use calcium alginate dressings for non-infected Category/Stage III and IV pressure injuries with moderate exudate. <p>Wound Dressings for Pressure Injuries with High Exudate</p> <ul style="list-style-type: none"> Use foam dressings (including hydropolymers) for Category/Stage II and greater pressure injuries with moderate/heavy exudate. Use super-absorbent wound dressings with a high capacity for absorption to manage heavily exuding pressure injuries. <p>Basic Wound Dressings</p> <ul style="list-style-type: none"> Use moist gauze dressings to maintain an appropriately moist wound environment when advanced wound dressings are not an option. Use a transparent film dressings as a secondary dressing when advanced wound dressings are not an option.
Biological Dressings	<p>Collagen Matrix Dressings</p> <ul style="list-style-type: none"> Consider applying collagen dressings to nonhealing pressure injuries to improve rate of healing and decrease signs and symptoms of wound inflammation. <p>Other Biological Dressings</p> <ul style="list-style-type: none"> Some evidence is available on other types of biological dressings for treating pressure injuries, including hyaluronic acid derivative wound dressing, a bi-layered cell therapy wound dressing and an amniotic membrane dressing. The volume of evidence for these biological dressing interventions is currently insufficient to make any specific recommendations.
Growth Factors	<ul style="list-style-type: none"> Consider applying platelet-rich plasma for promoting healing in pressure injuries. Consider applying platelet-derived growth factors for promoting healing in Category/Stage III and IV pressure injuries.

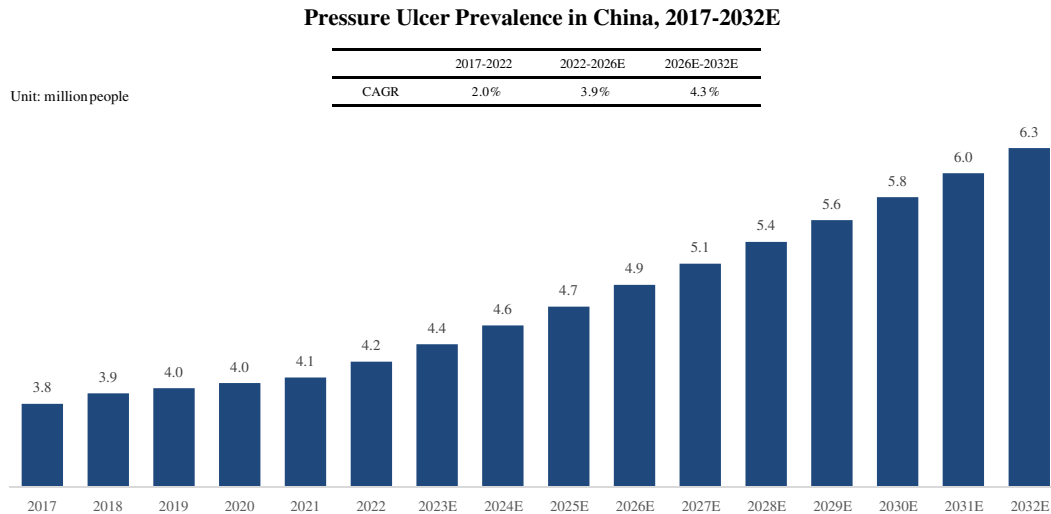
Source: *Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline, the Frost & Sullivan report*

Market size

The prevalence of pressure ulcers varied significantly by age group and tended to increase with age, with the lowest prevalence of 0.5% in the age group from 18 to 39 and the highest prevalence of 7.7% in the age group of 89 and above. The highest incidence of pressure ulcers among Chinese inpatients was found in the ICU, EICU, geriatrics and neurosurgery, mainly due to the fact that there are more comatose, critically ill and bedridden patients in these departments.

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The pressure ulcers prevalence in China increased from 3.8 million people in 2017 to 4.2 million people in 2022, at a CAGR of 2.0%. Factors such as aged population, an increase in inpatient numbers, and challenges in nursing care are expected to drive the prevalence up to an estimated 4.9 million people in 2026 and 6.3 million people in 2032, at a CAGR of 3.9% from 2022 to 2026 and 4.3% from 2026 to 2032. The following chart sets forth the historical and forecast pressure ulcer prevalence in China from 2017 to 2032:



Source: the Frost & Sullivan report

The pressure ulcer therapy market in China experienced steady growth from 2017 to 2022, increasing from RMB1.9 billion in 2017 to RMB2.1 billion in 2022, at a CAGR of 2.0%. Driven by an increasing demand for pressure ulcer care arising from an aging population, higher prevalence of chronic diseases and advancements in pressure ulcer treatment and management technologies, it is projected to experience accelerated growth from 2022 to 2032, reaching RMB2.5 billion in 2026 and RMB3.1 billion in 2032, at a CAGR of 4.2% from 2022 to 2026 and 4.0% from 2026 to 2032. The following chart sets forth the historical and forecast size of the pressure ulcer therapy market in China by sales amount from 2017 to 2032:



Source: the Frost & Sullivan report

INDUSTRY OVERVIEW

Growth Drivers and Future Trends

According to the Frost & Sullivan report, the growth of the PDGF-BB drug market has been, and is expected to continually be, driven by: (i) wide therapeutic potential; (ii) increasing prevalence of chronic diseases; and (iii) specialized therapies for rare conditions.

Meanwhile, in addition to the general trend of growth factor market, such as treatment personalization, therapeutic expansion and combination therapies, the PDGF-BB market has seen a notable increase in the clinical application, particularly for treating stubborn and hard-to-heal wounds such as chronic neuropathic diabetic ulcers and pressure ulcers. These types of wounds often resist conventional treatment methods due to underlying health issues, such as poor circulation or compromised immune systems in patients.

Entry Barriers

New entrants to the PDGF-BB drug market are mainly confronted with a number of barriers, including those relating to:

- **Extraction complexity.** The extraction of PDGF-BB is a procedure that entails intricate biological and biochemical techniques. It necessitates the utilization of specialized equipment, the expertise of highly skilled personnel and a meticulously controlled environment to satisfy stringent quality control protocols. Any slight deviations in the extraction process can lead to variations in the biological characteristics of PDGF-BB.
- **Preparation challenges.** The preparation of PDGF-BB into a pharmaceutically viable form introduces additional complexities. This stage is critical not only to maintain the biological activity of PDGF-BB, which is acutely sensitive to physical and chemical conditions, but also to ensure it meets the regulatory standards for safety, dosage accuracy, stability and other pharmaceutical criteria. Fulfilling these prerequisites demands an extensive knowledge of both biological sciences and pharmaceutical practices, alongside access to advanced pharmaceutical manufacturing facilities.
- **Continuous development and optimization.** In the context of the dynamic biotechnology and pharmaceutical sectors, there is an ongoing imperative for research and development to refine the processes of extraction and preparation, to augment the therapeutic potential of PDGF-BB and to explore novel application for the molecule. Such progress is contingent upon significant and sustained investment in research and development as well as a commitment to continual innovation, creating challenging environment for new entrants with limited resources to enter and sustain a presence in the market.

CHINA mRNA DRUG MARKET

Overview

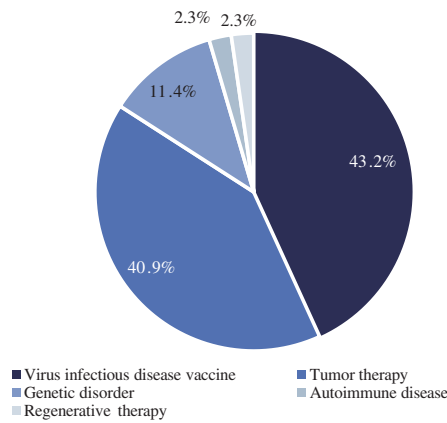
Ribonucleic Acid (RNA) is one of the major macromolecules essential for all known forms of life. Similar to DNA, RNA also encodes genetic information in a chain of nucleotides. It is usually found in cells and some virus as well and plays various roles in the cell including coding, decoding, regulating and expressing genes. As mRNA encodes protein, scientists can modify mRNA in order to express desired protein in the human body to achieve therapeutic effect. mRNA treatment includes tumor immunotherapy, infectious disease vaccine and gene therapy, among other things.

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Advantages of mRNA treatment includes: (i) mRNA is not required to enter the nucleus, translation can be done in cell cytoplasm; (ii) mRNA is not integrated into human genome, thus it is relatively safe; and (iii) mRNA can be produced through *in vitro* transcription, thus it can be mass produced relatively easily and cheaply.

The following charts illustrate a breakdown of clinical trials for mRNA drugs worldwide by application in 2021 and details on each application:

Global mRNA drug clinical trials, 2021



mRNA Drug Applications

Virus Infectious disease vaccine	<ul style="list-style-type: none"> Produce antigen in order to activate immune system
Tumor Therapy	<ul style="list-style-type: none"> Produce prostate-specific antigen. Antigen is displayed on the surface of the cell in order to activate immune system
Genetic disorder	<ul style="list-style-type: none"> Produce and replace defect proteins in the cell.
Autoimmune disease	<ul style="list-style-type: none"> Use Interleukin-2 (IL-2) mutant to increase the level of regulatory T cells.
Regenerative therapy	<ul style="list-style-type: none"> Input mRNA locally in order to express proteins with specific functions

Source: the Frost & Sullivan report

Drug delivery system is a core technology of mRNA. There are three types of mRNA delivery system currently, namely: (i) liposome complex, (ii) lipid nanoparticle (LNP); and (iii) polymer. In particular, lipid nanoparticle systems are the lead non-viral delivery systems for enabling the clinical potential of genetic drugs due to its low immunogenicity, high stability in the human body, and the practicality for mass production.

Market Size

As of 2021, no mRNA drug existed in the market in China. However, many companies have already entered the field with several clinical trials nearing NDA. In 2022, there begins a rapid growth phase with sales reaching RMB10.2 billion in the mRNA drug market in China. Subsequently, the market is expected to significantly decrease from RMB10.2 billion in 2022 to RMB4.4 billion in 2026, at a CAGR of negative 9.4%, mainly due to the decrease in demand for mRNA vaccines resulting from the gradual mitigation of the development of the COVID-19 outbreaks. The market is projected to gradually recover and reach RMB6.0 billion in 2032, at a CAGR of 2.4%, mainly driven by technological innovations and emerging vaccine demands.

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Future Trends

According to the Frost & Sullivan report, the mRNA drug market has demonstrated the following trends:

- **High efficiency & safe delivery system.** Enhancements in the delivery system significantly contribute to the viability of mRNA as a drug candidate. The development of delivery mechanisms, including lipid nanoparticles (LNP), is progressing swiftly, which will facilitate the administration of a broader range of mRNA medicinal formulations. While the stability and toxicity profiles of LNP offer room for further refinement, on the production front, numerous challenges remain to be addressed.
- **Improving industry value chain.** The field of mRNA therapeutics represents an emergent sector within the pharmaceutical industry, which is currently in the early stages of development. However, as the number of entrants in the market increases and capital inflows to these companies grow, it is anticipated that the industry’s value chain will experience rapid enhancement in the forthcoming period.
- **Broader medical applications.** The COVID-19 vaccine currently stands as the sole mRNA medicine authorized for market release. Nevertheless, the expanding focus on the development of mRNA therapeutics suggests that infectious diseases will soon cease to be the exclusive focus of this medical technology. Moreover, vaccines represent just one application of mRNA drugs. Numerous mRNA therapies targeting tumors are presently undergoing clinical trials. Looking ahead, it is expected that mRNA treatments will extend to a wider array of conditions, including tumors, rare genetic disorders and hereditary diseases.

Entry Barriers

New entrants to the mRNA drug market are mainly confronted with the following barriers:

- **RNA sequence design.** Creating mRNA sequences is a complex process that requires extensive research and expertise. The manner in which the sequence is constructed significantly affects the efficacy of the mRNA and the body’s react to it.
- **LNP delivery system.** The utilization of LNP is crucial for delivering mRNA drugs into the body. Well-established companies have their own systems, which are legally protected, posing challenges for new entrants who wish to utilize such technology without encountering legal complications.

CHINA ASO THERAPY MARKET

Overview

Antisense oligonucleotides (ASOs) are concise fragments of single-stranded DNA or RNA. These molecules operate by selectively binding to specific mRNA sequences through complementary pairing, thereby inhibiting the mRNA’s translation process. This targeted approach allows for the precise regulation of gene expression. Such characteristics of ASOs renders them invaluable in a multitude of medical fields, offering therapeutic potential for a range of genetic disorders, oncological conditions, central nervous system ailments, and as therapeutic tools to investigate disease mechanisms.

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Market Size

The ASO therapy market in China exhibited dynamic growth, increasing from RMB81.3 million in 2017 to RMB312.5 million in 2022, at a CAGR of 31.1%, mainly due to the innovative nature of ASO therapy, which targets specific genetic disorders by modulating gene expression. At the end of 2021, an ASO drug was approved for inclusion on the National Reimbursement Drug List of China, leading to a significant increase in the ASO therapy market in China. The ASO therapy market in China is expected to increase from RMB312.5 million in 2022 to RMB568.0 million in 2026 and further to RMB1,018.2 million in 2032, at a CAGR of 16.5% from 2022 to 2026 and 10.2% from 2026 to 2032, primarily driven by increasing recognition of ASO therapy’s efficacy in clinical trials, the expansion into new therapeutic areas and the development of novel ASO candidates.

Growth Drivers and Entry Barriers

According to the Frost & Sullivan report, the growth of the ASO therapy market in China has been, and is expected to continually be, driven by:

- ***Precision gene regulation.*** ASOs enable the specific inhibition of target genes by binding to their complementary mRNA sequences, which means ASOs can serve as a highly precise treatment for diseases caused by mutations or the abnormal expression of genes.
- ***Potential for treating intractable diseases.*** ASOs represent an innovative therapeutic approach for conditions that have historically been challenging to address with conventional medications, such as certain genetic diseases and neurodegenerative disorders.
- ***Technological advances.*** Improvements in chemical modification techniques have enhanced the stability and affinity of ASOs, reducing their degradation rate and potential immunogenicity in the body. The development of modern delivery systems, such as nanoparticles and silencing particles, has improved the efficient targeting of ASOs to specific cells and tissues.

New entrants to the ASO drug market mainly face following barriers:

- ***R&D challenges.*** The R&D of ASOs requires extensive knowledge and deep understanding in genetic engineering and molecular biology, and the R&D process encompasses complex activities including the selection of target genes, the design and synthesis of oligonucleotides and the development of drug delivery systems.
- ***Production complexities and high costs.*** The production process of ASO drugs necessitates a highly controlled manufacturing environment and sophisticated synthesis process. In addition, to enhance the drug stability and reduce immune responses, chemical modifications are frequently imperative, thereby arising higher costs.

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SOURCES OF THE INDUSTRY INFORMATION

We engaged Frost & Sullivan, an independent market research consultant, to conduct an analysis of, and to prepare a report on, the wound healing, the growth factor, the mRNA and the ASO markets in China for use in this document, which was commissioned by us for a fee of RMB0.7 million.

In preparing the Frost & Sullivan report, Frost & Sullivan conducted both primary and secondary research to obtain information from various sources. Primary research involved discussing the status of the industry with leading industry participants and industry experts; and secondary research involved reviewing company reports, independent research reports and data based on our own research database. In compiling and preparing the Frost & Sullivan report, Frost & Sullivan assumed that: (i) the global and China’s economy is likely to maintain steady growth in the next decade; (ii) the global and China’s social, economic and political environment is likely to remain stable in the forecast period; (iii) market drivers like increasing healthcare demand and growing growth factors and innovative technology are likely to drive the global and China’s growth factors market; and (iv) the wound healing market, the growth factor market, including the segment of PDGF-BB, the mRNA market and the ASO market, are likely to be propelled by the local development of relevant sectors and supportive policies.

Forecasts and assumptions included in the Frost & Sullivan report are inherently uncertain because of events or combinations of events that cannot be reasonably foreseen, including, without limitation, the actions of government, individuals, third parties and competitors. Except as otherwise noted, all of the data and forecasts contained in this section are derived from the Frost & Sullivan report. Our Directors confirm that to the best of their knowledge, and after making reasonable enquiries, there has been no adverse change in the industry since the date of the Frost & Sullivan report which may qualify, contradict or have an impact on the information set out in this document.

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LAWS AND REGULATIONS IN THE PRC

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

Drug Regulatory Regime

Major Regulatory Authorities

The drug industry in the PRC is mainly administered by three governmental agencies: the National Medical Products Administration (國家藥品監督管理局) (the “NMPA”), a department under the State Administration for Market Regulation (國家市場監督管理總局), the National Health Commission of the PRC (中華人民共和國國家衛生健康委員會) (the “NHC”) and the National Healthcare Security Administration (國家醫療保障局) (the “NHSA”).

The NMPA, which inherits the drug supervision function from its predecessor the China Food and Drug Administration (the “CFDA”), or the CFDA (before March 2018), is the primary drug regulator responsible for almost all of the key stages of the life-cycle of pharmaceutical products, including non-clinical researches, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution and pharmacovigilance.

The NHC, formerly known as the National Health and Family Planning Commission (the “NHFPC”), is China’s chief healthcare regulator. It is primarily responsible for drafting national healthcare policy and regulating public health, medical services, and health contingency system, coordinating the healthcare reform, and overseeing the operation of medical institutions and practicing of medical personnel.

The NHSA, established in May 2018, is responsible for drafting and implementing policies, plans and standards on medical insurance, maternity insurance and medical assistance; administering healthcare security funds; formulating a uniform medical insurance catalogue and payment standards on drugs, medical disposables and healthcare services; formulating and administering the bidding and tendering policies for drugs and medical disposables.

Reform of the Drug Approval System

According to the Administrative Measures for Drug Registration, upon completion of pharmacological and toxicological studies, clinical trials and other research supporting the marketing registration of drugs, determination of quality standards, completion of validation of commercial-scale production processes, and preparation for acceptance of verification and inspection for drug registration, the applicant may apply for the New Drug Approval (the “NDA”).

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The NMPA shall evaluate the application pursuant to applicable laws and regulations. The applicant must obtain the NDA before the drugs can be manufactured and sold in the PRC. If (i) a drug is used for the treatment of severe life-threatening diseases currently lacking effective treatment and the data of clinical trials of the drug can prove the efficacy and forecast the clinical value of the drug; (ii) a drug which is urgently needed for public health and the data of clinical trials of the drug can show the efficacy and forecast the clinical value of the drug; or (iii) a vaccine which is urgently needed to deal with major public health emergencies or deemed to be urgently needed by the NHC, and by assessment the benefit of the vaccine outweighs the risk, the applicant may apply for the conditional NDA during the clinical trials of the drug or vaccine.

On January 7, 2009, according to the Administrative Provisions on Special Examination and Approval of New Drug Registration (《新藥註冊特殊審批管理規定》) issued by the CFDA and effective therefrom, the special examination and approval by the CFDA for new drug registration applications applies when (i) the effective constituent extracted from plants, animals or minerals, etc. or the preparations thereof have never been marketed in the PRC, or the medicinal materials are newly discovered or the preparations thereof; (ii) the chemical raw medicines or the preparations thereof, or the biological products have not been approved for marketing either in the PRC or aboard; (iii) the new drugs are for the treatment of such diseases as AIDS, malignant tumors or rare diseases with distinctive clinical treatment advantages; or (iv) the new drugs are for the treatment of the diseases currently lacking effective treatment. Under the circumstances of (i) or (ii), the drug registration applicant (the “**Applicant**”) may apply for the special examination and approval when submitting the application for clinical trials of the new drug; while, under the circumstances of (iii) or (iv), the Applicant may only apply for the special examination and approval when applying for production. The CFDA shall, based on the application of the Applicant, give priority to those registration applications which are determined in compliance with the aforementioned conditions after examination during the registration process, and enhance the communication with the Applicant.

On August 9, 2015, the State Council promulgated the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices (《關於改革藥品醫療器械審評審批制度的意見》) (the “**Reform Opinions**”), which established a framework for reforming the evaluation and approval system for drugs and medical devices. The Reform Opinions indicated enhancing the standard of approval for drug registration and accelerating the evaluation and approval process for innovative drugs.

On November 11, 2015, the Announcement of the CFDA on Several Policies on the Evaluation and Approval of Drug Registration (《國家食品藥品監督管理總局關於藥品註冊審評審批若干政策的公告》) issued by the CFDA further simplified the approval process of drugs that the IND of new drugs are subject to one-off umbrella approval instead of declaration, evaluation and approval by stages.

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On March 4, 2016, the General Office of the State Council promulgated the Guiding Opinions on Promoting the Sound Development of the Medical Industry (《國務院辦公廳關於促進醫藥產業健康發展的指導意見》), which aims to accelerate the development of innovative drugs and biological products with major clinical needs, to speed up the promotion of green and intelligent pharmaceutical production technologies, to strengthen scientific and efficient supervision, and to promote the development of industrial internationalization.

On October 8, 2017, the General Office of Chinese Communist Party’s Central Committee and the General Office of the State Council jointly issued the Opinion on Strengthening the Reform of the Drug and Medical Device Review and Approval Process to Encourage Drug and Medical Device Innovation (《中共中央辦公廳、國務院辦公廳關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》)(the “**Innovation Opinion**”), which seek to streamline the clinical trial process and shorten the timeline. The Innovation Opinion provided special fast-track approval for new drugs and medical devices in urgent clinical need, and drugs and medical devices for rare diseases.

On December 21, 2017, the CFDA promulgated the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation (《關於鼓勵藥品創新實行優先審評審批的意見》), which further clarified that a fast-track clinical trial approval or drug registration pathway will be available to innovative drugs. The aforementioned opinion was repealed by the Announcement of NMPA on Issuing Three Documents including Working Procedures for Review of Breakthrough Therapeutics (Trial) (issued and took effect on July 7, 2020) (《國家藥監局關於發佈〈突破性治療藥物審評工作程序(試行)〉等三個文件的公告》).

On May 17, 2018, the NMPA and 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 clinical trial approval process.

On July 7, 2020, the Priority Evaluation and Approval Procedures for Marketing Approvals of Drugs (Trial) (《藥品上市許可優先審評審批工作程序(試行)》) issued by the NMPA further indicated that a fast-track IND or drug registration pathway will be available to the innovative drugs.

On March 31, 2023, the CDE issued the CDE’s Standards for Accelerating the Review Work for Marketing Approval Applications of Innovative Drugs (Trial) (《藥審中心加快創新藥上市許可申請審評工作規範(試行)》), which encouraging the development process of the innovative drugs of breakthrough therapy drug program, for children and for rare diseases, and is expected to expedite the marketing process of these drugs to meet relevant patients’ medication needs.

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Principal Regulatory Provisions

Laws and Regulations on New Drugs

Research and Development of New Drugs

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”) promulgated by the Standing Committee of the National People’s Congress (the “SCNPC”) in September 1984, last amended on August 26, 2019 and became effective on December 1, 2019, and the Implementation Regulations of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) (the “**Implementation Regulations**”) promulgated by the State Council in August 2002 and last amended on March 2, 2019, have laid down the legal framework for the establishment and maintenance of pharmaceutical manufacturing and trading enterprises, as well as for the administration of pharmaceutical products including the development and manufacturing of new drugs. According to the Drug Administration Law and the Implementation Regulations, the PRC encourages the research and development of new drugs, and protects the legal rights and interests in the research and development of new drugs. The developer and clinical trial applicant of any new drug shall truthfully submit the new drug’s manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data, documents and samples to the NMPA for approval before any clinical trial is conducted.

Non-clinical Research and Animal Testing

The non-clinical safety evaluation study for drugs for the purpose of applying for drug registration shall be conducted in accordance with the Administrative Measures for Good Laboratories Practice (《藥物非臨床研究質量管理規範》), which was promulgated in August 2003 and amended in July 2017 by the CFDA. In April 2007, the CFDA issued the Circular on Measures for Certification of Good Laboratory Practice (《藥物非臨床研究質量管理規範認證管理辦法》), last amended on January 19, 2023 and taking effect on July 1, 2023, which set forth the requirements for an institution to apply for a Certification of Good Laboratory Practice to undertake non-clinical research on drugs.

The State Science and Technology Commission, now known as the Ministry of Science and Technology, promulgated the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) on November 14, 1988, which were most recently amended by the State Council on March 1, 2017. The State Science and Technology Commission and the State Bureau of Quality and Technical Supervision (now merged into the State Administration for Market Regulation) jointly promulgated the Administrative Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) on December 11, 1997. The Ministry of Science and Technology and other regulatory authorities promulgated the

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Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) on December 5, 2001. All of these laws and regulations require a Certificate for Use of Laboratory Animals for performing experimentation on animals.

Application for Clinical Trial and Drug Clinical Trial Registration

According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA on March 17, 2017, the decision on the approval of clinical trials of drugs shall be made by China’s Center for Drug Evaluation of the NMPA (“CDE”) from May 1, 2017. According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the “Circular 27”), which was promulgated on January 22, 2020 and took effect on July 1, 2020, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. In accordance with Circular 27 and the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) issued in July 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the Applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

After obtaining the approval of clinical trial from the NMPA, the applicant must complete the clinical trial registration at the Drug Clinical Trial Information Platform for public disclosure in accordance with the Circular on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect in September 2013. The applicant shall complete the initial registration of the trial within one month after obtaining the approval of clinical trial to obtain an exclusive trial registration number, and then complete the subsequent information registration before the first patient is enrolled in the trial and submit the registration for public disclosure for the first time.

Conduct of Clinical Trial

After obtaining clinical trial approval, the applicant shall conduct clinical trials at qualified clinical trial institutions. The qualified clinical trial institutions refers to institutions that have the conditions to conduct clinical trials in accordance with the requirements and technical guidelines set forth in the Regulations for the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect on December 1, 2019. Such clinical trial institutions shall be subject to filing requirements, with the exception of institutions that only engage in analysis of biological samples which shall not be subject to such filing requirements. The NMPA is responsible for setting up a filing management information platform for the registration, filing and

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operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information from the supervision and inspection activities conducted by the drug regulatory authorities and competent healthcare authorities.

Clinical trials must be conducted in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) promulgated by NMPA and NHC on April 23, 2020 and effective on July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials, including pre-clinical trial preparation, trial protocols, protection of testees' rights and interests, duties of researchers, sponsors and monitors, as well as data management and statistical analysis.

According to the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》), where the application for clinical trial of new investigational drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for communication meetings to the CDE to discuss with the CDE the key technical questions 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》), revised by the NMPA on December 10, 2020, during the research and development periods and in the registration applications of, among others, the innovative new drugs, the applicants may propose to conduct communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development stages of drugs, mainly including meetings before submitting the clinical trial application, meetings upon the completion of Phase II trials and prior to Phase III trials, meetings before submitting the marketing application for a new drug, and meetings for risk evaluation and control. Type III meetings refer to other meetings not classified as Type I or Type II.

New Drug Registration

Pursuant to Circular 27, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes and completion of other related preparation works, the applicant may apply with the NMPA for the marketing authorization. The NMPA then determines whether to approve the application according to applicable laws and regulations and with the comprehensive evaluation opinion provided by the CDE of the NMPA. The applicant must obtain the marketing authorization for a new drug before the drug can be manufactured and sold in the China market. According to Circular 27, the holders of any of the following drugs can apply for conditional approval of such drugs: (i) drugs which are used for the

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treatment of severe life-threatening diseases currently lacking effective treatment and the data of clinical trials can confirm their efficacy and forecast their clinical value; (ii) drugs which are urgently needed for public health and data of clinical trials can demonstrate their efficacy and forecast their clinical value; and (iii) vaccines which are urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, the benefits of both of which are assessed to be outweigh the risk.

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

On January 30, 2015, the CFDA promulgated the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) (《關於發佈國際多中心藥物臨床試驗指南(試行)的通告》) (the “**IMCT Guidelines**”), which took effect on March 1, 2015, to provide guidance for the regulation of application, implementation and administration of international multi-center clinical trials in China. Pursuant to the IMCT Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicant plans to make use of the data derived from the international multi-center clinical trials for application to the CFDA for approval of NDA, such international multi-center clinical trials shall satisfy the requirements set forth in the PRC Drug Administration Law (《中華人民共和國藥品管理法》) and its implementation regulations and relevant laws and regulations.

On July 6, 2018, the NMPA issued the Technical Guiding Principles for the Acceptance of the 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》) (the “**Guiding Principles**”), which provides that overseas clinical data can be submitted for all kinds of registration applications in China, including the clinical trial authorization and NDA. The Guiding Principles clearly list the basic principles and requirements on the acceptance of overseas clinical trial data, and distinguish different levels of acceptance based on the quality of the data itself and different circumstances. The Guiding Principles require that the applicant shall ensure that the overseas clinical trial data are truthful, complete, accurate and traceable, and the generating process of the overseas clinical trial data shall comply with the relevant requirements of the Good Clinical Practice of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH-GCP).

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Marketing Authorization Holder Mechanism

Under the authorization of the SCNPC, the General Office of the State Council issued the Pilot Plan for the Drug Marketing Authorization Holder System (《藥品上市許可持有人制度試點方案》) on May 26, 2016, which provides a detailed pilot plan for the marketing authorization holder system, or MAH System, for drugs in 10 provinces (cities) in China and the plan ended on November 4, 2018. The pilot period was later extended to November 4, 2019 by the SCNPC.

Pursuant to the Drug Administration Law, China implements the marketing authorization holder mechanism for management of the drug industry. The drug marketing authorization holder refers to an enterprise or a drug research and development institution that has obtained the drug registration certificate. The drug marketing authorization holder shall be responsible for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting and processing of drugs in accordance with the provisions of the law.

The marketing authorization holders may manufacture drugs by themselves or entrust a pharmaceutical manufacturing enterprise to manufacture drugs. Likewise, they may sell drugs by themselves or entrust a pharmaceutical distribution enterprise to sell drugs. However, marketing authorization holders may not entrust a pharmaceutical manufacturing enterprise to produce blood products, narcotic drugs, psychotropic drugs, medical-use toxic drugs or pharmaceutical precursor chemicals, except as otherwise stipulated by the drug regulatory department under the State Council. The drug marketing authorization holder shall establish a drug quality assurance system and be equipped with special personnel to take charge of quality management on drugs independently. The drug marketing authorization holder shall regularly review the quality management system of the drug manufacturer and the drug distributor, and supervise its continuous quality assurance and control capabilities.

Where the marketing authorization holder is an overseas enterprise, its designated domestic enterprise shall perform the obligations of the marketing authorization holder and jointly assume responsibilities of the marketing authorization holder with the overseas enterprise.

Gathering, Collection and Filing of Human Genetic Resources

In June 1998, the Ministry of Science and Technology and the Ministry of Health (which was canceled in the institutional reform of the State Council in 2013, its functions were first inherited by the National Health and Family Planning Commission and then by the NHC, which was established in 2018) promulgated the Interim Measures for the Management of Human Genetic Resources (《人類遺傳資源管理暫行辦法》) which sets out rules for the protection and use of human genetic resources in China. Pursuant to the Service Guide for Administrative Licensing of

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Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources of Human genetic resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the Ministry of Science and Technology in July 2015 and the Notice on the Implementation of the Administrative License for the Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) promulgated by the Ministry of Science and Technology in August 2015, the gathering and collection of human genetic resources through clinical trials by a foreign-invested sponsor shall be filed for record with the China Human Genetic Resources Management Office through an online system. The Ministry of Science and Technology promulgated the Notice on Optimizing the Administrative Examination and Approval Process of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》) in October 2017, which has simplified the approval process for the gathering and collection of human genetic resources for the marketing of drugs in China.

Pursuant to the Regulations on the Management of Human Genetic Resources of the People’s Republic of China (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council in May 2019 and came into effect on July 1, 2019, and the last amendment will become effective on May 1, 2024, the state supports the rational use of human genetic resources for scientific research, development of the biomedical industry, improvement of diagnosis and treatment technology, improvement of China’s ability to guarantee biosafety and improvement of the level of people’s health. Foreign organizations, individuals and institutions established or actually controlled by them shall not gather or preserve Chinese genetic resources in China, or provide Chinese genetic resources to foreign countries. In addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall conform to ethical principles and conduct ethical review in accordance with relevant regulations. On May 26, 2023, the Ministry of Science and Technology issued the Implementing Rules of the Administrative Regulations on Human Genetic Resources (《人類遺傳資源管理條例實施細則》), effective from July 1, 2023, which further provided specific provisions on the collection, preservation, utilization and external provision of human genetic resources of the PRC.

On October 17, 2020, the PRC Biosecurity Law (《中華人民共和國生物安全法》) (the “**Biosecurity Law**”) was promulgated by the SCNPC, taking effect from April 15, 2021. The Biosecurity Law establishes a comprehensive legislative framework for the pre-existing regulations in such areas as epidemic control of infectious diseases for humans, animals and plants; research, development, and application of biology technology; biosecurity management of pathogenic microorganisms laboratories; security management of human genetic resources and biological resources; countermeasures for microbial resistance; and prevention of bioterrorism and defending threats of biological weapons.

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Regulations of Biological Products

According to Circular 27, drug registration shall be subject to registration and administration by categories, namely Chinese medicine, chemical medicine and biological products etc. Biological product registration shall be categorized in accordance with biological product innovative medicine, biological product improved new medicine, marketed biological products (including biosimilars), etc. In order to cooperate with the implementation of the Circular 27, the NMPA formulated the Registration Classification of Biological Products and Requirements for Application Materials (《生物製品註冊分類及申報資料要求》), and the Registration Classification of Biological Products part came into effect on July 1, 2020 while the Requirements for Application Materials part came into effect on October 1, 2020.

According to the Registration Classification of Biological Products and Requirements for Application Materials, biosimilars are classified as category 3.3. According to the Biosimilar Guidelines, biosimilars shall be filed under the application procedures for new drugs. Application materials for therapeutic biological products shall be submitted following specific requirements in the Biosimilar Guidelines. According to Guidelines on the Acceptance and Review for Registration of Therapeutic Biological Products (Trial) (《治療用生物製品註冊受理審查指南(試行)》), in general, therapeutic biological products under Categories 13 to 15 shall conduct Phase 3 clinical trial only and may submit plans for Phase 3 clinical trial and relevant clinical application materials.

Special Examination and Approval Procedures

On November 18, 2005, the CFDA promulgated the Procedures of the CFDA for the Special Examination and Approval of Drugs (《國家食品藥品監督管理局藥品特別審批程序》), which stipulates that in the case of any threatening or actual public health emergency, the CFDA shall take a series of measures to facilitate the approval procedures so that the drugs needed in responding to the public health emergency can be approved as soon as possible.

Administrative Protection and Monitoring Periods for New Drugs

According to the Drug Administration Law Implementing Measures, to protect public health, the NMPA may provide for administrative monitoring periods of up to five years for new drugs approved to be manufactured, to consistently monitor the safety of such new drugs. During the monitoring period of a new drug, the NMPA will not approve any other enterprises' applications to manufacture or import a similar new drug.

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Laws and Regulations on the Manufacturing of Drugs

Drug Manufacturing Certificate

Pursuant to the Drug Administration Law and the Implementing Regulations, a drug manufacturer must obtain a Drug Manufacturing Certificate (《藥品生產許可證》) from the drug regulatory authority at provincial, autonomous regional or municipal level before it may start manufacturing drugs in the PRC. The Drug Manufacturing Certificate shall indicate the validity period and the scope of production. Each Drug Manufacturing Certificate is valid for a period of five years and the manufacturer is required to apply for renewal of the permit within six months prior to its expiration date.

Good Manufacturing Practice

The World Health Organization encourages the adoption of GMP standards in the drug production, in order to minimize the risks of failure to pass the finished product tests in the drug production.

The Ministry of Health of the PRC (the “MOH”) first issued the Guidelines on Good Manufacturing Practices (《藥品生產質量管理規範》) on March 17, 1988, which was later revised on December 28, 1992. After its establishment, the NMPA revised the Guidelines on Good Manufacturing Practices on June 18, 1999, which became effective from August 1, 1999. The Guidelines on Good Manufacturing Practices revised by the MOH on October 19, 2010, which took effect on March 1, 2011 provided the basic standards for drug production, including production facilities, qualification of management personnel, production plant and facilities, documentation, material packaging and labeling, testing, production management, sales and return of products, complaints of customers, etc.

On August 2, 2011, the CFDA issued the Circular on Printing and Distributing the Administrative Measures for the Certification of Good Manufacturing Practice (《關於印發藥品生產質量管理規範認證管理辦法的通知》), which provided that newly established drug manufacturers, or existing drug manufacturers that wish to expand manufacturing scope or build new workshops shall apply for the GMP certification in accordance with the Drug Administration Law Implementing Measures. Those drug manufacturers that have already obtained the GMP certificates shall re-apply for the GMP certification within six months prior to the expiration date of the GMP certificates. On December 30, 2015, the CFDA issued the Notice on Effectively Implementing the 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 those drug manufacturers that failed to obtain the GMP certificates shall not be granted the drug manufacturing license.

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On November 29, 2019, the NMPA issued the Announcement on Matters relating to 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 the GMP certification would be canceled from December 1, 2019, and no application for GMP certification would be accepted and no GMP certificate would be granted. However, according to the Drug Administrative Law, drug manufacturers shall still comply with the GMP, establish and improve the GMP system, and ensure the whole drug production process consistently in compliance with statutory requirements.

On May 24, 2021, the NMPA issued the Administrative Measures for Drug Inspection (Trial) (《藥品檢查管理辦法(試行)》) which became effective on the same day, and last amended on July 19, 2023, and the Administrative Measures for the Certification of Good Manufacturing Practice was repealed. The Administrative Measures for Drug Inspection (Trial) provided that onsite inspections shall be conducted pursuant to the GMP on a drug manufacturer applying for the drug manufacturing license for the first time, while for the drug manufacturers applying for the renewal of drug manufacturing licenses, the review shall be conducted based on the risk management principles, in combination with the drug manufacturers’ compliance with the laws and regulations of drug administration, and the operation of the GMP and quality management system, and inspections on the drug manufacturers’ conformity to the GMP may be conducted where necessary.

Contract Manufacturing of Drugs

Pursuant to the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委托生產監督管理規定》) (the “**Contract Manufacturing Regulations**”) issued by the CFDA in August 2014, only when a drug manufacturer temporarily lacks manufacturing conditions due to technology upgrade or is unable to ensure market supply due to insufficient manufacturing capabilities, can such drug manufacturer entrust the manufacturing of the drug to another domestic drug manufacturer. Such contract manufacturing arrangements shall be approved by the provincial branch of the NMPA.

The Administrative Measures on Supervision of Drug Manufacturing (《藥品生產監督管理辦法》) (the “**Revised Administrative Measures of Drug Manufacturing**”) promulgated by the State Administration for Market Regulation on January 22, 2020 and effective on July 1, 2020 further implements the drug marketing authorization holder system as stipulated in the Drug Administration Law. Drug marketing authorization holders entrusting others to manufacture drugs shall enter into outsourcing agreements and quality agreements with qualified drug manufacturing enterprises and submit the relevant agreements together with the actual manufacturing site application materials to the competent drug administrative authority in order to apply for the Drug Manufacturing Certificate.

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Advertising of Drugs

According to the Advertising Law of the PRC (《中華人民共和國廣告法》), which was promulgated by the Standing Committee of the National People’s Congress on October 27, 1994 and last amended on April 29, 2021, certain contents such as statement on cure rate or efficiency shall not be included in the advertisement of drugs.

According to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food, and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) issued by the State Administration for Market Regulation on December 24, 2019 and came into effect on March 1, 2020, the advertisements for drugs shall not be released without being reviewed and the contents of a drug advertisement shall be based on the drug instructions approved by the drug administration departments.

Product Liability

According to the Civil Code of the PRC (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and effective from January 1, 2021, where a patient suffers damage due to defects in a drug, the patient may claim for compensation from the holder of the marketing approval for the drug, manufacturer or the medical institution. Where the patient claims for compensation from the medical institution, the medical institution, after making compensation, shall have the right of recovery against the liable holder of the marketing approval for the drug or manufacturer.

Other PRC Regulations Relating to the Pharmaceutical Industry

National Essential Drug List

According to the Opinions of the General Office of the State Council on Improving the National Essential Drugs System (《國務院辦公廳關於完善國家基本藥物制度的意見》) issued on September 13, 2018 and effective therefrom, the Circular on the Printing and Distribution of the Administrative Measures for the National Essential Drug List (《關於印發國家基本藥物目錄管理辦法的通知》) issued on February 13, 2015 and effective therefrom, and the National Essential Drug List (2018 version) (《國家基本藥物目錄(2018年版)》) (the “**National Essential Drug List**”) issued by the NHC on September 30, 2018 and effective from November 1, 2018, basic healthcare institutions funded by the government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in the National Essential Drug List. The drugs listed in the National Essential Drug List shall be purchased by centralized tender process and shall be subject to the price control by the National

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Development and Reform Commission (the "NDRC"). Remedial drugs listed in the National Essential Drug List are all listed in the medical insurance catalogue and the entire amount of the purchase price of such drugs is entitled to reimbursement.

Price Controls and Two-invoice System

Instead of direct price controls which were historically used in China, the government regulates prices mainly by establishing a consolidated procurement mechanism, revising medical insurance reimbursement standards and strengthening regulation of medical and pricing practices.

According to the Certain Regulations on the Trial Implementation of Centralised Tender Procurement of Drugs by Medical Institutions (《醫療機構藥品集中招標採購試點工作若干規定》) promulgated on July 7, 2000 and the Notice of NMPA on Further Improvement on the Implementation of Centralised Tender Procurement of Drugs by Medical Institutions (《國家藥品監督管理局關於進一步做好醫療機構藥品集中招標採購工作的通知》) promulgated on July 23, 2001, not-for-profit medical institutions established by county or higher level government are required to implement centralised tender procurement of drugs.

The Ministry of Health promulgated the Working Regulations of Medical Institutions for Procurement of Drugs by Centralised Tender and Price Negotiations (for Trial Implementation) (《醫療機構藥品集中招標採購和集中議價採購工作規範(試行)》) on March 13, 2002, which provides rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices. According to the Notice of the Financial Planning Department of Ministry of Health on Issue of Opinions on Further Regulating Centralised Procurement of Drugs by Medical Institutions (《衛生部財務規劃司關於印發〈進一步規範醫療機構藥品集中採購工作的意見〉的通知》) promulgated on January 17, 2009, not-for-profit medical institutions owned by the government at the county level or higher or owned by state-owned enterprises (including state-controlled enterprises) shall purchase pharmaceutical products by online centralized procurement. Each provincial government shall formulate its catalogue of drugs subject to centralised procurement. Except for drugs in the National List of Essential Drugs (the procurement of which shall comply with the relevant rules on National List of Essential Drugs), certain pharmaceutical products which are under the national government's special control, such as toxic, radioactive and narcotic drugs and traditional Chinese medicines, in principle, all drugs used by not-for-profit medical institutions shall be covered by the catalogue of drugs subject to centralised procurement. The Opinions of the General Office of the State Council on Improvement of the Policy of 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》) promulgated on January 24, 2017 by the General Office of the State Council aims to deepen the reform of medicine health system, improve the quality of the drug and regulate the distribution and use of the drug. The Notice of the General Office of the State Council on Issuing Pilot Plan of Centralised Procurement

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and Use of the Drug Organised by the State (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》) promulgated on January 1, 2019 aims to improve the pricing mechanism of the drug, which also further regulates the scope and mode of centralized procurement.

The centralized tender process takes the form of public tender operated and organized by provincial or municipal government agencies. The centralised tender process is in principle conducted once every year in the relevant province or city in China. The bids are assessed by a committee composed of pharmaceutical and medical experts who will be randomly selected from a database of experts approved by the relevant governmental authorities. The committee members assess the bids based on a number of factors, including but not limited to, bid price, product quality, clinical effectiveness, product safety, qualifications and reputation of the manufacturer, after-sale services and innovation. Only pharmaceuticals that have won in the centralised tender process may be purchased by public medical institutions funded by the governmental or state-owned enterprise (including state-controlled enterprises) in the relevant region.

In order to further optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical Reforms (《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, the “two-invoice system” (兩票制) will be fully implemented in the PRC. According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (for Trial Implementation) (《印發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)的通知》), or the Two-Invoice System Notice, which came into effect on December 26, 2016, the two-invoice system means one invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the medical institution, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to the medical institution.

According to the Two-Invoice System Notice and the Several Opinions of the General Office of the State Council on Further Reforming and Improving the Policies on Drug Production, Circulation and Use (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》) issued on January 24, 2017, the two-invoice system would be promoted in pilot provinces (or autonomous regions and municipalities directly under the central government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, and encouraged to be implemented nationwide in 2018.

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Coverage of the National Medical Insurance Program

The national medical insurance program was first adopted according to the Decision of the State Council on Establishing the Urban Employees' Basic Medical Insurance System (《國務院關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998, under which all employers and their employees in urban cities are required to enroll in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees. On July 10, 2007, the State Council issued the Guiding Opinions of the State Council on the Pilot Urban Resident Basic Medical Insurance (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》), which further expanded the coverage of the basic medical insurance program, and accordingly the urban non-employed residents of the pilot districts may voluntarily enroll in the Urban Resident Basic Medical Insurance. In addition, on January 3, 2016, the Opinions of the State Council on Integrating the Basic Medical Insurance Systems 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》) issued by the State Council required the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified basic medical insurance system, which will cover all urban and rural residents other than rural migrant workers and persons in flexible employment arrangements who participate in the basic medical insurance for urban employees. The participants of the medical insurance programs are eligible for full or partial reimbursement of the cost of the medicines included in the national medical insurance catalogue.

Pursuant to the Notice of the Tentative Administrative Measures of the Scope of Basic Medical Insurance Coverage for Pharmaceutical Products for Urban Employees (《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 Labor and Social Security, the Ministry of Finance and other authorities on May 12, 1999, a pharmaceutical product listed in the medical insurance catalogue must be clinically necessary, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet any of the following requirements: (i) being included in the pharmacopoeia of the PRC, (ii) satisfying the standards as set out by the NMPA, or (iii) having been approved by the NMPA for imported.

According to the Tentative Administrative Measures of the Scope of Basic Medical Insurance Coverage for Pharmaceutical Products for Urban Employees, the Ministry of Labor and Social Security and other relevant governmental authorities have the power to determine the medicines to be included in the national medical insurance catalogue, which is divided into two parts of Part A and Part B. Provincial governments are required to include all Part A medicines listed in the national medical insurance catalogue in their provincial medical insurance catalogue, but have the discretion to adjust upwards or downwards by no more than 15% from the total number of Part B medicines listed in the national medical insurance catalogue. As a result, the contents of Part B of the provincial medical insurance catalogues may differ from region to region in the PRC. Patients purchasing medicines included in Part A of the medical insurance catalogue are entitled to

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reimbursement in accordance with the regulations in respect of basic medical insurance. Patients purchasing medicines included in Part B of the medical insurance catalogue are required to pay a certain percentage of the purchase price and the remainder shall be reimbursed in accordance with the regulations in respect of basic medical insurance. The percentage of reimbursement for Part B medicines is decided by local authorities and as a result may differ from region to region.

Medical Insurance Reimbursement Standards

According to the Decision of the State Council on Establishing the Urban Employees' Basic Medical Insurance System, the Opinions on the Establishment of the New Rural Cooperative Medical System (《關於建立新型農村合作醫療制度意見的通知》) issued by the General Office of the State Council on January 16, 2003, the Guiding Opinions of the State Council on the Pilot Urban Resident Basic Medical Insurance and the Opinions of the State Council on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents, medical insurance shall be available to all employees and residents in both rural and urban areas.

According to the Notice on Printing and Distribution of the Opinion on the Management of Diagnosis and Treatment Items, Scope and Payment Standards of Medical Service Facilities Covered by the Urban Employees Basic Medical Insurance Program (《關於印發〈城鎮職工基本醫療保險診療項目管理、醫療服務設施範圍和支付標準意見〉的通知》) issued on June 30, 1999, the basic medical insurance program may cover a portion of the costs of diagnostic and treatment devices and diagnostic testing. The scope and rate of reimbursement shall be decided by provincial policies.

On June 20, 2017, the General Office of the State Council issued the Guidance on Further Deepening the Reform of the Payment Method of Basic Medical Insurance (《關於進一步深化基本醫療保險支付方式改革的指導意見》), which aimed to implement a diverse medical insurance payment mechanism that includes diagnosis-related groups, per-capita caps, and per-bed-day caps. By 2020, such new reimbursement mechanism will be implemented across the country, replacing the current reimbursement method based on service category and product price. Local medical insurance authorities shall implement the total budget control for their respective administrative regions and determine the amount of reimbursement to public hospitals based on their performance and the expenditure targets of the individual basic medical insurance funds.

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Laws and Regulations on Intellectual Properties

Patent

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》), which was promulgated by the SCNPC on March 12, 1984, last amended on October 17, 2020 and became effective on June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), which were promulgated by the State Council on June 15, 2001 and last amended on December 11, 2023. The Patent Law of the PRC and its Implementation Rules provide for three types of patents, “invention”, “utility model” and “design.” “Invention” refers to any new technical solution relating to a product, a process or improvement thereof; “utility model” refers to any new technical solution relating to the shape, structure, or their combination, of a product, which is suitable for practical use; and “design” refers to any new design of the shape, pattern, color or the combination of any two of them, of a product, which creates an esthetic feeling and is suitable for industrial application. The duration of a patent right for “invention” is 20 years, the duration of a patent right for “utility model” is 10 years, and the duration of a patent right for “design” is 15 years, from the date of application. According to the Patent Law of the PRC, for the purpose of public health, the patent administrative department of the State Council may grant mandatory licensing to manufacture and export patented drugs to countries or regions in comply with provisions of the relevant international treaty participated by the PRC.

Trade Secret

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》), promulgated by the SCNPC in September 1993 and last amended on April 23, 2019, the term “trade secrets” refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the Anti-Unfair Competition Law of the PRC, business persons are prohibited from infringing others’ trade secrets by: (1) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other means; (2) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (1) above; (3) disclosing, using, or allowing another person use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (4) abetting a person, or tempting another person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation of the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a

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misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and impose fine on the infringing parties.

Trademark

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the SCNPC on August 23, 1982, last amended on April 23, 2019 and became effective on November 1, 2019, the period of validity for a registered trademark is 10 years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within twelve months prior to the date of expiry as required if the registrant needs to continue to use the trademark. Where the registrant fails to do so, a grace period of six months may be granted. The period of validity for each renewal of registration is 10 years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided in accordance with applicable laws.

Copyright

Copyright in the PRC is primarily protected by the Copyright Law of the PRC (《中華人民共和國著作權法》), which was promulgated by the SCNPC on September 7, 1990, last amended on November 11, 2020 and became effective on June 1, 2021, and Implementation Regulations of the Copyright Law of PRC (《中華人民共和國著作權法實施條例》), which was promulgated by the State Council on August 2, 2002 and last amended on January 30, 2013. These law and regulation provide provisions on the classification of works and the obtaining and protection of copyright.

Domain Name

In accordance with the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) which was issued by the Ministry of Information Industry on August 24, 2017 and came into effect on November 1, 2017, the Ministry of Industry and Information Technology is responsible for supervision and administration of domain name services in the PRC. Communications administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of "first apply, first register." A domain name registrar shall, in the process of providing domain name registration

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services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

Regulations in Relation to Company Establishment, Foreign Investment and Outbound Investment

Company Establishment

The establishment, operation and management of corporate entities in China are governed by the Company Law of the PRC (《中華人民共和國公司法》) (the “**Company Law**”), which was promulgated by the Standing Committee of the National People’s Congress on December 29, 1993 and came into effect on July 1, 1994. It was subsequently amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013, October 26, 2018 and December 29, 2023. The last amendment of the Company Law will become effective on July 1, 2024. The major revisions made by the last amendment of the Company Law included improvement of the system for the establishment and exit of companies, optimization of organizational structures of companies, improvement of capital system of companies, strengthening the responsibilities of the controlling shareholder and management staff, enhancing the social responsibilities of companies, etc.

Foreign Direct Investment

According to the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “**FIL**”), which was promulgated by the National People’s Congress on March 15, 2019 and came into effect on January 1, 2020, and the Regulations for Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》), which was promulgated by the State Council on December 26, 2019 and came into effect on January 1, 2020, the foreign investment refers to the investment activities in China carried out directly or indirectly by foreign natural persons, enterprises or other organizations, including the following: (i) Foreign Investors establishing foreign-invested enterprises in China alone or collectively with other investors; (ii) Foreign Investors acquiring shares, equities, properties or other similar rights of Chinese domestic enterprises; (iii) Foreign Investors investing in new projects in China alone or collectively with other investors; and (iv) Foreign Investors investing through other ways prescribed by laws and regulations of the State Council. The State adopts the management system of pre-establishment national treatment and negative list for foreign investment. The pre-establishment national treatment refers to granting to Foreign Investors and their investments, in the stage of investment access, the treatment no less favorable than that granted to domestic investors and their investments; the negative list refers to special administrative measures for access of foreign

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investment in specific fields as stipulated by the State. The State will grant national treatment to foreign investments outside the negative list. The negative list will be released by or upon approval of the State Council.

Foreign investment in China is subject to the Catalogue for the Encouraged Investment Industries (2022 Edition) (《鼓勵外商投資產業目錄(2022年版)》) issued on October 26, 2022 and took effect on January 1, 2023, and the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2021 Edition) (《外商投資准入特別管理措施(負面清單)》)(2021年版) issued on December 27, 2021 and took effect on January 1, 2022, which together comprise the encouraged foreign-invested industries catalogue and the special administrative measures for the access of foreign investments to the restricted or the prohibited foreign-invested industries. The latter sets out restrictions such as percentage of shareholding and qualifications of senior management. According to the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》) which took effect on January 1, 2020, foreign investments that are not subject to special access administrative measures are only required to complete an online filing to the commerce departments.

Regulations on Data Security

On June 10, 2021, the SCNPC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》) (the “**Data Security Law**”), which became effective from September 1, 2021. According to the Data Security Law, a data classification protection system shall be established to protect data by classification. Entities engaged in data processing activities shall, in accordance with the laws and regulations, establish a sound whole-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 Civil Code of the PRC, personal information of natural persons is protected by law. Any organization or individual that needs to obtain personal information of others shall obtain legally and ensure the information security, and shall not illegally collect, use, process, transmit, trade, provide or disclose personal information of others. The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) promulgated by the SCNPC on August 20, 2021 and effective from November 1, 2021 further emphasized the duties and responsibilities of the processing personnel for the protection of personal information, and provided stricter protection measures for processing sensitive personal information.

The Cyberspace Administration of China (“CAC”), jointly with the other 12 governmental authorities, promulgated the Cybersecurity Review Measures (《網絡安全審查辦法》) on December 28, 2021, which became effective on February 15, 2022. Pursuant to Article 2 of the Cybersecurity Review Measures, to ensure the security of the supply chain of critical information infrastructure,

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security of network and data and safeguard national security, a cybersecurity review is required when national security has been or may be affected where critical information infrastructure operators (關鍵信息基礎設施運營者) purchase network product or service and network platform operators (網絡平台運營者) conduct data process activities. In addition, Article 7 of the Cybersecurity Review Measures stipulates that when a network platform operator in possession of personal information of over one million users intends to “list abroad” (國外), it must apply to CAC for a cybersecurity review.

According to the Measures on Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》, the “**Security Assessment Measures**”), which was promulgated by the CAC on July 7, 2022 and came into effect on September 1, 2022, data processors shall apply for cross-border security assessment with the CAC through the local provincial-level cyberspace administration department under any of the following circumstances: (i) cross-border transfer of important data by data processors; (ii) cross-border transfer of personal information by critical information infrastructure operators and data processors that process more than 1 million personal information; (iii) cross-border transfer of personal information by data processors that have made cross-border transfer of personal information of 100,000 people or sensitive personal information of 10,000 people cumulatively since January 1 of the previous year; and (iv) other circumstances where an application for security assessment of cross-border data transfer is required as prescribed by the CAC.

According to the Provisions on Promoting and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》), which was promulgated by the CAC on March 22, 2024 and came into effect on the same day, if the data have not been informed or publicly announced as important data by relevant departments or regions, data handlers are not required to declare security assessment for cross-border provision of the data as important data.

On July 12, 2018, the NHC issued the Administrative Measures on National Health and Medical Care Big Data Standards, Security and Services (Trial) (《國家健康醫療大數據標準、安全和服務管理辦法(試行)》) (the “**Measures on Health and Medical Care Big Data**”), which became effective on the same day. The Measures on Health and Medical Care Big Data provided the guidelines and principles of health and medical big data standard management, security management and service management. According to the Measures on Health and Medical Care Big Data, the NHC, together with other relevant departments, is responsible for the management of national health and medical care big data, while the authorities of health above the county level, together with other relevant departments, are responsible for the management of health and medical care big data within their respective administrative regions. Medical institutions and relevant enterprises, including those engaged by medical institutions to store or operate health and medical care big data, shall take measures, such as data classification, important data backup and encryption, to ensure the security of health and medical care big data, and provide secured

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channels for the query and replication of information. The responsible parties shall, pursuant to the Cybersecurity Law, strictly control the authorization to users at different levels to access and use data, and ensure the use of data within the scope of authorization. Without authorization, no unit or individual shall use or disseminate any health and medical care big data or data beyond the scope of authorization, nor obtain any data in illegal ways. The responsible parties shall abide by the relevant regulations when disclosing health and medical care big data, shall not divulge state secrets, trade secrets or personal privacy, shall not infringe upon the interests of the state or the public, and shall not infringe upon the legitimate rights and interests of citizens, enterprise entities or other organizations.

Regulations relating to Outbound Investment

Pursuant to the Administrative Measures on Outbound Investments (《境外投資管理辦法》) issued by the Ministry of Commerce of the PRC (商務部) (the “**MOFCOM**”) on March 16, 2009 and amended on September 6, 2014, the MOFCOM and the provincial competent departments of commerce shall subject the outbound investments of enterprises to filing or approval, depending on the actual circumstances of such investments. Outbound investments of enterprises involving sensitive country or region, or sensitive industry shall be subject to approval. Other outbound investments of enterprises shall be subject to filing.

Pursuant to the Administrative Measures for the Outbound Investments of Enterprises (《企業境外投資管理辦法》) issued by the NDRC on December 26, 2017 and effective from March 1, 2018, if an enterprise in the territory of the PRC (the “**Investor**”) intends to make outbound investments, it shall go through the formalities, such as approval or filing, for the outbound investment project (the “**Project**”), report relevant information and cooperate in the supervisory inspections. The sensitive Projects invested directly by the Investor or through the foreign enterprises controlled by the Investor shall be subject to approval. The non-sensitive Projects invested directly by the Investor, which involve the direct contribution of assets, rights and interests, or provision of financing or guarantee by the Investor, shall be subject to filing. The aforementioned sensitive Projects include the Projects involving sensitive country of region, or sensitive industry. The Catalogue of Sensitive Sectors for Outbound Investment (2018 Edition) (《境外投資敏感行業目錄(2018年版)》) issued by the NDRC on January 31, 2018 and effective from March 1, 2018 listed in detail the sensitive sectors.

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Laws and Regulations on Labor and Employee Incentives

Labor, Social Insurance and Housing Provident Funds

According to the Labor Law of the PRC (《中華人民共和國勞動法》), which was promulgated by the SCNPC in July 1994 and last amended and came into effect in December 2018, the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC in June 2007 and amended in December 2012 and came into effect in July 2013, and the Implementing Regulations of the Labor Contracts Law of the PRC (《中華人民共和國勞動合同法實施條例》), which was promulgated by the State Council and came into effect in September 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages shall not be lower than local minimum wages. The employers must establish a system for labor safety and sanitation, strictly comply with national rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor safety and sanitation conditions and necessary protection materials in compliance with national rules, and carry out regular health examinations for employees engaged in work involving occupational hazards.

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), which was promulgated by the SCNPC in October 2010 and last amended and came into effect in December 2018, and the Interim Regulations on the Collection and Payment of Social Security Funds (《社會保險費徵繳暫行條例》), which was promulgated by the State Council in January 1999 and last amended in March 2019, and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), which was promulgated by the State Council in April 1999 and last amended in March 2019, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance and maternity insurance and to housing provident funds. Any employer who fails to make the required contributions may be fined and ordered to compensate the deficit within a stipulated time limit.

Employee Stock Incentive Plans

On February 15, 2012, the State Administration of Foreign Exchange of the PRC (國家外匯管理局) (the “SAFE”) issued the Circular on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly Listed Companies (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) (the “Share Incentive Rules”). Under the Share Incentive Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent,

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which could be a PRC domestic company participating in such stock incentive plan, and complete certain procedures. In addition, the State Taxation Administration of the PRC (國家稅務總局) (the “STA”) has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax. The domestic qualified agent have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income tax of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC domestic companies fail to withhold, their individual income tax according to relevant laws, rules and regulations, the PRC domestic companies may face sanctions imposed by the tax authorities or other relevant PRC governmental authorities.

Laws and Regulations on Environmental and Fire Control

Environmental Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) (the “**Environmental Protection Law**”), which was promulgated by the SCNPC on December 26, 1989, came into effect on the same day and last amended on April 24, 2014, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Ecology and Environment is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Meanwhile, local environment protection authorities may formulate local standards which are more rigorous than the national standards, in which case, the concerned enterprises must comply with both the national standards and the local standards.

Environmental Impact Appraisal

According to the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), which was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, depending on the impact of the construction project on the environment, an construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. As to a construction project, for which an environmental impact report or the environmental impact statement is required, the construction employer shall, before the commencement of construction, submit the environmental impact report or the environmental impact statement to the relevant authority at the environmental protection administrative department for approval. If the environmental impact assessment documents of the construction project have not been examined or approved upon examination by the approval authority in accordance with the law, the construction employer shall not commence the construction. According to the Environmental Impact Appraisal

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Law of the PRC (《中華人民共和國環境影響評價法》) (the “**Environmental Impact Appraisal Law**”), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

Fire Control

Pursuant to the Fire Protection Law of the PRC (《中華人民共和國消防法》) promulgated by the SCNPC on April 29, 1998, and last amended on April 29, 2021 and effective therefrom, the Department of Emergency Management under the State Council and the local people’s governments at or above county level shall supervise and administer the matters of fire protection, while the fire control and rescue institutions of such people’s governments shall be responsible for implementation. The design of fire control of the construction projects must comply with the national technical standards of fire control. If the design of fire control of a construction project has not been examined pursuant to the relevant laws or failed to pass the examination, the construction of such project is not allowed. If a completed construction project has not gone through the fire safety inspection or failed to satisfy the requirements of fire safety upon inspection, such project is not allowed to be put to use or business.

Laws and Regulations on Foreign Exchange and Taxation

Foreign Exchange Administration

The principal law governing foreign currency exchange in the PRC is the PRC Administrative Regulations on Foreign Exchange (《中華人民共和國外匯管理條例》) (the “**Foreign Exchange Regulations**”), which was promulgated by the State Council on January 29, 1996 and most recently revised on August 5, 2008. According to the Foreign Exchange Regulations, international payments in foreign currencies and transfer of foreign currencies under current items shall not be restricted. Foreign currency transactions under the capital account are still subject to limitations and require approvals from, or registration with, the SAFE or its local counterpart and other relevant PRC governmental authorities.

Pursuant to the Regulation 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 which became effective on July 1, 1996, foreign-invested enterprises may only buy, sell or remit foreign currencies at banks authorized to conduct foreign exchange business after providing valid commercial supporting documents and, in the case of transactions under the capital account, obtaining approvals from the SAFE or its local counterpart.

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According to the Circular on Reforming the Management Approach regarding the Settlement of Foreign Exchange Capital 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》) (the “**Circular 19**”), which was promulgated by the SAFE on March 30, 2015, came into effect on June 1, 2015 and revised on December 30, 2019 and March 23, 2023, a foreign-invested enterprise may, according to its actual business needs, settle with a bank the portion of the foreign exchange capital in its capital account, i.e., a bank account opened by a foreign-invested enterprise where the foreign shareholder(s) are required to remit and deposit the amount of respective capital contributions, for which the relevant foreign exchange bureau has confirmed monetary contribution rights and interests (or for which the bank has registered the account-crediting of monetary contribution). Meanwhile, the use of such RMB should still comply with the restrictions set in the Circular 19 that it cannot be directly or indirectly used for making payments beyond the business scope of the enterprise or payments prohibited by national laws and regulations, investing in securities unless otherwise provided by laws and regulations, granting the entrust loans in RMB (unless permitted by the scope of business), repaying the inter-enterprise borrowings (including advances by the third party) repaying the bank loans in RMB that have been lent to a third party, and paying the expenses related to the purchase of real estate not for self-use, except for the foreign-invested real estate enterprises.

According to the Circular on Optimizing Foreign Exchange Administration to Support the Development of Foreign-related Business (《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 which took effect therefrom, the reform to facilitate the payments of proceeds under the capital accounts shall be promoted nationwide by the SAFE. Provided that the use of funds is true and compliant, and in compliance with the current administrative provisions on the use of the proceeds under the capital accounts, enterprises satisfying the requirements are not required to provide the banks with supporting documents to prove authenticity for each transaction beforehand when making domestic payments with the proceeds under the capital accounts, such as the capital funds and the proceeds of foreign debt or overseas listing

On June 9, 2016, the SAFE promulgated the Notice on Reforming and Standardizing the Administrative Provisions on Capital Account Foreign Exchange 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》) (the “**Circular 16**”) and revised on December 4, 2023. According to the Circular 16, enterprises registered in China could settle the external debts in foreign currencies to RMB at their own discretion. The SAFE Circular 16 sets a uniform standard for discretionary settlement of foreign currencies under capital accounts (including but not limited to foreign currency capital and external debts), which is applicable to all enterprises registered in China.

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Dividend Distribution

On January 26, 2017, the SAFE promulgated the Notice on Improving the Verification of Authenticity and Compliance to Further Promote Foreign Exchange Control (《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 several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (i) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities shall hold income to account for previous years’ losses before remitting the profits. Moreover, domestic entities shall make detailed explanations of sources of capital and utilization arrangements, and provide board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

Taxation

Individual Income Tax

Pursuant to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) (the “**IIT Law**”) promulgated by the SCNPC on September 10, 1980, last amended on August 31, 2018 and effective on January 1, 2019, and the Implementation Regulations for the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法實施條例》) (the “**Implementation Regulations for the IIT Law**”) last amended by the State Council on December 18, 2018 and implemented on January 1, 2019, dividend income derived by individual investors from PRC domestic enterprises (no matter the place of payment is in the PRC or not) shall be subject to individual income tax at a tax rate of 20% and shall be withheld by the PRC domestic enterprises, except for tax-exempt income stipulated in international conventions and agreements to which the PRC Government is a party, as well as other tax-exempt income and tax reduction circumstances stipulated by the State Council.

Pursuant to the IIT Law and the Implementation Regulations for the IIT Law, gains on transfer of properties (including gains derived by individuals from the transfer of priced securities, equity, shares of property in a partnership enterprise) in subject to individual income tax at the rate of 20%. Pursuant to the Circular on Declaring that Individual Income Tax Continues to Be Exempted over Individual Gains from Transfer of Shares (Cai Shui Zi [1998] No. 61) (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知(財稅字[1998]61號》)) issued jointly by the Ministry of Finance and the STA on March 30, 1998 and implemented therefrom, from January 1, 1997, gains of individuals from the transfer of shares of listed companies continue to be exempted from individual income tax.

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Enterprise Income Tax

The Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (the “**EIT Law**”), promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and amended on February 24, 2017 and December 29, 2018, as well as the Implementation Rules of the EIT Law (《中華人民共和國企業所得稅法實施條例》) (the “**Implementation Rules**”), promulgated by the State Council on December 6, 2007, came into force on January 1, 2008 and amended on April 23, 2019, are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and its Implementation Rules, enterprises are classified into resident enterprises and non-resident enterprises. Resident enterprises refer to enterprises that are legally established in the PRC, or are established under foreign laws but whose actual management bodies are located in the PRC. And non-resident enterprises refer to enterprises that are legally established under foreign laws and have set up institutions or sites in the PRC but with no actual management body in the PRC, or enterprises that have not set up institutions or sites in the PRC but have derived incomes from the PRC. A uniform income tax rate of 25% applies to all resident enterprises and non-resident enterprises that have set up institutions or sites in the PRC to the extent that such incomes are derived from their set-up institutions or sites in the PRC, or such income are obtained outside the PRC but have an actual connection with the set-up institutions or sites. And non-resident enterprises that have not set up institutions or sites in the PRC or have set up institutions or sites but the incomes obtained by the said enterprises have no actual connection with the set-up institutions or sites, shall pay enterprise income tax at the rate of 10% in relation to their income sources from the PRC. The Circular on Issues Relating to the Withholding and Remittance of Enterprise Income Tax by PRC Resident Enterprises on Dividends Distributed 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 STA on November 6, 2008 and implemented therefrom, further clarified that a PRC resident enterprise shall withhold enterprise income tax at a rate of 10% on the dividends of the year 2008 and onwards distributed to overseas non-resident enterprise shareholders of H shares.

Pursuant to the EIT Law and the Implementation Regulations for the EIT Law, a non-resident enterprise is subject to enterprise income tax for its PRC-sourced income (including gains from transfers of equity investments in the PRC enterprises), but shall be at a reduced tax rate of 10%, if such non-resident enterprise does not have an establishment or premises in the PRC or has an establishment or premises in the PRC but the PRC-sourced income is not connected with such establishment or premises in the PRC. The aforementioned income tax which shall be paid by non-resident enterprises shall be withheld at source, with the payer of the income being the withholding agent. Such withholding tax shall be withheld by the withholding agent from the amount paid or amount due and payable upon each payment or payment due and payable.

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Pursuant to the EIT Law and the EIT Rules, income from equity investment between qualified resident enterprises such as dividends and bonuses, which refers to investment income derived by a resident enterprise from direct investment in another resident enterprise, is tax-exempt income. Moreover, 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 Incomes (《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》) was promulgated by the STA on August 21, 2006 and was most recently amended by the Fifth Protocol ratified by the STA on July 19, 2019 and came into effect on December 6, 2019. The Arrangement stipulates that a PRC resident enterprise which distributes dividends to its Hong Kong shareholders should pay income tax according to PRC laws; however, if the beneficiary of the dividends is a Hong Kong resident enterprise, which directly holds no less than 25% equity interests of the aforementioned enterprise (i.e. the dividend distributor), the tax levied shall be 5% of the distributed dividends. If the beneficiary is a Hong Kong resident enterprise, which directly holds less than 25% equity interests of the aforementioned enterprise, the tax levied shall be 10% of the distributed dividends. Meanwhile, the Announcement of the State Taxation Administration on Certain Issues Concerning the “Beneficial Owners” in the Tax Treaties (《國家稅務總局關於稅收協定中“受益所有人”有關問題的公告》), promulgated by the STA on February 3, 2018 and came into effect on April 1, 2018, has stipulated some factors that are unfavorable to the determination of “beneficial owner.”

In addition, under the Circular of the STA on Relevant Issues Concerning the Implementation of Dividend Clauses in Tax Treaties (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》), which was promulgated by the STA and came into effect on February 20, 2009, all of the following requirements should be satisfied where a tax resident of the counterparty to the tax treaty needs to be entitled to such tax treatment specified in the tax treaty for the dividends paid to it by a PRC resident enterprise: (i) such tax resident who obtains dividends should be a company as provided in the tax treaty; (ii) the equity interests and voting shares of the PRC resident enterprise directly owned by such a tax resident reach a specified percentage; and (iii) the capital ratio of the PRC resident enterprise directly owned by such a tax resident reaches the percentage specified in the tax treaty at any time within 12 consecutive months prior to acquiring the dividends.

Value-Added Tax (the “VAT”)

The major PRC laws and regulations governing value-added tax are the Interim Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例》) issued on December 13, 1993 by the State Council, came into effect on January 1, 1994, and revised on November 10, 2008, February 6, 2016 and November 19, 2017, as well as the Implementation Rules for the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值稅暫行條例實施細則》) issued on December 25, 1993 by the Ministry of Finance (中華人民共和國財政部) (the

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“MOF”), came into effect on the same day and revised on December 15, 2008 and October 28, 2011, any entities and individuals engaged in the sale of goods, supply of processing, repair and replacement services, and import of goods within the territory of the PRC are taxpayers of VAT and shall pay the VAT in accordance with the law and regulation. The rate of VAT for sale of goods is 17% unless otherwise specified, such as the rate of VAT for sale of transportation is 11%. With the VAT reforms in the PRC, the rate of VAT has been changed several times. The MOF and the STA issued the Notice of on Adjusting VAT Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer’s VAT taxable sale or import of goods to 16% and 10%, respectively, this adjustment became effect on May 1, 2018. Subsequently, the MOF, the STA and the General Administration of Customs jointly issued the Announcement on Relevant Policies for Deepening the VAT Reform (《財政部、稅務總局、海關總署關於深化增值稅改革有關政策的公告》) on March 20, 2019 to make a further adjustment, which came into effect on April 1, 2019. The tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

Laws and Regulations on Overseas Securities Offering and Listing by Domestic Companies

Regulations relating to Overseas Listing

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Trial Measures**”) and relevant five guidelines. The Trial Measures will comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities and will regulate both direct and indirect overseas offering and listing of PRC domestic companies’ securities by adopting a filing-based regulatory regime.

According to the Trial Measures, a domestic company seeking direct overseas offering and listing shall file with the CSRC, submit the filing report, legal opinions and other relevant materials as required under the Trial Measures, and state the shareholders’ information and other matters in a truthful, accurate and complete manner. Where a domestic company submits an application for initial public offering to the competent overseas regulators, such domestic company shall file with the CSRC within three business days after such application is submitted. The Trial Measures also require subsequent reports to be filed with the CSRC on material events, such as a change-of-control event, or voluntary or forced delisting of the issuer who has completed the overseas offering and listing. If the issuer fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, it may be subject to

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administrative penalties, such as order to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines.

On the same day, the CSRC also held a press conference for the release of the Trial Measures and issued the Notice on Administration for the Filing of Overseas Offering and Listing by Domestic Companies (《關於境內企業境外發行上市備案管理安排的通知》), which, among others, clarified that, a domestic company that has already obtained the approval document from the CSRC for overseas public offering and listing may proceed with the overseas listing within the validity period of the approval document. Where the overseas listing has not been completed upon the expiration of the approval document, filing procedures specified in the Trial Measures shall be made as required.

H-share Full Circulation

“Full circulation” means listing and circulating on the stock exchange of the domestic unlisted shares of an H-share listed company, including unlisted domestic shares held by domestic shareholders prior to overseas listing, unlisted domestic shares additionally issued after overseas listing, and unlisted shares held by foreign shareholders. On November 14, 2019, the CSRC issued the Guidelines for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請“全流通”業務指引》) (the “**Guidelines for the Full Circulation**”), which was partly revised on August 10, 2023 according to the Decision on Revising and Abolishing Part of Securities and Futures Policy Documents by CSRC (《中國證券監督管理委員會關於修改、廢止部分證券期貨制度文件的決定》).

According to the Guidelines for the Full Circulation, shareholders of domestic unlisted shares may determine by themselves through consultation the amount and proportion of shares, for which an application will be filed for circulation, provided that the requirements laid down in the relevant laws and regulations and set out in the policies for state-owned asset administration, foreign investment and industry regulation are met, and the corresponding H-share listed company may be entrusted to file the said application for full circulation. To apply for full circulation, an H-share listed company shall file the application with the CSRC according to the administrative filing procedures necessary for the Overseas Listing Trial Measures. After the application for full circulation has been approved by the CSRC, the H-share listed company shall submit a report on the relevant situation to the CSRC within 15 days after the registration with CSDCC of the shares related to the application has been completed.

On December 31, 2019, CSDCC and the Shenzhen Stock Exchange (“SZSE”) jointly announced the Measures for Implementation of H-share Full Circulation Business (《H股“全流通”業務實施細則》) (the “**Measures for Implementation**”). The businesses in relation to the H-share

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full circulation business, such as cross-border transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, services of nominal holders, etc. are subject to the Measures for Implementation.

In order to fully promote the reform of H-share full circulation and clarify the business arrangement and procedures for the relevant shares’ registration, custody, settlement and delivery, CSDCC promulgated the Guide to the Program for Full Circulation of H-shares (《H股“全流通”業務指南》) on February 7, 2020, which specifies the business preparation, account arrangement, cross-border share transfer registration and overseas centralized custody, and other relevant matters. In February 2020, China Securities Depository and Clearing (Hong Kong) Limited (“CSDC (Hong Kong)”) also promulgated the Guide of China Securities Depository and Clearing (Hong Kong) Limited to the Program for Full Circulation of H-shares to specify the relevant escrow, custody, agent service, arrangement for settlement and delivery, risk management measures and other relevant matters.

According to the Measures for Implementation and the Guide to the Program for Full Circulation of H-shares, shareholders who apply for Full Circulation of H-shares (“**Participating Shareholders**”) shall complete the cross-border transfer registration for conversion of relevant domestic unlisted shares into H Shares before dealing in the shares, i.e., CSDCC as the nominal shareholder, deposits the relevant securities held by Participating Shareholders at CSDC (Hong Kong), and CSDC (Hong Kong) will then deposit the securities at [REDACTED] in its own name, and exercise the rights to the securities issuer through [REDACTED], while [REDACTED] as the ultimate nominal shareholder is listed on the register of shareholders of H-share listed companies.

According to the Guide to the Program for Full Circulation of H-shares, H-share listed companies shall be authorized by Participating Shareholders to designate the only domestic securities company (“**Domestic Securities Company**”) to participate in the transaction of converted H shares. The specific procedure is as follows:

Participating Shareholders submit trading orders of the converted H Shares through the Domestic Securities Company, which transmits the orders to the Hong Kong Securities Company designated by the Domestic Securities Company through Shenzhen Securities Communications Co., Ltd.; and Hong Kong Securities Company conducts corresponding securities transactions in the Hong Kong market in accordance with the aforementioned trading orders and the rules of the Stock Exchange. According to the Guide to the Program for Full Circulation of H-shares, upon the completion of the transaction, settlements between each of the Hong Kong Securities Company and CSDC (Hong Kong), CSDC (Hong Kong) and CSDCC, CSDCC and the Domestic Securities Company, and the Domestic Securities Company and the Participating Shareholders, will all be conducted separately.

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LAWS AND REGULATIONS 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).

Once a product candidate is identified for development, it enters pre-clinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Pre-clinical testing is conducted in accordance with the FDA’s Good Laboratory Practice regulations. A sponsor of an Investigational New Drug application (“**IND**”) must submit the results of the pre-clinical 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. The FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety

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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 (“GCP”) 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 the 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 generally involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetics and pharmacodynamics information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase III clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

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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 the 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 the FDA’s current Good Manufacturing Practices (“cGMP”).

U.S. Review and Approval Processes

The results of product development, pre-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of a New Drug Application (“NDA”) or a Biologics License Application (“BLA”). Unless deferred or waived, NDAs or BLAs, 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 or a BLA 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 or the BLA to ensure that it is sufficiently complete for substantive review before it accepts the NDA or the BLA for filing. After accepting the NDA or the BLA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product’s manufacturing is cGMP-compliant to assure the product’s identity, strength, quality and purity. Before approving the NDA or the BLA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA or the BLA to an advisory committee, generally consisting of a panel of experts, to review whether and under what conditions the application should be approved, and the FDA typically considers such recommendations when making decisions.

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

Expedited Development and Review Programs

Fast Track Designation

Fast Track is a process designed to facilitate the development, and expedite the review of, drugs to treat serious conditions and fill an unmet medical need. Fast Track designation must be requested by the drug company. The request can be initiated at any time during the drug development process. The FDA will review the request and make a decision within 60 days based on whether the drug fills an unmet medical need in a serious condition. Determining whether a disease is serious is a matter of judgment, but generally the FDA considers whether the proposed drug will affect factors such as survival, day-to-day functioning, and the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. To address an unmet medical need, the proposed drug may be developed as a treatment or preventative measure for a disease that does not have a current therapy. The type of information necessary to demonstrate unmet medical need varies with the stage of drug development: early in development, nonclinical data, mechanistic rationale, or pharmacologic data will suffice; later in development, clinical data should be utilized.

A sponsor may request Fast Track designation when the sponsor files an IND application or any time thereafter prior to the receipt of marketing approval. If a new drug product meets the requisite criteria for Fast Track designation, the FDA should grant the application. However, the

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FDA may rescind Fast Track designation, if the FDA determines the criteria for Fast Track designation are no longer met. The FDA will notify the sponsor in writing of its intent to rescind the designation through a “Intent to Rescind Fast Track Designation” letter, which will include the criteria for making the determination and provide the sponsor with an opportunity to submit additional data and justification to support the continuing designation and request a meeting to discuss the designation for the product. The rescinding of a Fast Track designation does not necessarily mean the product is not promising or that the product may not receive marketing approval. It means that the criteria for Fast Track designation are no longer met. The sponsor may request the designation to be rescinded/withdrawn. The impact of revocation is that the sponsor will lose all of the benefits of Fast Track designation, which include more frequent meetings and written communication with the FDA, rolling review, and eligibility for accelerated approval and priority review.

Priority Review

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

Accelerated Approval

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

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Breakthrough Designation

Another program potentially available for sponsors is the breakthrough therapy designation. A drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and according to FAQs published by the FDA (current as of February 3, 2022), the FDA must determine if the candidate qualifies for such designation within 60 days of receipt of the request. If so designated, the FDA shall act to expedite the development and review of the product’s marketing application, including by meeting with the sponsor throughout the product’s development, providing timely advice to the sponsor to ensure that the development program to gather pre-clinical and clinical data is as efficient as practicable.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OVERVIEW

Founded in 2012, we are a China-based innovative biopharmaceutical company committed to developing breakthrough therapies with an emphasis on protein drugs for indications with unmet medical needs and large market opportunities.

Our history dates back to April 24, 2012 when Beijing Zhonghong Saisi Biotechnology Limited (北京中宏賽思生物技術有限公司), our predecessor, was established in Beijing, PRC as a limited liability company with a registered capital of RMB10 million, led by Ms. Jia, our founder, chairperson of the Board, executive Director and one of our Controlling Shareholders, together with Mr. Li, another Controlling Shareholder of our Company and two then minority shareholders. For background of Ms. Jia and Mr. Li, see “Directors, Supervisors and Senior Management” and “Relationship with our Controlling Shareholders” of this document. On October 21, 2020, our Company changed its name to Beijing Huaren Biotechnology Limited (北京華荃生物技術有限公司) and was further renamed as Huaren Biotechnology (Qingdao) Limited (華荃生物科技(青島)有限公司) on June 25, 2023, with our registered office relocated to Qingdao in Shandong Province, PRC. Our Company was converted into a joint stock company with limited liability on April 1, 2024 and renamed as B&K Corporation Limited (華荃生物科技(青島)股份有限公司). As of the Latest Practicable Date, our Company has an issued share capital of 100,008,722 Shares in a nominal value of RMB1.00 each.

OUR MILESTONES

The following table sets forth our Group’s key business development milestones:

Year	Event
2012	• Our Company was established in April 2012
2013	• Commenced research and development of Pro-101-2 with the Institute of Bioengineering of AMMS jointly at the pre-IND stage in August 2013
2014	• The Research & Development Center of our Company was officially established in March 2014
2016	• Continued to optimize our production process with an upgrade from lab-scale to pilot-scale in June 2016
2018	• Recognized as National High and New Tech Enterprise* (國家高新技術企業) in September 2018

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Year	Event
	<p><u>Pro-101-2 for DFUs</u></p> <ul style="list-style-type: none">Completed the pilot-scale production for raw liquids in July 2018
2020	<p><u>Pro-101-2 for DFUs</u></p> <ul style="list-style-type: none">Submitted pre-IND communication application to the CDE in October 2020
2021	<p><u>Pro-101-2 for DFUs</u></p> <ul style="list-style-type: none">Submitted IND application in April 2021 and received the clinical trial notification issued by the CDE in July 2021Commenced Phase I clinical trial in August 2021 and completed the trial in October 2021, with a favorable safety and tolerability profile demonstrated <p><u>Research and development of mRNA</u></p> <ul style="list-style-type: none">Commenced the research and development and patent application of mRNA injection and drugs in June 2021 <p><u>Financing</u></p> <ul style="list-style-type: none">Completed Series Pre-A Financing in May 2021 with our post-money valuation reaching RMB805.40 million and Series A Financing in October 2021 with our Company’s post-money valuation reaching RMB2,021.11 million <p><u>Pro-101-1 for Thermal Burns</u></p> <ul style="list-style-type: none">Applied to the FDA for pre-IND communication meeting in December 2021
2022	<p><u>Pro-101-2 for DFUs</u></p> <ul style="list-style-type: none">Obtained the CDE’s written response, in which it did not raise any objection to our design of the Phase II clinical trial in February 2022, and we initiated the Phase II clinical trial in the same month

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Event
	<p><u><i>Pro-101-1 for Thermal Burns</i></u></p> <ul style="list-style-type: none">• Obtained the FDA’s written feedback in February 2022, in which the FDA agreed that the subsequent registration application would be made through BLA• Submitted the CDE clinical trial application in March 2022 and received a clinical trial notification in June 2022 <p><u><i>Research and development of mRNA</i></u></p> <ul style="list-style-type: none">• Established the nucleic acid pharmaceutical platform and synthesized the first batch of ionizable lipids in February 2022• Verified the structure and sequence of 3’ untranslated regions, which contributed to enhancing the stability of mRNA in April 2022
2023	<p><u><i>Financing</i></u></p> <ul style="list-style-type: none">• Completed Series B Financing in May 2023 with our post-money valuation being RMB3,300.29 million <p><u><i>Pro-101-2 for DFUs</i></u></p> <ul style="list-style-type: none">• New product specifications have been added and approved by the CDE in December 2023 <p><u><i>Pro-101-1 for Thermal Burns</i></u></p> <ul style="list-style-type: none">• Completed Phase IIa clinical study in October 2023, with a satisfactory efficacy and safety profiles demonstrated• Initiated Phase IIb clinical study and completed the first patient enrollment in December 2023
2024	<p><u><i>Pro-101-1 for Thermal Burns</i></u></p> <ul style="list-style-type: none">• Conducting Phase IIb clinical study, with 25 patients enrolled as of March 6, 2024

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

MAJOR CORPORATE DEVELOPMENT OF OUR COMPANY

1. Establishment of our Company

On April 24, 2012, our Company was established as a limited liability company under the laws of the PRC with an initial registered capital of RMB10 million. The shareholding structure of our Company upon establishment is set forth in the table below:

Shareholders	Registered Capital held	Percentage of shareholding
	(RMB)	(%)
Ms. Jia	4,500,000	45.00
Li Desheng (李得聖) ⁽¹⁾	2,500,000	25.00
Guo Jing (郭晶) ⁽¹⁾	2,000,000	20.00
Mr. Li ⁽²⁾	1,000,000	10.00
Total	<u>10,000,000</u>	<u>100.00</u>

Notes:

- (1) To the best of our Company’s knowledge, each of Li Desheng and Guo Jing is an Independent Third Party as of the Latest Practicable Date.
- (2) Mr. Li is one of our Controlling Shareholders. See “Relationship with our Controlling Shareholders” in this document for further background of Mr. Li.

2. Equity transfers in March 2013

In January 2013, Guo Jing transferred the registered capital of our Company of RMB2,000,000 (representing 20% of the then total registered capital of our Company, among which RMB1,000,000 remained outstanding and unpaid) to Ms. Jia at a consideration of RMB1,000,000, which was fully settled on March 27, 2013; while Ms. Jia transferred the registered capital of RMB1,000,000 (representing 10% of the then total registered capital of our Company) to Luo Bin (羅斌) at a consideration of RMB1,000,000.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon the completion of the above equity transfers, the shareholding structure of our Company in March 2013 was as follows:

Shareholders	Registered Capital held	Percentage of shareholding
	<i>(RMB)</i>	<i>(%)</i>
Ms. Jia	5,500,000	55.00
Li Desheng	2,500,000	25.00
Luo Bin ⁽¹⁾	1,000,000	10.00
Mr. Li	1,000,000	10.00
Total	<u>10,000,000</u>	<u>100.00</u>

Note:

(1) To the best of our Company’s knowledge, Luo Bin is an Independent Third Party as of the Latest Practicable Date.

3. Equity transfers in September 2013

In August 2013, Ms. Jia transferred a total RMB2,000,000 of our registered capital (representing 20% of the then total registered capital of our Company, which remained outstanding and unpaid) to Li Desheng and Mr. Li as to RMB1,000,000 each, which were fully paid in on September 24, 2013 and September 25, 2013, respectively.

Upon the completion of the above equity transfers, the shareholding structure of our Company in September 2013 was as follows:

Shareholders	Registered Capital held	Percentage of shareholding
	<i>(RMB)</i>	<i>(%)</i>
Ms. Jia	3,500,000	35.00
Li Desheng	3,500,000	35.00
Mr. Li	2,000,000	20.00
Luo Bin	1,000,000	10.00
Total	<u>10,000,000</u>	<u>100.00</u>

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4. Capital increase in December 2013

In October 2013, the registered capital of our Company was increased from RMB10,000,000 to RMB36,000,000 through (i) a capital injection of a total amount of RMB6,000,000 made by Ms. Zhang, which was fully settled on December 18, 2013, and (ii) a capital subscription of a total amount of RMB20,000,000 to be subscribed by the then existing shareholders of our Company.

Upon completion of the capital increase, the shareholding structure of our Company in December 2013 was as follows:

Shareholders	Registered capital held	Percentage of shareholding ⁽¹⁾
	(RMB)	(%)
Ms. Jia	10,500,000	29.17
Li Desheng	10,500,000	29.17
Mr. Li	6,000,000	16.67
Ms. Zhang ⁽²⁾	6,000,000	16.67
Luo Bin	3,000,000	8.33
Total	<u>36,000,000</u>	<u>100.00</u>

Notes:

- (1) Shareholding percentages may not add up to 100% due to rounding.
- (2) Ms. Zhang is one of our Controlling Shareholders. See “Relationship with our Controlling Shareholders” in this document for further background of Ms. Zhang.

5. Equity transfers from January 2015 to November 2020

In January 2015, Luo Bin agreed to transfer the registered capital of our Company of RMB3,000,000 (representing approximately 8.33% of the then total registered capital of our Company) to Shao Yubo (邵煜博), the cousin of Mr. Wang (the son of Ms. Jia and our current President, executive Director and vice chairperson of the Board), at a consideration of RMB3,000,000. Subsequently, in February 2017, Shao Yubo agreed to transfer the registered capital of our Company of RMB3,000,000 (representing approximately 8.33% of the then total registered capital of our Company) to Wang Shen (王紳), the cousin of Mr. Wang, at a consideration of RMB3,000,000.

In January 2018, Li Desheng entered into an equity transfer agreement with Mr. Wang, and agreed to transfer the registered capital of our Company of RMB10,500,000 (representing approximately 29.17% of the then total registered capital of our Company) to Mr. Wang at a

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

consideration of RMB10,500,000. In October 2018, in order to provide financial support for his other business initiatives, Mr. Wang agreed to transfer such total RMB10,500,000 registered capital of our Company to Jia Qiuli (賈秋麗), the sister of Ms. Jia, and Ms. Zhang as to RMB5,250,000 each at a consideration of RMB5,250,000 each. In October 2020, Jia Qiuli, to satisfy personal and family needs for flexibility in cash flow, transferred the registered capital of our Company of RMB5,250,000 (representing approximately 14.58% of the then total registered capital of our Company) to Ms. Jia at a consideration of RMB5,250,000; while Ms. Jia further transferred the registered capital of RMB5,250,000 (representing approximately 14.58% of the then total registered capital of our Company) to Mr. Wang at a consideration of RMB5,250,000.

In November 2020, to satisfy personal and family needs for flexibility in cash flow, Wang Shen transferred the registered capital of our Company of RMB3,000,000 (representing approximately 8.33% of the then total registered capital of our Company) to Jia Qiuli at a consideration of RMB3,000,000. Such registered capital was further transferred to Ms. Jia at a consideration of RMB3,000,000, and subsequently to Mr. Wang at a consideration of RMB3,000,000. The considerations of all the above-mentioned transfers have been fully settled by November 2020.

Upon the completion of the abovementioned equity transfers, the shareholding structure of our Company in November 2020 was as follows:

Shareholders	Registered capital held	Percentage of shareholding ⁽¹⁾
	<i>(RMB)</i>	<i>(%)</i>
Ms. Zhang	11,250,000	31.25
Ms. Jia	10,500,000	29.17
Mr. Wang	8,250,000	22.92
Mr. Li	6,000,000	16.67
Total	<u>36,000,000</u>	<u>100.00</u>

Note:

(1) Shareholding percentages may not add up to 100% due to rounding.

6. Equity transfer and capital increases in December 2020

In December 2020, Ms. Zhang transferred the registered capital of our Company of RMB2,880,000 (representing 8% of the then total registered capital of our Company) to Song Jianqing (宋建青) at a consideration of RMB2,880,000, which was fully settled on November 12, 2020.

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In the same month, the registered capital of our Company was increased from RMB36,000,000 to RMB40,000,000 through a capital subscription of RMB4,000,000 by Qingdao Huaren, one of our Employee Shareholding Platforms. For further details of Qingdao Huaren, see “— Employee Shareholding Platforms” below.

In late December 2020, the registered capital of our Company was further increased from RMB40,000,000 to RMB60,000,000 through a capital subscription of a total RMB20,000,000 by our then existing shareholders on a *pro rata* basis.

Upon completion of the above equity transfer and capital increases, the shareholding structure of our Company in December 2020 was as follows:

Shareholders	Registered capital held	Percentage of shareholding ⁽¹⁾
	(RMB)	(%)
Ms. Jia	15,750,000	26.25
Ms. Zhang	12,555,000	20.93
Mr. Wang	12,375,000	20.63
Mr. Li	9,000,000	15.00
Qingdao Huaren	6,000,000	10.00
Song Jianqing ⁽²⁾	4,320,000	7.20
Total	<u>60,000,000</u>	<u>100.00</u>

Note:

- (1) Shareholding percentages may not add up to 100% due to rounding.
- (2) Song Jianqing is an Independent Third Party, and is an existing Shareholder with approximately 5.76% interest in the Company as of the Latest Practicable Date.

7. Capital increase in May 2021

In May 2021, the registered capital of our Company was increased from RMB60,000,000 to RMB87,000,000 through (i) a capital injection of RMB4,785,000 by Hainan Huaren; and (ii) a capital subscription of a total RMB22,215,000 by our then existing shareholders, namely, Song Jianqing, Qingdao Huaren, Mr. Wang, Ms. Zhang, Mr. Li and Ms. Jia as to RMB1,440,000, RMB2,000,000, RMB5,605,000, RMB4,920,000, RMB3,000,000 and RMB5,250,000, respectively.

Similar to Qingdao Huaren, Hainan Huaren was established as one of our Employee Shareholding Platforms. For further details of Hainan Huaren, see “— Employee Shareholding Platforms” below.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the above capital increase, the shareholding structure of our Company in May 2021 was as follows:

Shareholders	Registered capital held	Percentage of shareholding ⁽¹⁾
	<i>(RMB)</i>	<i>(%)</i>
Ms. Jia	21,000,000	24.14
Mr. Wang	17,980,000	20.67
Ms. Zhang	17,475,000	20.07
Mr. Li	12,000,000	13.79
Qingdao Huaren	8,000,000	9.20
Song Jianqing	5,760,000	6.62
Hainan Huaren	4,785,000	5.50
Total	<u>87,000,000</u>	<u>100.00</u>

Note:

(1) Shareholding percentages may not add up to 100% due to rounding.

8. Series Pre-A Financing

On May 25, 2021, our Company and Zhang Hong (張鴻), among others, entered into a capital increase agreement, pursuant to which Zhang Hong agreed to subscribe for approximately 0.62% equity interest in our Company with a consideration of RMB5,000,000, which was fully settled on May 28, 2021. RMB543,750 out of such consideration was injected into the registered capital of our Company while the remaining amount of RMB4,456,250 was converted as the capital reserves of our Company. For further details of the Series Pre-A Financing, see “— Pre-[REDACTED] Investments” below.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the Series Pre-A Financing, the shareholding structure of our Company as of May 27, 2021 was as follows:

Shareholders	Registered capital held	Percentage of shareholding ⁽¹⁾
	<i>(RMB)</i>	<i>(%)</i>
Ms. Jia	21,000,000	23.99
Mr. Wang	17,980,000	20.54
Ms. Zhang	17,475,000	19.96
Mr. Li	12,000,000	13.71
Qingdao Huaren	8,000,000	9.14
Song Jianqing	5,760,000	6.58
Hainan Huaren	4,785,000	5.47
Zhang Hong ⁽²⁾	543,750	0.62
Total	<u>87,543,750</u>	<u>100.00</u>

Note:

- (1) Shareholding percentages may not add up to 100% due to rounding.
- (2) Zhang Hong is an Independent Third Party, and is an existing Shareholder with approximately 0.54% interest in the Company as of the Latest Practicable Date. For further details and background of Zhang Hong (張鴻), see “— Pre-[REDACTED] Investments — Information relating to our Pre-[REDACTED] Investors” below.

9. Series A Financing

On August 27, 2021, our Company, Ms. Jia, Qingdao CDH and Jiaxing CDH, among others, entered into a capital increase and equity transfer agreement, pursuant to which (i) Qingdao CDH agreed to acquire from Ms. Jia the registered capital of our Company of RMB1,459,063 at a consideration of RMB25,000,000, which was fully settled on October 8, 2021, and to subscribe for additional registered capital of our Company in the amount of RMB1,574,617 at a consideration of RMB35,000,000, which was fully settled on October 8, 2021; and (ii) Jiaxing CDH agreed to subscribe for additional registered capital of our Company in the amount of RMB1,799,562 at a consideration of RMB40,000,000, which was fully settled on September 17, 2021. For further details of the Series A Financing and background of Qingdao CDH and Jiaxing CDH, see “— Pre-[REDACTED] Investments” below.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the Series A Financing, the registered capital of our Company was increased from RMB87,543,750 to RMB90,917,929, and the shareholding structure of our Company as of October 29, 2021 was as follows:

Shareholders	Registered capital held	Percentage of shareholding
	<i>(RMB)</i>	<i>(%)</i>
Ms. Jia	19,540,937	21.49
Mr. Wang	17,980,000	19.78
Ms. Zhang	17,475,000	19.22
Mr. Li	12,000,000	13.20
Qingdao Huaren	8,000,000	8.80
Song Jianqing	5,760,000	6.34
Hainan Huaren	4,785,000	5.26
Qingdao CDH	3,033,680	3.34
Jiaxing CDH	1,799,562	1.97
Zhang Hong	543,750	0.60
Total	<u>90,917,929</u>	<u>100.00</u>

10. Series B Financing

On May 24, 2023, our Company and Qingdao Hitech, among others, entered into a capital increase agreement, pursuant to which Qingdao Hitech agreed to subscribe for additional registered capital of our Company in the amount of RMB9,090,793 at a consideration of RMB300,000,000, which was fully settled on October 24, 2023. For further details of the Series B Financing and background of Qingdao Hitech, see “— Pre-[REDACTED] Investments” below.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the Series B Financing, the registered capital of our Company was increased from RMB90,917,929 to RMB100,008,722, and the shareholding structure of our Company in June 2023 was as follows:

Shareholders	Registered capital held	Percentage of shareholding ⁽¹⁾
	<i>(RMB)</i>	<i>(%)</i>
Ms. Jia	19,540,937	19.54
Mr. Wang	17,980,000	17.98
Ms. Zhang	17,475,000	17.47
Mr. Li	12,000,000	12.00
Qingdao Hitech	9,090,793	9.09
Qingdao Huaren	8,000,000	8.00
Song Jianqing	5,760,000	5.76
Hainan Huaren	4,785,000	4.78
Qingdao CDH	3,033,680	3.03
Jiaxing CDH	1,799,562	1.80
Zhang Hong	543,750	0.54
Total	<u>100,008,722</u>	<u>100.00</u>

Note:

(1) Shareholding percentages may not add up to 100% due to rounding.

11. Conversion into a joint stock company with limited liability

On March 26, 2024, our Board passed resolutions approving, among other matters, the conversion of our Company from a limited liability company into a joint stock company with limited liability and the change of name of our Company from Huaren Biotechnology (Qingdao) Limited (華芒生物科技(青島)有限公司) to B&K Corporation Limited (華芒生物科技(青島)股份有限公司). Pursuant to the promoters’ agreement dated March 27, 2024 entered into by all the then Shareholders, all then existing Shareholders of our Company approved the conversion of the net assets value of our Company as of February 29, 2024 into 100,008,722 Shares of our Company with a nominal value of RMB1.00 each. On March 27, 2024, our Company convened a shareholders’ meeting, and passed the relevant resolutions approving the conversion of our Company into a joint stock company with limited liability, the articles of association and the relevant procedures. Upon completion of the conversion, the registered capital of our Company became RMB100,008,722 divided into 100,008,722 Shares with a nominal value of RMB1.00

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

each, which were subscribed by all the then Shareholders in proportion to their respective interests in our Company before the conversion. The conversion was completed on April 1, 2024 when our Company obtained a new business license.

SHAREHOLDING STRUCTURE AS OF THE LATEST PRACTICABLE DATE

The table below summarizes the shareholding structure of our Company as of the Latest Practicable Date and immediately prior to the completion of the [REDACTED]:

Shareholders	Type of Shares held	Number of Shares held	Percentage of shareholding ⁽¹⁾
			(%)
Ms. Jia	Unlisted Shares	19,540,937	19.54
Mr. Wang	Unlisted Shares	17,980,000	17.98
Ms. Zhang	Unlisted Shares	17,475,000	17.47
Mr. Li	Unlisted Shares	12,000,000	12.00
Qingdao Hitech	Unlisted Shares	9,090,793	9.09
Qingdao Huaren	Unlisted Shares	8,000,000	8.00
Song Jianqing	Unlisted Shares	5,760,000	5.76
Hainan Huaren	Unlisted Shares	4,785,000	4.78
Qingdao CDH	Unlisted Shares	3,033,680	3.03
Jiaxing CDH	Unlisted Shares	1,799,562	1.80
Zhang Hong	Unlisted Shares	543,750	0.54
Total		<u>100,008,722</u>	<u>100.00</u>

Note:

(1) Shareholding percentages may not add up to 100% due to rounding.

CONFIRMATION BY THE PRC LEGAL ADVISOR

As advised by our PRC Legal Advisor, all the necessary and material regulatory approvals, registrations or filings in relation to the changes in the registered capital and shareholding of our Company described above have been made and obtained, and the aforesaid changes in the registered capital and shareholding of our Company have been legally conducted and completed pursuant to the applicable PRC laws, regulations and rules in all material respects.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

CONCERT PARTY AGREEMENT

On April 16, 2024, with a view to acknowledging the previous control status of our Group and ensuring the stable ownership and business development of our Group, Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li entered into the Concert Party Agreement, pursuant to which they confirmed and acknowledged that, among other things, (i) since October 2020, they had communicated thoroughly before the Board meetings (as the case may be) and shareholders’ meetings of the Company, and had been acting in concert by aligning their votes at the Board meetings (as the case may be) and the shareholders’ meetings of the Company; and (ii) they will continue to communicate thoroughly and act in concert by aligning their votes at the Board meetings (as the case may be) and shareholders’ meetings of the Company until the earlier of (A) any of them ceases to be interested in the Shares directly or indirectly, or (B) the Concert Party Agreement is terminated by agreement among the Controlling Shareholders. See “Relationship with Our Controlling Shareholders” in this document for further information.

EMPLOYEE SHAREHOLDING PLATFORMS

In recognition of the contributions of our employees and the consultants and to incentivize them to further promote our development, Qingdao Huaren and Hainan Huaren were established pursuant to PRC laws as our Employee Shareholding Platforms.

Qingdao Huaren

Qingdao Huaren is a limited partnership established under the laws of the PRC on November 30, 2020 and managed by its executive partner, Tang Anqi (唐安琪), who is an employee of our Company and holds 0.625% partnership interests therein as of the Latest Practicable Date. As of the Latest Practicable Date, the remaining 99.375% partnership interests of Qingdao Huaren were held by 14 limited partners, including (i) two core connected persons of our Company, namely Dr. Zhai Junhui (翟俊輝) (our executive Director) and Ms. Chen Xuanyu (陳炫宇) (our Supervisor), who held approximately 13.75% and 3.125% partnership interests in Qingdao Huaren, respectively; and (ii) 12 other employees who held in aggregate approximately 82.5% partnership interests in Qingdao Huaren and none of whom is a core connected person of our Company or hold more than one third of interest in Qingdao Huaren. As of the Latest Practicable Date, Qingdao Huaren directly held approximately 8.00% equity interest in our Company. For details of the Employee Incentive Plan in respect of Qingdao Huaren, see “Statutory and General Information — C. Further Information about our Directors and Supervisors — 3. Employee Incentive Plans” in Appendix IV to this document.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Hainan Huaren

Hainan Huaren is a limited partnership established under the laws of the PRC on April 25, 2021 and managed by its executive partner, Zhang Liting (張麗婷), who is an employee of our Company and holds approximately 19.82% partnership interests therein as of the Latest Practicable Date. As of the Latest Practicable Date, the remaining approximately 80.18% partnership interests of Hainan Huaren were held by four limited partners, including (i) one core connected person of our Company, namely Ms. Song Bing (宋冰) (our Supervisor), who held approximately 21.66% partnership interests in Hainan Huaren; and (ii) three other employees who held in aggregate approximately 58.52% partnership interests in Hainan Huaren and none of whom is a core connected person of our Company or hold more than one third of interest in Hainan Huaren. As of the Latest Practicable Date, Hainan Huaren directly held approximately 4.78% equity interest in our Company. For details of the Employee Incentive Plan in respect of Hainan Huaren, see “Statutory and General Information — C. Further Information about our Directors and Supervisors — 3. Employee Incentive Plans” in Appendix IV to this document.

As of the Latest Practicable Date, all the Shares held by our Employee Shareholding Platforms had been granted to the relevant individuals and no further grants will be made after Listing.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

PRE-[REDACTED] INVESTMENTS

Overview

Details of the Pre-[REDACTED] Investments are set out below:

Name of Pre-[REDACTED] Investors	Subscription Method	Date of Investment Agreement	Date of Settlement of Consideration	Number of Shares Acquired	Consideration (in RMB)	Cost Per Share (in RMB)	Discount to the [REDACTED] ⁽¹⁾	Shareholding in the Company upon [REDACTED] (assuming the [REDACTED] is not exercised)
<i>Series Pre-A Financing</i>								
Zhang Hong (張鴻)	Subscription	May 25, 2021	May 28, 2021	543,750	5,000,000	9.20	[REDACTED]%	[REDACTED]%
<i>Series A Financing</i>								
Qingdao CDH	Transferred by Ms. Jia	August 27, 2021	October 8, 2021	1,459,063	25,000,000	17.13 ⁽²⁾	[REDACTED]%	[REDACTED]%
	Subscription	August 27, 2021	October 8, 2021	1,574,617	35,000,000	22.23	[REDACTED]%	[REDACTED]%
Jiaxing CDH	Subscription	August 27, 2021	September 17, 2021	1,799,562	40,000,000	22.23	[REDACTED]%	[REDACTED]%
<i>Series B Financing</i>								
Qingdao Hitech	Subscription	May 24, 2023	October 24, 2023	9,090,793	300,000,000	33.00	[REDACTED]%	[REDACTED]%

Notes:

- (1) Calculated based on the assumptions that the [REDACTED] is HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED].
- (2) To the best knowledge of our Company who was not a party to such transfer, the consideration of such capital transfer was determined upon arm’s length negotiation between Ms. Jia (as transferor) and Qingdao CDH (as transferee).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Principal Terms of the Pre-[REDACTED] Investments

Set out below are the principal terms of the Pre-[REDACTED] Investments:

	Series Pre-A	Series A ⁽¹⁾	Series B
Amount of registered capital increased (RMB)	543,750	3,374,179	9,090,793
Amount of registered capital after each round of Pre-[REDACTED] Investment (RMB)	87,543,750	90,917,929	100,008,722
Amount of consideration paid for the increased registered capital (RMB)	5,000,000	75,000,000	300,000,000
Cost per registered capital paid under the Pre-[REDACTED] Investments (RMB)	9.20	22.23 ⁽¹⁾	33.00
Post-money valuation of the Company ⁽²⁾ (RMB)	805.40 million	2,021.11 million	3,300.29 million

Use of proceeds from the Pre-[REDACTED] Investments : As of the Latest Practicable Date, we utilized approximately 45% of the proceeds Company obtained from the Pre-[REDACTED] Investments for research and development of our pipeline products, and our daily operation and administration, and the remaining approximately 55% of the net proceeds has not yet been utilized.

Strategic benefits the Pre-[REDACTED] Investors brought to our Company : We are of the view that our Company can benefit from the additional capital injected by the Pre-[REDACTED] Investors’ investments in our Company. Their investments also demonstrated their confidence in our Group’s operations and served as an endorsement of our Group’s performance, strengths and prospects. Our Company is also of the view that most of the Pre-[REDACTED] Investments are made by professional strategic investors in relevant industries which can provide us with their knowledge and experience which we believe are beneficial to our Group’s future development.

Basis of determining the consideration paid : The consideration for the Pre-[REDACTED] Investments were determined based on arm’s length negotiations between our Company (or the selling shareholder, as applicable) and the Pre-[REDACTED] Investors with reference to the appraised market value of our equity interests, the timing of the investments and the prospects of our business.

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- Special rights** : Pursuant to the supplemental agreement to the shareholders agreement dated February 23, 2024 entered into between the Company and the Shareholders, all the special rights granted to the Pre-[REDACTED] Investors, including, among others, the pre-emptive right, right of first refusal, director nomination right, information right and redemption right have been terminated on the date of such supplemental agreement.
- Lock-up** : Pursuant to the applicable PRC laws, within the 12 months following the [REDACTED], all current Shareholders (including the Pre-[REDACTED] Investors) shall not dispose of any of the Shares held by them.

Notes:

- (1) As part of the Series A Financing, Qingdao CDH also acquired from Ms. Jia the registered capital of our Company in the amount of RMB1,459,063 at a consideration of RMB25,000,000, with cost per registered capital paid being RMB17.13. Please see “— Major Corporate Development of our Company — 9. Series A Financing” and “— Pre-[REDACTED] Investments — Overview” above. As such, the above share transfer has not been taken into account for the purpose of the amount of registered capital increased, amount of registered capital after each round of Pre-[REDACTED] Investment and amount of consideration paid for the increased registered capital as illustrated in the table above. To the best knowledge of our Company who was not a party to such transfer, the consideration of such capital transfer was determined upon arm’s length negotiation between Ms. Jia (as transferor) and Qingdao CDH (as transferee).
- (2) The corresponding valuation is calculated based on the proposed post-money capitalization of our Company at the time of the investments, as agreed under the relevant investment agreements. The increase of valuation of the Company from Series Pre-A Financing to Series A Financing was due to (i) the R&D progress of pipeline products of our Group and our business growth; and (ii) management team, strategic development and future prospects of our Group. The valuation of our Company increased during the period from our Series A Financing to Series B Financing primarily because (i) we successfully initiated Phase II clinical trial for one of our Core Products, Pro-101-2, in February 2022 and (ii) we also received the approval from the CDE to directly commence the Phase IIa clinical trial of one of our Core Products, Pro-101-1, in June 2022.

Information relating to our Pre-[REDACTED] Investors

Our Pre-[REDACTED] Investors include Sophisticated Investor, namely CDH Investors, which has made meaningful investment in the Company at least six months before the [REDACTED] Date. The background information on our Pre-[REDACTED] Investors are as set out below.

Zhang Hong

Zhang Hong is an individual Pre-[REDACTED] Investor. He graduated from the Harbin Medical University with a bachelor’s degree in clinical medicine in July 1992 and an executive master of business administration from the University of Science and Technology of China in

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

March 2017. He has over 20 years of experience in the pharmaceutical industry. Zhang Hong joined Astellas Investment (China) Co., Ltd. (阿斯泰來(中國)投資有限公司) in March 2000 and held various positions including the manager of the business department, manager of government affairs department and director of market access with his latest position being head of the Greater China Government Affairs & Market Access.

CDH Investors

Qingdao CDH is a limited partnership established under the laws of the PRC, with Qingdao CDH Runzhong Investment Management Co., Ltd. (青島鼎暉潤中投資管理有限公司) as its general partner, which is in turn controlled by Shanghai CDH Baifu Investment Management Co., Ltd. (上海鼎暉百孚投資管理有限公司), which is ultimately controlled by Mr. Wu Shangzhi (吳尚志), an Independent Third Party. The limited partners of Qingdao CDH are all Independent Third Parties.

Jiaxing CDH is a limited partnership established under the laws of the PRC, with Shanghai CDH Baifu Investment Management Co., Ltd. (上海鼎暉百孚投資管理有限公司) as its general partner. An individual who is an Independent Third Party holds approximately 37.50% partnership interest in Jiaxing CDH, while the other limited partners of Jiaxing CDH are Independent Third Parties and none of them holds more than one-third of the partnership interest therein.

Both Qingdao CDH and Jiaxing CDH are affiliates of CDH Investments, which is a China-focused alternative investment management firm specializing in private equity investments in biomedical, consumer and technology sectors.

Qingdao Hitech

Qingdao Hitech is a limited liability company established under the laws of the PRC on June 26, 2001 and held as to 100% by Qingdao Laoshan Science and Technology Innovation Development Group Co. Ltd. (青島嶗山科技創新發展集團有限公司), which is wholly controlled by Finance Bureau of Laoshan District of Qingdao Municipal City (青島市嶗山區財政局). Qingdao Hitech recorded a total assets of over RMB10 billion as of December 31, 2022. Its major investment areas include artificial intelligence, intelligent manufacturing, and biomedicine, etc. In 2021, Qingdao Hitech participated in the investment of China AI Media & Entertainment Technology Co., Ltd. (中譯文娛科技(青島)有限公司), and in 2022, Qingdao Hitech invested in Qingdao Thunderobot Technology Co., Ltd. (青島雷神科技股份有限公司). It also invested in UBKang (Qingdao) Technology Co., Ltd. (優必康(青島)科技有限公司), being a non-wholly owned subsidiary of UBTECH ROBOTICS CORP LTD 深圳市優必選科技股份有限公司, whose H shares are listed on the Stock Exchange with stock code: 9880).

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To the best knowledge of our Directors, each of our Pre-[REDACTED] Investors and their respective ultimate beneficial owners is an Independent Third Party.

Compliance with the Guide for New Listing Applicants on Pre-[REDACTED] Investment

On the basis that the consideration for the Pre-[REDACTED] Investments was settled more than 28 clear days before the date of our first submission of the [REDACTED] application to the Stock Exchange and all special rights have been terminated, the Joint Sponsors confirmed that the Pre-[REDACTED] Investments are in compliance with Chapter 4.2 of the Guide for New Listing Applicants.

MAJOR ACQUISITION, DISPOSALS AND MERGERS

During the Track Record Period, we had not made any acquisitions, disposals or mergers that we consider to be material to us.

PUBLIC FLOAT

A total of 66,995,937 Shares controlled by Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li, all being our core connected persons, representing 66.99% of our total issued share capital as of the Latest Practicable Date or approximately [REDACTED]% of our total issued Shares upon [REDACTED] (assuming the [REDACTED] is not exercised), will not be counted towards the public float of our Company according to Rule 8.08 of the Listing Rules.

In addition, [REDACTED] Unlisted Shares held by Qingdao Hitech, Qingdao Huaren, Song Jianqing, Hainan Huaren, Qingdao CDH, Jiaxing CDH and Zhang Hong, representing [REDACTED]% of our total issued share capital as of the Latest Practicable Date, or approximately [REDACTED]% of our total issued Shares upon [REDACTED] (assuming the [REDACTED] is not exercised), will not be considered as part of the public float as the Unlisted Shares they hold are will not be converted into H Shares and [REDACTED] on the Main Board upon [REDACTED].

To the best knowledge of the Directors and after due enquiries, [REDACTED] Shares, representing [REDACTED]% of our total issued share capital as of the Latest Practicable Date, or approximately [REDACTED]% of our total issued Shares upon [REDACTED] (assuming the [REDACTED] is not exercised), held by Qingdao Hitech, Qingdao Huaren, Song Jianqing, Hainan Huaren, Qingdao CDH, Jiaxing CDH and Zhang Hong will be converted into H Shares and [REDACTED] following the completion of the [REDACTED]. As these entities will not be core connected person of our Company upon [REDACTED], are not accustomed to take instructions from core connected persons in relation to the acquisition, disposal, voting or other disposition of

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

their Shares and their acquisition of Shares were not financed directly or indirectly by core connected persons, the H Shares held by them will be counted towards the public float for the purpose of Rule 8.08 of the Listing Rules after the [REDACTED].

Following the Conversion of Unlisted Shares into H Shares and upon completion of the [REDACTED] (assuming that the [REDACTED] is not exercised): (i) assuming [REDACTED] H Shares are issued to the public Shareholders in the [REDACTED] and [REDACTED] Unlisted Shares held or controlled by our Shareholders who are not our core connected persons will be converted into H Shares, an aggregate of [REDACTED] H Shares representing approximately [REDACTED]% of our total issued Shares will be counted towards the public float, which is in compliance with the requirement under Rule 8.08 of the Listing Rules; and (ii) based on an [REDACTED] of HK\$[REDACTED] per Share (being the mid-point of the indicative [REDACTED]), the Company will have a market capitalization of at least HK\$375 million held by the public (excluding the H Shares to be subscribed by the [REDACTED] or any existing Shareholders) as required under Rule 18A.07 of the Listing Rules.

OUR SUBSIDIARIES

We conducted all our material operations through our Company during the Track Record Period and up to the Latest Practicable Date. Set forth below are details of our three subsidiaries as of the Latest Practicable Date. See Note 1 in Appendix I to this document.

<u>Name of subsidiary</u>	<u>Place of incorporation</u>	<u>Date of incorporation</u>	<u>Shareholding</u>	<u>Scope of business based on business license ⁽¹⁾</u>
Hainan Huaren Biotechnology	PRC	March 6, 2022	100%	Research and development
Beijing Huarene Biotechnology	Hong Kong	August 8, 2022	100%	Research and development
Huaren Yihai Biotechnology	PRC	July 21, 2023	100%	Research and development

Note:

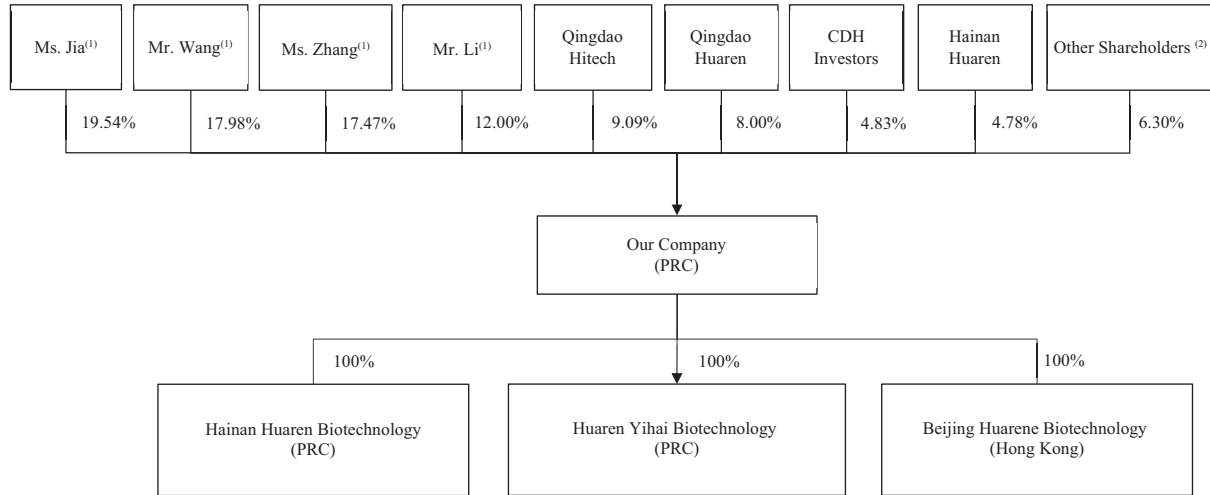
(1) As of the Latest Practicable Date, save for Huaren Yihai Biotechnology, which is engaged in some research and development work, the other two subsidiaries have not yet commenced any substantive business operation.

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CORPORATE STRUCTURE

Our corporate structure immediately prior to the [REDACTED]

The following chart sets forth our Group’s corporate structure immediately prior to the completion of the [REDACTED]:

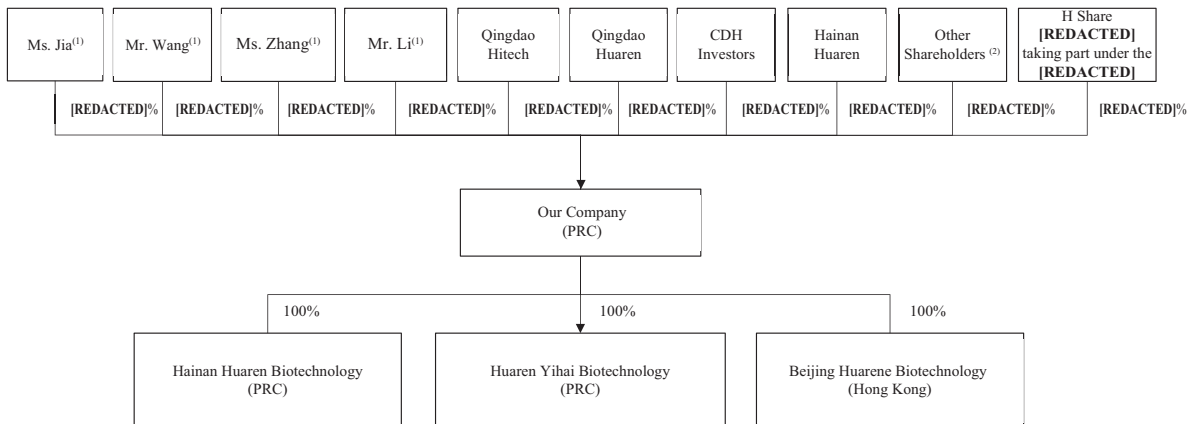


Note (1): Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li are parties acting in concert. For details of such arrangement, see “Relationship with Our Controlling Shareholders — Overview”.

Note (2): Other Shareholders include Song Jianqing and Zhang Hong.

Our corporate structure immediately following the [REDACTED]

The following chart sets forth our Group’s corporate structure immediately after the completion of the [REDACTED] (assuming that the [REDACTED] has not been exercised):



Notes (1) to (2): Please refer to the shareholding and corporate structure immediately prior to the completion of the [REDACTED].

BUSINESS

OVERVIEW

Founded in 2012, we are a China-based innovative biopharmaceutical company committed to developing breakthrough therapies with an emphasis on protein drugs for indications with unmet medical needs and large market opportunities. We primarily focus on the discovery, development and commercialization of multifunctional therapies for wound healing, currently PDGF drugs.

Our Core Products, namely Pro-101-1 and Pro-101-2, are recombinant human platelet-derived growth factor-BB (rhPDGF-BB) drugs. Pro-101-1 is the most advanced PDGF drug candidate in terms of clinical development progress for the treatment of thermal burns in China, and has the potential to be the first commercialized PDGF product in China for this indication, according to the Frost & Sullivan report. Meanwhile, with respect to Pro-101-2, we are one of the leading biopharmaceutical companies with the potential to first achieve commercialization of PDGF drugs in DFUs in China, according to the same source. PDGF is one of the growth factors secreted by platelets after injury. It promotes the development of new blood vessels, regulation of inflammation, and stimulation of cell proliferation and migration, among other things, which eventually leads to wound closure and healing. PDGF drugs have been clinically used as growth factor therapeutic products in DFUs for more than 20 years mainly in the U.S. PDGF is the sole recombinant growth factor that has received approval from the FDA for topical use, specifically in treating DFUs. PDGF drugs have demonstrated notable efficacy with a favorable safety profile in treating DFUs across multiple clinical studies over the years. Meanwhile, as of the Latest Practicable Date, due to the high barriers in research and development and production of PDGF drugs, there were no PDGF drugs commercially available in China.

Designed to address both acute and chronic wounds as well as minor and hard-to-heal wounds, our PDGF candidates are currently being developed for a broad spectrum of wound healing indications including (i) thermal burns, (ii) DFUs, (iii) fresh wounds, (iv) pressure ulcers, (v) radiation ulcers, (vi) dry eye syndrome, (vii) corneal injury, (viii) photodermatitis, (ix) alopecia, (x) hemorrhoids and (xi) gastric ulcers. In addition, PDGF drugs have the potential to enjoy applications in nearly 20 other indications of multiple medical specialties, according to the Frost & Sullivan report. As of the Latest Practicable Date, we had entered the Phase IIb clinical trial of Pro-101-1 in thermal burns in China, and the Phase II clinical trial of Pro-101-2 in DFUs in China, and submitted a pre-IND communication application to the FDA in December 2021 with respect to Pro-101-1 for thermal burns. Meanwhile, we are also advancing the pre-clinical development of PDGF candidates for nine other indications.

Given the vast number of discrete patient populations that it can target, we believe our PDGF candidates are a key pipeline asset in wound healing area. Their potential extensive applications indicate substantial market opportunities, and enable us to capture the vast market opportunities in the PRC wound healing market. According to the Frost & Sullivan report, the market size of

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wound healing drugs in China increased from RMB79.3 billion in 2017 to RMB92.9 billion in 2023, growing at a CAGR of 2.7%, and is expected to reach RMB114.5 billion in 2032, growing at a CAGR of 2.4% from 2023 to 2032. In particular, with respect to our Core Products:

- **Thermal Burns.** According to the Frost & Sullivan report, China has a relatively high thermal burn incidence rate. Despite a decreasing growth rate due to enhanced awareness and precaution, the PRC thermal burn market size remains large, at RMB1.5 billion in 2022, and is expected to reach RMB1.8 billion in 2032, with second-degree burns making up around 80% of the total market size.

Our Phase IIa clinical results demonstrate that Pro-101-1 is effective in expediting the healing process of both superficial and deep second-degree burn wounds, with a favorable safety and tolerability profile. We entered the Phase IIb clinical trial of Pro-101-1 in thermal burns in China in December 2023, and expect to complete the trial in the second quarter of 2025. We intend to initiate the Phase III clinical trial in the third quarter of 2025 and complete the trial in the fourth quarter of 2026. We plan to launch the product in China in 2027. We also submitted a pre-IND communication application to the FDA in December 2021 with respect to Pro-101-1 for thermal burns. In their response, the FDA agreed with our proposal to carry out the clinical trials and submit a BLA via section 351(a) pathway (the pathway for approval of innovator biologics) for Pro-101-1 in thermal burns. We expect to submit the IND application to the FDA in the first quarter of 2026.

- **DFUs.** According to the Frost & Sullivan Report, China has one of the largest diabetic populations in the world, at approximately 136.8 million in 2022, which is expected to reach 174.0 million in 2032. According to the same source, around one fourth of the diabetic populations in China are expected to develop DFUs at some point during their lifetime. In 2022, the prevalence of DFUs in China was 8.0 million, which is expected to reach 10.4 million in 2032. Coupled with a lack of existing therapeutics with affirmative efficacy in China, DFUs have placed heavy financial burdens on patients, families and society, which presents a significant unmet medical need with promising market opportunities.

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Our Phase I clinical results demonstrate a favorable safety and tolerability profile of Pro-101-2 in the treatment of DFUs. We entered the Phase II clinical trial of Pro-101-2 in DFUs in China in February 2022. Since then, we had made registration of new product specification and certain revision to the existing clinical trial protocol. We expect to complete the Phase II clinical trial in the second quarter of 2027. We intend to initiate the Phase III clinical trial in the third quarter of 2027 and complete the trial in the second quarter of 2029. We plan to launch the product in China in 2030.

Our Core Products have demonstrated a consistent favorable safety profile with notable increases in wound healing rates across multiple clinical studies for different wound healing indications. According to the Frost & Sullivan report, based on several clinical trials, PDGF has demonstrated to help accelerate tissue repair and regeneration, enable patients to recover faster, reduce their hospitalization time, minimize complications and reduce the need for re-treatments. Since the commencement of our research and development of PDGF candidates in 2013, we have improved the gene sequence combination and gene modification of PDGF and developed a proprietary PDGF gene sequence for manufacturing purposes, applicable for our protein/peptide pharmaceutical platform and nucleic acid pharmaceutical platform. These improvements and developments have facilitated the development of PDGF candidates in a more efficient manner and further contributed to a significant technological barrier for our competitors to enter the market.

While developing our unique PDGF pipeline, we have also invested in and developed our pipelines of innovative early-stage mRNA and ASO candidates to cover solid tumors, brain glioma and TNBC. As of the Latest Practicable Date, all such candidates were in pre-clinical development.

Our pipeline consisted of ten candidates with substantial market potential covering a wide range of indications, including two Core Products, namely Pro-101-1 and Pro-101-2, currently undergoing the Phase II & IIb clinical trials in China, as of the Latest Practicable Date. The following chart summarizes our pipeline and the development status of each pipeline candidate as of the same date:

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Candidate	Mechanism/Target	Indication	Form	Clinical Trial Region	Development Phase				Upcoming Milestone	Competent or Regulatory Authorities	Commercial Rights	Self-developed or Co-developed
					Pre-Clinical	Phase I	Phase II IIa	Phase II IIb				
★ Pro-101-1		Thermal burns	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	Expected to complete Phase IIb in 2025Q2 and initiate Phase III in 2025Q3	NMPA	Global	Self-developed
					U.S.	Phase I	Phase II IIa	Phase II IIb				
★ Pro-101-2		DFUs	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	Expected to complete Phase II in 2027Q2 and initiate Phase III in 2027Q3	NMPA	Global	Co-developed with the Institute of Biengineering of AMMS®
					China	Phase I	Phase II IIa	Phase II IIb				
Pro-101-3	PDGF receptor	Fresh wounds	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	Self-developed
		Pressure ulcers	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	
		Radiation ulcers	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	
		Photodermatitis	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2026	NMPA	Global	
		Alopecia	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2026	NMPA	Global	
		Hemorrhoids	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2026	NMPA	Global	
		Fresh wounds	Spray	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2028	NMPA	Global	
		Photodermatitis	Spray	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2028	NMPA	Global	
		Dry eye syndrome	Eye drops	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	
		Corneal injury	Eye drops	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	
Pro-104		Alopecia	Medical devices	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2029	NMPA	Global	Self-developed
					China	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2027			
Pro-105		Gastric ulcers	Oral	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2027	NMPA	Global	Self-developed
					China	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2027			
Mes-201 (mRNA)	TSA	Solid tumor	Injection	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2027	NMPA	Global	Self-developed
Oli-101 (ASO)	IneRNA	Brain glioma	Injection	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2028	NMPA	Global	Self-developed
Oli-201 (ASO)	IneRNA	TNBC	Injection	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2029	NMPA	Global	Self-developed

★ Core Products

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Notes:

1. Phase I clinical trial data of Pro-101-2 for the indication of DFUs are shared with indications of thermal burns and fresh wounds.
2. We submitted a pre-IND communication application to the FDA in December 2021 with respect to Pro-101-1 for thermal burns. In lieu of a meeting, the FDA provided written responses in February 2022. The FDA replied that whether the Phase I clinical trial of Pro-101-2 in the treatment of DFUs and our current nonclinical studies are sufficient to support the initiation of the US IND-opening trial will be determined after the FDA’s review of the complete initial IND submission, including the product quality and nonclinical components. The FDA also provided useful guidance on CMC process and the design of our Phase II clinical trial of Pro-101-1 in the treatment of thermal burns. As we are currently focusing on the development of Pro-101-1 in China, we expect to submit the IND filing to the FDA in the first quarter of 2026.
3. Even though the Phase II clinical trial of Pro-101-2 for DFUs began in February 2022, we expect to complete the same in the second quarter of 2027, mainly because we had made registration of new product specification and certain revision to the existing clinical trial protocol since we entered the Phase II clinical trial of Pro-101-2 in DFUs. We expect to initiate the patient enrollment process in the second quarter of 2024. In particular, the revision in the clinical trial protocol is mainly related to our intention to rely on the clinical evidence obtained from immunogenicity studies in the Phase IIa clinical trial of Pro-101-1 in thermal burns, as the enrollment process of thermal burn patients is faster than that of DFU patients. Such revision has been confirmed by the CDE in October 2023.
4. In December 2021, we submitted application materials for a pre-IND meeting with the CDE to discuss the IND application, the plan to directly conduct Phase Ib clinical trial based on the results of the Phase I clinical trial of Pro-101-2 in the treatment of DFUs and the design of the Phase Ib clinical trial. In lieu of a meeting, the CDE provided written responses in March 2022. The CDE provided useful guidance on the design of the Phase Ib clinical trial of Pro-101-3 in the treatment of fresh wounds and suggested that whether additional safety studies are necessary should depend on the MOA, dosage, administration timing and systemic/local exposure of the result of Pro-101-2 in the treatment of DFUs. Meanwhile, as we believe conducting studies to evaluate the safety, tolerability, pharmacokinetics and immunogenicity of Pro-101-1 on thermal burn patients can render more representative results compared to subjects in other indications, we have decided to conduct the Phase IIa clinical trial of Pro-101-1 in thermal burns first. Then, depending on the actual results, we plan to share the relevant results of pharmacokinetics and immunogenicity of Pro-101-1 with clinical studies of Pro-101-3 in fresh wounds, and directly proceed with the Phase II clinical trial on the efficacy and safety of Pro-101-3 in fresh wounds. We have completed the Phase IIa clinical trial of Pro-101-1 in thermal burns in May 2023 and entered the Phase IIb clinical trial in December 2023. We plan to submit the IND application for Pro-101-3 in fresh wounds to the NMPA in the first quarter of 2025 based on the Phase IIa and Phase IIb clinical trial results of the Pro-101-1 in thermal burns and the Phase I clinical trial results of the Pro-101-2 in DFUs. We expect to directly initiate the Phase II clinical trial of Pro-101-3 in fresh wounds upon obtaining the IND approval from the NMPA.
5. Both the Company and the Institute of Bioengineering of AMMS are holders of the relevant patents. Nevertheless, according to its written confirmation dated October 8, 2023, the Institute of Bioengineering of AMMS acknowledged that the rights to own, commercialize and use such patents belong exclusively to the Company. We cooperated with the Institute of Bioengineering of AMMS in pre-clinical development of Pro-101-2 for DFUs, which we have independently researched and developed after the IND approval. For details on our arrangements with the Institute of Bioengineering of AMMS, see “— Collaboration, Licensing and Transfer Arrangements — Collaboration with the Institute of Bioengineering of AMMS and JinBang.”

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Over the years, we have achieved a strong competitive edge in PDGF candidates via breakthroughs of multi-dimensional barriers in research and development and production. Such edge is also protected by our comprehensive, unique and bench-to-bedside patent matrix. Leveraging our experienced drug discovery team and rigorous drug discovery methodology, we have proprietary intellectual property rights with respect to all of our clinical-stage and pre-clinical candidates. As of the Latest Practicable Date, we owned a total of 13 patents, and filed 19 patent applications, including two PCT patent applications. In addition, according to the Frost & Sullivan report, we are the most advanced biopharmaceutical company in terms of the number of PDGF-related technologies and patents in China.

Our solid research and development capabilities are bolstered by a seasoned research and development team and our robust patent matrix, as well as advanced technology platforms, details of which are as follows:

- Our General Manager, Dr. ZHAI Junhui, is responsible for the overall strategies of our research and development work. He is a distinguished scientist in microbiology, molecular biology, virology and preventive medicine with around 30 years of experience in biomedical science research. Dr. Zhai headed and participated in many national-level and other major medical projects, such as the research and development of nucleic acid-based *in vitro* diagnostic reagents for SARS and H1N1 vaccines. He also published more than 100 scientific papers on subjects concerning microbiology, viral genomics and novel virus detection technologies. In addition, as of the Latest Practicable Date, Dr. Zhai was the co-inventor of 24 of our patents applications, ten of which had been approved.
- Our Chief R&D Officer, Dr. ZHAO Xinghui, is responsible for our research and development work. She is a distinguished scientist in biotechnology, genetics and microbiology with around 20 years of experience in biomedical science research. Her primary research areas include protein engineering drugs, pathogen infection mechanisms, tumor molecular markers and epigenetic regulation, and hematopoietic stem cell aging. As of the Latest Practicable Date, Dr. Zhao published 37 Science Citation Index (“SCI”) papers, receiving approximately 900 citations with an H index of 18. She also led two research projects of the National Natural Science Foundation of China (the “NSFC”) and taught several students pursuing a master’s or a doctorate degree. As of the Latest Practicable Date, Dr. Zhao was the co-inventor of 25 of our patent applications, seven of which had been approved.
- Our research and development team has extensive experience in drug development, comprising talents of different specialties, including biology, medicine, pharmacology, formulation, pathology, chemistry, fermentation and molecular biology. Our scientists

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previously worked in renowned hospitals, leading Chinese and international pharmaceutical companies and prestigious research institutes. Core members of our research and development team have on average over 15 years of industry experience.

- We have established systematic and well-integrated biomolecular therapeutic drug development platforms, including a protein/polypeptide pharmaceutical platform and a nucleic acid pharmaceutical platform. Our protein/polypeptide pharmaceutical platform is fortified by a combination of innovative technologies, including eukaryotic expression technology, prokaryotic expression technology and recombinant DNA technology. Based on such platform, we have developed capabilities in new drug formulation development and indication expansion. Meanwhile, our nucleic acid pharmaceutical platform is underpinned by mRNA molecular design technology and lipid nanoparticle (“LNP”) delivery technology. In particular, the protein/polypeptide pharmaceutical platform is integral to the advancement of our product portfolio, particularly that of our Core Products. Its capabilities in both prokaryotic and eukaryotic expression technologies have been instrumental in the creation and refinement of recombinant proteins and peptide drugs.

We aim to dedicate ourselves to developing breakthrough biological products with a vision to eventually become a leading biopharmaceutical company in China. We intend to leverage our platforms, technologies, patents, pipeline candidates, teamwork and corporate culture to launch products with promising safety and efficacy. We intend to continually advance the pre-clinical and clinical development of our pipeline candidates with our in-house research and development capabilities. Meanwhile, we plan to strategically enhance our manufacturing and sales and marketing capabilities to support the potential commercialization of our pipeline candidates, thereby creating a bench-to-bedside innovative biologics platform integrating the entire biologics value chain.

OUR STRENGTHS

Leading innovative biopharmaceutical company of PDGF drugs in China in a vast wound healing market of blue ocean opportunities with a significantly unmet medical need

We are an innovative biopharmaceutical company primarily focused on the discovery, development and commercialization of multifunctional therapies for wound healing, with a primary emphasis on PDGF drugs. One of our Core Products, Pro-101-1, is the most advanced PDGF drug candidate in terms of clinical development progress for the treatment of thermal burns in China, and has the potential to be the first commercialized PDGF product in China for this indication, according to the Frost & Sullivan report. Meanwhile, with respect to the other Core Product, Pro-101-2, we are one of the leading biopharmaceutical companies with the potential to first

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achieve commercialization of PDGF drugs in DFUs in China, according to the same source. In addition, we are the most advanced biopharmaceutical company in terms of the number of PDGF-related technologies and patents in China, which can effectively ensure the progressiveness of our technologies.

PDGF is one of the growth factors secreted by platelets after injury. It promotes the development of new blood vessels, regulation of inflammation, and stimulation of cell proliferation and migration, among other things, which eventually leads to wound closure and healing. Given the vast number of discrete patient populations that it can target, we believe our PDGF candidates are a key pipeline asset in wound healing area. Our PDGF candidates are currently being developed for a broad spectrum of wound healing indications, designed to address both acute and chronic wounds as well as minor and hard-to-heal wounds. As of the Latest Practicable Date, we had entered the Phase IIb clinical trial of Pro-101-1 in thermal burns in China, and the Phase II clinical trial of Pro-101-2 in DFUs in China, and we submitted a pre-IND communication application to the FDA in December 2021 with respect to Pro-101-1 for thermal burns. Meanwhile, we are also advancing the pre-clinical development of PDGF candidates for nine other indications, comprising fresh wounds, pressure ulcers, radiation ulcers, dry eye syndrome, corneal injury, photodermatitis, alopecia, hemorrhoids and gastric ulcers. Other than the indications that we are currently striving to develop, PDGF drugs have the potential to enjoy wide applications in nearly 20 other indications across multiple medical specialties, including general surgery (such as varicose ulcers, phlebitis, and venous ulcers of the lower limbs), radiotherapy (such as skin repair after radiotherapy), dermatology, medical esthetics (such as wound care after plastic surgeries), ophthalmology (such as keratitis, refractive surgeries, refractive errors, cataracts, and glaucoma), orthopedics (such as tennis elbow, fasciitis, osteoarthritis and osteoporosis), dentistry (such as gum recession, periodontal disease and alveolar bone defects), and obstetrics and gynecology (such as cesarean wound care), according to the Frost & Sullivan report. Their potential extensive applications indicate substantial market opportunities, and enable us to capture the vast market opportunities in the PRC wound healing market. According to the Frost & Sullivan report, the market size of wound healing drugs in China increased from RMB79.3 billion in 2017 to RMB92.9 billion in 2023, growing at a CAGR of 2.7%, and is expected to reach RMB114.5 billion in 2032, growing at a CAGR of 2.4% from 2023 to 2032. Our significant first-mover advantages are expected to help us seize the blue ocean opportunities in the vast wound healing market. In particular, with respect to the two indications of our Core Products:

- *Thermal Burns.* According to the Frost & Sullivan report, China has a relatively high thermal burn incidence rate. Despite a decreasing growth rate due to enhanced awareness and precaution, the PRC thermal burn market size remains large, at RMB1.5 billion in 2022 and is expected to reach RMB1.8 billion in 2032, with second-degree

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burns making up around 80% of the total market size. In particular, young children are particularly susceptible to thermal burns as they generally have less control over their environment and may not be fully aware of the dangers associated with heat sources.

- *DFUs.* According to the Frost & Sullivan Report, China has one of the largest diabetic populations in the world, at approximately 136.8 million in 2022, which is expected to reach 174.0 million in 2032. According to the same source, around one fourth of the diabetic populations in China are expected to develop DFUs at some point during their lifetime. DFUs are associated with high rates of limb amputation and mortality. According to the same source, globally, a diabetic patient undergoes amputation every 20 seconds, with DFU patients experiencing an annual mortality rate of up to 11%, and amputated patients facing an even higher mortality rate of 22%. Meanwhile, the prevalence of DFUs in China was 8.0 million in 2022 and is expected to reach 10.4 million in 2032, growing at a CAGR of 2.7%. As the sores and wounds of DFUs require long-term care that is both labor intensive and costly, and coupled with a lack of existing therapeutics with affirmative efficacy in China, DFUs have placed heavy financial burdens on patients, families and society. According to the Frost & Sullivan Report, the market size of the DFU drugs in China was RMB36.4 billion in 2022 and is expected to reach RMB47.3 billion in 2032, growing at a CAGR of 2.7%.

Moreover, hard-to-heal wounds are typically prevalent among the elderly, with decreased healing speed and increased risk of wound complications, which can greatly reduce the patient's quality of life and requires continuous and frequent treatment. PDGF drugs can help speed up patient healing, shorten hospitalization time, and reduce medical costs, thereby alleviating clinical, social, and patients' economic burdens, which indicates potentially a large demand for PDGF drugs upon commercialization. In addition, benefiting from its wide applications and favorable efficacy, PDGF drugs have both consumer and medical attributes in the area of wound healing, thereby enjoying an even wider market potential.

As of the Latest Practicable Date, due to the high barriers in research and development and production of PDGF drugs, there were no PDGF drugs commercially available in China, leaving a significant unmet medical need. In contrast, PDGF drugs have been clinically used as growth factor therapeutic products in DFUs for more than 20 years mainly in the U.S. According to the Frost & Sullivan report, PDGF is the sole recombinant growth factor that has received approval from the FDA for topical use, specifically in treating DFUs. PDGF drugs have demonstrated notable efficacy with a favorable safety profile in treating DFUs in several clinical studies over the years. As PDGF drugs, our Core Products have demonstrated a consistent favorable safety profile with notable increases in wound healing rates across multiple clinical studies. According to the Frost & Sullivan report, based on several clinical trials, PDGF has demonstrated to help accelerate tissue repair and regeneration, enable patients to recover faster, reduce their hospitalization time,

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minimize complications and reduce the need for re-treatments. Accordingly, we believe our position as a leading innovative biopharmaceutical company of PDGF drugs can enable us to capitalize on the blue ocean opportunities of the vast wound healing market.

Strong competitive edge achieved in PDGF drugs via breakthroughs of multi-dimensional barriers in research and development and production

One of our Core Products, Pro-101-1, is the most advanced PDGF drug candidate in terms of clinical development progress for the treatment of thermal burns in China, and has the potential to be the first commercialized PDGF product in China for this indication, according to the Frost & Sullivan report. Since the commencement of our research and development of PDGF drugs in 2013, we have improved the gene sequence combination of PDGF and developed a proprietary PDGF gene sequence for manufacturing purposes, applicable for our protein/peptide pharmaceutical platform. These improvements and developments have facilitated the development of PDGF drugs in a more efficient manner and further contributed to a significant technological barrier for our competitors to enter the market. Compared to the only PDGF drug for treating DFUs approved by the FDA in the U.S. which used the *Saccharomyces cerevisiae* expression technology, our PDGF candidates employ *Pichia pastoris* as their carrier and have a lower glycosylation level, extracellular secretion and expression of the target product, a mature fermentation process and an easy separation and purification process. In comparison with *Saccharomyces cerevisiae*, the *Pichia pastoris* expression system has a higher efficiency of secretory expression, and can make purification of recombinant protein easier due to its limited production of endogenous secretory proteins. They are based on PDGF of DNA sequences distinct from those of the only PDGF drug approved by the FDA in the U.S. for treating DFUs. In particular, the sequence of our PDGF candidates is reduced by five amino acids that are prone to cleavage, which enables higher stability and consistency of our PDGF candidates.

Leveraging our years of research and development expertise and experience with PDGF drugs, we have achieved breakthroughs in preparation techniques of PDGF drugs in terms of purity, production volume and stability, among other things. In particular, the production of purified PDGF is sophisticated and involves several challenges due to its complex structure and biological activity. It requires the selection of an appropriate expression system for optimal bioactivity. Meticulous gene engineering efforts are necessary to the extent to enhance the expression efficiency and protein production volume and quality. Moreover, PDGF is prone to protein aggregation and misfolding, which can lead to impaired functionality and reduced yield and requires robust quality control methods to manage. Additionally, as PDGF is a protein molecule, compared to small chemical molecules, it also calls for proper formulation and storage conditions to maximize protein activity. Capitalizing on our accumulated knowhow and technology platforms, we are able to tackle the foregoing challenges and develop PDGF in a cost-effective and scalable manner.

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Meanwhile, our competitive edge is protected by our comprehensive, unique and bench-to-bedside patent portfolio. We have established a robust patent matrix that encompasses a diverse range of indications, processes and new dosage forms. Patents are the cornerstone of our product research and development. Leveraging our experienced drug discovery team and rigorous drug discovery methodology, we have proprietary intellectual property rights with respect to all of our clinical-stage and pre-clinical candidates. As of the Latest Practicable Date, we owned a total of 13 patents, and filed 19 patent applications, including two PCT patent applications. According to the Frost & Sullivan report, we are the most advanced biopharmaceutical company in terms of the number of PDGF-related technologies and patents in China. Such patent matrix brings challenges to new market entrants and potential competitors that are in clinical development of PDGF drugs. Meanwhile, we are able to capitalize on such patent matrix and continually explore new technologies and opportunities so as to fully exploit the innovation potential of PDGF drugs. Additionally, to protect our existing patent advantages, we have implemented a number of measures such as making patent applications as to our Core Products in unpatented indications and techniques and filing PCT applications. In light of the scope of coverage by and the number of our existing issued patents and pending patent applications, as well as high technological barriers in producing biologic drugs, we believe we are well protected by our patent portfolio.

In particular, our proprietary patent portfolio features industry leading patents with unique technical characteristics, including a recombinant human platelet-derived growth factor and its coding gene and expression method, a recombinant human platelet-derived growth factor gel, and a pH-responsive hydrogel bio carrier and its application. Moreover, our patent matrix encompasses the full bench-to-bedside cycle of drug development from discovery, development to clinical applications. For example, we have filed applications for two process invention patents in April 2023, one pertaining to fermentation and the other to purification processes, and for one patent relating to drug inspecting method in December 2023. Such comprehensive patent portfolio can effectively ensure the quality, safety and consistency of our candidates. Furthermore, our proprietary patent portfolio covers patent applications of four different indications (namely, thermal burns, DFUs, pressure ulcers and radiation ulcers), and two patent applications for eye drops, which indicates our notable pipeline and dosage form expansion capabilities.

In addition, we have the rights to develop and commercialize all of our candidates currently in our pipelines globally. Meanwhile, we have some pending patent applications in China and overseas, which we believe can enable us to develop candidates in more indications and dosage forms. This may in turn bring about opportunities for us to work with well-known multinational pharmaceutical companies, which can potentially pave the way for our expansion into the overseas market in the future.

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Favorable clinical data of our Core Products demonstrating satisfactory efficacy and safety profiles based on years of research in PDGF drugs, which can enhance the certainty of commercialization of such candidates

Our Core Products have demonstrated a consistent favorable safety profile with notable increases in wound healing rates across multiple clinical studies for different wound healing indications. As of the Latest Practicable Date, we had entered the Phase IIb clinical trial of Pro-101-1 in thermal burns in China, and the Phase II clinical trial of Pro-101-2 in DFUs in China. As to thermal burns, our Phase IIa clinical results demonstrate that Pro-101-1 is effective in expediting the healing process of both superficial and deep second-degree burn wounds, with a favorable safety and tolerability profile. Meanwhile, our Phase I clinical results demonstrate a favorable safety and tolerability profile of Pro-101-2 in the treatment of DFUs. Details of our clinical studies are as follows:

- *Thermal Burns.* Thermal burns are typically classified into first-degree burns, second-degree burns (further divided into superficial and deep second-degree burns), and third-degree burns, and Pro-101-1 is expected to be effective in treating superficial and deep second-degree burns. We completed the Phase IIa clinical trial of Pro-101-1 in May 2023. During the Phase IIa clinical trial, neither serious adverse events (the “SAEs”) nor deaths were reported, and Pro-101-1 demonstrated a favorable safety and tolerability profile and was able to promote the healing of superficial second-degree and deep second-degree burn wounds, shortening the healing time and accelerating the healing process. The following tables set forth some details on the results of the Phase IIa clinical trial:

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Time to complete healing of target wound surface in subjects with superficial second-degree burns (FAS)

	High Dose Group N=10	Low Dose Group N=9	Placebo Group N=10
Case number (missing case).	10 (0)	9 (0)	10 (0)
Average time to complete healing (days).	10.4	11.6	17.6
Testing method, P value . . .	Wilcoxon rank sum test, 0.069	Wilcoxon rank sum test, 0.140	

Time to complete healing of target wound surface in subjects with deep second-degree burns (FAS)

	High Dose Group N=10	Low Dose Group N=10	Placebo Group N=10
Case number (missing case).	10 (0)	10 (0)	10 (0)
Average time to complete healing (days).	14.3	19.0	20.5
Testing method, P value . . .	Wilcoxon rank sum test, 0.017	t test, 0.603	

Source: Company data

Note: Time to complete healing is defined as the time from a randomized date to the date of complete healing. For missing data on key efficacy indicators, the time to complete healing for subjects with superficial/deep second-degree burns was 28 days; if assumption of normality is met, group comparisons were made using a t test with two independent samples; if assumption of normality is not met, group comparisons were made using a Wilcoxon rank sum test.

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We entered the Phase IIb clinical trial of Pro-101-1 in thermal burns in China in December 2023, and expect to complete the trial in the second quarter of 2025. We intend to initiate the Phase III clinical trial in the third quarter of 2025 and complete the trial in the fourth quarter of 2026. We plan to launch the product in China in 2027. We also submitted a pre-IND communication application to the FDA in December 2021 with respect to Pro-101-1 for thermal burns. In their response, the FDA agreed with our proposal to carry out the clinical trials and submit a BLA via section 351(a) pathway (the pathway for approval of innovator biologics) for Pro-101-1 in thermal burns. We expect to submit the IND application to the FDA in the first quarter of 2026.

- *DFUs*. As one of the common complications caused by diabetes, DFUs can be classified into six grades in terms of severity under the Wagner Ulcer Grade Classification System, with grade 0 being the least severe and grade 5 being the most. See “Industry Overview” for more details. Pro-101-2 is expected to be effective in treating Wagner grade 1 to 5 DFUs. In particular, Pro-101-2 has shown good efficacy in the treatment of Wagner grade 1 and grade 2 DFUs and can prevent Wagner grade 1 and grade 2 DFUs from deteriorating to Wagner grade 3. We completed the Phase I clinical trial of Pro-101-2 in DFUs in October 2021, during which Pro-101-2 demonstrated a favorable safety and tolerability profile. During the Phase I clinical trial, neither SAE nor deaths were reported, and all adverse events (the “AEs”) were Grade 1 in terms of severity.

We entered the Phase II clinical trial of Pro-101-2 in DFUs in China in February 2022. Since then, we had made registration of new product specification and certain revision to the existing clinical trial protocol. We expect to complete the Phase II clinical trial in the second quarter of 2027. We intend to initiate the Phase III clinical trial in the third quarter of 2027 and complete the trial in the second quarter of 2029. We plan to launch the product in China in 2030.

Concurrently, we are advancing the pre-clinical development of PDGF candidates for nine other indications, while exploring more indications for which topical medications are possible. Moreover, we are also seeking to expand our range of dosage forms. For example, other than the topical gel form of our Core Products used in treating thermal burns and DFUs, we are researching a spray for fresh wounds and photodermatitis, eye drops for dry eye syndrome and corneal injury, an oral medication for gastric ulcers, and a medical device for alopecia. We believe our favorable clinical trial results can benefit the clinical development of PDGF candidates for other indications and enhance the certainty of commercialization of such candidates.

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Capabilities to continually develop new products of significance, as bolstered by a distinguished research and development team and well-established methodical technology platforms encompassing core areas such as protein/polypeptide and mRNA

Our distinguished research and development team is the driving force behind our success. Directed by our corporate value of independent research and innovation, we have assembled a professional research and development team with extensive experience in drug development. Our scientists are specialized in biology, medicine, pharmacology, formulation, pathology, chemistry, fermentation and/or molecular biology, and previously worked in renowned hospitals, leading Chinese and international pharmaceutical companies and/or prestigious research institutions, such as AMMS, the Chinese Academy of Sciences, North China Pharmaceutical, Columbia University, and University of Kentucky. Core members of our research and development team have on average over 15 years of industry experience.

Our General Manager, Dr. ZHAI Junhui, is responsible for the overall strategies of our research and development work. He is a distinguished scientist in microbiology, molecular biology, virology and preventive medicine with around 30 years of experience in biomedical science research, and his primary research areas include microbiology and viral genomics, discovery of new pathogens in emerging infectious diseases, and development of novel virus detection technologies. He obtained his doctorate degree in preventive healthcare from AMMS and was a postdoctoral research scientist in microbiology at Columbia University School of Public Health (Infection and Immunity Center Laboratory). His postdoctoral supervisor is Professor Walter Ian Lipkin, biomedical expert known as the "Virus Hunter." As a former researcher of a research institute of AMMS, Dr. Zhai headed and participated in many national-level and other major medical projects, such as the research and development of nucleic acid-based *in vitro* diagnostic reagents for SARS and H1N1 vaccines. He served as the UN inspector of Iraq's biological weapons and the deputy chief of the biosecurity team for the 2008 Olympic Games in China. He also published more than 100 scientific papers on subjects concerning microbiology, viral genomics and novel virus detection technologies, and he is the owner of multiple national invention patents. In addition, as of the Latest Practicable Date, Dr. Zhai was the co-inventor of 24 of our patent applications, ten of which had been approved.

Our Chief R&D Officer, Dr. ZHAO Xinghui, is responsible for our research and development work. She is a distinguished scientist in biotechnology, genetics and microbiology with around 20 years of experience in biomedical science research. Her primary research areas include protein engineering drugs, pathogen infection mechanisms, tumor molecular markers and epigenetic regulation, and hematopoietic stem cell aging, and she is specialized in multiple expression systems, including mammalian expression systems based on *Escherichia coli*, *Pichia pastoris* and CHO cells. Dr. Zhao obtained her bachelor's degree in biotechnology major at Shandong University and doctorate degree in genetics from AMMS, and was a postdoctoral fellow at

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Cincinnati Children's Hospital Medical Center and a research associate at University of Kentucky School of Medicine. As of the Latest Practicable Date, Dr. Zhao published 37 SCI papers, receiving approximately 900 citations with an H index of 18. She also led two research projects of the NSFC and taught several students pursuing a master's or a doctorate degree. In addition, as of the Latest Practicable Date, Dr. Zhao was the co-inventor of 25 of our patent applications, seven of which had been approved.

Bolstered by our distinguished research and development team and our robust patent matrix, we have successfully established advanced platforms of solid technologies, encompassing core areas such as protein/polypeptide and mRNA, which empower us with the capabilities to continually develop new products and technologies of significance. The details of our technology platforms are as follows:

Protein/polypeptide Pharmaceutical Platform. Our protein/polypeptide pharmaceutical platform benefits from a robust combination of eukaryotic expression technology, prokaryotic expression technology and recombinant DNA technologies. Based on such platform, we have developed capabilities in new drug formulation development and indication expansion. This platform plays a pivotal role in the progression of our pipelines, particularly in the development of PDGF therapies. Our protein/polypeptide pharmaceutical platform has eukaryotic and prokaryotic expression technologies. In particular, eukaryotic expression technology, predicated on the *Pichia pastoris* system, is crucial in ensuring the exemplary quality and yield of PDGF products, and poised to facilitate the robust commercialization potential for our PDGF pipeline. Meanwhile, prokaryotic expression technology, utilizing the *Escherichia coli* system, features straightforward culture conditions, expeditious growth and reproduction, commendable safety profile, cost-effectiveness, high efficiency and scalability. These attributes render it an ideal expression system for the production of recombinant proteins and peptides, and we expect to augment our protein/polypeptide therapeutic pipeline based on such expression system. We protect the novelty of these two technologies through invention patent applications. Meanwhile, by leveraging the aforementioned technologies, our research and development endeavors encompass a diverse array of dosage forms, including but not limited to, gels, eye drops and sprays. We are also dedicated to researching various transdermal preparations and medical devices, such as soluble microneedles. We have obtained an invention patent for a pH-responsive gel in China since November 2021, and filed a PCT patent application for the same in March 2022. Additionally, we have applied for two invention patents for eye drops.

Nucleic Acid Pharmaceutical Platform. Our nucleic acid pharmaceutical platform is underpinned by mRNA molecular design and LNP delivery technologies, ensuring we remain at the forefront of the rapidly evolving field of genetic and RNA-based therapeutics. Our research includes developing mRNA and ASO candidates for indications such as solid tumors, brain glioma and TNBC. We are currently conducting pre-clinical research on these candidates. Key

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technologies of this nucleic acid pharmaceutical platform include mRNA molecular design technology and LNP delivery technology. In particular, mRNA molecular design technology helps to ensure that mRNA drugs achieve high levels of expression and reduce potential side effects. We have filed five invention patents in August 2022 for this technology. Meanwhile, LNP delivery technology can help us design and screen several ionizable lipids so as to identify our proprietary molecule candidates. We screened multiple new cationic lipids and obtained four invention patents in China in November 2022, and applied for a new LNP formulation invention patent in May 2022.

We intend to further develop our biomolecular therapeutic drug development platforms to support more application scenarios for our pipeline candidates. We believe that our strong research and development capabilities empowered by such platforms can contribute to the sustainable development of PDGF candidates and cancer therapeutics and enhancement of our product portfolio, and enable us to maintain a competitive position in the biopharmaceutical industry.

Seasoned management team and strong support from Shareholders

Our corporate culture is characterized by inclusiveness, collaboration, professional pride, commitment and innovation. Led by our experienced management team, we have been fully committed to implementing such corporate culture to develop and commercialize our candidates and achieve sustainable business growth. Details of some of our management team members are as follows:

- Our Chairperson and founder, Ms. JIA Lijia, has around 30 years of experience in the pharmaceutical industry. She has extensive experience in the operation and management of pharmaceutical companies. Prior to the establishment of our Company in 2012, Ms. Jia held senior positions at in various pharmaceutical companies. She has maintained well-established long-term cooperative relationships with various domestic pharmaceutical research institutions, such as Institute of Biophysics and Chinese Academy of Science.
- Our president and Vice Chairperson, Mr. WANG Kelong, is an experienced entrepreneur with over nine years of experience in corporate operation and management. Before joining us in 2018, he held management positions in various technology companies for an extended period, accruing years of industry experience in cutting-edge fields such as biotechnology and artificial intelligence technology, along with a wealth of experience in the management of technology enterprises. After joining us, Mr. Wang was a co-inventor of 29 of our patent applications. Mr. Wang previously worked for Berkshire Hathaway Automotive. Mr. Wang was named in the Hurun China under 30s to Watch list in 2018 and the Forbes Under 30 list in 2019. Mr. Wang also co-authored several published papers on aspects such as cyber intelligence and drug delivery.

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- Our Chief Financial Officer, vice president and secretary to the Board, Mr. HO Hung Tim Chester, has over 20 years of experience in the management and development of various listed companies. Prior to joining us in 2023, Mr. Ho served as the senior deputy chief financial officer at China Resources Holdings Company Limited and assistant general manager of Corporate Planning and Development Department at China Resources Beer (Holdings) Company Limited (successor of China Resources Enterprise, Limited). He currently also serves as an independent non-executive director and a member of the Audit Committee at Grand Baoxin Auto Group Limited, a company listed on the Hong Kong Stock Exchange (stock code: 1293). Mr. Ho holds a Master of Business Administration from the University of Toronto, and a Bachelor of Arts with First Class Honor in Economics and Social Studies from the University of Manchester. Mr. Ho holds various professional qualifications in finance and accounting in the U.S., Canada and Hong Kong.
- Our Chief Marketing Officer and vice president, Mr. XU Zhenyu, has over 25 years of experience in the life sciences industry and over 20 years of leadership experience in multinational pharmaceutical sales. Before joining us in 2021, he served as a sales director at Eli Lilly (Asia) Co., Limited, and has a profound understanding of product commercialization, cross-cultural business operations, resource integration, emerging business development, international mergers and acquisitions, as well as corporate management. His extensive background positions him as a seasoned leader in the global life sciences sector.
- Our medical director, Dr. CHENG Long, is a highly qualified medical professional with a doctorate degree and postdoctoral experience in Medicine. He is an associate pharmacist and serves as a supervisor for master’s degree students. With around 15 years of experience in medicine research and development, Dr. Cheng’s expertise spans pre-clinical pharmacology and toxicology, pharmaceuticals and clinical research. He also held positions at multiple listed biopharmaceutical companies. He has been involved in two national-level research projects and has led three research projects. Dr. Cheng has published over ten academic papers, including 11 in SCI-indexed journals, with six as the first or corresponding author.
- For biographies of Dr. Zhai and Dr. Zhao, our research and development key personnel, see “— Capabilities to continually develop new products of significance, as bolstered by a distinguished research and development team and well-established methodical technology platforms encompassing core areas such as protein/polypeptide and mRNA.”

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In addition to our seasoned management team, strong shareholder support is also one of the key factors of our success. We have introduced CDH Investments as a strategic investor and completed a round of financing in October 2021. In May 2023, we also obtained strategic investment from Qingdao High-Tech Industrial Development Co., Ltd. The support of remarkable and professional investors not only gives us financial assistance, recognition and industry guidance, but also creates mutually beneficial cooperation for our future development.

OUR STRATEGIES

Continually advance the research and development of our Core Products to reach commercialization

Our pipeline candidates consist primarily of the PDGF pipeline, as complemented by the mRNA and ASO pipeline. In particular, our PDGF pipeline comprised seven candidates, including two Core Products, currently being developed for 11 wound healing indications. Such layout enables us to maximize the synergies of pre-clinical and clinical studies among different indications. For example, we directly commenced the Phase IIa clinical trial of Pro-101-1 in thermal burns based on the Phase I clinical trial data of Pro-101-2 in DFUs. Supported by our strong research and development capabilities, rich research and development experience and extensive clinical resources, we plan to continually advance the pre-clinical and clinical development of our pipeline candidates, particularly our PDGF pipeline, to reach commercialization soon. We expect to commercialize at least two innovative drugs independently in the next six years. In particular:

- ***Thermal Burns.*** We plan to conduct the clinical trials for this indication both in China and the U.S. In China, we applied for NMPA approval to directly commence the Phase II clinical trial of Pro-101-1 for the treatment of thermal burns based on the data of the treatment of DFUs’ Phase I clinical trial, and received such approval in June 2022. We completed the Phase IIa clinical trial of Pro-101-1 in thermal burns in May 2023, during which Pro-101-1 demonstrated efficacy in expediting the healing process of both superficial and deep second-degree burn wounds, with a favorable safety and tolerability profile. We entered the Phase IIb clinical trial of Pro-101-1 in thermal burns in China in December 2023, and expect to complete the trial in the second quarter of 2025. We intend to initiate the Phase III clinical trial in the second quarter of 2025 and complete the trial in the fourth quarter of 2026. We plan to launch the product in China in 2027. In the U.S., we submitted a pre-IND communication application to the FDA in December 2021 with respect to Pro-101-1 for thermal burns. In their response, the FDA agreed with our proposal to carry out the clinical trials and submit a BLA via section

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351(a) pathway (the pathway for approval of innovator biologics) for Pro-101-1 in thermal burns. We expect to submit the IND application to the FDA in the first quarter of 2026. We have the rights to develop and commercialize Pro-101-1 for thermal burns globally.

- **DFUs.** We received the IND approval of Pro-101-2 from NMPA for the treatment of DFUs in July 2021 and completed the Phase I clinical trial in October of the same year. We entered the Phase II clinical trial in China in February 2022, and expect to complete the Phase II clinical trial in the second quarter of 2027⁽¹⁾. We intend to initiate the Phase III clinical trial in the third quarter of 2027 and complete the trial in the second quarter of 2029. We plan to launch the product in China in 2030. We have the rights to develop and commercialize Pro-101-2 for DFUs globally. For details relating to our arrangements on Pro-101-2 for DFUs, see “— Collaboration, Licensing and Transfer Arrangements — Collaboration with the Institute of Bioengineering of AMMS and JinBang.”
- **Fresh Wounds.** We submitted application materials with the CDE to request approval for directly commencing the Phase Ib clinical trial of Pro-101-3 for treating fresh wounds based on the data from the Phase I clinical trial of Pro-101-2 in DFUs in December 2021. In lieu of a meeting, the CDE provided written responses in March 2022. The CDE provided useful guidance on the design of the Phase Ib clinical trial of Pro-101-3 in fresh wounds and suggested that whether additional safety studies are necessary should depend on the MOA, dosage, administration timing and systemic/local exposure of the result of Pro-101-2 in the treatment of DFUs. We plan to submit the IND application to the NMPA in the first quarter of 2025⁽²⁾ based on the Phase IIa and Phase IIb clinical trial results of the Pro-101-1 in thermal burns and the Phase I clinical trial results of the Pro-101-2 in DFUs.

We believe that experience and recognition to be gained from the initial commercialization of Pro-101-1 will benefit the regulatory approval process and commercialization of Pro-101-2 and other PDGF candidates in the future.

(1) Even though the Phase II clinical trial of Pro-101-2 for DFUs began in February 2022, we expect to complete the same in the second quarter of 2027, mainly because we had made registration of new product specification and certain revision to the existing clinical trial protocol since we entered the Phase II clinical trial of Pro-101-2 in DFUs. We expect to initiate the patient enrollment process in the second quarter of 2024.

(2) Even though the application with the CDE in respect of Pro-101-3 for fresh wounds was submitted in December 2021, in response to which we received written responses in March 2022, we plan to submit the IND application to the NMPA in the first quarter of 2025, mainly because we plan to base the clinical research of Pro-101-3 in fresh wounds on the relevant results of pharmacokinetics and immunogenicity evaluations observed in the Phase IIa and Phase IIb clinical trials of Pro-101-1 in thermal burns. We have completed the Phase IIa clinical trial of Pro-101-1 in thermal burns in May 2023 and entered the Phase IIb clinical trial in December 2023. We expect to complete the Phase IIb clinical trial of Pro-101-1 in thermal burns in the second quarter of 2025. We plan to submit the IND application for Pro-101-3 in fresh wounds to the NMPA in the first quarter of 2025.

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Rapidly establish production and commercialization systems of Core Products and well-rounded comprehensive capabilities encompassing research, manufacture and sales

We plan to continually advance the establishment of production and commercialization systems of our Core Products, in order to reinforce our comprehensive capabilities encompassing research, manufacture and sales.

In anticipation of future commercialization of our pipeline candidates, we plan to build our commercial manufacturing capabilities in compliance with the GMP standards of China, the U.S. and other relevant jurisdictions. As of the Latest Practicable Date, we were exploring effective strategies to initiate the large-scale production of our product candidates upon commercialization. Options under consideration include leasing production facilities, constructing our own manufacturing sites, and collaborating with CMOs to ensure GMP-compliant production of such candidates. We will ascertain in due course the most appropriate option for the Company in light of subsequent developments and the interests of the Shareholders. For details, see “— Manufacturing and Quality Control — Our Planned Manufacturing Capacities” In connection with any such new facilities constructed or leased, we may also recruit qualified personnel to strengthen our in-house manufacturing capabilities.

In addition, while continually enhancing our research and development and production capabilities, we intend to build supply chain systems and gather market development team to strategically enhance our sales and marketing capabilities to support the potential commercialization of our pipeline candidates, thereby creating a bench-to-bedside innovative biologics platform integrating the entire biologics value chain. We expect to capitalize on our first-mover advantages in PDGF drugs so as to further enhance our competitive position to ensure our solid competitive edge. In line with our pipeline expansion, we plan to build our in-house commercialization team by recruiting qualified and experienced business development personnel, sales and marketing personnel and legal professionals to support and promote the future commercialization of our pipeline candidates. In terms of commercialization strategies, we will consider starting from key hospitals with advantages in thermal burn and DFU treatment in China’s first- and second-tier cities to establish brand name and reputation, and extend our efforts to hospitals in second- and third-tier cities through business partners. We will also extend sales of our products to channels such as retail pharmacies and e-commerce platforms, so as to enhance our brand image and patient awareness, and thereby quickly increasing our products’ market share.

Further enhance our research and development capabilities and collaborations, and continually upgrade and launch product pipelines of huge potential leveraging our core technology platforms

We intend to further expand our talent pool to reinforce our research and development capabilities. To attract and retain talents, we encourage and motivate innovation and we are committed to building a dynamic corporate culture. We have also set up a scientific technology committee to support the research and development of our pipeline candidates, the design of

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clinical trials and the selection of pipeline candidates and target indications for development. We intend to continually provide various internal and external training opportunities for our research and development personnel and optimize our employee incentive programs.

In addition, we plan to continually enhance our advanced biomolecular therapeutic drug development platforms to support the research and development of our innovative candidates. In particular, we have established a protein/polypeptide pharmaceutical platform that plays a vital role in the development of PDGF therapies, and a nucleic acid pharmaceutical platform underpinned by mRNA molecular design and LNP delivery technologies, which ensure that we remain at the forefront of the rapidly evolving field of protein and peptide as well as genetic and RNA-based therapeutics.

Moreover, innovation in dosage forms is pivotal for the strategic market positioning of a product. In particular, our patent matrix included two patent applications for eye drops, while our research and development endeavors also encompass a diverse array of other dosage forms such as sprays. We intend to continually research innovative dosage forms to support more application scenarios for our pipeline candidates towards commercialization.

Leveraging our experience in building our existing drug development platforms, we intend to further strengthen our collaborations with leading Chinese and international pharmaceutical companies and research institutions to continually invest in the research and development of innovative drugs, and expand the capabilities of our existing drug development platforms. For example, we are collaborating with a leading university in Hong Kong to screen for natural small molecule compounds that activate or inhibit PDGF and their role in treating depression. We are currently in the process of selecting the most pivotal molecules for patent application. Furthermore, we are collaborating with a company in Hong Kong focusing on ultrasound-mediated delivery. Preliminary experiments have been conducted and have yielded positive results. We anticipate to commence the animal efficacy evaluation by the end of 2024. Meanwhile, we are committed to continually developing and accumulating in-house technical and biological know-how for purposes of exploring new therapeutics and developing candidates of great potential in the future.

Continue to explore potential business development opportunities overseas, deepen international development strategy and reinforce global partnerships

We have established strategic partnerships with prestigious academic institutions and industry leaders, including well known universities and research institutions. We intend to continually maintain a close and stable collaborative relationship with top pharmaceutical companies in China and proactively pursue cooperation opportunities with well-known pharmaceutical companies around the world. In particular, leveraging our Hong Kong laboratory, we expect to establish an overseas research and development platform and strengthen scientific research collaborations with universities in Hong Kong. In addition, we plan to promote and strengthen the collaboration with our business partners in product identification and research and development.

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We are also seeking opportunities in overseas markets for our pipeline candidates to strengthen our overseas business development. We expect to actively enhance our brand awareness and continually explore the commercial value of our pipeline candidates and proprietary technology in the overseas market through international collaborations, out-licensing and technology transfers. We aim to increase our international influence by utilizing Hong Kong’s geographical location, talent pool, and investment and financing advantages. Additionally, to support our business development and overseas expansion strategies mentioned above, we also plan to continually recruit new and retain existing talents with outstanding backgrounds and rich experience in the relevant fields.

Furthermore, as an innovative biopharmaceutical company, we plan to further explore opportunities to expand our pipelines via acquisitions, investments or in-licensing to identify biomolecular drugs or inhibitors, enhancers or compounds closely related to biomolecular drugs that are in line with our positioning, target markets and overall strategies, in order to reinforce our impacts in the relevant fields.

OUR CANDIDATES

As of the Latest Practicable Date, we had researched and developed three pipelines consisting of ten candidates covering 14 indications, including two Core Products, namely Pro-101-1 and Pro-101-2, currently undergoing the Phase II & I Ib clinical trials for two indications in China, respectively. Seven of our candidates are PDGF candidates covering a broad spectrum of wound healing indications comprising (i) thermal burns, (ii) DFUs, (iii) fresh wounds, (iv) pressure ulcers, (v) radiation ulcers, (vi) dry eye syndrome, (vii) corneal injury, (viii) photodermatitis, (ix) alopecia, (x) hemorrhoids and (xi) gastric ulcers. Our PDGF candidates are being developed in several dosage forms, including (i) topical gel, (ii) spray, (iii) eye drops and (iv) oral, while we are also exploring routes of administration that are supported by medical devices. We are also developing mRNA and ASO injections.

Our Core Products, Pro-101-1 and Pro-101-2, are PDGF candidates for the treatment of thermal burns and DFUs, respectively. As of the Latest Practicable Date, we had entered the Phase I Ib clinical trial of Pro-101-1, and the Phase II clinical trial of Pro-101-2, while we were also advancing the pre-clinical development of the PDGF candidates for the nine other indications. Meanwhile, we have developed our pipeline of innovative early-stage mRNA candidate for the treatment of solid tumor, as well as ASO candidate to cover brain glioma and TNBC. The following chart summarizes our pipeline and the development status of each product candidate and indication as of the Latest Practicable Date:

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Candidate	Mechanism/Target	Indication	Form	Clinical Trial Region	Development Phase				Upcoming Milestone	Competent or Regulatory Authorities	Commercial Rights	Self-developed or Co-developed
					Pre-Clinical	Phase I	Phase II IIa	Phase II IIb				
★ Pro-101-1		Thermal burns	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	Expected to complete Phase IIb in 2025Q2 and initiate Phase III in 2025Q3	NMPA	Global	Self-developed
					U.S.	Phase I	Phase II IIa	Phase II IIb				
★ Pro-101-2		DFUs	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	Expected to complete Phase II in 2027Q2 and initiate Phase III in 2027Q3	NMPA	Global	Co-developed with the Institute of Biengineering of AMMS®
					China	Phase I	Phase II IIa	Phase II IIb				
Pro-101-3	PDGF receptor	Fresh wounds	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	Self-developed
		Pressure ulcers	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	
		Radiation ulcers	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	
		Photodermatitis	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2026	NMPA	Global	
		Alopecia	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2026	NMPA	Global	
		Hemorrhoids	Topical gel	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2026	NMPA	Global	
		Fresh wounds	Spray	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2028	NMPA	Global	
		Photodermatitis	Spray	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2028	NMPA	Global	
		Dry eye syndrome	Eye drops	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	
		Corneal injury	Eye drops	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2025	NMPA	Global	
Pro-104		Alopecia	Medical devices	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2029	NMPA	Global	Self-developed
					China	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2027			
Pro-105		Gastric ulcers	Oral	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2027	NMPA	Global	Self-developed
					China	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2027			
Mes-201 (mRNA)	TSA	Solid tumor	Injection	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2027	NMPA	Global	Self-developed
Oli-101 (ASO)	IneRNA	Brain glioma	Injection	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2028	NMPA	Global	Self-developed
Oli-201 (ASO)	IneRNA	TNBC	Injection	China	Pre-Clinical	Phase I	Phase II IIa	Phase II IIb	IND submission in China expected in 2029	NMPA	Global	Self-developed

★ Core Products

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Notes:

1. Phase I clinical trial data of Pro-101-2 for the indication of DFUs are shared with indications of thermal burns and fresh wounds.
2. We submitted a pre-IND communication application to the FDA in December 2021 with respect to Pro-101-1 for thermal burns. In lieu of a meeting, the FDA provided written responses in February 2022. The FDA replied that whether the Phase I clinical trial of Pro-101-2 in the treatment of DFUs and our current nonclinical studies are sufficient to support the initiation of the US IND-opening trial will be determined after the FDA’s review of the complete initial IND submission, including the product quality and nonclinical components. The FDA also provided useful guidance on CMC process and the design of our Phase II clinical trial of Pro-101-1 in the treatment of thermal burns. As we are currently focusing on the development of Pro-101-1 in China, we expect to submit the IND filing to the FDA in the first quarter of 2026.
3. Even though the Phase II clinical trial of Pro-101-2 for DFUs began in February 2022, we expect to complete the same in the second quarter of 2027, mainly because we had made registration of new product specification and certain revision to the existing clinical trial protocol since we entered the Phase II clinical trial of Pro-101-2 in DFUs. We expect to initiate the patient enrollment process in the second quarter of 2024. In particular, the revision in the clinical trial protocol is mainly related to our intention to rely on the clinical evidence obtained from immunogenicity studies in the Phase IIa clinical trial of Pro-101-1 in thermal burns, as the enrollment process of thermal burn patients is faster than that of DFU patients. Such revision has been confirmed by the CDE in October 2023.
4. In December 2021, we submitted application materials for a pre-IND meeting with the CDE to discuss the IND application, the plan to directly conduct Phase Ib clinical trial based on the results of the Phase I clinical trial of Pro-101-2 in the treatment of DFUs and the design of the Phase Ib clinical trial. In lieu of a meeting, the CDE provided written responses in March 2022. The CDE provided useful guidance on the design of the Phase Ib clinical trial of Pro-101-3 in the treatment of fresh wounds and suggested that whether additional safety studies are necessary should depend on the MOA, dosage, administration timing and systemic/local exposure of the result of Pro-101-2 in the treatment of DFUs. Meanwhile, as we believe conducting studies to evaluate the safety, tolerability, pharmacokinetics and immunogenicity of Pro-101-1 on thermal burn patients can render more representative results compared to subjects in other indications, we have decided to conduct the Phase IIa clinical trial of Pro-101-1 in thermal burns first. Then, depending on the actual results, we plan to share the relevant results of pharmacokinetics and immunogenicity of Pro-101-1 with clinical studies of Pro-101-3 in fresh wounds, and directly proceed with the Phase II clinical trial on the efficacy and safety of Pro-101-3 in fresh wounds. We have completed the Phase IIa clinical trial of Pro-101-1 in thermal burns in May 2023 and entered the Phase IIb clinical trial in December 2023. We plan to submit the IND application for Pro-101-3 in fresh wounds to the NMPA in the first quarter of 2025 based on the Phase IIa and Phase IIb clinical trial results of the Pro-101-1 in thermal burns and the Phase I clinical trial results of the Pro-101-2 in DFUs. We expect to directly initiate the Phase II clinical trial of Pro-101-3 in fresh wounds upon obtaining the IND approval from the NMPA.
5. Both the Company and the Institute of Bioengineering of AMMS are holders of the relevant patents. Nevertheless, according to its written confirmation dated October 8, 2023, the Institute of Bioengineering of AMMS acknowledged that the rights to own, commercialize and use such patents belong exclusively to the Company. We cooperated with the Institute of Bioengineering of AMMS in pre-clinical development of Pro-101-2 for DFUs, which we have independently researched and developed after the IND approval. For details on our arrangements with the Institute of Bioengineering of AMMS, see “— Collaboration, Licensing and Transfer Arrangements — Collaboration with the Institute of Bioengineering of AMMS and JinBang.”

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PDGF

As of the Latest Practicable Date, we had 8 PDGF candidates, including 2 clinical-stage Core Products, namely Pro-101-1 and Pro-101-2. The advancement of clinical trials for on Pro-101-1 and Pro-101-2 is instrumental in the progression of our research and development of other PDGF candidates in the development pipeline. The active substance of the PDGF candidates is rhPDGF-BB, which is a form of PDGF-BB manufactured in laboratories using recombinant DNA technology and used for clinical treatments. rhPDGF-BB shares the same biological functions of PDGF-BB, which stimulates the proliferation and migration of key cells involved in wound healing, such as fibroblasts and endothelial cells, leading to faster tissue repair and regeneration. We acquired the PDGF-related technology, patents and know-how in relation to the treatment of DFUs at a pre-clinical stage in 2013 and have been independently developing the PDGF candidates for the treatment of other indications since then.

As of the Latest Practicable Date, we had entered the Phase IIb clinical trial of Pro-101-1 and the Phase II clinical trial of Pro-101-2. We completed the Phase I clinical trial of Pro-101-2 in October 2021 in China. As Pro-101-2 demonstrated a favorable safety and tolerability profile in the Phase I clinical trial, we applied for NMPA approval to directly commence the Phase II clinical trial of Pro-101-1 based on such clinical results and received the approval in June 2022. We completed the Phase IIa clinical trial of Pro-101-1 in May 2023, and commenced the Phase IIb clinical trial in December 2023.

According to the Frost & Sullivan Report, as of the Latest Practicable Date, due to the high barriers in research and development and production of PDGF drugs, there were no PDGF drugs commercially available in China. With strong mitogenic properties, PDGF stimulates cell proliferation and angiogenesis and is particularly effective in healing chronic wounds. One of our Core Products, Pro-101-1, is the most advanced PDGF drug candidate in terms of clinical development progress for the treatment of thermal burns in China, and has the potential to be the first commercialized PDGF product in China for this indication, according to the Frost & Sullivan report. Meanwhile, with respect to the other Core Product, Pro-101-2, we are one of the leading biopharmaceutical companies with the potential to first achieve commercialization of PDGF drugs in DFUs in China, according to the same source. We hold patents and have filed patent applications related to our PDGF candidates in China. We also have exclusive rights to develop and commercialize our PDGF candidates globally.

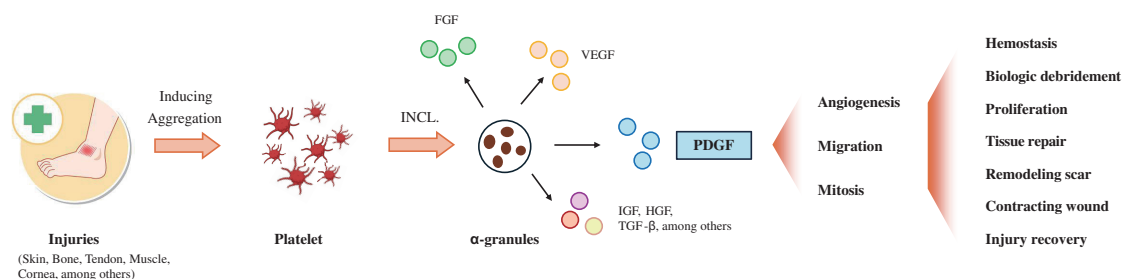
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MOA

PDGF is a potent mitogen, chemoattractant and survival factor for cells of mesenchymal origin such as fibroblasts, smooth muscle cells, or glial cells. In adult organisms, PDGFs participate in wound healing, regulation of blood vessel tonus, and maintenance of the interstitial fluid pressure.

The primary role of PDGF in wound healing includes stimulating cell proliferation and angiogenesis, and, with strong mitogenic properties, it is effective in healing chronic wounds. The PDGF family contains five members found naturally in the body — AA homodimer, AB heterodimer, BB homodimer, CC homodimer and DD homodimer. The various forms of PDGF manifest their effects on cells through interaction with and activation of two closely related protein tyrosine kinase receptors, known as the α -receptor and the β -receptor. The engagement of these PDGF receptors results not only in the promotion of cellular proliferation but also in alterations to cellular morphology and movement. PDGF triggers the reorganization of the actin filament network and incites chemotaxis, that is, the directed movement of cells towards a PDGF gradient. Such directed movement is critical for recruiting cells, such as fibroblasts and macrophages, to the wound site. By guiding these cells to the site of injury, PDGF ensures that essential cellular activities, such as inflammation, formation of granulation tissue, and remodeling of the tissue, occur in a coordinated and timely manner, thereby enhancing the overall process of wound healing.

The following illustration demonstrates the mechanism and role of PDGF in healing and angiogenesis:



Source: *the Frost & Sullivan report*

Upon injury, platelets aggregate at the site of damage, releasing contents from their α -granules, which include growth factors like VEGF (Vascular Endothelial Growth Factor), IGF (Insulin-like Growth Factor), HGF (Hepatocyte Growth Factor), TGF- β (Transforming Growth Factor-beta), and PDGF itself.

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PDGF specifically stimulates several key processes in the healing cascade, which are: (i) angiogenesis, which is essential for providing oxygen and nutrients to the injured area to support the healing process; (ii) migration, where PDGF contributes to tissue repair by promoting the movement of cells, such as fibroblasts and endothelial cells; and (iii) mitosis, where PDGF increases the number of cells available for repairing the damaged tissue by encouraging cell division.

PDGF-BB is a cytokine consisting of two BB subunits forming a homodimer that facilitates cell processes such as proliferation, migration, and tissue repair. It interacts with specific receptors on the cell surface, initiating signals that regulate cellular functions, and is integral to wound healing by activating fibroblasts and other crucial cell types. rhPDGF-BB is a form of PDGF-BB. rhPDGF-BB and PDGF-BB share the same biological functions but differ in their origin, with PDGF-BB being a protein that naturally occurs in the human body and is involved in physiological processes such as cell proliferation and tissue repair, and rhPDGF-BB being a form of PDGF-BB manufactured in laboratories using recombinant DNA technology and used for clinical treatments, such as promoting wound healing. rhPDGF-BB, the active ingredient in our Core Products and other PDGF candidates, mimics the biological activities of PDGF-BB, including stimulating cell growth, migration, and angiogenesis, and is used for therapeutic purposes, such as in wound healing. The following illustration demonstrates the roles of rhPDGF-BB in injury repair as an example:



Source: *the Frost & Sullivan report*

rhPDGF-BB can stimulate cells in the G0/G1 phase to enter the S phase by increasing the concentration of calcium ions in the cells, activating transcription factors in the cell nucleus, inducing the synthesis of growth factors, among others. It promotes cell growth, differentiation, and migration.

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There are four pathways of rhPDGF-BB's action within cells: (i) when PDGF binds to PDGFR, phospholipase C γ is activated by protein tyrosine kinase, hydrolyzing phosphatidylinositol biphosphate to generate inositol triphosphate (IP3) and diacylglycerol (DAG). IP3 can induce an increase in intracellular Ca ions and mitosis. The shared activity of DAG and Ca ions can enhance cellular proliferation; (ii) after being phosphorylated by tyrosine protein kinase, STATs create homodimers or heterodimers. These dimers enter the nucleus and instigate gene transcription upon binding to DNA; (iii) the phosphorylation and binding of PDGF receptor to phosphatidylinositol 3-kinase produce signals used in downstream signaling. Coupling and activation with PKB promote the phosphorylation of nuclear factors and their entry into the nucleus, where they bind with the target gene promoter; and (iv) the transformation of stationary Ras-GDP into activated Ras-GTP triggers Ras, which subsequently activates Raf1, MEK1/2, and ERK1/2 in order, transferring the corresponding signals into the nucleus, thereby instigating the phosphorylation of various transcription factors to amplify transcription activity, and triggering cell growth, differentiation, and migration.

Market Opportunity and Competition

Market Opportunities

PDGF has demonstrated effectiveness in promoting wound healing and ensuring a favorable safety profile. PDGF has shown promising results in the clinical evaluations for the treatment of thermal burns and DFUs, and shown positive results in pre-clinical trials of fresh wounds, dry eye syndrome, corneal damages, radiation ulcers and pressure ulcers. PDGF has the potential to broaden its therapeutic applications across various indications within the wound healing market. According to the Frost & Sullivan report, the market size of wound healing drugs in China is expected to increase from RMB92.9 billion in 2023 to RMB114.5 billion in 2032, growing at a CAGR of 2.4%.

The large number of thermal burn incidence cases, DFU patients and fresh wound incidents demonstrate considerable market opportunities in the treatment of DFUs, thermal burns and fresh wounds. According to the Frost & Sullivan report, China's annual thermal burn incidence cases are expected to increase from 29.7 million in 2023 to 32.5 million in 2032 over a CAGR of 1.0%. Further, China's thermal burn market is expected to grow from RMB1.5 billion in 2023 to RMB1.8 billion in 2032 over a CAGR of 2.0%. In addition, the number of diabetic patients in China is expected to increase from 140.5 million in 2023, to 174.0 million in 2032. DFUs are one of the most common complications of diabetes. If not treated timely and properly, DFUs could lead to amputation. According to the Frost & Sullivan report, the number of DFU patients in China is expected to increase from 8.2 million in 2023 to 10.4 million in 2032 at a CAGR of 2.7%. According to the Frost & Sullivan report, the market size of DFU drugs in China is expected to increase from RMB37.3 billion in 2023 to RMB47.3 billion in 2032, growing at a CAGR of 2.7%.

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In addition, benefited from its ability to stimulate cell proliferation and angiogenesis, which is critical for tissue repair and regeneration, PDGF plays an effective role in fresh wound healing. The application of PDGF in fresh wounds has shown to enhance the strength of the healing tissue, reduce recovery time, and minimize the risk of complications, making it a valuable adjunct in postoperative care and tissue engineering. According to the Frost & Sullivan report, the fresh wound healing market in China is expected to increase from RMB38.4 billion in 2023 to RMB46.6 billion in 2032, growing at a CAGR of 2.1%.

Competitive Advantages

According to the Frost & Sullivan report, with an aging global population and a rise in chronic conditions such as diabetes, the demand for effective treatments for non-healing wounds is increasing. PDGF-BB-based products are gaining traction for their ability to accelerate the healing process, leading to a growing market presence in both clinical and consumer-oriented applications. As research uncovers more about the growth factor's functions, its market potential is likely to diversify further, opening up new avenues for product development and application across different sectors.

PDGF products have unique advantages in wound healing when compared to other growth factor products, which include: (i) being able to create optimal conditions for the healing process to occur; (ii) acting as a self-delivery depot to sustain the release of PDGF, ensuring a continuous supply of the growth factor at the wound site; (iii) promoting angiogenesis and tissue regeneration essential for wound healing; (iv) reducing the time taken for the wound to completely heal by enhancing the pace and quality of wound healing; and (v) being particularly beneficial in instances where the healing process may be slowed down or compromised, such as in diabetic wounds, as they help to increase healing efficiency by overcoming down-regulation of growth factor receptors.

Treatment of DFUs include medical treatment, *i.e.* metabolic management and medication, as well as surgical treatment. Existing DFU treatment mainly includes local wound care with surgical debridement, dressings promoting a moist wound environment, wound off-loading, vascular assessment, treatment of active infection, and glycemic control. Many types of growth factors have been studied for adjunct use in the treatment of DFUs, among which PDGF has notable features in stimulating cell proliferation and angiogenesis, thus effective in chronic wounds. PDGF can increase the tear strength of the wound tissue, shorten the wound healing time and significantly increase fibroblasts and mast cells in the granulation tissue. As Pro-101-2 is an rhPDGF-BB drug, it has the common advantages of PDGF.

As of the Latest Practicable Date, Regranex was the only commercialized PDGF drug for the treatment of DFUs in the world. However, Regranex is not commercially available in China. Therefore, as of the Latest Practicable Date, there was no PDGF drug commercially available to

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treat DFUs in China. Compared to Regranex, in terms of molecular structure, the sequence of our PDGF candidates is reduced by five amino acids, which enables higher molecular activity in human body so that our PDGF candidates can reach the action sites faster and stimulate cell proliferation faster. In terms of manufacturing process, we adopt the *Pichia pastoris* expression technology. We have optimized the strain based on glycosylation to make the glycosylation strategy of the strain more reasonable and closer to the glycosylation level of human body. In contrast, Regranex uses *Saccharomyces cerevisiae* expression technology, whose PDGF peptide chains generally have relatively long sugar chains. Based on the results of a parallel control experiment conducted by us on the comparison between the *Pichia pastoris* and *Saccharomyces cerevisiae* expression, relatively long sugar chains could limit the protein activity and hence the efficacy of PDGF drug candidates. In particular, the experiment showed that the activity of PDGF drug candidates using the *Pichia pastoris* expression technology was 75 times higher than that of PDGF drug candidates using the *Saccharomyces cerevisiae* expression technology. During the Phase I clinical trial, Pro-101-2 demonstrated encouraging results in safety and tolerability in healthy subjects, indicating a promising commercial and therapeutic potential to address the sizable and growing DFU drug market in China.

We have completed the Phase IIa clinical trial of Pro-101-1 and have initiated the Phase IIb clinical trial of Pro-101-1. We have completed the Phase I clinical trial of Pro-101-2 and have initiated the Phase II clinical trial of Pro-101-2. According to the Frost & Sullivan report, our Core Products Pro-101-1, is the most advanced PDGF drug candidate in terms of clinical development progress for the treatment of thermal burns in China, and has the potential to be the first commercialized PDGF product in China for this indication. Meanwhile, with respect to the other Core Product, Pro-101-2, we are one of the leading biopharmaceutical companies with the potential to first achieve commercialization of PDGF drugs in DFUs in China, according to the same source. The following table illustrates the PDGF-BB drugs currently undergoing clinical trials in China for the treatment of thermal burns and DFUs as of the Latest Practicable Date:

Drug	Applicants	Indication	Stage	Status	Initial Date	Clinical No.
rhPDGF-BB (gel)	Tasly Pharmaceutical	Skin ulceration of lower extremity in chronic diabetes	III	In-progress	January 22, 2014	CTR20132176
rhPDGF-BB (gel) ¹	B&K Corporation	Thermal burns	IIb	In-progress	November 14, 2023	CTR20233683
rhPDGF-BB (gel) ²	B&K Corporation	DFUs	II	In-progress	March 24, 2022	CTR20220638

Notes:

1. This refers to Pro-101-1.
2. This refers to Pro-101-2.

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Summary of Clinical Trial Results

Phase I Clinical Trial of Pro-101-2

We have completed the Phase I trial of Pro-101-2 in healthy volunteers, based on the results of which we subsequently achieved the CDE approval for the Phase II trial of Pro-101-2 and the Phase IIa trial for Pro-101-1 in China. We are currently evaluating Pro-101-1 in a Phase IIb trial in patients with second-degree thermal burns.

As Pro-101-2 demonstrated encouraging results in pre-clinical studies, with the IND approval obtained in July 2021, we initiated our Phase I clinical trial of Pro-101-2 in August 2021. During the Phase I clinical trial, Pro-101-2 demonstrated encouraging results in safety and tolerability in healthy subjects, indicating a promising commercial and therapeutic potential to address the sizable and growing DFU drug market.

Trial status: The Phase I clinical trial was completed in October 2021, and we finalized the clinical report in November 2021.

Trial design: The Phase I clinical trial was a single-center, randomized, double-blind, placebo-controlled, single-dose, dose-escalation study to evaluate the safety and tolerability of Pro-101-2 by topical administration to healthy volunteers. The primary and secondary endpoints are drug-related adverse events as determined following the NCI CTCAE v5.0 grading criteria. During the Phase I clinical trial, after cleaning the back with normal saline, Pro-101-2 was applied evenly at one time to a designated area on the back of the trial subjects. The trial subjects were required to keep the prone position for 1.5 hours. Afterwards, the area was covered with sterile gauze. Then the subjects could stop maintaining the prone position and change the position under the guidance of the researcher. The administration sites shall not be washed or wiped within 24 hours after administration. The dressing shall be removed 24 hours after administration and the administration area shall be rinsed with water to remove residual gel.

We planned to enroll 36 healthy subjects in the trial, who would be divided into five cohorts at dose levels of 2.1 $\mu\text{g}/\text{cm}^2$ (Cohort 1), 7 $\mu\text{g}/\text{cm}^2$ (Cohort 2), 14 $\mu\text{g}/\text{cm}^2$ (Cohort 3), 21 $\mu\text{g}/\text{cm}^2$ (Cohort 4) and 21 $\mu\text{g}/\text{cm}^2$ (Cohort 5), with the respective application areas of 10x10 cm^2 , 10x10 cm^2 , 10x10 cm^2 , 10x10 cm^2 and 16x16 cm^2 . Each cohort consisted of eight subjects (six receiving Pro-101-2 and two receiving placebo) except for Cohort 1, which enrolled four subjects (three receiving Pro-101-2 and one receiving placebo). During the Phase I clinical trial, eligible subjects were administered with Pro-101-2 or placebo once on the back area on Day 1, followed by 48-hour in-hospital observation and received end-of-treatment examinations on Day 3 (discharge).

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Safety data: At the beginning of the Phase I clinical trial, we enrolled in total 38 subjects, including two alternative trial subjects. Among the 38 subjects, two subjects withdrew from the study. Among these two subjects, one subject in Cohort 2 withdrew from the study within half an hour after being administered with Pro-101-2 because the subject was unable to remain in prone position for 1.5 hours. This subject was still included in the safety analysis set according to the clinical trial protocol. The other withdrawing subject in Cohort 4 withdrew from the study before receiving any treatment or placebo. Therefore, in total 37 subjects were included in the safety analysis set.

The table below summarizes the drug exposure information of Pro-101-2 Phase I clinical trial:

Cohort	Dose ($\mu\text{g}/\text{cm}^2$)	Medication area (cm^2)	No. of subjects receiving Pro-101-2	No. of subjects receiving placebo
1	2.1	10x10	3	1
2	7	10x10	6	2
3	14	10x10	6	2
4	21	10x10	7 ¹	2
5	21	16x16	6	2

Note:

1. Represents 6 subjects who finished the study and 1 subject who withdrew from the study within half an hour after being administered with Pro-101-2 who was included in the safety analysis.

Source: Company data

Among the 37 subjects in the study, 30 subjects (81.1%) experienced AEs with a total of 47 cases and 25 subjects (67.6%) experienced ADRs with a total of 32 cases. Among the 28 subjects who received Pro-101-2, 24 (85.7%) had 38 cases of AEs and 20 (71.4%) had 26 cases of ADRs. Of the 9 subjects receiving placebo, 6 (66.7%) had 9 cases of AEs and 5 (55.6%) had 6 cases of ADRs. Except for the outcome of two AEs that was unknown due to the subjects' refusal to review, the other AEs disappeared spontaneously before the end of the study without treatment. The table below sets forth the summary of AEs and ADRs during Pro-101-2 Phase I clinical trial:

	AEs			ADRs		
	Subject Number	%	Case number	Subject Number	%	Case Number
37 subjects in total	30	81.1	47	25	67.6	32
28 subjects receiving Pro-101-2	24	85.7	38	20	71.4	26
9 subjects receiving placebo . . .	6	66.7	9	5	55.6	6

Source: Company data

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The AEs (incidence of $\geq 3\%$) observed in both the Pro-101-2 group and the placebo group were erythema (67.9% vs 44.4%) and papules (3.6% vs 11.1%) at the administration sites. AEs (incidence of $\geq 7\%$) observed only in the Pro-101-2 group included: elevated aspartate aminotransferase (7.1%), abnormal T wave of electrocardiogram (7.1%) and prolonged QT interval of electrocardiogram (7.1%); AEs (incidence of $\geq 7\%$) observed only in the placebo group included: ventricular extrasystole (11.1%), sinus bradycardia (11.1%) and skin redness (11.1%). The abovementioned AEs all occurred at least once. The common ADRs reported in subjects receiving Pro-101-2 included erythema and papules at the application sites and increased blood uric acid. The common ADRs reported in subjects receiving placebo included erythema and papules at the application sites. As drug-related administration site reactions were observed in both groups, they may be related to skin irritation due to the method of application. Only one case of increased blood uric acid was reported in the Pro-101-2 groups. This increased blood uric acid case was not deemed meaningful due to the limited number of subjects participating in the study.

All AEs were Grade 1 (mild) in terms of severity under the Common Terminology Criteria for Adverse Events (CTCAE version 5.0) and neither serious adverse events (the "SAEs") nor deaths were reported. No early withdrawal of the trial subjects was caused by the AEs. Among the 47 cases of AEs, 32 cases were possibly drug-related, 14 cases were possibly non-drug-related and 1 case was non-drug-related. No abnormal changes in physical examinations and vital signs were observed in the study. As a conclusion, a single administration of Pro-101-2 to healthy subjects demonstrated a favorable safety profile, with the subjects exhibiting a high degree of tolerance.

Phase IIa Clinical Trial of Pro-101-1

Trial status: The Phase IIa clinical trial for Pro-101-1 was completed in May 2023, and we finalized the clinical report in November 2023.

Trial design: The Phase IIa clinical trial on Pro-101-1 was a multi-center, randomized, double-blind, placebo-controlled study evaluating the safety, tolerability, preliminary efficacy, and pharmacokinetics of Pro-101-1 with localized superficial second-degree and deep second-degree burns. The primary endpoint is the time it takes for subjects in each group to achieve complete healing. The secondary endpoints include: (i) the proportion of subjects in each group with complete healing of the treated area on days 2, 4, 6, 10, 14, 21, and 28; (ii) the percentage change in the target wound area from baseline at the dates of wound assessment; and (iii) the healing status of the target wound, including the presence or absence of erythema, oedema, ulceration, crusting, rash or blistering symptoms. Trial subjects were divided by burn depth into superficial second-degree and deep second-degree groups and randomized to receive either the trial drug or a placebo. Concomitant with standard of care, subjects were administered the trial drug or placebo once daily. Commencing on the second day of treatment, prior to the administration of the daily dose, the target wound area was evaluated, with subsequent assessments occurring on alternate

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days. During routine dressing changes, investigators conducted examinations to monitor wound healing progress and signs of infection. An increase in the target wound area or exacerbation of wound condition, such as infection, could necessitate withdrawal from the study, with such events documented as AEs. At the conclusion of week two, subjects who had completed 14 days of treatment underwent a safety evaluation. Subjects with superficial second-degree burns whose target wound areas remained unhealed at the end of week two, and who were assessed by investigators as tolerating the investigational drug well with clinical benefit, were eligible to continue treatment until week four or until complete wound healing, or treatment failure was observed; subjects with deep second-degree burns continued treatment until week four or until complete wound healing or treatment failure. The occurrence of any SAEs mandated cessation of treatment. Upon completion of the medication regimen, all subjects were subjected to a safety assessment, and, irrespective of recovery, treatment failure, early withdrawal or completion of the treatment phase, a safety follow-up visit was scheduled on the 14th day after the last application of the trial drug.

We planned to enroll 60 subjects in the trial, consisting of 2 cohorts each with 30 subjects with superficial second-degree burns and 30 subjects with deep second-degree burns respectively. Each cohort consisted of 10 subjects at dose levels of 14 $\mu\text{g}/\text{cm}^2$ (the “**High Dose Group**”), 10 subjects at 7 $\mu\text{g}/\text{cm}^2$ (the “**Low Dose Group**”), and 10 subjects receiving placebo (the “**Placebo Group**”). We utilized a digital camera in conjunction with a ruler-based analysis method to measure the surface area of burn wounds. Subjects were randomly assigned to the three groups, and the exact drug dosage is calculated based on the target wound surface area. A one-time application tool is used to evenly spread the drug or placebo across the wound surface. The treated area must not be washed or wiped within 12 hours post-application.

Safety data: During the Phase IIa clinical trial, we enrolled 60 subjects, and 59 were actually treated. In the Low Dose Group for superficial second-degree burns, there were 9 subjects, one fewer than the planned 10. Among the superficial second-degree burn cohort, a total of 27 subjects completed the treatment: one subject from each of its High Dose Group and Placebo Group decided to withdraw, leading to an early termination of the treatment. Among the deep second-degree burn cohort, all its High Dose Group subjects completed the treatment; in its Low Dose Group, one subject, and in its Placebo Group, two subjects, withdrew from the treatment prior to completion, all due to the subjects’ personal decisions.

Among the 59 subjects in the study, 23 subjects (39.0%) experienced 54 AEs, with 5 subjects (8.5%) experiencing 8 AEs related to the trial drug. There were no instances of SAE. Specifically,

- Out of the subjects with superficial second-degree burns, 9 subjects (31.0%) experienced a total of 18 AEs: in the High Dose Group, there were 4 subjects (40.0% of participants) with 11 AEs; in the Low Dose Group, there were 3 subjects (33.3%) with 4 AEs; and in

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the Placebo Group, there were 2 subjects (20.0%) with 3 AEs. Out of these, 13 AEs in 9 subjects were resolved/recovered, 2 AEs in 2 subjects were alleviated, 2 AEs in 2 subjects were unresolved/unrecovered, and 1 AE in 1 subject was of unknown outcome.

- Among the subjects with deep second-degree burns, 14 subjects (46.7%) experienced a total of 36 AEs: in the High Dose Group, there were 3 subjects (30.0% of subjects) with 6 AEs; in the Low Dose Group, there were 4 subjects (40.0%) with 14 AEs; and in the Placebo Group, there were 7 subjects (70.0%) with 16 AEs. Out of these, 27 AEs in 13 subjects were resolved/recovered, 1 AE in 1 subject was alleviated, 7 AEs in 5 subjects were unresolved/unrecovered, and 1 AE in 1 subject had an unknown outcome.

Based on the facts that (i) approximately 8.5% of subjects experienced AEs related to the trial drug, (ii) no instances of SAE occurred during the clinical trial and (iii) the majority of the AEs were resolved/recovered or alleviated, Pro-101-1 has demonstrated good safety and tolerability when applied topically once a day for a continuous period of 4 weeks at dosage 14 $\mu\text{g}/\text{cm}^2$ and 7 $\mu\text{g}/\text{cm}^2$ respectively for subjects with superficial second-degree and deep second-degree burns.

Efficacy data: After treatment of superficial second-degree burn wound, the mean time for wound healing based on FAS was 10.4 days in the High Dose Group and 11.6 days in the Low Dose Group, which were 7.2 days and 6 days shorter than 17.6 days in the Placebo Group, respectively. Based on the Per Protocol Set (PPS) analysis, the mean time for wound healing was 10.8 days in the High Dose Group and 11.6 days in the Low Dose Group, which were 6.8 days and 6 days shorter than the 17.6 days in the Placebo Group, respectively. The healing time of the High Dose Group and the Low Dose Group was shorter than that of the Placebo Group. Based on PPS, the comparison of efficacy between the High Dose Group and the Placebo Group was $P < 0.05$ ($P = 0.047$), indicating that the efficacy of the High Dose Group was better than that of the Placebo Group. During wound healing, the proportion of completely healed subjects in the High Dose Group and Low Dose Group was higher than that in the Placebo Group, and the reduction of target wound area from baseline in High Dose Group and Low Dose Group was also better than that in the Placebo Group.

After treatment of deep second-degree burn wound, the mean time for wound healing based on FAS was 14.3 days in the High Dose Group and 19.0 days in the Low Dose Group, which were 6.2 days and 1.5 days shorter than the 20.5 days in the Placebo Group, respectively. Based on PPS, the mean time for wound healing was 14.3 days in the High Dose Group and 19.0 days in the Low Dose Group, which were 5 days and 0.3 days shorter than the 19.3 days in the Placebo Group, respectively. The healing time of the High Dose Group and the Low Dose Group was shorter than that of the Placebo Group, and based on PPS, the comparison of efficacy between the High Dose Group and the Placebo Group showed a significant difference ($P < 0.05$ ($P = 0.017$)), indicating that the efficacy of the High Dose Group was better than that of the Placebo Group. During wound

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healing, the proportion of completely healed subjects in the High Dose Group and the Low Dose Group was higher than that in placebo group, and the reduction of target wound area from baseline in the High Dose Group and the Low Dose Group was also better than that in the Placebo Group.

For both superficial second-degree and deep second-degree burns, the High Dose Groups and Low Dose Groups exhibited shorter healing times compared to the Placebo Groups. Furthermore, based on PPS, the High Dose Groups’ efficacy surpassed that of the Placebo Groups’. The reduction in target wound surface area from baseline was also more pronounced in the High Dose Groups and Low Dose Groups when compared to the Placebo Groups. Pro-101-1 can accelerate the healing of superficial second-degree and deep second-degree burn wounds, shorten the healing time and accelerate the healing speed.

Clinical Development Plan

We initiated the Phase IIb clinical trial of Pro-101-1 in December 2023. Our Phase IIb clinical trial on Pro-101-1 is designed as a multi-center, randomized, double-blind, placebo-controlled study in China to evaluate the safety and efficacy of Pro-101-1 by topical administration to patients with superficial and deep second-degree thermal burns. We plan to enroll a total of 351 subjects. We expect to complete the Phase IIb clinical trial in the second quarter of 2025, and to initiate the Phase III clinical trial in the third quarter of 2025. We expect to complete the Phase III clinical trial in the fourth quarter of 2026 and to launch the product in China in 2027.

We initiated the Phase II clinical trial of Pro-101-2 in February 2022. Our Phase II clinical trial is designed as a multi-center, randomized, double-blind, placebo-controlled study in China to evaluate the safety and efficacy of Pro-101-2 by topical administration to patients with DFUs. We plan to enroll a total of 160 subjects. We expect to complete the Phase II clinical trial in the second quarter of 2027 and to initiate the Phase III clinical trial in the third quarter of 2027. We expect to complete the Phase III clinical trial in the second quarter of 2029 and to launch the product in China in 2030.

As of the Latest Practicable Date, no material unexpected or adverse changes had occurred since the date of the issue of the relevant regulatory approvals for our Core Products.

Licenses, Rights and Obligations

We hold patents and patent applications related to Pro-101-1 and Pro-101-2 in China. We hold the rights to develop and commercialize Pro-101-1 and Pro-101-2 globally.

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Material Communications with Competent Authorities

Pro-101-2

In October 2020, we, together with AMMS, submitted application materials of Pro-101-2 for a pre-IND meeting with the CDE to discuss the sufficiency of pharmacological and toxicological studies, the dosage design and the necessity of immunogenicity testing of the Phase I clinical trial design of Pro-101-2. In lieu of a meeting, the CDE provided written responses in January 2021. In its responses, the CDE raised questions on the adequacy of the pre-clinical pharmacodynamics studies, the selection basis of species for pre-clinical drug toxicity studies, the clinical trials of domestic and foreign growth factors products (both commercialized and under development) for DFUs and the *in vivo* behavior of the related substance of active pharmaceutical ingredients of Pro-101-2. In addition, the CDE provided useful guidance on the design of the Phase I clinical trial. In January 2021, we and AMMS submitted supplemental data to address the CDE's questions and revised our dose design of the Phase I clinical trial for Pro-101-2. In April 2021, we and AMMS jointly submitted the IND application for Pro-101-2 to the CDE and received the IND approval in July 2021.

After the completion of the Phase I clinical trial in October 2021, we submitted application materials for a meeting with the CDE to discuss the design of the Phase II clinical trial of Pro-101-2 and whether we can initiate such trial after receiving the approval of the institutional review board. The CDE responded in writing in February 2022 that we have the discretion to assess the timing of the commencement of the Phase II clinical trial and did not raise any objection to our design of the Phase II clinical trial. We initiated the Phase II clinical trial in February 2022.

Pro-101-1

Communications with the CDE: In March 2022, we submitted application materials of Phase IIa clinical trial of Pro-101-1 based on the Phase I clinical trial results of Pro-101-2. NMPA issued an IND approval for the Phase IIa clinical trial in June 2022, and required us to communicate with the NMPA regarding key issues of the Phase III clinical trial design before we initiate the Phase III clinical trial. We initiated the Phase IIa clinical trial in September 2022, and completed the trial in May 2023. We subsequently filed the Phase IIb clinical trial with NMPA in November 2023, and then initiated the Phase IIb clinical trial in December 2023.

Communications with the FDA: In December 2021, we submitted application materials for a pre-IND meeting with the FDA to discuss the CMC aspects, the adequacy of our proposed nonclinical development plan and the proposed initial clinical study and overall clinical development plan in the United States. In lieu of a meeting, the FDA provided written responses in

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February 2022. The FDA replied that whether the Phase I clinical trial of Pro-101-2 and our current nonclinical studies are sufficient to support the initiation of the US IND-opening trial will be determined after the FDA's review of the complete initial IND submission, including the product quality and nonclinical components. The FDA also provided useful guidance on CMC process and the design of our Phase II clinical trial of Pro-101-1. As of the Latest Practicable Date, we are not aware of any legal claims or proceedings that may have an adverse effect on development for the pipeline, any objection to the clinical development plans, or any material adverse change had occurred with respect to the regulatory review or approval process.

Pro-101-3 for the treatment of fresh wounds

In December 2021, we submitted application materials for a pre-IND meeting with the CDE to discuss the IND application, the design of the Phase Ib clinical trial and the plan to directly conduct Phase Ib clinical trial based on the results of the Phase I clinical trial of Pro-101-2. In lieu of a meeting, the CDE provided written responses in March 2022. The CDE provided useful guidance on the design of the Phase Ib clinical trial of Pro-101-3 for the treatment of fresh wounds and suggested that whether additional safety studies are necessary should depend on the MOA, dosage, administration timing and systemic/local exposure of the result of Pro-101-2.

Summary of Pre-clinical Studies Results

Pre-clinical Studies Results of Pro-101-1

We conducted a pre-clinical study to investigate the efficacy of Pro-101-1 in second degree scald model of miniature pigs. Each miniature pig received two scald surfaces, one superficial second-degree scald and one deep second-degree scald, located on the left and right sides of the spine, respectively. After the scald modeling, the animals were randomly divided into five groups, namely the model control group (group A), control substance group (group B), Pro-101-1 low-dose group (group C), Pro-101-1 medium-dose group (group D) and Pro-101-1 high-dose group (group E). On the second day of modeling, percutaneous administration was performed on the scalded sites of the miniature pigs, with the area of administration covering the burnt sites, once a day for 21 consecutive days. The drug should be removed before the next administration. Group A was not administrated and only the back skin (or burnt sites) was disinfected daily. Group B was administrated with 300IU/cm² of control substance, and groups C, D, and E were administrated with 3.5 µg/cm², 7 µg/cm², and 14 µg/cm² of Pro-101-1, respectively.

The results demonstrated that the control substance (300IU/cm²) and the Pro-101-1 (14µg/cm²) could significantly increase the wound healing rate of miniature pigs with superficial and deep second-degree scald. The Pro-101-1 (3.5µg/cm²) could significantly increase the wound healing rate of superficial second-degree scald model miniature pigs. The Pro-101-1 (7µg/cm²)

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could significantly increase the wound healing rate of deep second-degree scald model pigs during the 14-day observation period. The control substance (300IU/cm²) and the Pro-101-1 (3.5, 7, 14µg/cm²) could improve the recovery of wound injury in miniature pigs with superficial and deep second degree scald, and promote neovascularization and proliferation of fibroblasts. The improvement degree of healing of superficial and deep second-degree scald model was as follows: control substance (300IU/cm²) > Pro-101-1 (14µg/cm²) > Pro-101-1 (7µg/cm²) > Pro-101-1 (3.5µg/cm²).

Wound healing rate of miniature pigs with superficial and deep second-degree scald

Parts	Group	Number of animals	Healing rate (%)				
			D3	D6	D9	D14	D22
Left side (superficial second-degree)	Group A	6	4.2±5.0	5.5±6.0	11.4±8.2	27.9±6.3	57.6±11.3
	Group B	6	0.0±0.0	16.9±18.7	16.4±9.1	41.4±10.1*	77.1±16.6*
	Group C	6	2.9±5.6	9.0±7.5	11.2±8.7	28.9±8.5	80.2±12.6**
	Group D	6	0.2±0.4	10.0±8.3	8.6±1.9	33.5±8.1	66.8±11.1
	Group E	6	0.0±0.0	6.3±8.3	8.0±11.8	32.7±15.9	75.5±10.7*
Right side (deep second-degree)	Group A	6	0.6±1.3	3.7±4.4	5.6±4.1	20.2±7.1	50.6±14.0
	Group B	6	3.0±4.9	21.0±17.4	19.1±10.3*	40.2±10.6**	76.6±18.9*
	Group C	6	3.8±5.9	5.1±6.6	11.3±8.3	28.3±5.0*	65.4±12.2
	Group D	6	3.3±4.9	9.8±8.5	16.7±7.7*	35.0±11.5*	59.5±17.7
	Group E	6	2.6±6.5	10.7±7.9	12.5±8.7	29.0±9.5	71.1±16.5*

Notes:

1. "*" indicates that the difference is significant (P<0.05) when compared with the model control group (Group A);
 "**" indicates that the difference is very significant (P<0.01) when compared with the model control group (Group A).
2. Groups A, B, C, D, and E represent the model control group, listed control substance group, and PDGF low-, medium-, and high-dose groups, respectively.

Source: Company data

Pre-clinical Studies results of Pro-101-2

The Institute of Bioengineering of AMMS initiated the pre-clinical research of Pro-101-2 in May 2005. The pre-clinical studies of Pro-101-2 included eight pharmacodynamic studies, three toxicity studies and one pharmacokinetic study. Pro-101-2 has demonstrated favorable safety and efficacy results in these studies.

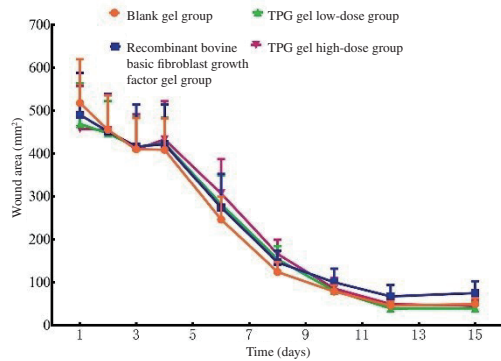
— Pharmacodynamic Studies

We conducted a study to observe the effect of Pro-101-2 on skin incision healing of diabetic SD rats induced by streptozotocin ("STZ"). The SD rats were evenly assigned into four groups including a blank gel group, a recombinant bovine basic fibroblast growth factor gel group, a Pro-101-2 low-dose group (30 µg/g), and a Pro-101-2 high-dose group (300 µg/g). A single STZ was injected to induce diabetes. After anesthesia, two (left/right) round full-thickness resection wounds with a diameter of about 20 mm at symmetrical positions on both sides of the spine were prepared by resection. The transparent dressing film was applied to the surface of the wounds to prevent animals from scratching and licking. The drugs were applied topically to each wound once a day for a total of 12 days. The results demonstrated that compared with the recombinant bovine

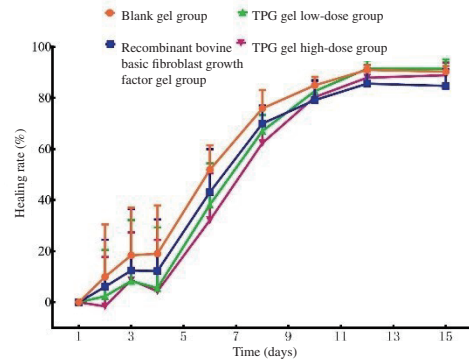
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basic fibroblast growth factor gel group, the wound area in the Pro-101-2 low-dose group significantly decreased on Day 15 ($P \leq 0.05$) and its wound healing rate increased significantly on Day 15 ($P \leq 0.05$), and there was no statistically significant difference in wound area or wound healing rate between the groups at other observation time points ($P > 0.05$).

Change in wound area of rats

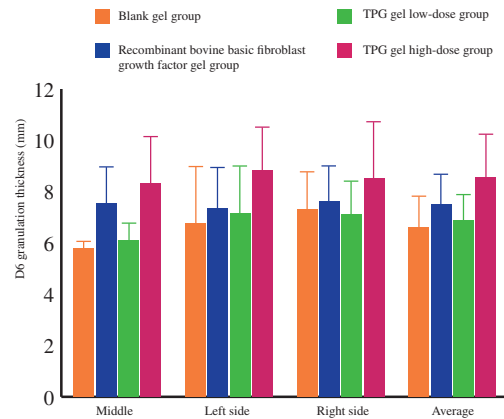
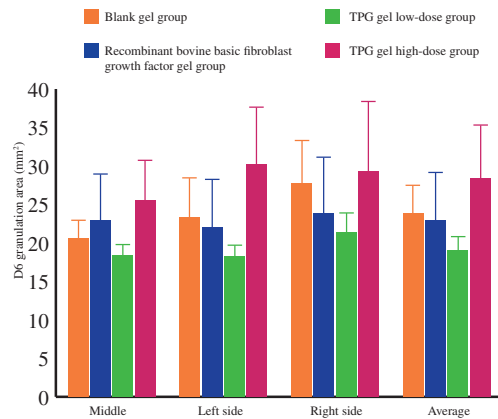


Change in healing rate of rats



Source: Company data

The results also demonstrated that compared with the recombinant bovine basic fibroblast growth factor gel group, the high-dose of Pro-101-2 had better effect on the proliferation of granulation tissues on Day 6.



Source: Company data

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— Toxicity Studies

We conducted a four-week toxicity study to observe possible toxic reactions and metabolism in the body after continuous skin application of Pro-101-2 once a day for four weeks in Bama miniature pigs. The Bama minipigs were randomly assigned to five groups. Group 1 was given sodium chloride injection as a negative control; Group 2 was given a blank gel as an excipient control; Groups 3 and 4 were given 700 µg/animal and 2,100 µg/animal of Pro-101-2, respectively; and Group 5 was given 50 µg/kg Pro-101-2 drug substance as a subcutaneous injection control. Groups 1 and 5 were administered subcutaneously, and Groups 2 to 4 were given dermal administration. Doses were administered once daily for 28 consecutive days.

During the study, no mortality or moribundity was observed in any group and no treatment-related abnormal changes were observed in body temperature, ECG parameters and waveforms, blood cell counts, urinalysis or lymphocyte subsets of animals in any group. The results demonstrated in Groups 3 and 4, inflammatory reaction and stress reaction after skin removal in animals were found and no toxicity related to administration was found. After repeated skin application of Pro-101-2 to miniature pigs for 28 days and repeated subcutaneous injection of Pro-101-2 drug substance to miniature pigs for 28 days, a slight immune reaction to Pro-101-2 with low antibody titers was observed in miniature pigs.

We conducted a skin irritation study of Pro-101-2 to observe whether 14-day repeated skin application of Pro-101-2 would induce irritation reaction at the administration sites in female New Zealand rabbits. The rabbits were randomly divided into two groups, namely the normal skin group and the damaged skin group. The study was conducted using the homologous left- and right-side control method with simultaneous dermal administration to the normal and damaged skin. The test article, or Pro-101-2, was administered at a concentration of 0.2%. After the negative control article and test article were uniformly applied, the surface was covered with a layer of cellophane and fixed with nonirritating tape, gauze, or bandage for a period of 4 hours (\pm 10 min). Doses were administered once daily for 14 consecutive days.

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During the study, no mortality or moribundity was observed in any of the animal, and no test article-related abnormalities were observed during clinical observations. The results demonstrated that repeat application of 100 µg/g Pro-101-2 once a day for 14 days to the normal skin of New Zealand rabbits had no irritation at the administration sites. After repeated application of 100 µg/g Pro-101-2 to the damaged skin of New Zealand rabbits, microscopic examination showed epidermal squamous cell hyperplasia and ulcers, as well as dermal inflammation cell infiltration, dermal fibrous tissue hyperplasia, dermal hemorrhage, and aggravated epidermal scab, which indicated that Pro-101-2 had mild irritation.

We conducted an active cutaneous anaphylaxis test of Pro-101-2 in guinea pigs to observe whether Guinea pigs develop active cutaneous anaphylaxis by applying Pro-101-2 during Day 1 to Day 15 once a week, and after sensitization of Guinea pigs 3 times to evoke the reaction on Day 29. The guinea pigs were divided into 4 groups: negative control group, positive control group, test article (Pro-101-2) group and excipient control group.

During the study, no animals in any group died or were moribund. Erythema, edema, ulceration, and scabbing were observed at the administration sites of all animals in the positive control group after sensitization. No abnormalities were observed at the administration sites of all animals in the negative control group, test article group, and excipient control group after sensitization. After evoking any reactions, no local erythema and edema were observed in the animals of the negative control group, the test article group, and the excipient control group, with sensitization rate of 0% for these groups. Mild/moderate erythema and mild/moderate edema were observed in all animals of the positive control group, with sensitization rate of 100%, indicating extreme sensitization. The results demonstrated that repeated dermal application of Pro-101-2 did not result in skin allergic reactions in the Guinea pigs.

We conducted a toxicity study of Pro-101-2 in Bama miniature pigs to evaluate toxicity of Pro-101-2 administered by dermal application or subcutaneous injection to Bama miniature pigs for 26 weeks, and the reversibility of toxicity following a four-week recovery period. The Bama miniature pigs were randomly assigned to five groups, were treated with sodium chloride injection as negative control for Groups 1 and 2, and Pro-101-2 at doses of 700 µg/animal and 2,100 µg/animal for Groups 3 and 4, respectively. The drug substance (DS) of Pro-101-2 at a dose of 50 µg/kg was treated for Group 5 as subcutaneous injection control. Animals from Groups 1 and 5 were injected subcutaneously and animals from Groups 2 to 4 were administered via dermal application once daily for 182 consecutive days. The animals in each group were euthanized by batches after 13 weeks of dosing (Day 92), after 26 weeks of dosing (Day 183), and following a 4-week recovery period (Day 211). Parameters evaluated in this study were clinical observations, body weight, body temperature, electrocardiogram, ophthalmoscopic examinations, hematology,

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coagulation, clinical chemistry, urinalysis, Immunophenotype (CD3*, CD* and CD8), cytokines detection (VEGF-A and PDGF), antibody detection, toxicokinetics, organ weights, macroscopic and microscopic examinations.

During the study, two animals from subcutaneous injection negative control group were found dead due to accidental infection; and one animal from dermal application negative control group and one animal from Pro-101-2 at 700 µg/animal group were found dead, which was unrelated to the test article. Pro-101-2 by dermal wound application to animals did not result in significant systemic or local toxicity, and the drug substance (DS) of Pro-101-2 by subcutaneous injection to animals did not result in significant systemic toxicity, but pathological examination showed inflammatory changes (subcutaneous fibrosis, hemorrhage, vessel wall/perivascular necrosis, dermal/subcutaneous inflammatory cell infiltration) at the injection site, which could be completely recovered after the end of the 4-week recovery period. Under the conditions of the study, the no observed adverse effect level (NOAEL) by Pro-101-2 was 2,100 µg/animal. Serum anti-rhPDGF antibody detection showed that some animals had low antibody titers, suggesting that miniature pigs had a minimal immune response to the test article.

— Pharmacokinetic Studies

We conducted a study to assess the distribution characteristics of Pro-101-2 in the local tissues of Bama miniature pigs after a dermal administration of Pro-101-2. The Bama miniature pigs were randomly divided into two groups according to the gender segment using the computer system. All animals were cut at 10 cm×10 cm full-thickness skin on the left and right sides of the back to make a miniature pig trauma model, with the subcutaneous tissue exposed. The animals were euthanised by batches 4 hours, 12 hours, 48 hours and 72 hours after dosing. Sample tissues were collected at the wound sites.

The results demonstrated that Pro-101-2 was distributed in all tissues after a single dermal administration to Bama miniature pigs. Pro-101-2 reached the highest concentration at 4 hours post-dosing (except for the 0.5 cm and 1.5 cm skin tissues in females, which reached the highest concentration at 48 hours post-dosing). Pro-101-2 was detected in all local tissues 72 hours after the administration. Except for the adipose tissue of the wounds, the Pro-101-2 content in other tissues was low and close to the lower limit of quantification. The higher concentration was detected in the adipose tissue 72 hours after the administration, indicating that Pro-101-2 can still remain in the wound sites after 72 hours, which is conducive to the continuous exertion of the pharmaceutical effect.

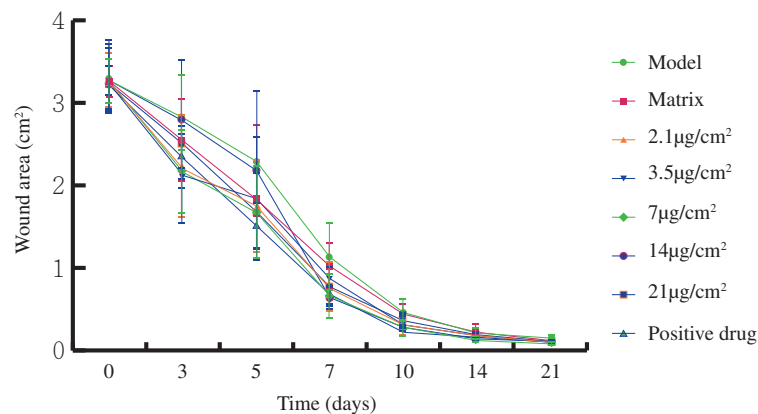
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Pre-clinical Studies results of Pro-101-3 for the treatment of fresh wounds

We conducted a study to observe the effect of Pro-101-3 for the treatment of fresh wounds on wound repair and to explore the time-effect and dose-effect relationship of the Pro-101-3 for the treatment of fresh wounds on wound healing in full-thickness skin defect animal model of Wistar rats. Circular wounds with a diameter of 20 mm were made on each side of the Wistar rat spine to create a full-thickness skin defect model. The Wistar rats were divided into eight groups: model group, matrix control group, five kinds of Pro-101-3 for the treatment of fresh wounds treatment group ($2.1\mu\text{g}/\text{cm}^2$, $3.5\mu\text{g}/\text{cm}^2$, $7\mu\text{g}/\text{cm}^2$, $14\mu\text{g}/\text{cm}^2$ and $21\mu\text{g}/\text{cm}^2$) and positive drug group ($300\text{IU}/\text{cm}^2$ recombinant bovine basic fibroblast growth factor gel). The Wistar rats were dosed once a day.

During the study, it was observed that Pro-101-3 for the treatment of fresh wounds can significantly promote the proliferation of granulation tissue, repair the wounds and shorten the healing time in the repair of full-thickness skin defect wounds in Wistar rats. The $3.5\mu\text{g}/\text{cm}^2$, $7\mu\text{g}/\text{cm}^2$ and $14\mu\text{g}/\text{cm}^2$ Pro-101-3 for the treatment of fresh wounds dose groups showed reduction of the wound area of the Wistar rats, acceleration in wound healing and improvement in the quality of wound healing on Day 7, Day 10 and Day 14, and there is a certain dose-effect and time-effect relationship. There was significant difference in wound area between the $7\mu\text{g}/\text{cm}^2$ dose group and the matrix control group. There was no obvious repair effect in the $2.1\mu\text{g}/\text{cm}^2$ and $21\mu\text{g}/\text{cm}^2$ dose groups. The granulation tissue of the wound surface gradually disappeared, and the new epithelium increased significantly on Day 7. After the wound surface was completely healed on Day 21, the wound surface of each dose group of Pro-101-3 for the treatment of fresh wounds was smoother than that of the control group and the wound healing result was better.

Changes of wound area at different time in Wistar rats model



Source: Company data

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We conducted an efficacy evaluation and preliminary study of the MOA of Pro-101-3 on wound healing in Wistar rats. Circular wounds with a diameter of 20 mm were made on each side of the Wistar rat spine to create a full-thickness skin defect model. The Wistar rats were divided into seven groups: normal control group, model control group, matrix control group, three kinds of Pro-101-3 treatment group ($3.5\mu\text{g}/\text{cm}^2$, $7\mu\text{g}/\text{cm}^2$ and $14\mu\text{g}/\text{cm}^2$) and positive drug group (recombinant bovine basic fibroblast growth factor gel, $300\text{IU}/\text{cm}^2$). Administration was applied once a day to observe the effect of Pro-101-3 on wound healing.

During the study, it was observed that Pro-101-3 can significantly promote the proliferation of granulation tissue and increase angiogenesis in the repair of full-thickness skin defect wounds in Wistar rats. In particular, the high dose of Pro-101-3 ($14\mu\text{g}/\text{cm}^2$) significantly promoted the proliferation of granulation tissue and angiogenesis in the wounds from Day 3 to Day 7. However, the wound area was larger than the control group, indicating that high-dose Pro-101-3 would affect the wound repair process. Pro-101-3 significantly promoted the growth of wound granulation tissue and increased angiogenesis, and the wound area was significantly reduced on Day 7. The wound area was reduced, the granulation tissue of the wounds gradually disappeared, and the new epithelium was obvious in all Pro-101-3 groups from Day 7 to Day 14. After the wound surface was completely healed on Day 21, the wound surface of each dose group of Pro-101-3 was smoother than that of the control group and the wound healing quality was better. In addition, no adverse reactions were observed during the study.

Effect of Pro-101-3 on wound healing of full-thickness skin defect in Wistar rats (cm^2 , mean \pm SD)

Group	1d	3d	7d	14d	21d
Model group	3.64 \pm 0.43 (n=16)	2.34 \pm 0.37 (n=16)	0.8 \pm 0.13 (n=16)	0.2 \pm 0.06 (n=16)	0.14 \pm 0.06 (n=16)
Matrix control group	3.54 \pm 0.52 (n=16)	2.42 \pm 0.34 (n=16)	0.81 \pm 0.14 (n=16)	0.19 \pm 0.05 (n=16)	0.12 \pm 0.02 (n=16)
Pro-101-3 treatment group ($3.5\mu\text{g}/\text{cm}^2$)	3.56 \pm 0.47 (n=18)	2.44 \pm 0.34 (n=16)	0.83 \pm 0.14 (n=18)	0.14 \pm 0.05 (n=20)	0.1 \pm 0.03 (n=18)
Pro-101-3 treatment group ($7\mu\text{g}/\text{cm}^2$)	3.56 \pm 0.44 (n=20)	2.49 \pm 0.39 (n=20)	0.64 \pm 0.22* (n=18)	0.13 \pm 0.04** (n=20)	0.1 \pm 0.04 (n=18)
Pro-101-3 treatment group ($14\mu\text{g}/\text{cm}^2$)	3.62 \pm 0.61 (n=20)	2.57 \pm 0.58 (n=20)	0.88 \pm 0.16 (n=16)	0.14 \pm 0.04 (n=20)	0.09 \pm 0.03 (n=20)
Positive drug group	3.34 \pm 0.62 (n=18)	2 \pm 0.28* (n=18)	0.62 \pm 0.16** (n=18)	0.12 \pm 0.04** (n=18)	0.09 \pm 0.04 (n=18)

Note: Changes in wound area of Wistar rats on the day of surgery and in wound area of each group on Day 1, 3, 7, 14, and 21 post-injury, *P<0.05 when compared with the matrix control group at the same time point; ** P<0.01 when compared with the matrix control group at the same time point; n= number of wounds.

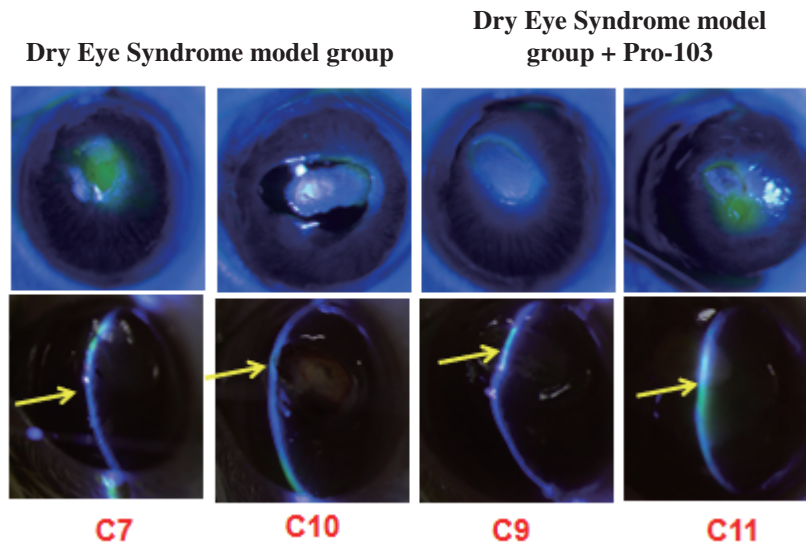
Source: Company data

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Pre-clinical Studies results of Pro-103 for the treatment of dry eye syndrome

We conducted a study to observe the therapeutic effect of Pro-103 by establishing an animal model of dry eye syndrome in Sprague-Dawley rats and to explore the reparative function of Pro-103 on dry eye damage. Our preliminary experimental results found that Pro-103 can increase the tear content in the conjunctival sac after injury, suggesting that PDGF may have a certain reparative effect on dry eye syndrome. The effect of Pro-103 at 5 μ g/ml was better than that of other groups, indicating that Pro-103 can improve the ocular surface microenvironment in dry eye syndrome and play a role in the treatment of the condition.

The comparison of a rat model of dry eye (benzalkonium chloride-induced damage) and the reparative results of Pro-103



Note: The yellow arrows indicate the degree of smoothness of the reparative surface, in which the surface of C7/C10 in the damage group is uneven with bumps; the surface of C9/C11 in the Pro-103 group is relatively smooth and even

Source: Company data

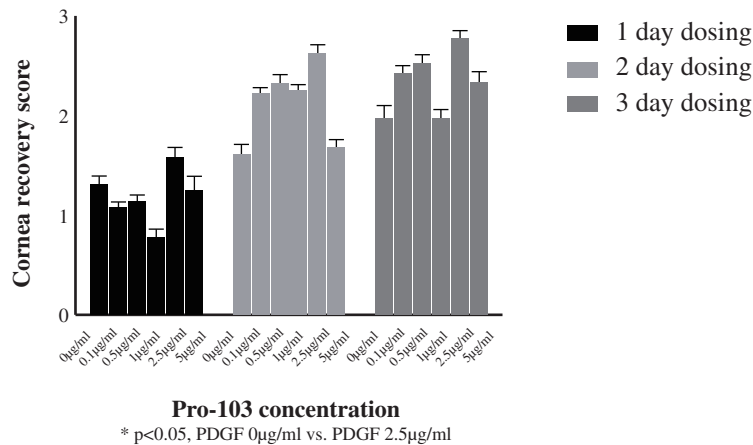
The corneas of dry eye rat models showed signs of damage, losing their smooth and intact appearance. Following the application of Pro-103, a measure of therapeutic enhancement was observed. Slit-lamp photography showed that the corneal surface of rats with dry eye syndrome was not smooth and was accompanied by neovascularization. Phenol red thread testing revealed that after the administration of Pro-103, symptoms of dry eye were alleviated to a certain extent, showing a degree of therapeutic improvement. The concentration of Pro-103 suitable for treating dry eye syndrome in rats has been identified as the group with 5 μ g/ml, which has a certain reparative effect.

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Pre-clinical Studies results of Pro-103 for the treatment of corneal injuries

We conducted a study to observe the effects of Pro-103 on the repair of corneal epithelial tissue damage by establishing rat and rabbit corneal alkali burn models. The models were also used to explore the dosage and timing of Pro-103 for the treatment of corneal alkali burns administration, aiming to select an appropriate formulation prescription. Our rat corneal damage experiment results indicate that timely treatment with Pro-103 for the treatment of corneal alkali burns after injury can effectively promote the repair of corneal damage. On Day 2 of treatment, 2.5µg/ml Pro-103 for the treatment of corneal alkali burns showed good therapeutic effects. The timing of Pro-103 for the treatment of corneal alkali burns administration and cessation is crucial for the repair effect; stopping Pro-103 for the treatment of corneal alkali burns after 3 days and observing on Day 10 showed significant repair. The rabbit corneal damage experiment results indicated that the best therapeutic effect was achieved when the PDGF concentration was 500-5,000ng/ml, with a designated prescription formula.

Statistical results of corneal alkali burn repair in rats using different concentrations of Pro-103



Source: Company data

Pre-clinical Studies results of Pro-101-3 for the treatment of radiation ulcers

We conducted a study to investigate the healing effect of Pro-101-3 for the treatment of radiation ulcers on radiation-induced skin ulcers in Wistar rats by establishing a radiation-induced skin ulcer model in Wistar rats through a single application of local X-ray irradiation to the dorsolateral skin of such rats. The SPF-grade male Wistar rats had their dorsolateral region shaved and then received a localized X-ray irradiation over a 3cm x 3cm area. The parameters of the irradiation included an absorbed dose rate of 350 cGy/min, a duration of 660 seconds, and a total

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dose of 38.5 Gy. After 22 days post-irradiation, rats that exhibited successful ulcer development were chosen and randomly assigned to groups, categorized by the size of the ulcerated skin area: the model control group, the positive control group and the test substance group. The positive control group was treated with 600 IU/cm² of a recombinant bovine basic fibroblast growth factor gel, the test substance group with 14 µg/cm² of Pro-101-3 for the treatment of radiation ulcers, and the model control group with a corresponding volume of inert gel matrix, for a continuous period of 24 days. Throughout the treatment phase, the rats’ overall health, body weight and the ulcerated area was assessed regularly.

During the study, animal fatalities occurred in the model control, positive control, and test substance groups. At the study’s conclusion, the survival rates from highest to lowest were as follows: test substance group (8 out of 10) > positive control group (7 out of 10) > model control group (5 out of 10). The trial demonstrated that the test substance Pro-101-3 for the treatment of radiation ulcers, administered at a daily total dose of 14 µg/cm² effectively mitigated inflammatory responses at the wound sites, reduced dermal necrosis, encouraged the growth of fibrous connective tissue, and improved the healing process of radiation-induced ulcerated skin. It also significantly lowered the mortality rate in the Wistar rat model for radiation-induced ulcers. Notably, the test substance group exhibited a considerably smaller average ulcer surface area on Day 18, 21, and 24 when compared to the model control group, achieving the smallest average ulcer size by Day 24, the final point of the study.

Statistical Data Table for Wound Surface Area (cm², Mean±SD)

No.	Group	Dose levels (mg/kg)	Pre	D2	D4	D7	D10	D14	D18	D21	D24
1	Model control group	—	3.78±0.89	3.52±0.77	2.62±0.90	2.66±0.90	1.69±0.62	1.28±0.58	1.14±0.56	1.05±0.64	0.69±0.55
2	Positive control group	600IU/cm ²	3.80±0.96	3.01±0.87	2.32±0.90	2.18±1.14	1.58±1.23	0.99±0.87	0.84±1.14	0.65±1.00	0.53±0.89
3	Test substance group	14µg/cm ²	3.80±0.94	2.97±0.74	2.40±0.71	2.14±0.65	1.34±0.65	0.95±0.55	0.52±0.45	0.32±0.37	0.29±0.29

Statistical Data Table for Wound Healing Rate (% , Mean±SD)

No.	Group	Dose levels (mg/kg)	D2	D4	D7	D10	D14	D18	D21	D24
1	Model control group	—	4.15±23.46	29.36±22.26	28.73±21.10	53.68±21.13	66.99±16.39	70.12±19.71	73.06±16.28	81.88±14.12
2	Positive control group	600IU/cm ²	19.89±14.33	38.51±16.60	44.69±19.84	63.36±22.82	79.54±17.51	81.26±22.16	85.92±19.59	88.51±17.54
3	Test substance group	14µg/cm ²	22.72±9.41	38.19±8.01	45.17±5.70	66.27±9.51	77.54±9.89	87.98±8.40	91.86±7.78	92.90±7.49

Source: Company data

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Pre-clinical Studies results of Pro-101-3 for the treatment of pressure ulcers

We conducted a study in Bama miniature Pigs to evaluate the efficacy of Pro-101-3 for the treatment of pressure ulcers by creating a Stage II pressure ulcer model. Following an acclimatization period, the selected Bama miniature pigs were subjected to the induction of Stage II pressure ulcers, with four wounds generated on each animal. Subsequently, the pigs were evenly and randomly allocated into four groups according to the scores of the ulcer locations and gender distribution, respectively, the untreated model control group (Group A), the group treated with a commercially available product (Group B), and two groups treated with Pro-101-3 for the treatment of pressure ulcers at low doses (Group C) and high doses (Group D) respectively. Groups C and D received $7\mu\text{g}/\text{cm}^2$ and $21\mu\text{g}/\text{cm}^2$ of Pro-101-3 for the treatment of pressure ulcers, respectively, corresponding to one and three times the clinical dose, respectively. In contrast, the group treated with the commercially available product received $300\text{IU}/\text{cm}^2$ of recombinant bovine basic fibroblast growth factor gel, which is equivalent to the standard clinical dose. Group A did not receive any medication and only underwent daily disinfection of the skin at the sites of the induced ulcers. From the second day post-ulcer induction, Groups B, C, and D had the respective test substances applied to the pigs, covering not only the ulcers but also extending 0.5cm beyond their edges. The treatment regimen was maintained for a continuous period of 21 days, during which various healing indicators were closely monitored.

During the study, no changes of toxicological relevance were observed in parameters including weight, rectal temperature, hematology and coagulation functions, biochemistry, or in the pathological examination of major organs (except for the area where the model was applied). Both Pro-101-3 for the treatment of pressure ulcers at the specified dosages and the recombinant bovine basic fibroblast growth factor gel significantly enhanced the healing rate of wounds in miniature pigs with Stage II pressure ulcers. Additionally, both Pro-101-3 for the treatment of pressure ulcers at the specified dosages and the recombinant bovine basic fibroblast growth factor gel markedly increased the expression of Ki-67 in the wound areas of the pressure ulcer model in miniature pigs, which is indicative of enhanced fibroblast proliferation at the wound sites. This suggests an improvement in the repair processes of wound damage in Stage II pressure ulcer models in miniature pigs, including the promotion of new blood vessel formation, proliferation of fibroblasts and fibrocytes, and the regeneration of collagen fibers. The extent of improvement in the wound area of the Stage II pressure ulcer model in miniature pigs was in the order of: Pro-101-3 for the treatment of pressure ulcers at 3 times the clinical dosage ($21\mu\text{g}/\text{cm}^2$) > the commercial control product recombinant bovine basic fibroblast growth factor gel at the clinical dosage ($300\text{IU}/\text{cm}^2$) > Pro-101-3 for the treatment of pressure ulcers at the clinical dosage ($7\mu\text{g}/\text{cm}^2$).

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Results of the wound healing rate for pressure ulcers in miniature pigs ($\bar{x} \pm S$)

Time	Healing rate (%)			
	Group A	Group B	Group C	Group D
Number of samples (n)	24	24	24	24
D8	38.61±8.47	45.34±6.79**	46.28±8.51**	44.14±9.15*
D15	46.58±4.89	52.63±6.43*	56.80±6.16**	52.08±5.31*
Number of samples (n)	12	12	12	12
D22	49.38±4.88	59.14±11.05*	57.82±11.19*	58.34±5.44**

Notes:

1. Group A, Group B, Group C, and Group D represent the model control group, the commercial control product group, and the Pro-101-3 for the treatment of pressure ulcers low- and high-dose groups, respectively.
2. “**” indicates P<0.05 compared with the model control group (Group A); “***” indicates P<0.01 compared with the model control group (Group A).

Source: Company data

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR PDGF CANDIDATES SUCCESSFULLY.

mRNA AND ASO

In addition to our PDGF candidates for several pre-clinical-stage indications, we are developing three pre-clinical candidates in our pipeline, namely an mRNA drug Mes-201 and two ASO drugs, Oli-101 and Oli-201. With the support of the nucleic acid pharmaceutical platform, we meticulously evaluate these candidates’ toxicity and pharmacological effects in a variety of pre-clinical studies using *in vitro* and *in vivo* laboratory testing techniques, and we actively explore their clinical development opportunities. As of the Latest Practicable Date, we were intensively researching the continuous optimization of PDGF in application, developing new PDGF formulations and expanding PDGF indications. At the same time, we were conducting pre-clinical biological, cytological and pharmacological researches on mRNA and ASO molecules.

We are developing Mes-201, an mRNA injection targeting solid tumors to determine their safety and efficacy in treating various types of solid tumors. mRNA products targeting tumors represent an innovative approach in the field of cancer therapy. These products are designed to harness the body’s own immune system to fight cancer by instructing cells to produce proteins that can trigger an immune response against tumor cells. The mRNA sequence encodes antigens that are specific to cancer cells, and once delivered into the body, these antigens are presented on the surface of cells, alerting the immune system to the presence of cancer and stimulating an attack on the tumor. mRNA tumor vaccines are personalized, as they can be tailored to the unique genetic makeup of an individual’s cancer, potentially increasing their effectiveness.

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According to the Frost & Sullivan report, mRNA injection is expected to become a new therapy with great potential for tumor immunotherapy in the future. The new case number of cancer in China is expected to increase from 5.1 million in 2023 to 6.2 million in 2032 over a CAGR of 2.3%. The oncology drug market in China is expected to increase from RMB303.0 billion in 2023 to RMB846.0 billion in 2032 over a CAGR of 12.1%.

The development of mRNA drugs involves multiple key technologies and optimisation processes, including the design, preparation, and delivery of mRNA. The mRNA structure is optimized for stability and efficient translation, with components such as the 5' cap, 5' and 3' UTRs, and the poly-A tail being crucial for protecting the mRNA and regulating its translation. The lipid nanoparticle (LNP) delivery system is a leading non-viral method for delivering genetic drugs, with low immunogenicity and high stability. Our nucleic acid pharmaceutical platform incorporates mRNA molecular design technology, which enables the enhancement of the stability and efficient expression of mRNA, allowing for the optimized combination to be applied to the development of various mRNA drugs. This technology has made innovations in the optimization of 3'-UTR, for which we have filed five invention patents in China in August 2022. Such technology helps to ensure that mRNA drugs achieve high levels of expression and reduce potential side effects. With the LNP delivery technology incorporated in the mRNA platform, we are designing and screening several ionizable lipids based on existing well-established LNP technology and expect to identify our proprietary molecule candidates. We possess a proprietary LNP formulation that boasts high delivery efficiency, for which we have filed a patent application in China. We have also been granted four patents in China for ionizable lipids. The technologies we grasp in the mRNA delivery system could significantly enhance the efficacy of mRNA-based therapeutics and injections, positioning our Company at the cutting edge of genetic medicine technology.

In addition to our work on mRNA, we have been conducting pre-clinical studies of ASO drugs, namely, Oli-101 and Oli-201, based on lncRNA technologies. lncRNAs are a diverse class of RNA molecules that have significant regulatory roles within the cells and can influence tumor behavior and patient outcomes. They can act as oncogenes or tumor suppressors, modulating cancer progression through various mechanisms, such as affecting gene expression, altering cell signaling pathways, and interacting with other molecular players within the cell. The role of lncRNA has been recognized as crucial in glioma pathogenesis, with their aberrant expression linked to tumor growth, metastasis, and therapy resistance, thereby correlating with adverse patient outcomes. The development of drug resistance and continuous recurrence are the main causes of mortality in patients with glioma. ASOs designed to target oncogenic lncRNAs present a therapeutic avenue in gliomas, aiming to inhibit tumor growth and progression by modulating the expression of these lncRNAs, disrupting the molecular pathways essential for tumor survival and proliferation. The ASO therapy market in China is expected to increase at a CAGR of 16.5% from RMB312.5 million in 2022 to RMB568.0 million in 2026, after which the growth is projected to reach RMB1,018.2 million by 2032 at a CAGR of 10.2% from 2026 to 2032.

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Our Oli-101 is designed for the treatment of brain glioma. Malignant gliomas represent the most frequently occurring primary brain tumors in the adult population. The incidence rate of these tumors differs among various demographics, typically falling within the range of 5 to 10 cases per 100,000 individuals annually. Prognostically, malignant gliomas are associated with relatively poor outcomes. Survival rates for these tumors can vary, influenced by factors such as the specific type of glioma, patient age, how extensively the tumor can be surgically removed, and the tumor’s molecular properties. Generally speaking, for glioblastoma, which is the most prevalent type of malignant glioma, the median overall survival rate is usually estimated to be between 12 and 15 months. According to the Frost & Sullivan report, the market size of glioma drugs and therapies for the treatment of glioma in China is expected to reach 1.9 billion in 2032. Our Oli-201 is designed for the treatment of TNBC. TNBC stands out as a particularly aggressive breast cancer subtype, characterized by its heterogeneity and intricate molecular pathways. This type of cancer is notorious for its high metastatic risk and presents significant challenges in patient management. According to the Frost & Sullivan report, the market size of TNBC drugs and therapies for the treatment TNBC in China is expected to reach RMB8.7 billion in 2032. There are currently no ASO drugs targeting lncRNA on the market, presenting us with a unique opportunity to pioneer this space and develop innovative treatments.

Specifically, we have been developing an innovative *in vivo* platform that identifies lncRNAs associated with drug resistance based on lncRNA technologies for the treatment of brain glioma and TNBC, which is also part of our layout in our development of the nucleic acid pharmaceutical platform. The analysis of lncRNA differences between resistant and sensitive cell strains through bioinformatics plays a pivotal role in the treatment of glioma. By utilizing advanced computational tools to scrutinize the vast array of genomic data, we can identify specific lncRNAs that are associated with resistance to chemotherapy. This platform allows for the development of targeted therapies that can overcome resistance mechanisms, thereby improving the efficacy of glioma treatments. Moreover, the identification of lncRNA signatures can also serve as biomarkers for predicting patient response to therapy, enabling personalized treatment plans that are tailored to the individual’s genetic profile, thus enhancing the chances of successful intervention and patient survival rates.

lncRNA plays critical roles in modulating epigenetic gene expression, cellular proliferation and apoptosis, as well as tumor invasiveness and the propensity for metastasis. Consequently, lncRNA-focused strategies hold potential for early diagnosis and therapeutic intervention, particularly in severe TNBC cases. The cell- and tissue-specific expression of lncRNA makes them valuable for the precise diagnosis, treatment planning, and ongoing monitoring of TNBC patients. Thus, identifying novel diagnostic and prognostic biomarkers within the realm of lncRNA is paramount.

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In our pre-clinical studies of the *in vivo* platform, the process for screening lncRNAs involved in glioma resistance begins by implanting glioma cell lines into immunodeficient mice, which are then allowed to develop tumors. Once tumor formation is confirmed, the mice are administered temozolomide (TMZ), a standard treatment for glioma. As resistance to TMZ develops, the process of inoculation and drug administration is repeated to enhance the selection of resistant cells. After three iterations, the resulting resistant cells undergo high-throughput sequencing to identify lncRNAs related to TMZ resistance. We then employ CRISPR activation (CRISPRa) and interference (CRISPRi) libraries to pinpoint lncRNAs that contribute to TMZ resistance in gliomas. For particular lncRNA candidates, ASOs are engineered based on the sequence and structure of lncRNA. Effects of these ASOs are then evaluated in patient-derived xenograft (PDX) models using human glioma tissues. We found one lncRNA is a potential target for overcoming TMZ resistance. ASOs targeting this lncRNA have demonstrated a substantial therapeutic effect, significantly shrinking the tumors. Furthermore, extensive administration of these ASOs in mice over a 30-day period has not resulted in any significant organ damage or immune response, indicating that the treatment may be both safe and efficacious.

Licenses, Rights and Obligations

We developed the mRNA and ASO products in-house and will have the global rights to develop and commercialize such technology.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET mRNA AND ASO PRODUCTS SUCCESSFULLY.

RESEARCH AND DEVELOPMENT

We focus on utilizing our systematic and well-integrated biomacromolecule therapeutic drug development platforms to develop innovative biopharmaceutical drugs for a wide variety of diseases, including thermal burns, DFUs, pressure ulcers, hemorrhoids, photodermatitis, radiation ulcers, fresh wounds, gastric ulcers, dry eye syndrome, corneal injury and alopecia. We believe research and development is critical to our future growth and our ability to remain competitive in the global biopharmaceutical market. We are dedicated to building an innovative product pipeline with a focus on PDGF- and RNA-based therapeutics by leveraging our in-house research and development capabilities, which span internal discovery, CMC, pre-clinical, and clinical development. We incurred research and development expenses of approximately RMB34.8 million and RMB39.9 million in 2022 and 2023 respectively accounting for 44.1% and 48.7%, respectively, of our total operating expenses in the same years. In 2022 and 2023, we incurred R&D costs for our Core Products of RMB26.8 million and RMB33.3 million, respectively, which accounted for 33.9% and 40.6%, respectively, of our operating expenses during the same periods.

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The increase in such expenses was primarily in line with the progress of the R&D of our Core Products. See “Financial Information — Description of Major Components of Our Results of Operations — Research and Development Expenses.”

Our Research and Development Platforms

With more than a decade of experience in research and application of biomolecular therapeutic technologies, we have established systematic and well-integrated biomolecular therapeutic drug development platforms, including a protein/peptide pharmaceutical platform and a nucleic acid pharmaceutical platform.

Protein/peptide pharmaceutical platform

The protein/peptide pharmaceutical platform is integral to the advancement of our product portfolio, particularly with the development of PDGF therapies. This platform’s capabilities in both prokaryotic and eukaryotic expression technologies have been instrumental in the creation and refinement of recombinant proteins and peptide drugs. Our PDGF candidates, especially our Core Products, have greatly benefited from the innovations and efficiencies provided by this platform. The protein/peptide pharmaceutical platform is also crucial for our future research and development of other proteins, peptides and polypeptides. The platform has the potential to support a greater variety of active proteins, peptides, and polypeptide molecules, and will involve further research into the molecular structure and function of protein/peptide drugs, including targeted mutagenesis, to achieve the desired functionality and activity.

The platform is set to underpin the research and development of an expanded range of biomolecules. With the potential to explore and produce a diverse array of active proteins, peptides, and polypeptides, the platform will also facilitate in-depth research into the molecular structure and function of these biomolecules. Through techniques such as targeted mutagenesis, we aim to fine-tune the functionality and activity of our protein/peptide drugs to meet specific therapeutic needs, thereby enhancing our competitive edge in the biopharmaceutical market. Especially, the support of the technologies embedded in the platform enables our exploring a variety of indications for PDGF across various pharmacodynamic models. Core technologies of the protein/peptide platform include:

- *Eukaryotic Expression Technology.* Our proprietary eukaryotic expression technology, predicated on the *Pichia pastoris* system, is crucial in ensuring the exemplary quality and yield of PDGF products. We are dedicated to continually refining this technology and have sought to secure its innovations through the application for two process

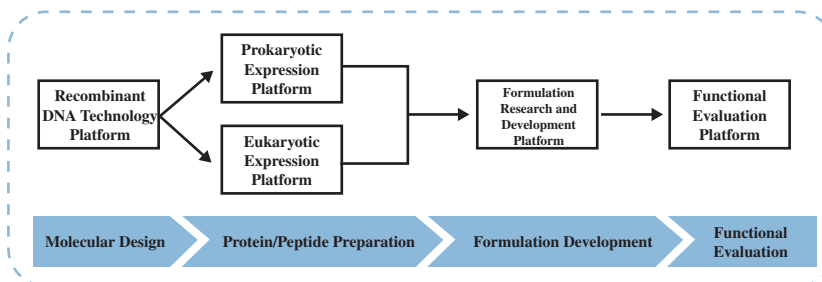
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invention patents filed in April 2023, one pertaining to fermentation and the other to purification processes. This suite of technology is poised to facilitate the robust commercialization strategy for our PDGF pipeline.

- *Prokaryotic Expression Technology.* Our prokaryotic expression technology, utilizing the *Escherichia coli* system, features straightforward culture conditions, expeditious growth and reproduction, commendable safety profile, cost-effectiveness, high efficiency and scalability. These attributes render it an ideal expression system for the production of recombinant proteins and peptides. We recently applied for a patent grounded in this technology in China, a recombinant protein drug for the prevention and treatment of influenza virus and its application, specifically for sialidase, which was authorized in February 2022. The deployment of this technology is anticipated to augment our protein/polypeptide therapeutic pipeline.
- *New Drug Formulation Development.* Our research and development endeavors encompass a diverse array of dosage forms, including but not limited to, gels, eye drops and sprays. We are also dedicated to researching various transdermal preparations and medical devices, such as soluble microneedles. We have obtained an invention patent for a pH-responsive gel in China since November 2021, and filed a PCT patent application for the same in March 2022. Additionally, we have applied for two invention patents for eye drops. This technology enables us to further diversify our pipeline candidate portfolio in response to different clinical needs in terms of dosage forms.
- *Recombinant DNA Technology.* Our expertise in recombinant DNA molecular cloning technology enables us to manipulate and recombine DNA sequences to create novel genetic constructs. We have applied for a patent related to a PDGF-B mutant in December 2023.

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The following flowchart illustrates the research and development processes of our protein/polypeptide pharmaceutical platform:



- **Molecular Design Phase:** This stage employs recombinant DNA technology to identify and construct the target protein/peptide, using bioinformatics for structure-function prediction and gene sequence optimization.
- **Protein/Peptide Preparation Phase:** This stage involves (i) the Prokaryotic Expression Platform, which focuses on maximizing expression in prokaryotic cells and refining purification and (ii) the Eukaryotic Expression Platform, which ensures proper folding and modifications in eukaryotic cells, with scale-up for testing needs.
- **Formulation Development Phase:** This stage develops stable, bioavailable formulations, selecting optimal components and conducting stability studies to determine shelf life.
- **Functional Evaluation Phase:** This stage assesses biological activity, efficacy and safety through assays and pre-clinical studies, informing refinements before clinical trials.

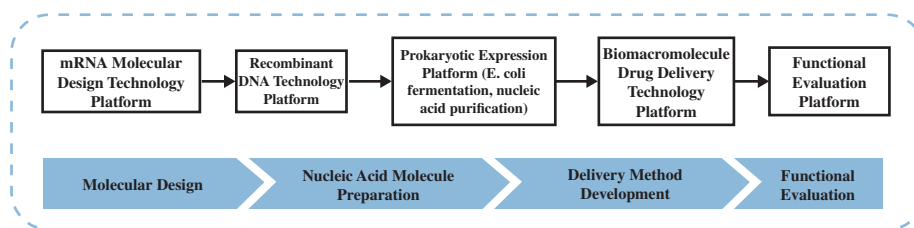
Nucleic acid pharmaceutical platform

Our nucleic acid pharmaceutical platform is underpinned by mRNA molecular design and LNP delivery technologies, ensuring that we remain at the forefront of the rapidly evolving field of genetic and RNA-based therapeutics. Our research includes developing RNA candidates for indications such as solid tumors, brain glioma and TNBC. We are currently conducting pre-clinical research of our RNA candidates, including mRNA injectables targeting tumor and injectables where the ASO is used to modulate the activity of a lncRNA implicated in glioma and TNBC. As of the Latest Practicable Date, we owned proprietary intellectual property rights to our mRNA candidates as a result of our in-house research and development efforts. Core technologies of the nucleic acid pharmaceutical platform include:

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- *mRNA Molecular Design Technology.* mRNA molecular design technology plays a critical role in the research and development of mRNA therapeutics. Advances in enzymatic capping, the design of the length and structure of 3’ and 5’ untranslated regions (“UTRs”), optimization of the Poly(A) tail length, codon optimization, and nucleotide modifications all contribute to enhancing the stability and efficient expression of mRNA. The combination of different modifications is crucial for the efficiency and stability of mRNA. Our platform technology allows for the optimized combination to be applied to the development of various mRNA drugs. This technology has made innovations in the optimization of 3’-UTR, for which we have filed five invention patents in August 2022. Such technology helps to ensure that mRNA drugs achieve high levels of expression and reduce potential side effects.
- *LNP Delivery Technology.* LNPs are among the most frequently used non-viral vectors for *in vivo* RNA delivery. We are designing and screening several ionizable lipids based on existing well-established LNP technology and expect to identify our proprietary molecule candidates. We screened multiple new cationic lipids and have been granted four invention patents in China in June 2023, and applied for a new LNP formulation invention patent in May 2022.

The following flowchart illustrates the research and development processes of our nucleic acid pharmaceutical platform:



- **mRNA Molecular Design Phase:** This stage focuses on the computational design and optimization of mRNA sequences for robust stability and efficient translation.
- **Nucleic Acid Molecule Preparation Phase:** This stage involves cloning the optimized gene into vectors and using prokaryotic systems like *E. coli* fermentation for plasmid DNA production and purification.
- **Delivery Method Development Phase:** This stage optimizes the formulation of delivery vectors, such as lipid nanoparticles for effective cellular uptake and reduced immunogenicity.

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- **Functional Evaluation Phase:** This stage assesses the therapeutic efficacy, specificity and safety of the nucleic acid-based treatment through rigorous pre-clinical testing.

Our Research and Development Team

Our research and development team is supervised by our General Manager, Dr. ZHAI Junhui. Dr. Zhai is a distinguished scientist in microbiology, molecular biology, virology and preventive medicine with around 30 years of experience in biomedical science research. He obtained his doctorate degree in preventive healthcare from AMMS and was a postdoctoral research scientist in microbiology at Columbia University School of Public Health (Infection and Immunity Center Laboratory).

Our research and development is led by our Chief R&D Officer, Dr. ZHAO Xinghui. Dr. Zhao is a distinguished scientist in biotechnology, genetics, and microbiology, specifically, majoring in protein-engineered drugs, pathogen infection mechanisms, tumor molecular markers and epigenetic regulation, and hematopoietic stem cell aging, with around 20 years of experience in biomedical science research.

Dr. Zhai is responsible for handling the research and development of our PDGF candidates and has over 20 years of research experience in such area. Dr. Zhao is responsible for handling the research and development for our PDGF and mRNA candidates and has years of research experience on such area. Dr. Zhai and Dr. Zhao are responsible for handling the research and development for our ASO candidates.

Our research and development team has four segments (namely, early detection, clinical development, regulatory affairs and quality assurance) and can be further divided into nine functional areas, including protein/nucleic acid molecule construction, functional evaluation, fermentation, purification, formulation, clinical trial, clinical registration, quality assurance and quality control, and each functional area is headed by experienced professionals. As of the Latest Practicable Date, our research and development department in China had eight members holding doctorate degrees and four members holding master's degrees. The following table sets forth a breakdown of our research and development team by function as of the Latest Practicable Date:

	Number of employees by function as of the Latest Practicable Date
Early Detection	13
Clinical Development	5
Regulatory Affairs	8
Quality Assurance	7
Total	33

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Our pre-clinical research staff are primarily responsible for designing, planning and conducting our research experiments, as well as managing and overseeing our CROs, CDMOs, CMOs and research and medical institutions, with respect to the development of our delivery platforms and our product candidates that utilize our delivery platforms. Our clinical research staff are primarily responsible for regulatory filings, planning of clinical trials and protocols and the management and oversight of the relevant CROs and research and medical institutions. Our manufacturing staff are primarily responsible for optimizing manufacturing of our delivery platforms, quality assurance and quality control management, manufacturing process development for our delivery platforms and product candidates and the management and oversight of CDMOs and CMOs. During the Track Record Period and as of the Latest Practicable Date, all key R&D personnel involved in the development of our Core Products remained employed. As we continually provide various internal and external training opportunities for our research and development personnel, and plan to support our business development and overseas expansion strategies by continually recruit new and retain existing talents with outstanding backgrounds and rich experience in the relevant fields, we believe the departure of our key R&D employees will not have material impact on our R&D of Core Products.

Currently, our primary research laboratory is located in Fengtai District in Beijing. Our facilities in Fengtai District consist of laboratory facilities and office space with GFA of approximately 1,781 square meters. Our laboratory facilities include cell and tissue culture laboratory, liquid chromatography laboratory, molecular biology laboratory, physical and chemical testing laboratory, fermentation laboratory and sample preparation laboratory. To ensure the efficient and scientific utilization of our equipment and the success of our research and development, each laboratory facility is equipped with well-trained professionals and technicians. Our laboratory facilities have over 100 pieces of imported and domestic instruments and equipment for molecular biology, cytology, fermentation, formulation and physicochemical testing.

Engagement of Third Parties in Research and Development

We engage reputable CROs, CDMOs, CMOs and research and medical institutions to manage and support our pre-clinical studies and clinical trials. In particular, CROs provide us with an array of products and services necessary for pre-clinical experimentation and complex clinical trials. We select CROs by reviewing various factors, including their professional qualifications, research experience and industry reputation. We have selected CROs that have experience serving large international pharmaceutical companies. In order to protect the integrity and authenticity of the data from our trials and studies, we closely supervise our CROs to ensure that they perform their obligations in a manner that complies with our protocols and applicable laws.

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Our pre-clinical CROs mainly provide us with services related to pre-clinical toxicity and safety evaluations and efficacy testing, such as animal studies, of our candidates. Our clinical CROs assist us in the implementation and management of clinical trials, including submission of ethical documents, data management, and statistical analysis for clinical trials. We will make payments after fulfillment of certain milestones under the relevant agreements. Key terms of an agreement we typically enter into with our CROs are summarized as below:

- *Services.* The CRO provides us with services related to a pre-clinical or clinical research project as specified in the agreement or a work order.
- *Term.* The CRO is required to complete the pre-clinical or clinical research project within the prescribed time limit.
- *Payments.* We are required to make payments to the CRO in accordance with the payment schedule agreed by the parties.
- *Intellectual property rights.* We own all intellectual property rights arising from the pre-clinical or clinical research project.

Our CDMOs are responsible for manufacturing candidates for pre-clinical and clinical studies and provide manufacturing process development and optimization services.

Our CMOs are responsible for manufacturing candidates for pre-clinical studies and clinical trials.

Research and medical institutions engaged by us generally include academic and other research institutions that conduct pre-clinical studies for us. During the Track Record Period, we also engaged a medical institution that provides clinical trial facilities and related services.

We are the owner of our candidates and the sponsor of the relevant clinical development activities. The CROs, CDMOs, CMOs and research and medical institutions engaged by us do not have any rights to our candidates. We are in charge of the full lifecycle management of the candidate including research and development, manufacturing and future commercialization. We make key decisions regarding the overall development direction, clinical trial plans and procedures and provide funding for the trials and studies.

The involvement and roles of third-party service providers in the development of novel molecule candidates are typically standardized and similar among different projects. The work scope of these third parties in the development of our candidates may vary slightly, subject to our overall management and instructions.

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The following table sets forth the number of independent CROs, CDMOs, CMOs and research and medical institutions we engaged during the Track Record Period:

	As of December 31,	
	2022	2023
CRO	6	3
CDMO	—	1
CMO.....	2	2
Research and medical institutions	1	—
Total	9	6

The following table sets forth the total fees incurred by us with respect to all CROs, CDMOs, CMOs and research and medical institutions for the Track Record Period:

	Year ended December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
CRO	4,806	8,612
CDMO	—	2,487
CMO.....	2,889	4,001
Research and medical institutions	109	—
Total	7,804	15,100

During the Track Record Period, our expenses attributable to CROs, CDMOs, CMOs and research and medical institutions have increased, reflecting our R&D progress and advancement.

The following table sets forth the identities and background of CROs, CDMOs and CMOs engaged by us wherein aggregate expenses incurred exceeded RMB1 million during the Track Record Period. The amount of expenses incurred to research and medical institutions did not exceed RMB1 million in aggregate for any one institution during the Track Record Period.

	Name/Background	Expenses incurred by us during the Track Record Period
		<i>(RMB in thousands)</i>
CRO	A Tianjin-based clinical research services company	7,933.6
	A Suzhou-based clinical research services company	3,439.1
	A Tianjin-based clinical research services company	1,287.7

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	Name/Background	Expenses incurred by us
		during the Track Record Period
		<i>(RMB in thousands)</i>
CDMO.	A Changchun-based development and manufacturing services company	2,487.0
CMO.	A Shijiazhuang-based manufacturing services company	1,441.4
	A Shijiazhuang-based manufacturing services company	5,448.1

To the knowledge of our Directors, other than the ordinary business relationship, none of the CROs, CDMOs and CMOs, nor any research and medical institution engaged by us (including their directors, shareholders and senior management), had any past or present relationships (including, without limitation, business, employment, family, trust, financing or otherwise) with our Group, our shareholders, Directors, senior management or any of their respective associates during the Track Record Period.

COLLABORATION, LICENSING AND TRANSFER ARRANGEMENTS

Collaboration with the Institute of Bioengineering of AMMS and JinBang

In August 2013, the Institute of Bioengineering of AMMS, JinBang and we entered into a statement of amendment to contract implementation entity, under which the parties agreed that the implementation entity of a project formerly between the Institute of Bioengineering of AMMS and JinBang to research on PDGF in DFUs (which later became Pro-101-2) (the “**Project**”) would be changed to the Institute of Bioengineering of AMMS and us, and the Institute of Bioengineering of AMMS and us should jointly complete the follow-up work for the Project. In January 2019, the Institute of Bioengineering of AMMS and we entered into a supplemental agreement for the Project, and on October 8, 2023, the Institute of Bioengineering of AMMS issued a written confirmation to us with respect to the Project. Pursuant to such supplemental agreement and confirmation, the parties agreed that:

- (i) The main pre-clinical studies of the Project have been completed and the Project is eligible for application for clinical studies.
- (ii) The Institute of Bioengineering of AMMS will transfer the technological achievements of the Project to us, and we will be responsible for the subsequent clinical studies and the NDA application for Pro-101-2 after obtaining the IND approval for the same from the NMPA. In particular, the Institute of Bioengineering of AMMS acknowledged that the rights to own, commercialize and use such patents belong exclusively to the Company.

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- (iii) After obtaining the NDA approval, we will be responsible for the manufacturing and marketing of Pro-101-2, and the Institute of Bioengineering of AMMS will not participate in the commercialization of the same.
- (iv) We would pay a fixed technology transfer fee to the Institute of Bioengineering of AMMS upon receipt of the IND approval for Pro-101-2.
- (v) We will pay an annual transfer fee to the Institute of Bioengineering of AMMS at a fixed single-digit percentage of the annual sales of Pro-101-2 after we launch the same.
- (vi) We are not allowed to transfer or license the Project to any third party without the written consent of the Institute of Bioengineering of AMMS.
- (vii) Should any dispute arise, both parties shall settle it through mutual consultation, or alternatively, initiate legal proceedings before a court of competent jurisdiction.

In June 2020, JinBang and we entered into a supplementary agreement to amend the terms of a technology transfer contract signed between JinBang and us in 2013, given that JinBang intended to enter the process of deregistration and thus could not continue to perform its obligations under the technology transfer contract. Under the amended terms, the parties agreed on a new fixed technology transfer fee. Both the technology transfer fee to the Institute of Bioengineering of AMMS and that to JinBang have been settled.

In October 2020, we, together with AMMS, submitted application materials of Pro-101-2 for a pre-IND meeting with the CDE to discuss the sufficiency of pharmacological and toxicological studies, the dosage design and the necessity of immunogenicity testing of the Phase I clinical trial design of Pro-101-2. In April 2021, we and AMMS jointly submitted the IND application for Pro-101-2 to the CDE, and received the IND approval in July 2021.

Subject to the supplemental agreement for the Project between the Institute of Bioengineering of AMMS and us, the Institute of Bioengineering of AMMS has transferred the technological advancements from the Project to us. Following the issuance of the IND approval, the Institute of Bioengineering of AMMS ceased participation in any further clinical trials or research and development activities of ours. We will hold exclusive ownership and full rights to any new patents we create, develop and register that are based on these technological advancements, as well as to any new patents we file independently after the expiration of the patents acquired from the Project. We are not required to seek any form of consent, confirmation, or authorization from the Institute of Bioengineering of AMMS when applying for new patents.

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INTELLECTUAL PROPERTY RIGHTS

Intellectual property rights are critical to our research and development activities and our business. Our success depends in part on our ability to obtain and maintain proprietary intellectual property protection for our candidates, discoveries, product development technologies, inventions, improvements and know-how. Our success also depends in part on our ability to defend and enforce our patents including any patent that we have or may issue from our patent applications, preserve the confidentiality of our trade secrets and other confidential or proprietary information, and operate without infringing, misappropriating or otherwise violating intellectual property rights of other parties.

We have a comprehensive portfolio of patents to protect our candidates and technologies. As of the Latest Practicable Date, we owned 13 issued patents and 19 pending patent applications. Our issued patents and any patents to be issued from our pending patent applications are scheduled to expire on various dates from July 2024 through January 2044 without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees. Further details on certain segments of our patent portfolio are included below.

PDGF

With regard to our PDGF candidates, as of the Latest Practicable Date, we owned 3 issued patents and filed 12 patent applications in China. The expected expirations for the issued patents and any patents that may issue from the pending patent application range from July 2024 to January 2044, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

In particular, as of the Latest Practicable Date, with respect to our Core Products, we had one issued patent, which is expected to expire in July 2024, and we had filed seven patent applications, currently under review. We do not rely on our soon-to-be expired patents for the further research and development of our PDGF candidates. According to the Frost & Sullivan report, we are the most advanced biopharmaceutical company in terms of the number of PDGF-related technologies and patents in China. Such patent matrix brings challenges to new market entrants and potential competitors that are in clinical development of PDGF drugs. Additionally, to protect our existing patent advantages, we have implemented a number of measures such as making patent applications as to our Core Products in unpatented indications and techniques and filing PCT applications. We may rely on such pending patent applications that we have filed in respect of our new advances and developments to our PDGF candidates in our future research and development. In light of the scope of coverage by and the number of our existing issued patents and pending patent applications, as well as high technological barriers in producing biologic drugs, as advised by our PRC Legal Advisor, before the review of our patent applications concludes, generic drug

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manufacturers are faced with potential patent infringement risks. In addition, we will continue to have the right to develop our candidates, including our Core Products, and use the technology covered by our soon-to-be expired patents, while leveraging a combination of our own patents and patent applications and other intellectual property protection laws, including trade secrets and fair trade practice. As a result, we expect that the expiration of such patents will have no material adverse impact on our business operations, finance performance and prospects going forward. For details on the relevant risks, see “Risk Factors — Risks Relating to Our Intellectual Property Rights — Even if we are able to obtain patent protection for our candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and it would have a material adverse effect on our ability to successfully commercialize any product or technology.”

RNA

mRNA

With regard to Mes-201, as of the Latest Practicable Date, we owned 4 issued patents and filed 6 patent applications in China. The expected expirations for the issued patents and any patents that may issue from the pending patent application range from May 2042 to November 2042, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

ASO

As of the Latest Practicable Date, we did not own any patents regarding Oli-101 or Oli-201.

The following table summarizes the details of the material invention patents owned by us on our Core Products and certain pre-clinical product candidates:

Subject Area	Title	Jurisdiction	Status	Date of Grant	Date of Expiration ⁽¹⁾	Commercial Rights	Patentee
PDGF	A recombinant human platelet-derived growth factor and its encoding gene and expression method*	China	Granted	June 24, 2009	July 14, 2024	Proprietary rights	The Institute of Bioengineering of AMMS and the Company ⁽²⁾

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Subject Area	Title	Jurisdiction	Status	Date of Grant	Date of Expiration ⁽¹⁾	Commercial	
						Rights	Patentee
PDGF	A recombinant human platelet-derived growth factor gel	China	Granted	December 26, 2007	November 28, 2025	Proprietary rights	The Institute of Bioengineering of AMMS and the Company ⁽²⁾
PDGF	pH-responsive hydrogel biocarrier and application thereof	China	Granted	May 20, 2022	November 2, 2041	Proprietary rights	The Company
mRNA.	Ionizable cationic lipid C6-A1 and nanoliposome particles composed of it	China	Granted	June 16, 2023	November 2, 2042	Proprietary rights	The Company
mRNA.	Ionizable cationic lipid C6 and the nanoliposome particles composed thereof	China	Granted	June 16, 2023	November 2, 2042	Proprietary rights	The Company
mRNA.	Ionizable cationic lipid C5 and nanoliposome particles composed of it	China	Granted	June 20, 2023	October 31, 2042	Proprietary rights	The Company
mRNA.	Ionizable cationic lipid C5-A2 and nanoliposome particles composed of it	China	Granted	June 20, 2023	November 3, 2042	Proprietary rights	The Company
Research and Development Platforms	Extract with auxiliary hypoglycaemic and hypolipidemic and preparation method thereof	China	Granted	April 13, 2018	December 9, 2034	Proprietary rights	The Company
Research and Development Platforms	A recombinant protein drug for the prevention and treatment of influenza virus and its application	China	Granted	February 11, 2022	November 4, 2041	Proprietary rights	The Company
Others	Genes of the novel coronavirus B.1.351 South African mutant strain RBD and its application	China	Granted	August 13, 2021	May 17, 2041	Proprietary rights	The Company

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Subject Area	Title	Jurisdiction	Status	Date of Grant	Date of Expiration ⁽¹⁾	Commercial	
						Rights	Patentee
Others	Genes of the British mutant strain RBD of the novel coronavirus B.1.1.7 and its application	China	Granted	September 7, 2021	May 30, 2041	Proprietary rights	The Company
Others	Genes of the novel coronavirus B.1.525 Nigerian mutant strain RBD and its application	China	Granted	September 7, 2021	June 3, 2041	Proprietary rights	The Company
Others	Genes of the Brazilian variant of the novel coronavirus P.1 mutant strain RBD and its application	China	Granted	October 15, 2021	June 10, 2041	Proprietary rights	The Company

Notes:

* Patent related to our Core Products

1. Patent expiration date is estimated based on current filing status, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.
2. The Institute of Bioengineering of AMMS has ceased participation in any further clinical trials or research and development activities of ours. Despite that both the Company and the Institute of Bioengineering of AMMS are holders of the two PDGF-related patents, according to its written confirmation dated October 8, 2023, the Institute of Bioengineering of AMMS acknowledged that the rights to own, commercialize and use such patents belong exclusively to the Company. We will hold exclusive ownership and full rights to any new patents we create, develop and register that are based on such technological advancements, as well as to any new patents we file independently after the expiration of the patents acquired from the Project. We are not required to seek any form of consent, confirmation, or authorization from the Institute of Bioengineering of AMMS when applying for new patents. See “— Collaboration, Licensing and Transfer Agreements — Collaboration with the Institute of Bioengineering of AMMS and JinBang.”

The following table summarizes the details of the material invention patent applications and PCT applications filed by us in connection with our clinical stage product candidates and certain pre-clinical product candidates:

Subject Area	Title	Jurisdiction	Status	Date of Application	Commercial Rights	Applicant
PDGF	pH-responsive hydrogel biocarrier and application thereof	PCT	Pending	March 7, 2022	Proprietary rights	the Company
PDGF	Application of PDGF gel in the preparation of full-thickness skin defect wound injury treatment drugs*	China	Pending	March 23, 2022	Proprietary rights	the Company

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Subject Area	Title	Jurisdiction	Status	Date of Application	Commercial Rights	Applicant
PDGF	Application of PDGF gel in the preparation of drugs for the treatment of burns*	China	Pending	March 23, 2022	Proprietary rights	the Company
PDGF	Application of PDGF gel in the preparation of drugs for the treatment of radioactive ulcers*	China	Pending	April 4, 2022	Proprietary rights	the Company
PDGF	Application of PDGF gel in the preparation of drugs for the treatment of pressure ulcers*	China	Pending	April 4, 2022	Proprietary rights	the Company
PDGF	Platelet-derived growth factor is used in the preparation of burn drugs*	PCT	Pending	June 23, 2022	Proprietary rights	the Company
PDGF	An efficient purification method for recombinant human platelet-derived growth factor BB*	China	Pending	April 29, 2023	Proprietary rights	the Company
PDGF	A high-density fermentation method for Pichia pastoris to produce PDGF-BB*	China	Pending	April 30, 2023	Proprietary rights	the Company
PDGF	Recombinant human platelet-derived growth factor eye drops	China	Pending	November 28, 2023	Proprietary rights	the Company
PDGF	Detection method for carboxymethylcellulose sodium gel pharmaceutical preparations	China	Pending	December 14, 2023	Proprietary rights	the Company
PDGF	A platelet-derived growth factor B mutant and its application	China	Pending	December 28, 2023	Proprietary rights	the Company
PDGF	Platelet-derived growth factor mutant eye drops	China	Pending	January 10, 2024	Proprietary rights	the Company
mRNA	Nanoliposome particle delivery vehicle containing polylactic acid-glycolic acid copolymer	China	Pending	May 24, 2022	Proprietary rights	the Company
mRNA	A 3' UTR derived from TM SB10 to enhance mRNA expression and its application	China	Pending	August 12, 2022	Proprietary rights	the Company

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Subject Area	Title	Jurisdiction	Status	Date of Application	Commercial Rights	Applicant
mRNA	A 3' UTR derived from AGBL5 to enhance mRNA expression and its application	China	Pending	August 12, 2022	Proprietary rights	the Company
mRNA	A 3' UTR for enhanced mRNA expression from human sources and its applications	China	Pending	August 12, 2022	Proprietary rights	the Company
mRNA	A 3' UTR derived from cytochrome C oxidase family genes and its application	China	Pending	August 12, 2022	Proprietary rights	the Company
mRNA	A 3' UTR for enhancing mRNA expression and its application	China	Pending	August 12, 2022	Proprietary rights	the Company
Research and Development Platforms	Polyionic composite nanomaterial polypeptide carrier and preparation method thereof	China	Pending	July 15, 2021	Proprietary rights	the Company

Note:

* Patent applications related to our Core Products

In addition to our patents and patent applications, we place emphasis on trade secrets, confidential information, know-how, unpatented technology and other proprietary information to protect aspects of our technology. We seek to protect our trade secrets and other proprietary or confidential technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors. We have entered into confidentiality agreements and non-competition agreements with our senior management and key members of our research and development team and other employees who have access to our trade secrets and other proprietary or confidential information relating to our business. However, these agreements may not provide sufficient protection of our trade secrets and other proprietary or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secrets and other proprietary or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and other proprietary or confidential information may become known or be independently developed by a third party or misused by any collaborator or other third party to whom we disclose such information. Despite any measures taken to protect our trade secrets, confidential or proprietary information and other 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.

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We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises 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. See “Risk Factors — Risks Relating to Our Business — Risk Relating to Our Intellectual Property Rights.”

As of the Latest Practicable Date, we had registered 29 trademarks, including 27 in Mainland China and 2 in Hong Kong, and had 2 trademark applications pending review, including 1 in Mainland China and 1 in Hong Kong. As of the same date, we owned 12 computer software copyrights in Mainland China. We are also the registered owner of 2 domain names. We do not currently own any issued trademark registrations of “B&K,” “B&K Corporation,” “華芒” or “華芒生物” in Mainland China. To enhance the protection over our brands, we have filed trademark applications in Mainland China and Hong Kong with respect to “B&K,” which were under review as of the Latest Practicable Date. See “Risk Factors — Risks Relating to Our Business — If our trademarks and trade names are not adequately protected, we may not be able to build brand recognition in our markets of interest which may have an adverse effect on our business.” We have entered into collaboration agreements and other relationships with pharmaceutical companies and other industry participants to leverage our intellectual property and gain access to the intellectual property of others. See “— Collaboration, Licensing and Transfer Arrangements.”

As of the Latest Practicable Date, our Directors confirm that we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringements of, any third-party intellectual property that are threatened or pending. See “Appendix IV — Statutory and General Information.”

PROCUREMENT

We procure raw materials and equipment, as well as technical and other services, needed for the operation of our business from qualified suppliers. The main raw materials that we procure for our pre-clinical studies and clinical trials primarily include yeast extract, peptone, double-distilled water and glucose (dextrose). During the Track Record Period and up to the Latest Practicable Date, the raw materials of our candidates, as well as of the placebo and other experimental products for clinical trials were primarily supplied by third-party CMOs.

In addition, we procure equipment for the development and manufacturing of our product candidates from reputable manufacturers and suppliers. We also procure technical services, such as CRO services and consulting services that support our clinical trials and pre-clinical studies. See “— Research and Development — Engagement of Third Parties in Research and Development.”

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We engage experienced and qualified third parties such as CROs, CDMOs and consultants to support our research and clinical trials. We conduct regular review on qualified suppliers and suppliers that fail to pass such review will be removed from the list of qualified suppliers. We select our suppliers by considering their qualifications, compliance with relevant regulations and industry standards, quality, prices, business scale, market share, reputation and after-sales service quality. We supervise and monitor these third-party service providers closely to ensure their compliance with our quality control procedures and applicable laws and the integrity of the data resulting from our trials and studies. See “— Suppliers.”

MANUFACTURING AND QUALITY CONTROL

Chemistry, Manufacturing and Control (“CMC”)

Since our inception, we have established an internal CMC team which primarily function in:

- (i) ***analytical method development*** — our analytical method development team implements a science-driven, phase-appropriate and commercial oriented approach to the development and application of both classic and state-of-the-art analytical techniques and tools throughout the development life cycle of each of our product candidates, including but not limited to development and validation of analytical methods for drug substance and drug product, technical transfer of process and analytical methods, establishment of specifications, and testing and releasing of each batch of drug product; and
- (ii) ***quality assurance and control*** — with well-documented and comprehensive quality system, our quality assurance and quality control team is responsible for testing and verifying the product quality with predefined standards to assure the quality of all batches of the drug substance and drug products manufactured at every manufacturing/processing stage.

We currently work with qualified CMOs and CDMOs to manufacture product candidates for pre-clinical and clinical supply. We also cooperate with CDMOs in the refinement of product candidates. We have adopted procedures to ensure that the production qualifications, facilities and processes of our CMOs and CDMOs comply with the relevant regulatory requirements and our internal guidelines. We select our CMOs and CDMOs by reviewing a number of factors, including their qualifications, research and development capabilities, relevant expertise, production capacity and product quality. As of the Latest Practicable Date, we had not experienced any difficulties in engaging our CMOs and CDMOs. As we maintain good relationships with our CMOs and CDMOs and there are adequate alternative sources for CMOs and CDMOs, we do not foresee any difficulties in engaging qualified CMOs and CDMOs in the future, should the need arise. To

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monitor and evaluate service performed by our CMOs and CDMOs, we set a series of pre-defined specifications on in-process control and release tests, and review manufacturing related documents including batch records and quality control test results to ensure specifications are met.

Our Planned Manufacturing Capacities

As of the Latest Practicable Date, we were exploring effective strategies to initiate the large-scale production of our product candidates upon commercialization. Options under consideration include leasing production facilities, constructing our own manufacturing sites, and collaborating with CMOs to ensure GMP-compliant production of such candidates, including the fermentation, crude extraction and purification of bulk solutions, as well as formulation, filling and packaging of dosages. We will ascertain in due course the most appropriate option for the Company in light of subsequent developments and the interests of the Shareholders. To ensure a reliable supply of our products and to accommodate potential growth in business demand, we may consider implementing a hybrid manufacturing model, which would integrate our internal manufacturing capabilities with those of CMOs. In addition, we expect such approach to support our clinical trials in China, and potentially to support our clinical trials globally in the future. The facilities are expected to be equipped with systems and equipment from leading, highly reputable manufacturers and suppliers of the industry.

Our manufacturing team will consist of three departments in the future, including a manufacturing technology department, an engineering equipment department and a quality assurance and quality control department.

Based on the current progress of the Phase IIa clinical trial of Pro-101-1 and Phase II clinical trial of Pro-101-2, we expect that the Phase III clinical trial of Pro-101-1 will be completed in the fourth quarter of 2026, and the Phase III clinical trial of Pro-101-2 will be completed in the second quarter of 2029. We plan to launch Pro-101-1 in 2027 and launch Pro-101-2 in 2030. We expect that our manufacturing capacities will match our production demand.

Our Quality Assurance and Quality Control Team

The manufacturing process of biopharmaceutical products is subject to extensive regulations that impose various procedural and documentation requirements governing record keeping, manufacturing process and controls, personnel, quality assurance, quality control and others matters. See “Regulatory Overview.”

Our quality assurance and quality control team is responsible for testing and verifying the product quality with predefined standards to assure the quality of all batches of drug substance and drug products manufactured at every manufacturing/processing stage. Our quality assurance and quality control team coordinates with our production team to oversee and manage the quality of

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our facilities and our products in our manufacturing process. Our production team designs the production plan based on clinical development plan, procures materials according to the production plan, and issues production directives to the production lines. We implement strict procedures for the receiving and releasing of the raw materials used in the production process, intermediate products, bulk solutions, and products in strict compliance with the GMP requirements. Our quality assurance and quality control team, which consisted of seven employees as of the Latest Practicable Date, inspect raw materials, intermediate products, raw liquids and products, and decides whether to release the above samples. Such procedures help us ensure that substandard intermediate products and raw liquids do not enter the next process and deficient products are not released for use out of the factory.

We will periodically review the quality of our drugs after they have been launched in order to assess the effectiveness of current controls measures and to continuously improve the quality of our drugs. We keep the risk information of our drugs updated, and adopt appropriate risk management tools and risk minimization measures to ensure that the benefits of our drugs continuously outweigh the risks. We proactively conduct studies of post-marketing drugs, including the collection of data and information from the full lifecycle of a drug to assess potential risks and further ensure the safety, efficacy and quality controllability of post-marketing drugs. We strengthen risk prevention and control measures throughout the drug's life cycle, including risk management in stages of registration, manufacturing, storage and transportation, use and regulation, to achieve effective risk control throughout the drug's life cycle and to ensure the sustainable and stable production of drugs that meet the intended use and registration requirements.

To prevent the risk of excessive methanol content that may arise from the adoption of the *Pichia pastoris* expression technology, during the late stage of yeast fermentation, we control the consumption of all methanol by detecting the changes of dissolved oxygen levels before proceeding to purification stage. At the purification stage, the properties of methanol and the target product are different from each other and can be easily separated, which, together with a large amount of buffer rinsing, ensures that the methanol content in the stock solution is almost non-existent. At the quality control stage, we further monitor the methanol content in the stock solution by gas chromatography to confirm that it complies with the quality standard.

We implement quality management for the full life cycle of our products. With the construction of our manufacturing facilities, we will improve our internal quality control measures and pharmaceutical quality assurance measures in time in the near future, including manufacturing process quality assurance system, public engineering control system, equipment control system, material control system, standard operating procedures for quality management of manufacturing process, quality testing system, document management system, verification control system, user feedback management system. We also have standard process procedures in place to ensure that the drugs meet the process requirements for registration.

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COMMERCIALIZATION

Our Marketing Strategy

We believe that the scale and effectiveness of our commercial operation will be crucial to our business. We plan to launch Pro-101-1 in 2027 and launch Pro-101-2 in 2030. We intend to persistently augment our manufacturing capacities to align with market demands and to realize economies of scale, thereby diminishing production expenditures. See “— Manufacturing and Quality Control — Our Planned Manufacturing Capabilities”.

We will employ a strategic marketing model to increase our market penetration, to promote our products and to achieve geographical and channel coverage. We plan to conduct marketing activities in China first, and as our operations mature, we intend to expand our marketing activities overseas. We expect to facilitate academic engagement and education around our products by establishing relationships with KOLs, hospitals, and renowned doctors through clinical trials, R&D collaboration, and academic conferences. We also intend to enter into strategic partnerships with medical companies with advantageous sales and marketing networks. In addition, we plan to seek cooperations with retail e-commerce platforms as part of our marketing channels.

In addition, our strategy includes a phased approach to entering all levels of markets, aiming for comprehensive national reach over the medium term. Initially, our efforts will be directed towards the top hospitals in top and second tier provinces that possess a significant patient population. As we progress into tier three and four provinces, our commitment to enhancing our local presence and market penetration will persist. We aim to fortify our connections with pivotal stakeholders in each province to promote diagnosis and treatment, as well as to facilitate negotiations for reimbursement inclusion in the national medical insurance reimbursement catalog. Through these measures, we believe we will expand the market share of our PDGF candidates in China.

Along with the clinical development of our pipeline products, we will schedule the recruitment, training and evaluation of our sales and marketing team in accordance with the clinical development progress of our pipeline products, aiming to ensure the timely commercialization of our pipeline products once we obtain relevant approvals. We plan to build up our sales and marketing team by recruiting professionals with extensive industry knowledge and biopharmaceutical marketing skills to engage in the academic promotion, marketing, commercialization and channel management of our pipeline products. Our sales and marketing team will consist of medical directors and medical science liaisons who would be responsible for medical education, medical conference management and investigator-initiated study support, which facilitates the advocacy of our product candidates. Team members shall also be responsible for

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exploring collaboration patterns and promoting collaboration with strategic partners, as well as the academic promotion of our products to hospitals and doctors, which helps expand our distribution channels to commercialize our products.

We aim to gain market coverage by leveraging our current and future business partners’ expertise and business network. Our strategy and business development team explores global and local cooperation opportunities with other industry players. These opportunities may include co-development, in-licensing and out-licensing arrangements. Further, we intend to seek partners by setting comprehensive selection criteria, primarily including commercialization teams with extensive biopharmaceutical industry backgrounds, superior track record in commercialization partnership, and recognition of our vision and commitment to our pipeline products. We will also evaluate partnership options to maximize market potential of our products.

Pricing

As of the Latest Practicable Date, our Core Products were still in the clinical trial phase and had not been commercialized. As such, we have not established any definitive pricing policy for our Core Products. As our Core Products progress towards potential approval and commercialization in the future, either we or a partner will determine pricing by evaluating multiple factors, including the clinical attributes of our Core Products and the existing market prices of other comparable drugs. We or a partner may conduct extensive market research involving KOLs, hospitals, physicians and patients as well as regulatory authorities before pricing our Core Products and may take into account various factors such as insights gathered from these parties, our production costs, the comparative safety and efficacy of our Core Products against its competing products, the estimated demand for our Core Products and the clinical value to patients. For pricing in China, we or a partner may determine pricing based on the affordability for local patients and the price of comparable products. The pricing in overseas markets may be adjusted to reflect the unique market conditions of each region, which includes the pricing strategies of multinational competitors. With expectations of higher drug pricing and market demand, we anticipate the revenue from sales of our Core Products to be substantially higher than its associated R&D costs.

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SUPPLIERS

Our suppliers are primarily reputable CROs, CMOs, CDMOs and research and medical institutions, as well as providers of raw materials for biological products and housing rental services. We collaborate with CROs, CMOs, CDMOs and research and medical institutions on pre-clinical and clinical trials in China. We primarily procure raw materials, equipment, research and development services and other professional services from our suppliers to support the development and manufacturing of our candidates. We select our suppliers by taking into account a number of factors, including their qualifications, industry reputation, cost competitiveness and compliance with relevant laws and regulations. In 2022 and 2023, our purchases from our five largest suppliers in the aggregate accounted for 34.1% and 50.4% of our total purchases, respectively, while purchases from our largest supplier in each year accounted for 10.9% and 17.3% of our total purchases, respectively.

The following table sets forth certain information of our five largest suppliers for the year ended December 31, 2022:

Supplier	Products/services procured	Supplier Background	Location	Year of Commencing Business Relationship	Purchase amount	% of total purchase
<i>(RMB in thousands)</i>						
Supplier A	R&D services	A public company that provides biotechnology drugs and other pharmaceutical products research and development, production and sales services	China	2021	2,888.9	10.9
Supplier B	R&D services	A public company that provides research and experimental development services	China	2021	2,164.2	8.1
Supplier C	R&D services	A private company that provides drug research and development services	China	2022	1,400.9	5.3
Supplier D	Housing Rental services	A private company that provides laboratory rental service	China	2021	1,387.7	5.2
Supplier E	R&D services	A private company that provides clinical research services for life science solutions	China	2022	1,214.1	4.6
Total					9,055.8	34.1

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The following table sets forth certain information of our five largest suppliers for the year ended December 31, 2023:

Supplier	Products/services procured	Supplier Background	Location	Year of Commencing	Purchase amount	% of total purchase
				Business Relationship		
<i>(RMB in thousands)</i>						
Supplier E	R&D services	A private company that provides clinical research services for life science solutions	China	2022	6,719.5	17.3
Supplier F	Financial advisory services	A private company that provides business consulting services	China	2023	4,455.4	11.5
Supplier A	R&D services	A public company that provides biotechnology drugs and other pharmaceutical products research and development, production and sales services	China	2021	4,000.6	10.3
Supplier G	R&D services	A private company that provides drug consignment development and manufacturing services	China	2023	2,487.0	6.4
Supplier B	R&D services	A public company that provides research and experimental development services	China	2021	1,892.6	4.9
Total					19,555.1	50.4

During the Track Record Period, we were generally granted credit terms of 30 days upon receipt of invoice. We generally settle the payments to the suppliers through bank transfer. All of our five largest suppliers during the Track Record Period were Independent Third Parties. 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, had any interest in any of our five largest suppliers during the Track Record Period.

In addition, we believe that adequate alternative sources for such supplies exist, and we have developed alternative sourcing strategies for these supplies. We will establish necessary relationships with alternative sources based on supply continuity risk assessment. Other than the agreements with certain CROs, CDMOs and CMOs, we order supplies and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements.

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CUSTOMERS

During the Track Record Period and up to the Latest Practicable Date, we had not generated any revenue from product sales, and we do not expect to generate any revenue from product sales before the commercialization of one or more of our candidates.

Nevertheless, we generated revenue of RMB0.5 million in 2023 from the provision of research services to a single customer in relation to a project on medical devices for wound healing. Such business is not part of our core business. For details, see “Financial Information — Description of Major Components of Our Results of Operations — Revenue.” This customer is a private company in China in the businesses of medical equipment trades and biotechnology research and development. The payment for our provision of the research services was made based on the terms of the relevant contract, and was settled through bank transfer. 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, had any interest in this customer during the Track Record Period.

COMPETITION

There are currently no PDGF products approved by NMPA in the China. One of our Core Products, Pro-101-1, is the most advanced PDGF drug candidate in terms of clinical development progress for the treatment of thermal burns in China, and has the potential to be the first commercialized PDGF product in China for this indication, according to the Frost & Sullivan report. Meanwhile, with respect to the other Core Product, Pro-101-2, we are one of the leading biopharmaceutical companies with the potential to first achieve commercialization of PDGF drugs in DFUs in China, according to the same source. We believe our PDGF candidates have unique advantages in wound healing compared to other growth factor products. However, the pharmaceutical industry is highly competitive and subject to rapid and significant changes. While we believe that our strong research and development capability, integrated research and development platform and seasoned leadership team provide us with competitive advantages, we encounter competition from international and China-based biopharmaceutical companies and specialty pharmaceutical and biotechnology companies of various sizes, as well as academic institutions and research institutions. Any candidates that we successfully develop and commercialize will compete with existing drugs and products or any new drugs or products that may become available in the future. See “Industry Overview.”

PROPERTIES

As of December 31, 2023, none of the properties held or leased by us had a carrying amount of 15% or more of our consolidated total assets. According to section 6(2) of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice,

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this document is exempt from the requirements of section 342(1)(b) of the Companies (Winding up and Miscellaneous Provisions) Ordinance to include all interests in land or buildings in a valuation report as described under paragraph 34(2) of the Third Schedule to the Companies (Winding up and Miscellaneous Provisions) Ordinance.

As of the Latest Practicable Date, we did not own any property in China.

As of the Latest Practicable Date, we leased nine properties in Mainland China, comprising four properties with an aggregate gross floor area of approximately 3,577.9 sq.m., which were primarily used for research and development and office space, and five properties used as employee dormitory. The majority of our leased properties are located in Beijing, while we also have leased properties in Qingdao, Shandong Province and Haikou, Hainan Province. The expiry dates of our leased properties range from May 2024 to October 2026. As of the same date, we leased one property in Hong Kong with a gross floor area of approximately 473.0 square feet, which we used for research and development. The expiration of such lease is in May 2025. For risks relating to our leased properties, see “Risk Factors — Risks Relating to Our Operations — We are subject to risks associated with leasing properties.”

During the Track Record Period, we did not experience any dispute arising out of our leased properties.

INTERNAL CONTROL AND RISK MANAGEMENT

We have devoted ourselves to establishing and maintaining risk management and internal control systems consisting of policies, procedures and risk management methods that we consider to be appropriate for our business operations, and we are dedicated to continuously improving these systems. We have adopted and implemented comprehensive internal control and risk management policies in various aspects of our business operations such as financial reporting, information system, quality assurance and quality control and human resources management.

Our Board of Directors is responsible for establishing and maintaining appropriate and effective internal control system to safeguard our Shareholders’ investment at all times. Our internal control policies set out a framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis.

During the Track Record Period, we have regularly reviewed and enhanced our risk management and internal control systems. We believe that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

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Financial Reporting Risk Management

We have in place a set of accounting policies in connection with our financial reporting risk management, such as budget management policies, financial accounting policies and funds management policies. We have various procedures in place to implement accounting policies and our finance department reviews our management accounts based on such procedures.

Information System Risk Management

We use specialized information management systems, including financial management system and data management system. In terms of information management, we have formulated special information management and data security standards and signed confidentiality agreements with employees to enhance their awareness of information protection. Our clinical operation department is responsible for supervising the data protection practice during clinical trials. We have kept all patient data such as personal information since they enrolled in our clinical trials for an indefinite period unless deletion of such data is required by relevant laws and regulations or requested by the relevant users. We also provide on-board training with respect to the handling of personal data to all of our employees when they join us.

Quality Control Risk Management

Our quality control system includes a quality assurance department and a quality control department. We have formulated quality risk management regulations and established a special quality risk management organization, including the quality management department, storage, and transportation department, supply department, sales department, human resources department, and other related departments. Therefore, our quality risk management runs through the entire product life cycle and minimizes the adverse consequences of risks to ensure the quality of medicines.

Our employees are required to be aware of the risk of drug quality. We have established a special quality control team, the members of which have rich medical expertise for approximately 20 years. We also continue to train and test quality control team members on a regular basis.

Human Resources Risk Management

Our recruitment team has rich recruitment experience in the pharmaceutical field. We formulate recruitment plan for the upcoming year based on our future business plan, and we constantly improve our recruitment process with the aid of information technology.

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Anti-bribery and Anti-kickback

We strictly prohibit bribery or other improper payments in any of our business operations. This prohibition applies to all business activities anywhere in the world, whether involving government officials, medical professionals or private or public payors. 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 details. We also ensure that our commercialization team complies with applicable promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

LEGAL PROCEEDINGS AND 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 which would have a material and adverse impact on our business, financial condition or results of operations, and we were not aware of any pending or threatened legal, arbitral or administrative proceedings against us or our Directors that could, individually or in the aggregate, have a material adverse effect on our business, financial condition and results of operations.

Compliance

We obtained the approval of our environmental impact assessment report for our Fengtai research laboratory from the competent authorities and obtained the relevant approval documents from such authorities. However, as of the Latest Practicable Date, we were in the process of fulfilling the subsequent procedures for the environmental impact acceptance check, and had not yet passed such acceptance check. As advised by our PRC Legal Advisor, according to the PRC Regulations on Environmental Protection Management of Construction Projects (《建設項目環境保護管理條例》), after the completion of construction projects that require the preparation of an environment impact assessment report, the construction entity must conduct an acceptance check for the construction projects, following the standards and procedures stipulated by the environmental protection administrative department of the State Council, and prepare an acceptance report. If a construction project is put into production or use without undergoing an acceptance check, or if it fails the acceptance check, the environmental protection administrative department at the county level or above shall order the entity to rectify within a specified time limit and impose a fine ranging from RMB200,000 to RMB1,000,000. If the entity fails to rectify within the given time frame, a fine ranging from RMB1,000,000 to RMB2,000,000 shall be

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imposed, and fines ranging from RMB50,000 to RMB200,000 shall be levied on the person in charge and other responsible individuals. In cases of severe environmental pollution or ecological damage, the entity may be ordered to cease production or use, or, upon approval from the relevant people’s government entity, be ordered to shut down. As of the Latest Practicable Date, we had not received any administrative penalties or any investigation or rectification notices from the relevant authorities. We had obtained the documentation from the competent authorities confirming that we had no penalty record during the Track Record Period regarding municipal ecology and environment. Ms. Jia and Mr. Wang, two of our Controlling Shareholders, have undertaken to be responsible for the payment of any fines imposed on us by the competent authorities after the proposed [REDACTED] due to the incomplete environmental impact acceptance check process. Based on the above, our PRC Legal Advisor is of the view, and accordingly, our Directors are of the view, that the non-compliance issues related to the environmental protection acceptance of our Fengtai research laboratory will not have a material adverse effect on our business operations.

Our Directors confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our business, financial condition or results of operations. Our PRC Legal Advisor confirmed that during the Track Record Period, we had not been subject to administrative penalties by the relevant competent authorities in all material respects for material violations of relevant laws and regulations.

Licenses and Permits

Save as disclosed in “— Compliance,” we have obtained all material licenses, permits, approvals and certificates that are material for our business operations and such licenses, permits, approvals and certificates are valid and subsisting.

The following table sets forth the major certificates, permits, licenses and other approvals held by us as of the Latest Practicable Date:

Certificates/Licenses/Permits	Holder	Authority	Date of Grant	Expiry Date
National High-tech Enterprise	The Company	Beijing Department of Science and Technology, Beijing Department of Finance, Beijing Taxation Bureau, State Taxation Administration	December 17, 2021	December 17, 2024
Expert and Innovative Small and Medium-sized Enterprises	The Company	Beijing Municipal Bureau of Economy and Information Technology	May 2022	May 2025

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Certificates/Licenses/Permits	Holder	Authority	Date of Grant	Expiry Date
Quality Management System Certificate (GB/T 19001-2016/ISO 9001:2015 — R&D of TPG gel drugs (Phase I and Phase II clinical stages).	The Company	HXC (Beijing) Certification Center Co. Ltd	July 11, 2022	July 10, 2025
Environmental Management System Certificate (GB/T 24001-2016/ISO 14001:2015 — R&D of TPG gel drugs (Phase I and Phase II clinical stages).	The Company	HXC (Beijing) Certification Center Co. Ltd	July 11, 2022	July 10, 2025
Occupational Health and Safety Management System Certificate (GB/T 45001-2020/ISO 45001:2018 — R&D of TPG gel drugs (Phase I and Phase II clinical stages).	The Company	HXC (Beijing) Certification Center Co. Ltd	July 11, 2022	July 10, 2025

We intend to apply for renewal of the above key licenses, permits and certificates prior to their expiry dates. The successful renewal of our existing licenses, permits and certifications will be subject to our fulfillment of relevant requirements. Our Directors are not aware of any reason that would cause or lead to the non-renewal of the licenses, permits and certificates. As of the Latest Practicable Date, there was no legal impediment for us to renew the licenses, permits and certificates as long as we comply with the relevant legal requirements.

EMPLOYEES

As of the Latest Practicable Date, we had 77 full-time employees in total, comprising 45 employees in Beijing, 29 employees in Qingdao, Shandong Province, and 3 employees in Hong Kong. The following table sets out a breakdown of our employees by business function as of the Latest Practicable Date:

	Number of Employees	Percentage of Total Employees
General and administrative	44	57.1%
Research and Development	33	42.9%
Total	77	100.0%

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Our company leadership places great importance on the retention of key staff and talent. We endeavor to attract and retain our employees by offering stock options to employees and employee benefits including but not limited to offering recognizing employee commitment and achievement by offering bonus and cash incentive award on performance basis and promotions based on annual performance appraisal process. Our company leadership recognizes that the key members of our company with unique skills and niche knowledge are important assets in the growth of our business.

We adopt performance management, training management and succession planning system to form a set of the talent management system, through the establishment of a KPI performance system in line with each department, daily supplemented by training, learning and improvement in combination with job requirements, and providing outstanding talents at all levels with continuous growth opportunities. We provide development channels to our employees to strengthen their personnel management and positive guidance.

We enter into standard confidentiality and employment agreements with our key management and research staff. The contracts with our key personnel typically include a standard non-competition agreement that prohibits the employee from competing with us, directly or indirectly. The contracts also typically include undertakings regarding assignment of inventions and discoveries made during the course of employment.

As required by PRC laws and regulations, we participate in various employee social security plans for our employees that are administered by local governments, including housing provident fund, pension insurance, medical insurance, maternity insurance, work-related injury insurance and unemployment insurance. We provide various incentives and benefits to our employees. Employees typically receive welfare benefits, including medical care, pension, occupational injury insurance and other miscellaneous benefits.

We believe that we maintain a good working relationship with our employees. During the Track Record Period, we did not have any strikes, protests or other material labor conflicts that may materially affect our business and image. As of the Latest Practicable Date, we had not established any labor union.

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INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. We have a group insurance policy for our employees. We have elected not to maintain certain types of insurance, such as business interruption insurance. See “Risk Factors — Risks Relating to our Operations — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.”

ENVIRONMENTAL MATTERS, SOCIAL RESPONSIBILITY AND WORKPLACE SAFETY

We are committed to operating our business in a manner that protects the environment and providing our employees with a healthy and safe workplace. We have implemented a set of policies on environment, employee welfare and corporate governance, which we believe are in line with industry standards and in compliance with the requirements of the Listing Rules.

Our Board believes our continued growth rests on integrating social values into our business. We have established an environment, health and security department (“**EHS Department**”) that is responsible for evaluating and managing material ESG issues, such as waste management and recycling efforts, energy consumption, pollutants/green house gas emissions and reporting. Our EHS Department, along with our administrative department, oversee the implementation of our policies relating to material ESG issues by taking into consideration any metrics and targets stipulated in applicable laws, regulations and industry standards, including pollutants/greenhouse gas emissions, water and electricity consumption, among others. We also plan to follow the principles below:

- We strictly comply with all applicable laws and regulations for ESG matters.
- We plan to hold periodically training sessions to improve employee awareness and equip them with the sustainable and environmental friendly techniques and knowledge.

In addition, in order to ensure that our operations are in compliance with the applicable laws and regulations, we have implemented group-wide environmental, health and safety policies and standard operating procedures, mainly comprising management systems and procedures relating to wastewater generation and treatment, management of process safety and hazardous substances, third-party safety management and emergency planning and response. We conduct environmental evaluation and take environmental protection measures relating to emissions of air and wastewater generation and treatment. Since we do not currently have the production conditions, we selected a third-party partner and signed a cooperation agreement, stipulating that the third-party is responsible for providing production records and other related records that meet GMP requirements

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and is responsible for providing corresponding inspection records and inspection reports. We have also established wastewater, waste gas, waste treatment systems, and signed contracts with qualified third parties to deal with hazardous substances and waste.

Our Board sets targets for each material KPI in accordance with the disclosure requirements of Appendix 27 to the Listing Rules and other relevant rules and regulations upon [REDACTED]. Our material KPIs primarily include hazardous waste disposal levels and expenses related to hazardous waste disposal and electricity and water usage. In setting targets for the ESG-related KPIs, our Group has taken into account the material KPIs’ respective historical levels for 2022 and 2023 and has considered our future business expansion thoroughly and prudently with a view of balancing business growth and environmental protection to achieve sustainable development. We will also review our KPIs on a yearly basis to ensure that they remain appropriate to our Group. In 2022 and 2023, our hazardous waste discharge levels were approximately 0.3 tons and 1.5 tons, respectively. In the same years, our costs on hazardous waste disposal, electricity and water consumption were approximately RMB137.9 thousand and RMB214.2 thousand, respectively.

We do not operate in a highly polluting industry, while our operation may involve the use and disposal of hazardous materials and wastes. We contract with qualified third parties for the disposal of hazardous materials and wastes. We require their operational qualifications in accordance with relevant governmental laws and regulations. We establish a regular assessment as to our suppliers’ safety performance and strengthen our supervision and management of our suppliers. Our contracted third-party service providers are required under our agreements to comply with all applicable laws. We also implement measure to improve energy efficiency, including requiring employee to turn off all electrical appliances when they are not in use and maintaining indoor temperature at a certain level to reduce unnecessary use of energy. As advised by our PRC Legal Advisor, during the Track Record Period, we had not been subject to administrative penalties by the relevant competent authorities in all material respects for material violations of laws and regulations relating to environmental, occupational health, production safety and fire safety.

In respect of social responsibilities, we have entered into employment agreements with our employees in accordance with the applicable PRC laws and regulations. We hire employees based on their qualifications and experiences and it is our corporate policy to offer equal opportunities to our employees regardless of gender, age, race, religion or any other social or personal characteristics.

In addition, we have implemented measures to identify and address potential risks relating to environment, health and work safety. These measures include continuous employee trainings to enhance our employees’ awareness of environment, health and work safety issues and skills to comply with safety and operation guidelines, timely provision of protection equipment to our

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employees, periodic inspection of our operational facilities, special health examinations for employees who may have contact with hazards, medical examination for employees and establishment of procedures to appropriately handle work safety incidents. We have installed video surveillance systems inside our facilities to monitor the operation process.

Our safety committee is responsible for monitoring and enforcing the compliance of our operations with environment, health and safety laws and regulations. Upon identification of any EHS risks, our safety committee will make filings with local governmental authorities if required under local laws and regulations and take all applicable measures to reduce the impact of such risks or incidents.

CONNECTED TRANSACTIONS

OVERVIEW

We have entered into transactions with certain entity that will become our connected person (as defined under Chapter 14A of the Listing Rules) upon the [REDACTED]. Such transactions will continue after the [REDACTED] and will therefore constitute our continuing connected transactions under Chapter 14A of the Listing Rules.

CONNECTED PERSON

Upon [REDACTED], the following entity with which we have entered into transaction will become our connected person under the Listing Rules:

<u>Connected Person</u>	<u>Connected Relationship</u>
Beijing Houmingde New Material Packaging Co., Ltd (北京厚明德新材料包装有限公司) (“ Beijing Houmingde ”)	<p>Ms. Jia is our founder, chairperson of the Board, executive Director and one of our Controlling Shareholders. Therefore, Ms. Jia and her associates constitute our connected persons pursuant to Chapter 14A of the Listing Rules.</p> <p>Beijing Houmingde, wholly owned by Ms. Jia Zile (賈子樂), sister of Ms. Jia, will therefore be an associate of Ms. Jia and our connected person pursuant to Chapter 14A of the Listing Rules. Beijing Houmingde is a company established in the PRC and principally engages in the production and sales of packaging materials.</p>

CONNECTED TRANSACTIONS

SUMMARY OF OUR CONTINUING CONNECTED TRANSACTIONS

No.	Nature of transactions	Applicable Listing Rules	Waiver sought
One-off connected transaction			
1.	Lease of property by our Company from Beijing Houmingde.	14A.34	N/A
Fully exempt continuing connected transactions			
2.	Lease of vehicle by our Company from Beijing Houmingde	14A.76(1)(c)	N/A
3.	Payment of electricity fee by our Company to Beijing Houmingde	14A.98	N/A

ONE-OFF CONNECTED TRANSACTION

1. Lease of property by our Company from Beijing Houmingde

Our Group has entered into a property leasing agreement dated January 2, 2024 (the “**Property Leasing Agreement**”) with Beijing Houmingde, pursuant to which Beijing Houmingde agreed to lease to our Company certain premises in Huairou District, Beijing, the PRC with a total gross floor area of approximately 1,536 sq.m. (the “**Premises**”) for a term of one year commencing on January 1, 2024 and expiring on December 31, 2024 (both days inclusive) at an annual rent of RMB1,124,352.00. The rent was determined by the parties at arm’s length negotiations with reference to prevailing market price.

We have historically leased such Premises from Beijing Houmingde as one of the R&D bases that we use on a continuous basis in Beijing. While we are in the process of searching for appropriate premises in Qingdao with a view to relocating our R&D laboratory to Qingdao, being the city where our registered office is located, we have not yet confirmed or secured any suitable premises at the moment. As such, relocation of our R&D laboratory at the current stage to other premises will cause unnecessary disruptions to our normal business operation and incur unnecessary costs. We believe that such Property Leasing Agreement will ensure the continuing smooth operation of our Group and to save costs before a suitable venue in Qingdao is confirmed, which is in the interests of our Group and our Shareholders as a whole.

CONNECTED TRANSACTIONS

In accordance with IFRS 16 “Leases”, the lease under the Property Leasing Agreement is recognized as right-of-use assets on our balance sheet. Therefore, the entering into the Property Leasing Agreement will be regarded as the acquisition of capital assets and one-off connected transaction, rather than continuing connected transaction.

Accordingly, the reporting, announcement, annual review and independent Shareholders’ approval requirements in Chapter 14A of the Listing Rules will not be applicable.

FULLY-EXEMPT CONTINUING CONNECTED TRANSACTIONS

2. Lease of vehicle by our Company from Beijing Houmingde

During the Track Record Period, our Company has entered into a vehicle leasing agreement with Beijing Houmingde, pursuant to which Beijing Houmingde agreed to lease to our Company the vehicle designated therein at a total fee of RMB40,000 for the period commencing from January 1, 2023 and ending on December 31, 2025 (representing a rate of approximately RMB13,333.33 on an annual basis). The vehicle leasing agreement is subject to renewal through mutual consents by the parties.

As the vehicle was leased by our Company from Beijing Houmingde in the ordinary and usual course of business, and on normal commercial terms or better, the highest applicable percentage ratio for the fees payable by us to Beijing Houmingde, is expected to be less than 5% on an annual basis and the maximum annual transaction amount is less than HK\$3,000,000, such transaction contemplated under the above-mentioned vehicle leasing agreement will be fully exempt from all of the reporting, annual review, announcement, circular and independent Shareholders’ approval requirements under Chapter 14A of the Listing Rules pursuant to Rule 14A.76(1)(c).

3. Payment of electricity fees by our Company to Beijing Houmingde under the Property Leasing Agreement

In connection with the Property Leasing Agreement, as there is no independent electricity meter installed for the Premises, in addition to the rent payable by our Company thereunder, we also need to pay to Beijing Houmingde the electricity fees incurred in connection with our operation at the Premises on a monthly basis starting from March 1, 2024 to December 31, 2024. Such electricity fees payable by us to Beijing Houmingde under the Property Leasing Agreement will be determined on a cost basis.

CONNECTED TRANSACTIONS

Such arrangement on payment of the electricity fees under the Property Leasing Agreement constitutes the sharing of administrative services on a cost basis under Rule 14A.98 of the Listing Rules, and the costs are identifiable and can be allocated to the parties on a fair and equitable basis. Therefore, such transaction will be fully exempt from the reporting, annual review, announcement, circular and independent shareholders' approval requirements under Chapter 14A of the Listing Rules.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board of Directors comprises nine Directors, including three executive Directors, three non-executive Directors and three independent non-executive Directors. The powers and duties of the Board include convening general meetings, determining our Group’s business plans and investment plans, implementing the Group’s established line of business, formulating our Group’s annual budget and final accounts, formulating proposals for profit distributions and the increase or reduction of share capital as well as exercising other powers, functions and duties as conferred by our Articles of Association. Our Directors are elected for a term of three years and are subject to re-election upon expiration of the term of office.

The following table sets forth information regarding our Directors.

Name	Age	Position	Date of joining our Group	Date of appointment as Director	Roles and responsibilities	Relationship with other Directors, Supervisors or senior management
Chairperson of the Board and Executive Director						
Ms. JIA Lijia (賈麗加)	55	Chairperson of the Board and executive Director	April 2012	April 2012	Providing leadership and governance of the Board, responsible for the overall business strategies and management of our Group	Mother of Mr. WANG Kelong
Executive Directors						
Mr. WANG Kelong (王軻龍)	33	President, executive Director and vice chairperson of the Board	October 2020	October 2020	Overseeing the execution of the overall strategy, business development, management and financing of our Group	Son of Ms. JIA Lijia
Dr. ZHAI Junhui (翟俊輝)	55	executive Director and general manager	October 2019	December 2020	Formulating product research and development plan and overseeing the technology advancement of our Group	None

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Position	Date of joining our Group	Date of appointment as Director	Roles and responsibilities	Relationship with other Directors, Supervisors or senior management
Non-executive Directors						
Mr. MIAO Tianxiang (苗天祥)	66	Non-executive Director	July 2023	July 2023	Providing opinions and judgment on corporate business strategies to the Board	None
Ms. LIN Ying (林穎)	42	Non-executive Director	July 2023	July 2023	Providing opinions and judgment on corporate business strategies to the Board	None
Mr. YUAN Fei (袁飛)	45	Non-executive Director	June 2023	June 2023	Providing opinions and judgment on corporate business strategies to the Board	None
Independent Non-executive Directors						
Mr. FOK Chi Tat Michael (霍志達) .	50	Independent non-executive Director	March 2024	March 2024	Providing independent advice on the operations and management of our Group	None
Mr. LI Jiayan (李嘉焱)	60	Independent non-executive Director	March 2024	March 2024	Providing independent advice on the operations and management of our Group	None
Mr. YUE Yichun (岳儀春)	58	Independent non-executive Director	March 2024	March 2024	Providing independent advice on the operations and management of our Group	None

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Chairperson and Executive Director

Ms. JIA Lijia (賈麗加), aged 55, is our founder and has served as our Director and chairperson of the Board since the establishment of our Company in April 2012. She was re-designated as our executive Director in April 2024. She is primarily responsible for providing leadership and governance of the Board, responsible for the overall business strategies and management of our Group. She currently also serves as director of Huaren Yihai Biotechnology and director of Hainan Huaren Biotechnology.

Ms. Jia has over 27 years of experience in the pharmaceutical industry. Prior to the establishment of our Group, Ms. Jia served as a sales manager at Mudanjiang Lingtai Medicment Co., Ltd. (Beijing Branch) (牡丹江靈泰藥業股份有限公司(北京辦事處)) from January 1997 to September 2004. Ms. Jia then served as a deputy general manager at Beijing Sheng Hongye Pharmaceutical Technology Development Co., Ltd. (北京盛宏業醫藥科技發展有限公司), a company primarily engaged in pharmaceutical technology development, from October 2004 to December 2010, where she was primarily responsible for sales and operation management.

Ms. Jia obtained a degree of Master of Business Administration from Macau University of Science and Technology (澳門科技大學) in Macau, the PRC in June 2007.

Executive Directors

Mr. WANG Kelong (王軻龍), aged 33, has served as our Director since October 2020 and was re-designated as our executive Director in April 2024. He currently also serves as vice chairperson of our Board and president of our Company. He is primarily responsible for overseeing the execution of the overall strategy, business development, management and financing of our Group. He currently also serves as a director of our subsidiary, Beijing Huarene Biotechnology.

Mr. Wang has over nine years of experience in corporate operation and management. Prior to joining our Group, Mr. Wang worked for Berkshire Hathaway Automotive. He subsequently founded Beijing Green Auto Technology Co., Ltd. (北京綠汽科技有限公司) and served as chief executive officer from April 2017 to September 2020, where he was responsible for its overall operation.

Mr. Wang became a member of the Greater China Council of The Nature Conservancy in May 2023. Mr. Wang was named in the Forbes China “30 under 30” Elite List in 2019 (2019福布斯中國30歲以下精英榜) and the Hurun China “30×30” Entrepreneurial Leaders List in 2018 (2018胡潤30×30創業領袖). Mr. Wang also co-authored several published papers on aspects such as cyber intelligence and drug delivery.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Wang obtained a degree of Master of Business Administration from The University of Texas at Arlington in Texas, the United States in August 2014. Mr. Wang attended advanced management program at Harvard Business School in in Massachusetts, the United States in 2022.

Dr. ZHAI Junhui (翟俊輝), aged 55, has been serving as our general manager since October 2019, and our Director since December 2020, and was re-designated as our executive Director in April 2024. Dr. Zhai is primarily responsible for formulating product research and development plan and overseeing the technology advancement of our Group. He currently also serves as a director of our subsidiary, Beijing Huarene Biotechnology.

Dr. Zhai has over 28 years of experience in biomedical science research as well as experience in the areas of microbiology, molecular biology, virology and preventive medicine. Prior to joining our Group, he successively served as a research trainee, a research assistant and an associate researcher in microbiology at AMMS from July 1995 to February 2005, where he headed and participated in a number of major national-level medical projects. Dr. Zhai then worked as a postdoctoral research scientist in microbiology at Columbia University from March 2005 to May 2007. He then returned to AMMS and worked as an associate researcher in microbiology from August 2007 to August 2010, and subsequently served as the scientific consultant, technical director, and chief scientist of United Well Bio-Instruments (Shanghai) Limited (匯佳生物儀器(上海)有限公司) from November 2010 to August 2017. He subsequently served as the general manager of Yicheng Huaxia (Beijing) Technical Inspection Co. (益誠華夏(北京)技術檢測有限公司) from September 2017 to September 2019.

Dr. Zhai obtained a bachelor’s degree in microbiology from Shandong University (山東大學) in Shandong Province, the PRC in July 1992 and a master’s degree in medical science from AMMS in Beijing, the PRC in July 1995. He further obtained his doctorate degree in preventive healthcare from AMMS in Beijing, the PRC in July 2002.

Non-executive Directors

Mr. MIAO Tianxiang (苗天祥), aged 66, has been serving as our Director since July 2023, and was re-designated as our non-executive Director in April 2024. He is primarily responsible for providing opinions and judgment on corporate business strategies to the Board.

Mr. Miao has over 29 years of experience in financial and corporate management. He previously worked at Dongbei University of Finance and Economics (東北財經大學) as a lecturer and an associate professor consecutively from March 1988 to March 1994. Mr. Miao then worked at Viatrix Pharmaceuticals Co., Ltd. (暉致醫藥有限公司, formerly known as Pfizer Puqiang Pharmaceutical Trading Co., Ltd. (輝瑞普強醫藥貿易有限公司)) from August 1994 to May 2021, where he had held various roles therein, including financial controller of Pfizer Pharmaceuticals

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Limited (輝瑞製藥有限公司), currently known as Viartis Pharmaceuticals (Dalian) Co., Ltd. (暉致製藥(大連)有限公司)), senior director of finance department of Pfizer Investment Co., Ltd. (輝瑞投資有限公司), chief executive officer of Hisun Pfizer Pharmaceuticals Co., Ltd. (海正輝瑞製藥有限公司), vice president of Pfizer China financial department of Pfizer Investment Co., Ltd., with his last position being Regional Office Chairman of the Greater China Region.

Mr. Miao obtained a bachelor’s degree in economics from Liaoning University of Finance and Economics (遼寧財經大學, currently known as Dongbei University of Finance and Economics) in Liaoning Province, the PRC in August 1982 and a master’s degree in economics from Dongbei University of Finance and Economics in Liaoning Province, the PRC in July 1987. Mr. Miao was recognized as a Certified Public Accountants by the Chinese Institute of Certified Public Accountants in the PRC in December 2009. He was awarded 2016 China International Financial Leader of the Year (2016中國國際財務領袖年度人物) by China Enterprise Financial Evaluation Expert Committee (中國企業財務評價專家委員會) in December 2016. He was awarded 2019 Most Leadership in Social Responsibility Award (2019年度社會責任最具領導力人物獎) by Social Responsibility Conference (社會責任大會組委會).

Ms. LIN Ying (林穎), aged 42, has been serving as our Director since July 2023, and was re-designated as our non-executive Director in April 2024. Ms. Lin is primarily responsible for providing opinions and judgment on corporate business strategies to the Board.

Ms. Lin has over 17 years of experience in accounting, finance, and corporate management. She previously served as a senior auditor of PricewaterhouseCoopers Zhong Tian LLP (普華永道中天會計師事務所(特殊普通合夥)) from August 2006 to March 2011, professional deputy director of the finance department of China Resources (Holdings) Company Limited (華潤(集團)有限公司) from April 2011 to September 2016, chief financial officer of Nanjing Huaxia Health Industry Group Limited (南京華夏健康產業集團有限公司) from October 2016 to September 2018, a director of Gaohe Pharmaceuticals Investment (Shenzhen) Co. Ltd. (高和藥業投資(深圳)有限公司) since April 2019, and executive director of Qingdao CDH Runzhong Investment Management Co., Ltd. (青島鼎暉潤中投資管理有限公司) from December 2019 to July 2023. She has been a director, executive vice president and chief financial officer of JonjeE Hi-Tech Industrial and Commercial Holding Co., Ltd. (中炬高新技術實業(集團)股份有限公司, a company listed on the Shanghai Stock Exchange with stock code: 600872) since July 2023.

Ms. Lin obtained a bachelor’s degree in investment economics and a master’s degree in national economics from Xiamen University (廈門大學) in Fujian Province, the PRC in China in July 2003 and July 2006, respectively. She was recognized as a non-practicing Certified Public Accountant by Shenzhen Institute of Certified Public Accountants in the PRC in December 2011. She was also recognized as a Chartered Financial Analyst in September 2017 by CFA Institute.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. YUAN Fei (袁飛), aged 45, has been serving as our Director since June 2023, and was re-designated as non-executive Director in April 2024. Mr. Yuan is primarily responsible for providing opinions and judgment on corporate business strategies to the Board.

Mr. Yuan has over 12 years of experience in corporate administrative management. He served as director of the general affairs department of Qingdao Hitech from December 2011 to June 2013. He then served as deputy director of general management department from September 2018 to May 2020 and has been serving as chief of general management office at Qingdao Hitech from May 2020 to March 2024. Mr. Yuan currently works at Qingdao Jinjialing Holding Co., Ltd. (青島金家嶺控股集團有限公司) since March 2024.

Mr. Yuan completed his undergraduate study in business administration in December 2006 at Correspondence College of the Party School of the Communist Party of China (中共中央黨校函授學院) in the PRC. He also obtained the title of Junior Level Accountant (初級會計) from Ministry of Personnel of PRC (中華人民共和國人事部, currently known as Ministry of Human Resources and Social Security of PRC) in May 2005.

Independent Non-executive Directors

Mr. FOK Chi Tat Michael (霍志達), aged 50, was appointed as our independent Director in March 2024, and re-designated as our independent non-executive Director in April 2024. He is primarily responsible for providing independent advice on the operations and management of our Group.

Mr. Fok has over 20 years of extensive experience in auditing, corporate finance and investment banking focusing on IPO sponsorship, mergers and acquisitions, fund raising and corporate restructuring. He previously served as a director of Anglo Chinese Corporate Finance, Limited from August 2006 to July 2014, and then served as the deputy head of investment banking department in Huatai Financial Holdings (Hong Kong) Limited from August 2014 to October 2019. He has been serving as the managing director of Maxa Capital Limited since he founded this company in November 2019. Mr. Fok also has been serving as an independent non-executive director of Talent Property Group Limited (a company listed on the Stock Exchange with stock code: 0760) since August 2019.

Mr. Fok obtained a degree of Bachelor of Commerce from University of Toronto in Ontario, Canada in June 1997 and received his degree of Master of Corporate Finance from The Hong Kong Polytechnic University in Hong Kong in October 2008. Mr. Fok has been a member of American Institute of Certified Public Accountants since August 2000.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. LI Jiayan (李嘉焱), aged 60, was appointed as our independent Director in March 2024, and re-designated as our independent non-executive Director in April 2024. He is primarily responsible for providing independent advice on the operations and management of our Group.

Mr. Li has approximately 30 years of experience in finance and corporate management. Mr. Li previously served as the deputy division chief in Project Approval Section of Wuhan Municipal Foreign Investment Office (武漢市外商投資辦公室項目審批處), the division chief in Foreign Investment Enterprise Complaints Center (武漢市外商投訴中心), director in Coordination Office of Wuhan Municipal Foreign Investment Office (武漢市外商投資辦公室協調管理處) and deputy general manager of Anpeng International Industry (Wuhan) Co., Ltd. (安鵬國際實業(武漢)有限公司) from March 1994 to January 2000. He subsequently joined China Everbright Bank Company Limited (中國光大銀行股份有限公司, “**CEB Bank**”, a company listed on the Stock Exchange with stock code: 6818 and the Shanghai Stock Exchange with stock code: 601818) in November 2005, and successively served as the deputy general manager of the Development Research Department, the deputy general manager of the Strategic Management Department, the deputy chief of Office of the Board of Supervisors and Directors (deputy general manager level), the deputy chief of Office of the Board of Directors (Listing Office), securities affairs representative (general manager level), the chief of the Listing Office (general manager level), and the general manager of the Capital and Securities Affairs Management Department. Mr. Li also served as the secretary to the Board of Directors and the company secretary of CEB Bank from January 2018 to November 2021, as well as a member of the Party Committee of CEB Bank (vice president level) and the securities affairs representative of CEB Bank from July 2019 to November 2021. Mr. Li currently works for Hisense Group Holdings Co., Ltd. (海信集團控股股份有限公司) and has served as vice president, deputy director of Strategy and Investment Committee of the Board of Directors since June 2022. He has also been serving as a guest professor at Beijing Foreign Studies University Law School (北京外國語大學法學院) since June 2008.

Mr. Li was awarded with the title of “Financial Services Competent Person” (金融服務能手) by the National Committee of Chinese Financial Workers’ Union (中國金融工會全國委員會) in May 2011. He was awarded with the title of “Most Innovative Board Secretary” (最具創新力董秘) in the 15th Gold Prize of Round Table of Chinese Boards of Listed Company (第十五屆中國上市公司董事會金圓桌獎) by the Journal of Board of Directors (董事會雜誌社) in December 2019. He was also awarded with the title of Outstanding Board Secretary (優秀董秘) by Shanghai Securities News Company Limited (上海證券報社有限公司) in December 2020.

Mr. Li received a bachelor’s degree in international law in July 1985 and a master’s degree in international economic law in July 1988 from Wuhan University School of Law (武漢大學法學院) in Hubei Province, the PRC. He then received a degree of Master of Law and a degree of Juris Scientiae Doctor from University of California at Berkeley in California, the United States in May 2002 and December 2005, respectively.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. YUE Yichun (岳儀春) (former name: YUE Yichun (岳義春)), aged 58, was appointed as our independent Director in March 2024, and re-designated as our independent non-executive Director in April 2024. He is primarily responsible for providing independent advice on the operations and management of our Group.

Mr. Yue has extensive experience in energy sector, focusing on financial management and corporate operation. Prior to joining our Group, he worked at Beijing Deyuan Investment Company Limited (北京德源投資有限公司) from November 2003 to July 2006. Mr. Yue then worked at China Electric Power Finance Co., Ltd. (中國電力財務有限公司, a subsidiary of State Grid Corporation of China (國家電網有限公司)), from August 2006 to September 2010, where he had served as the chief accountant. He has been serving as chairman of the board of directors at Beijing Rongqing Technology Group Limited (北京融慶科技集團有限公司) since July 2014. Mr. Yue obtained the title of Senior Accountant (高級會計師) from State Power Corporation of China (國家電力公司) in December 2001.

Mr. Yue obtained a college’s degree in business management in the power industry from North China Electric Power College (華北電力學院) in Hebei Province, the PRC in July 1990. He then obtained a bachelor’s degree in business administration from North China Electric Power University (華北電力大學) in Hebei Province, the PRC in June 2004, a master’s degree in business administration from China Europe International Business School (中歐國際工商學院) in Shanghai, PRC in September 2006 and a doctorate degree in information management from Beijing Jiaotong University (北京交通大學) in Beijing, the PRC in July 2011.

Mr. Yue’s project headed Demonstration Construction of State Grid Company’s Informatization SG186 Project (《國家電網公司信息化「SG186」工程示範建設》) won the Special Prize of Science and Technology Advancement Award of State Grid Corporation of China (國家電網公司科學技術進步特等獎) in 2008. His project headed China Electric Power Finance Company Limited’s “Electric Wealth Link” — Online Fund Service System for Enterprises (《中國電力財務有限公司「電財通」— 企業網上資金服務系統》) won the Second Prize of Science and Technology Advancement Award of State Grid Corporation of China (國家電網公司科學技術進步二等獎) in 2008. His paper headed Outsourcing of Enterprise Information Systems under Information Asymmetry (《信息不對稱條件下的企業信息系統外包》) was published on China Soft Science (《中國軟科學》) in 2008. His paper headed Discussing the Role of Strategic Partnership Supervision in Enterprise Informatization Construction (《淺談戰略合作夥伴型監理在企業信息化建設中的作用》) was published on Electricity Informationization (《電力信息化》) in November 2008. His paper headed Analysis of Outsourcing of Enterprise Informatization Engineering Decision Making Based on Resource Sharing Coefficient (《基於資源共享系數的企業信息化工程決策外包分析》) was published on China Soft Science in 2009. His paper headed Research on Self-Organizing System of Enterprise Informatization and Its Evolutionary Path (《企業信息化的自組織系統及其演化路徑研究》) was published in June 2009.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

SUPERVISORY COMMITTEE

The PRC Company Law requires our Company to establish a supervisory committee that is responsible for supervising the performance of the Board and senior management, the Company’s financial operations, internal control and risk management. Our Supervisory Committee consists of three Supervisors. Our Supervisors are elected for a term of three years and are subject to re-election upon their expiration of the term of office.

The following table sets forth information regarding our Supervisors.

Name	Age	Position	Date of joining our Group	Date of appointment as a Supervisor	Roles and responsibilities	Relationship with other Directors, Supervisors or senior management
Ms. SONG Bing (宋冰)	57	Chairperson of the Supervisory Committee	June 2021	June 2021	Overseeing our operations, financial activities and internal controls	None
Ms. LIU Yali (劉亞利)	39	Supervisor	March 2017	March 2024	Overseeing our operations, financial activities and internal controls	None
Ms. CHEN Xuanyu (陳炫宇)	24	Supervisor	October 2023	March 2024	Overseeing our operations, financial activities and internal controls	None

Ms. SONG Bing (宋冰), aged 57, has been serving as the chairperson of the Supervisory Committee (監事會主席) and our Supervisor since June 2021. She is primarily responsible for overseeing our operations, financial activities and internal controls.

Ms. Song has over 18 years of experience in legal profession and capital market. From July 2005 to June 2017, she worked at Goldman Sachs (China) Securities Company Limited (高盛(中國)證券有限責任公司) (“**GS China**”) and its affiliate, and served successively as Chief Legal Officer of Beijing Gaohua Securities Co., Ltd. (北京高華證券有限責任公司) (“**Gaohua Securities**”) from July 2005 to January 2012, secretary to the board of GS China and Gaohua Securities from March 2008 to January 2012, vice general manager of Gaohua Securities from December 2009 to June 2014, Co-Chief Operating Officer of Gaohua Securities from May 2011 to June 2014 and general manager and legal representative of GS China from September 2012 to April 2017. Ms. Song has been serving as an independent director of GS China since October 2021. She currently serves as a senior vice president of Berggruen Institute (博古睿研究院) since September 2017 and is the founding director of the Institute’s China Center.

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Ms. Song obtained a bachelor’s degree in international law from Peking University (北京大學) in Beijing, PRC in July 1988. She obtained a master’s degree in international relations from St. Antony’s College, University of Oxford in Oxford, the United Kingdom in June 1991. and a master’s degree in international trade law from New York University School of Law in New York, the United States in July 1997.

Ms. LIU Yali (劉亞利), aged 39, has been serving as our Supervisor since March 2024, and is primarily responsible for overseeing our operations, financial activities and internal controls.

Ms. Liu has over 16 years of experience in administration and human resources management. She joined our Group in March 2017 and has been serving as a human resources specialist of our Company since then. Ms. Liu is primarily responsible for corporate matters in relation to remuneration and salary of our employees, office administration system, and management of our Company’s seal, contracts and internal records. Prior to joining our Group, she served as an officer at Beijing Shenzhou Business Travel Asian Games Village Hotel Management Co., Ltd. (北京神舟商旅亞運村酒店管理有限公司) from June 2008 to July 2012, and then worked as a human resources specialist for at Beijing Xiangyue Yangguang Beauty Co. Ltd. (北京相約陽光美容有限公司) from December 2014 to February 2017.

Ms. Liu obtained a bachelor’s degree in human resources management from Hebei University of Economics and Business (河北經貿大學) in Hebei Province, the PRC in June 2008.

Ms. CHEN Xuanyu (陳炫宇), aged 24, has been serving as our Supervisor since March 2024, and is primarily responsible for overseeing our operations, financial activities and internal controls.

Ms. Chen joined our Group in July 2023 and has been serving as the internal audit director of our Company since then. She is primarily responsible for overseeing our supplier selection process and review the reasonableness of prices offered by the suppliers of our Company, reviewing and implementing remedial measures in responses to internal control issues identified and optimization of our Company’s key business process. Prior to joining our Group, she served as a technical design supervisor of “HOWOW.D2Y”, a brand launched by Shanghai Haowu Zaozuo Cultural Creativity Co., Ltd. (上海好物造作文化創意有限公司), from October 2022 to May 2023.

Ms. Chen obtained a degree of Bachelor of Arts in advertising from Soochow University (蘇州大學) in Jiangsu Province, the PRC in October 2020.

SENIOR MANAGEMENT

Our senior management is responsible for the day-to-day management of our business.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

The following table sets forth general information regarding our senior management.

Name	Age	Position	Date of joining our Group	Date of appointment as a senior management member	Roles and responsibilities	Relationship with other Directors, Supervisors or senior management
Ms. JIA Lijia (賈麗加)	56	Chairperson of the Board and executive Director	April 2012	April 2012	Providing leadership and governance of the Board, responsible for the overall business strategies and management of our Group	Mother of Mr. Wang Kelong
Mr. WANG Kelong (王軻龍)	33	President, executive Director and vice chairperson of the Board	October 2020	November 2020	Overseeing the execution of the overall strategy, business development, management and financing of our Group	Son of Ms. Jia Lijia
Dr. ZHAI Junhui (翟俊輝)	55	Executive Director and general manager	October 2019	October 2019	Formulating product research and development plan and overseeing the technology advancement of our Group	None
Mr. HO Hung Tim Chester (何鴻添)	57	Chief Financial Officer, vice president and secretary to the Board	May 2023	May 2023	Overseeing corporate finance, audit and capital management of the Group, offshore capital market operations of our Group and secretarial affairs of the Board	None
Mr. XU Zhenyu (徐震宇)	54	Chief Marketing Officer and vice president	December 2020	December 2020	Responsible for planning of the commercialization of the products of our Group	None
Dr. ZHAO Xinghui (趙興卉)	45	Chief R&D Officer	May 2021	May 2021	Responsible for leading pre-clinical research and development efforts of our Group	None

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Name	Age	Position	Date of joining our Group	Date of appointment as a senior management member	Roles and responsibilities	Relationship with other Directors, Supervisors or senior management
Dr. CHENG Long (成龍)	46	Medical director	October 2020	October 2020	Responsible for directing clinical development, formulating clinical strategy and conducting clinical trials of our Group	None

Ms. JIA Lijia (賈麗加), see “— Board of Directors — Chairperson and Executive Director” for her biographical details.

Mr. WANG Kelong (王軻龍), see “— Board of Directors — Executive Directors” for his biographical details.

Dr. ZHAI Junhui (翟俊輝), see “— Board of Directors — Executive Directors” for his biographical details.

Mr. HO Hung Tim Chester (何鴻添), aged 57, has served as Chief Financial Officer, vice president and secretary to the Board of our Company since May 2023. He was appointed as one of our joint company secretaries in April 2024 which will take effect upon [REDACTED]. He is primarily responsible for overseeing corporate finance, audit and capital management of the Group, offshore capital market operations of our Group and secretarial affairs of the Board.

Mr. Ho has over 20 years of experience in the management and development of various listed and unlisted companies. Mr. Ho has been an independent non-executive director and a member of the Audit Committee of Grand Baoxin Auto Group Limited (廣匯寶信汽車集團有限公司) (a company listed on the Stock Exchange with stock code: 1293) since June 2021. Mr. Ho has also been the external independent member of the Investment Committee of Canadian Race Relations Foundation, a Canadian federal crown corporation dedicated to the elimination of racism and all forms of racial discrimination in Canadian society, since April 2020. From April 2008 to December 2014, Mr. Ho worked in China Resources (Holdings) Company Limited, a Fortune 500 Chinese state-owned enterprise that owns a variety of businesses in Hong Kong and mainland China and was the senior deputy chief financial officer of its Finance Department when he left. From June 2002 to April 2008, Mr. Ho worked in China Resources Enterprise, Limited (華潤創業有限公司) (now known as China Resources Beer (Holdings) Company Limited (華潤啤酒(控股)有限公司), a company listed on the Stock Exchange with stock code: 0291) and was the assistant general manager of its Corporate Planning and Development Department when he left. From August 2000

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to June 2002, Mr. Ho worked in Hang Lung Properties Limited (恒隆地產有限公司) (a company listed on the Stock Exchange with stock code: 0101)) as a senior investment manager of its Investment Division. From May 1995 to July 2000, Mr. Ho worked in Anglo Chinese Corporate Finance, Limited, a corporate finance advisory firm and was promoted to director when he left. Mr. Ho was a senior accountant of Ernst & Young from December 1992 to September 1994.

Mr. Ho obtained a bachelor’s degree of arts with first class honor in economic and social studies from the University of Manchester in Manchester, the United Kingdom in July 1988 and a master’s degree of business administration from the University of Toronto in Ontario, Canada in November 1990. He has been a member of the American Institute of Chartered Financial Analyst since September 1998, a Fellow of Canadian Securities Institute since September 1997, a Certified Investment Manager of The Canadian Securities Institute since June 1994, a member of the Hong Kong Institute of Certified Public Accountants since April 1993, a member of the Institute of Chartered Professional Accountants of Ontario (Canada) since October 1992 and a member of the American Institute of Certified Public Accountants since May 1992.

Mr. XU Zhenyu (徐震宇), aged 54, has been serving as the Chief Marketing Officer and vice president of our Company since December 2020. He is primarily responsible for planning of the commercialization of our products.

Mr. Xu has over 30 years of experience in pharmaceutical and healthcare industry. Prior to joining our Group, Mr. Xu served as a research trainee at Shanghai Institute of Pharmaceutical Industry, Co, Ltd. (上海醫藥工業研究院有限公司) from 1993 to 1995, and then a sales director at Eli Lilly (Asia) Co., Limited, a pharmaceutical company, from 1996 to 2007, where he was primarily responsible for sales and marketing. From July 2007 to December 2012, Mr. Xu served as a vice president at China NT Pharma Group Company Limited (中國泰凌醫藥集團有限公司, a pharmaceutical company listed on the Stock Exchange with stock code: 1011).

Mr. Xu obtained a bachelor’s degree in chemical pharmacy from East China University of Science and Technology (華東理工大學) in Shanghai, the PRC in July 1993.

Dr. ZHAO Xinghui (趙興卉) (former name: ZHAO Dongna (趙冬娜)), aged 45, has been serving as our Chief R&D Officer since May 2021. She is primarily responsible for leading pre-clinical research and development efforts of our Group.

Dr. Zhao has over 18 years of experience in medical research and development. She served as a research assistant at the Institute of Microbiology and Epidemiology of AMMS from October 2005 to March 2012, during which she also worked as a postdoctoral fellow at Cincinnati Children’s Hospital Medical Center from July 2009 to June 2011. She then served successively as a research assistant and an associate researcher at the Institute of Bioengineering of AMMS from

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

April 2012 to December 2017. Dr. Zhao also served as an associate researcher at Beijing Cancer Hospital (北京腫瘤醫院) from April 2018 to March 2019, and further worked as a research associate at University of Kentucky in the United States from April 2019 to April 2021.

Dr. Zhao received a bachelor's degree in biotechnology from Shandong University (山東大學) in Shandong Province, the PRC in July 2000 and received a doctorate degree in genetics from AMMS in Beijing, the PRC in July 2005. She qualified as a researcher (senior professional title) (研究員(正高級職稱)) in biopharmaceutical research recognized by Beijing Bureau of Human Resources and Social Security (北京人力資源和社會保障局) in December 2022.

Dr. CHENG Long (成龍), aged 46, has been serving as our medical director since October 2020. He is primarily responsible for directing clinical development, formulating clinical strategy and conducting clinical trials of our Group.

Dr. Cheng has approximately 15 years of experience in medicine research and development. Prior to joining the Group, he served as a quality control engineer for Henan Lingrui Pharmaceutical Co., Ltd. (河南羚銳製藥股份有限公司, a company listed on the Shanghai Stock Exchange with stock code: 600285) from January 2003 to February 2004. He served as a project manager of clinical trials at Beijing Konruns Pharmaceutical Co., Ltd. (北京康辰藥業股份有限公司, a company listed on the Shanghai Stock Exchange with stock code: 603590) from July 2007 to July 2009. He worked as a postdoctoral fellow at Chinese Academy of Medical Sciences & Peking Union Medical College (中國醫學科學院北京協和醫學院) from November 2012 to October 2017. He served as an academic director for Guizhou Bailing Group Pharmaceutical Co., Ltd. (貴州百靈企業集團製藥股份有限公司, a company listed on the Shenzhen Stock Exchange with stock code: 002424) from March 2013 to March 2015. Dr. Cheng also served as vice chairman of the first committee of the Division of Sleep Science (睡眠科學分會) of China Association of Gerontology and Geriatrics (中國老年學和老年醫學) from December 2015 to December 2020.

Dr. Cheng received a master's degree in traditional Chinese medicine from Jiangxi College of Traditional Chinese Medicine (江西中醫學院, currently known as Jiangxi University of Traditional Chinese Medicine (江西中醫藥大學)) in Jiangxi Province, the PRC in July 2007. He then received a doctorate degree in fundamentals of integrative Chinese and western medicine from China Academy of China Medical Sciences (中國中醫科學院) in Beijing, the PRC in June 2012. He qualified as an associate pharmacist (副主任藥師) recognized by Guizhou Medical Products Administration (貴州省藥品監督管理局) in December 2019.

INTERESTS OF DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Saved as disclosed above, to the best of the knowledge, information and belief of our Directors having made all reasonable enquiries, as of the Latest Practicable Date, none of our Directors, Supervisors and senior management had been a director of any public company the securities of which were listed on any securities market in Hong Kong or overseas in the three

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

years immediately preceding the date of this Document. There are no other matters with respect to the appointment of our Directors and Supervisors that need to be brought to the attention of the Shareholders, nor is there any information relating to our Directors and Supervisors that is required to be disclosed pursuant to Rules 13.51(2)(h) to (v) of the Listing Rules.

Saved as disclosed above, as of the Latest Practicable Date, none of our Directors, Supervisors or senior management were related to other Directors, Supervisors or senior management of our Company. Saved as disclosed in “Relationship with our Controlling Shareholders”, “Substantial Shareholders” and “Appendix IV — Statutory and General Information — D. Disclosure of Interests — 1. Disclosure of Interests of Directors and Chief Executive of the Company”, as of the Latest Practicable Date, none of our Directors and chief executive held any interest in the securities within the meaning of Part XV of the SFO.

JOINT COMPANY SECRETARIES

Mr. HO Hung Tim Chester (何鴻添), see “— Senior Management” above for his biographical details.

Ms. WONG Wai Yee Ella (黃慧兒) was appointed as one of our joint company secretaries in April 2024 which will take effect upon [REDACTED]. Ms. Wong is a director of corporate services in Vistra Group.

Ms. Wong has over 20 years of experience in the corporate secretarial field and provides corporate secretarial and compliance services to Hong Kong listed companies as well as multinational, private and offshore companies. Ms. Wong currently holds company secretary or joint company secretary positions in multiple companies listed on the Stock Exchange.

Ms. Wong received her bachelor’s degree of Economics from the University of Hong Kong and her postgraduate diploma in corporate administration from the City University of Hong Kong. Ms. Wong is a chartered secretary, chartered governance professional and fellow of The Hong Kong Chartered Governance Institute (HKCGI) (formerly known as The Hong Kong Institute of Chartered Secretaries) and a fellow of The Chartered Governance Institute (CGI) (formerly known as The Institute of Chartered Secretaries and Administrators).

BOARD COMMITTEES

Our Board delegates certain responsibilities to various committees. In accordance with the relevant PRC laws and regulations and the Corporate Governance Code, Appendix C1 to the Listing Rules, our Company has formed three Board committees, namely the Audit Committee, the Remuneration Committee and the Nomination Committee.

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Audit Committee

We have established an Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code as set forth in Appendix C1 to the Listing Rules. The Audit Committee consists of three Directors, namely Mr. YUE Yichun (岳儀春), Mr. FOK Chi Tat Michael (霍志達) and Mr. MIAO Tianxiang (苗天祥) with Mr. YUE Yichun being the chairperson of the Audit Committee. Mr. YUE Yichun and Mr. FOK Chi Tat Michael are independent non-executive Directors who hold the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules. The primary duties of the Audit Committee include, but not limited to, the following:

- reviewing and evaluating the work of external auditors;
- monitoring and making recommendations to internal audit work of our Company;
- reviewing and making recommendations to the financial reports of our Company;
- evaluating the effectiveness of internal control work;
- ensuring coordination between the management, internal audit department and relevant departments and external auditors; and
- performing other duties and responsibilities as assigned by our Board.

Remuneration Committee

We have established a Remuneration Committee with written terms of reference in compliance with the Corporate Governance Code as set forth in Appendix C1 to the Listing Rules. The Remuneration Committee consists of three Directors, namely Mr. YUE Yichun (岳儀春), Mr. LI Jiayan (李嘉焱) and Ms. JIA Lijia (賈麗加) with Mr. YUE Yichun being the chairperson of the Remuneration Committee. The primary duties of the Remuneration Committee include, but not limited to, the following:

- reviewing and approving remuneration proposals of members of our senior management in accordance with our Company’s policies and objectives as approved by our Board from time to time;

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- making recommendations to our Board on our Company’s policy and structure for all Directors’ and senior management remuneration and on the establishment of a formal and transparent procedure for developing remuneration policy, including but are not limited to, performance evaluation standards, procedures and evaluation systems;
- conducting the evaluation of the annual performance of all Directors and senior management;
- monitoring compensation payable to all Directors and senior management;
- reviewing and/or approving matters relating to share schemes under Chapter 17 of the Listing Rules; and
- performing other duties and responsibilities as assigned by our Board.

Nomination Committee

We have established a Nomination Committee with written terms of reference in compliance with the Corporate Governance Code as set forth in Appendix C1 to the Listing Rules. The Nomination Committee consists of three Directors, namely Mr. YUE Yichun (岳儀春), Mr. LI Jiayan (李嘉焱) and Ms. JIA Lijia (賈麗加) with Mr. YUE Yichun being the chairperson of the Nomination Committee. The primary duties of the Nomination Committee include, but not limited to, the following:

- reviewing and making recommendations to the Board on the composition and number of our Board and senior management with reference to our Company’s business activities, the scale of assets and shareholding structure;
- identifying individuals suitably qualified to become a member of our Board and senior management and making recommendations to our Board on the selection of individuals nominated for directorships and senior management;
- reviewing the structure and diversity of the Board and selecting individuals to be nominated as Directors;
- accessing and making recommendations to the selection of other senior management appointed by our Board; and
- performing other duties and responsibilities as assigned by our Board.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into (i) an employment contract, and (ii) a confidentiality and non-competition agreement with our senior management members and other key personnel. Set forth below are the key terms of these contracts we normally enter into with our senior management and other key personnel.

Confidentiality

The employee shall, during the course of employment with the Group and thereafter, keep in confidence all confidential information (including but not limited to trade secrets, technical secrets and other undisclosed confidential information) that belongs to the Group. During the term of employment, the employee shall not, without clear written authorization from the Company, directly or indirectly, disclose or divulge any confidential information of the Group to any third party in any way and shall not use such confidential information apart from discharging his/her duties as an employee of the Group. The employee is also obliged to prevent the disclosure, leakage, loss of and improper use of confidential information in relation to the Group. The employee shall return the documents and materials of the Group upon the termination of his/her employment contract. Such obligations of confidentiality shall subsist for the term of his/her employment and after the termination of his/her employment contract so long as the confidential information is not known to the public.

Non-competition

The non-competition obligations shall subsist throughout the employee's period of employment and up to two years after termination of employment. During the non-competition period, the employee shall not seek, induce, cause, allow, or assist other employees of our Company to terminate his or her labor relations or employment relationship with the Company, nor shall they act as an intermediary or contact person to support or assist any other employee to terminate his or her labor relations or employment relationship with the Company. During the term of employment and without prior written consent of the Company, the employee shall not engage in any business or engage in a course of employment that produces, or operates products, or provides services that are the same or similar to those offered by the Company, including acting as a partner, director, supervisor, manager, working staff, agent, advisor or any other collaborations. Regardless of the reason for the employee's departure, the employee shall provide us with relevant information of the new employer within three days after taking up employment with the new employer.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Intellectual Property Rights

Our Company has a complete, absolute and exclusive right, title and interest in the work (including but not limited to the invention, utility model, design and technical solution) that the employee produces, solely or jointly with others, arising from the performance of employment duties or from the use of our Company's material and technical conditions and business information, during the period of the employee's employment with our Company.

CORPORATE GOVERNANCE

Our Company is committed to achieving a high standard of corporate governance with a view to safeguarding the interests of our Shareholders. To accomplish this, our Company intends to comply with the Corporate Governance Code set out in Appendix C1 to the Hong Kong Listing Rules and the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix C3 to the Hong Kong Listing Rules after the [REDACTED].

BOARD DIVERSITY POLICY

In order to enhance the effectiveness of our Board and to maintain the high standard of corporate governance, we have adopted the board diversity policy which sets out the objective and approach to achieve and maintain diversity of our Board. Pursuant to the board diversity policy, we seek to achieve Board diversity through the consideration of a number of factors when selecting the candidates to our Board, including but not limited to gender, skills, age, professional experience, knowledge, cultural, education background, ethnicity and length of service. The ultimate decision of the appointment will be based on merit and the contribution which the selected candidates will bring to our Board.

Our Directors currently consists of two female Directors and seven male Directors with a balanced mix of gender, knowledge and skills, including but not limited to knowledge and experience in overall management and strategic development, quality assurance and control, finance and accounting and corporate governance in addition to industry experience relevant to our Group's operations and business. Considering 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 reviewing the structure and diversity of the Board and selecting individuals to be nominated as Directors. After the [REDACTED], our Nomination Committee will monitor and evaluate the implementation of the Board Diversity Policy from time to time to ensure its continued effectiveness, and when necessary, make any revisions that may be required and recommend any such revisions to our Board for consideration

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

and approval. The Nomination Committee will also include in annual reports a summary of the Board Diversity Policy, including any measurable objectives set for implementing the Board Diversity Policy and the progress on achieving these objectives.

CONFIRMATION FROM OUR DIRECTORS

Rule 8.10 of the Listing Rules

Each of our Directors confirms that as of the Latest Practicable Date, he or she did not have any interest in a business which competes or is likely to compete, either directly or indirectly, with our Company’s business which would require disclosure under Rule 8.10 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 April 2024, and (ii) understands his or her obligations as a director of a listed issuer under the Listing Rules.

Rule 3.13 of the Listing Rules

Each of the independent non-executive Directors has confirmed (i) his independence as regards each of the factors referred to in Rules 3.13(1) to (8) of the Listing Rules, (ii) he has no past or present financial or other interest in the business of our Company or our subsidiaries or any connection with any core connected person of our Company under the Listing Rules as of the Latest Practicable Date, and (iii) that there are no other factors that may affect his independence at the time of his appointment.

EMOLUMENT OF DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

We offer our executive Directors, Supervisors, and senior management members, who are also employees of our Company, emolument in the form of salaries, bonuses, allowances, benefits in kind, share-based payment and pension scheme contributions. Our independent non-executive Directors receive emolument based on respective positions and duties, including being a member or the chairperson of Board committees.

For the years ended December 31, 2022 and 2023, the aggregate amount of remuneration paid or payable to our Directors amounted to approximately RMB2,409,000 and RMB6,399,000, respectively. No share-based payment to our Directors was incurred during the Track Record Period. For remuneration details of all Directors for the years ended December 31, 2022 and 2023, please refer to Note 8 in Appendix I to this document.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

For the years ended December 31, 2022 and 2023, the amount of remuneration paid or payable to our Supervisors, without taking into account any share-based payment, were approximately RMB70,000 and nil, respectively. The share-based payments to our Supervisors for the years ended December 31, 2022 and 2023 were RMB6,116,000 and RMB6,384,000, respectively. The total emoluments paid or payable to our Supervisors, including the share-based payments, amounted to RMB6,186,000 and RMB6,384,000, for the years ended December 31, 2022 and 2023, respectively.

Under the arrangement currently in force, we estimate the total compensation before taxation, without taking into account any share-based payment, to be accrued to our Directors and our Supervisors for the year ending December 31, 2024 to be approximately RMB7,500,000. The actual remuneration of Directors and Supervisors in 2024 may be different from the expected remuneration.

For each of the years ended December 31, 2022 and 2023, there were nil, and one Directors among the five highest paid individuals, respectively. The total emoluments for the remaining individuals among the five highest paid individuals amounted to approximately RMB26,866,000 and RMB16,450,000, for the years ended December 31, 2022 and 2023, respectively.

We confirmed that during the Track Record Period, no consideration was paid by our Company to, or receivable by, our Directors for making available directors' services or as termination benefits.

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.

COMPLIANCE ADVISOR

We have appointed Orient Capital (Hong Kong) Limited as our Compliance Advisor pursuant to Rules 3A.19 of the Listing Rules. The Compliance Advisor 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 Advisor 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;

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

- (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 Stock Exchange makes an inquiry to our Company regarding unusual movements in the price or trading volume of its listed securities or any other matters in accordance with Rule 13.10 of the Listing Rules.

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].

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

OVERVIEW

As of the Latest Practicable Date, Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li directly held approximately 19.54%, 17.98%, 17.47% and 12.00% of our total issued share capital, respectively.

Pursuant to the Concert Party Agreement, Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li confirmed and acknowledged that, among other things, (i) since October 2020, they had communicated thoroughly before the Board meetings (as the case may be) and shareholders’ meetings of the Company, and had been acting in concert by aligning their votes at the Board meetings (as the case may be) and the shareholders’ meetings of the Company; and (ii) they will continue to communicate thoroughly and act in concert by aligning their votes at the Board meetings (as the case may be) and shareholders’ meetings of the Company until the earlier of (A) any of them ceases to be interested in the Shares directly or indirectly, or (B) the Concert Party Agreement is terminated by agreement among the Controlling Shareholders.

In light of the Concert Party Agreement, Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li together controlled the voting rights attaching to approximately 66.99% of the total issued share capital of the Company as of the Latest Practicable Date, and Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li are considered as a group of Controlling Shareholders for the purpose of the Listing Rules.

Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li will continue to control in aggregate approximately [REDACTED]% of our total issued share capital. Therefore, Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li will remain as a group of Controlling Shareholders upon [REDACTED].

For the biographical details of each of Ms. Jia and Mr. Wang, see “Directors, Supervisors and Senior Management” of this document.

Ms. Zhang has been our individual Shareholder since October 2013. She graduated from Renmin University of China (中國人民大學), majoring in financial accounting. Ms. Zhang has approximately 20 years of experience in the operation and management of biopharmaceutical enterprises. She has an in-depth understanding of the management and operation mode of pharmaceutical enterprises, and has extensive experience in the formulation of marketing strategies and corporate business plans.

Mr. Li has been our individual Shareholder since the establishment of our Company in April 2012. He graduated from Lanzhou University (蘭州大學) in 1989 with a bachelor’s degree in mathematics, and has over 30 years of experience in corporate operation and management. Mr. Li currently serves as an executive director of New World Strategic Investment Limited (新世界策略投資有限公司), the chairman of the board of Yunnan Guoyi Mining Investment Co., Ltd. (雲南國

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

—礦業投資有限公司), the chairman of the board of Shanghai Kaishiyi Network Technology Co., Ltd. (上海開示藝網絡科技有限公司), and the vice chairman of the board of Beijing Zhongbei TV Art Center Co., Ltd. (北京中北電視藝術中心有限公司). Mr. Li joined Chinalin Securities Co., Ltd. (華林證券股份有限公司, a company listed on the Shenzhen Stock Exchange with stock code: 002945) in November 2013, and served as its director from March 2016 to May 2022.

COMPETITION

As of the Latest Practicable Date, none of our Controlling Shareholders, their respective close associates and our Directors had any interest in any business which competes or is likely to compete, either directly or indirectly with our Group’s business which would require disclosure under Rule 8.10 of the Listing Rules.

INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDERS

Having considered the following factors, our Directors are satisfied that we are capable of carrying on our business independent from the Controlling Shareholders and their close associates after the [REDACTED].

Operational independence

Our Company has full rights to make all decisions on, and to carry out, our own business operations independently. We do not rely on our Controlling Shareholders and their close associates for our finance, audit and control, sales and marketing, human resources, administration or company secretarial functions. We have established our own organizational structure with independent departments specializing in respective areas of responsibilities. We are also in possession of all relevant licenses and own all relevant intellectual properties and research and development facilities necessary to carry on and operate our business, and we have sufficient operational capacity in terms of capital and employees independently.

In addition, we also entered into certain transactions with connected person in connection with our Controlling Shareholders, which will constitute continuing connected transactions of our Group after [REDACTED]. For details of such transactions, see “Connected Transactions.” For details about our related party transactions during the Track Record Period, see Note 27 in Appendix I to this document. The transactions under the Property Leasing Agreement will not undermine the operational independence of our Group on the basis that, with our access to independent sources and in a sufficiently competitive market, our Group will be able to identify other suppliers or lessors who are Independent Third Parties, and other suitable substitutes for our business premises through arm’s length negotiation at similar terms and conditions to meet our business and operational needs, without causing any undue delay or material disruption to our operations.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Accordingly, our Directors are satisfied that we will be able to function and operate independently from our Controlling Shareholders and their close associates.

Management independence

Our business is managed and conducted by our Board and senior management. Upon [REDACTED], our Board of Directors will consist of nine Directors, including three executive Directors, three non-executive Directors and three independent non-executive Directors. Our Directors are of the view that we are able to carry on our business independently from our Controlling Shareholders from a management perspective for the following reasons:

- (i) each of our Directors is fully aware of his/her fiduciary duties as a Director which require, among other things, that he/she acts for the benefit and in the best interests of our Company and our Shareholders as a whole, and does not allow any conflict between his/her duties as a Director and his/her personal interest to exist;
- (ii) we have three independent non-executive Directors which (i) account for one-third of the Board; and (ii) possess requisite industry knowledge and experience and are qualified to provide independent, sound and professional advice to our Company;
- (iii) in the event that there is a potential conflict of interest arising out of any transaction to be entered into between our Group and our Directors or their respective associates, the interested Director(s) is required to declare the nature of such interest before voting at the relevant Board meetings of our Company in respect of such transactions; and
- (iv) the daily management and operation of our Group are carried out by a senior management team, all of whom have substantial experience in the industry in which our Company is engaged, and will therefore be able to make business decisions that are in the best interests of our Group. For further details of the industry experience of our senior management team, see "Directors, Supervisors and Senior Management" in this document;
- (v) we have adopted a series of corporate governance measures to manage conflicts of interest, if any, between our Group and our Controlling Shareholders which would support our independent management. Please see "— Corporate Governance Measures" below for further details.

Based on the above, our Directors are satisfied that the Board as a whole, together with our senior management team, is able to perform the managerial role in our Group independently.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Financial independence

Our Company has its own independent financial, internal control and accounting system. We make financial decisions and determine our use of funds according to our own business needs. In addition, we are capable of obtaining financing from third parties without relying on any guarantee or security provided by our Controlling Shareholders. As of the Latest Practicable Date, save as disclosed in Note 27 in Appendix I to this document, there were no loans, advances and balances due to and from our Controlling Shareholders, nor any pledges and guarantees provided by our Controlling Shareholders on our Group's borrowing.

Based on the above, our Directors are of the view that our business is financially independent from our Controlling Shareholders.

CORPORATE GOVERNANCE MEASURES

Our Directors recognize the importance of good corporate governance to protect the interests of our Shareholders. We have adopted the following corporate governance measures to safeguard good corporate governance standards and to avoid potential conflict of interests between our Group and our Controlling Shareholders:

- (i) our Company has established internal control mechanisms to identify connected transactions. Upon [REDACTED], if our Group enters into connected transactions with our Controlling Shareholders or their associates, our Company will comply with the applicable requirements under the Listing Rules;
- (ii) where a Shareholders' meeting is to be held for considering proposed transactions in which our Controlling Shareholders or any of their close associates has a material interest, our Controlling Shareholders will not vote on the resolutions and shall not be counted in the quorum for the voting;
- (iii) our Board consists of a balanced composition of executive, non-executive and independent non-executive Directors, with not less than one-third of independent non-executive Directors to ensure that our Board is able to effectively exercise independent judgment in its decision-making process and provide independent advice to our Shareholders. Our independent non-executive Directors individually and collectively possess the requisite knowledge and experience to perform their duties. They will review whether there is any conflict of interests between our Group and provide impartial and professional advice to protect the interests of our minority Shareholders;

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

- (iv) where the advice from an independent professional, such as a financial or legal advisor, is reasonably requested by our Directors (including the independent non-executive Directors), the appointment of such an independent professional will be made at our Company's expenses; and

- (v) we have appointed Orient Capital (Hong Kong) Limited as our Compliance Advisor, who will provide advice and guidance to us in respect of compliance with the applicable laws and the Listing Rules, including various requirements relating to Directors' duties and corporate governance matters.

Based on the above, our Directors are satisfied that sufficient corporate governance measures have been put in place to manage conflict of interests between our Group and our Controlling Shareholders and to protect our minority Shareholders' rights after the [REDACTED].

SHARE CAPITAL

This section presents certain information regarding our share capital before and upon completion of the [REDACTED].

BEFORE THE [REDACTED]

As of the Latest Practicable Date, the registered capital of our Company was RMB100,008,722, comprising 100,008,722 Unlisted Shares with nominal value of RMB1.00 each.

UPON COMPLETION OF THE [REDACTED]

Immediately following completion of the [REDACTED] and the Conversion of Unlisted Shares into H Shares, assuming the [REDACTED] is not exercised, the share capital of our Company will be as follows:

Description of Shares	Number of Shares	Approximate percentage to total share capital (%)
Unlisted Shares in issue	[REDACTED]	[REDACTED]
H Shares to be converted from Unlisted Shares.	[REDACTED]	[REDACTED]
H Shares to be issued under the [REDACTED]	[REDACTED]	[REDACTED]
Total	[REDACTED]	100.00

Immediately following completion of the [REDACTED] and the Conversion of Unlisted Shares into H Shares, assuming the [REDACTED] is fully exercised, the share capital of our Company will be as follows:

Description of Shares	Number of Shares	Approximate percentage to total share capital ⁽¹⁾ (%)
Unlisted Shares in issue	[REDACTED]	[REDACTED]
H Shares to be converted from Unlisted Shares.	[REDACTED]	[REDACTED]
H Shares to be issued under the [REDACTED]	[REDACTED]	[REDACTED]
Total	[REDACTED]	100.00

Note:

(1) Shareholding percentages may not add up to 100% due to rounding.

SHARE CAPITAL

The Conversion of Unlisted Shares into H Shares will involve an aggregate of [REDACTED] Unlisted Shares held by all [REDACTED] existing Shareholders, representing approximately [REDACTED]% of total issued Shares of the Company as of the Latest Practicable Date and approximately [REDACTED]% of total issued Shares of the Company upon completion of the Conversion of Unlisted Shares into H Shares and the [REDACTED] (assuming the [REDACTED] is not exercised). Set out below are such number of Shares held by our existing Shareholders and their respective shareholding upon completion of the Conversion of Unlisted Shares into H Shares and the [REDACTED] (assuming the [REDACTED] is not exercised).

Shareholders	Total Shares as of the Latest Practicable Date	Shares immediately after the Conversion of Unlisted Shares into H Shares and the [REDACTED] (assuming the [REDACTED] is not exercised)			
		H Shares to be Converted from Unlisted Shares	Approximate Percentage	Unlisted Shares	Approximate Percentage
Ms. Jia	19,540,937	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%
Mr. Wang.	17,980,000	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%
Ms. Zhang	17,475,000	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%
Mr. Li.	12,000,000	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%
Qingdao Hitech	9,090,793	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%
Qingdao Huaren.	8,000,000	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%
Song Jianqing (宋建青) . .	5,760,000	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%
Hainan Huaren	4,785,000	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%
Qingdao CDH.	3,033,680	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%
Jiaxing CDH.	1,799,562	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%
Zhang Hong (張鴻).	543,750	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%
Total	100,008,722	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%

OUR SHARES

Upon completion of the [REDACTED] and the Conversion of Unlisted Shares into H Shares, our Shares will consist of Unlisted Shares and H Shares. Unlisted Shares and H Shares are both ordinary Shares under the same class in the share capital of our Company.

Our H Shares may only be subscribed for and traded in Hong Kong dollars. Our Unlisted Shares, on the other hand, may only be subscribed for and traded in RMB. 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 (such as our certain existing Shareholders the Unlisted Shares held by whom will be converted in to H shares according to the approval of the

SHARE CAPITAL

CSRC), H Shares generally cannot be subscribed for by or traded between legal or natural persons of the PRC. Our Unlisted Shares, on the other hand, can be purchased or transferred between legal or natural persons of the PRC, qualified foreign institutional investors and qualified foreign strategic investors. Unlisted Shares and H Shares shall rank *pari passu* with each other in all respects and, in particular, will rank equally for dividends or distributions declared, paid or made. All dividends for H Shares will be denominated and declared in Renminbi, and paid in Hong Kong dollars or Renminbi, whereas all dividends for unlisted Shares will be paid in Renminbi. Other than cash, dividends could also be paid in the form of shares.

CONVERSION OF UNLISTED SHARES INTO H SHARES

Pursuant to the regulations prescribed by the securities regulatory authorities of the State Council and the Articles of Association, the Unlisted Shares may be converted into [REDACTED] Shares. Such converted Shares could be [REDACTED] on an overseas stock exchange, provided that prior to the conversion and [REDACTED] of such converted Shares, any requisite internal approval process has been duly completed, all the filing procedures with relevant PRC regulatory authorities, including the CSRC are followed. In addition, such conversion and [REDACTED] shall comply with the regulations, requirements and procedures prescribed by the relevant overseas stock exchange. If any of the Unlisted Shares are to be converted, [REDACTED] as H Shares on the Hong Kong Stock Exchange, such conversion, [REDACTED] will need the approval of the relevant PRC regulatory authorities, including the CSRC, and the approval of the Hong Kong Stock Exchange.

Filing with the CSRC and Full Circulation Application

In accordance with the Overseas Listing Trial Measures and related guidelines, H-share listed companies which apply for the conversion of unlisted shares into H shares for listing and circulation on the Hong Kong Stock Exchange shall file with the CSRC. An unlisted joint stock company may apply for “full circulation” when applying for an overseas listing.

We [have filed] with the CSRC for, and the CSRC has registered the conversion of [REDACTED] Unlisted Shares into H Shares on a one-for-one basis upon the completion of the [REDACTED] and CSRC issued the filing notice in respect of the [REDACTED] dated [•], 2024.

SHARE CAPITAL

[REDACTED] Approval by the Hong Kong Stock Exchange

We have applied to the [REDACTED] of the Hong Kong Stock Exchange for the granting of the [REDACTED] of, and permission to [REDACTED], our H Shares to be issued pursuant to the [REDACTED] (including any H Shares which may be issued pursuant to the exercise of the [REDACTED]) and the H Shares to be converted from [REDACTED] Unlisted Shares on the Hong Kong Stock Exchange, which is subject to the approval by the Hong Kong Stock Exchange.

We will perform the following procedures for the conversion of the relevant Unlisted Shares into H Shares after receiving the approval of the Hong Kong Stock Exchange: (1) giving instructions to our [REDACTED] regarding relevant share certificates of the converted H Shares; and (2) enabling the converted H Shares to be accepted as eligible securities by [REDACTED] for deposit, clearance and settlement in the [REDACTED].

RESTRICTION ON TRANSFER OF SHARES ISSUED PRIOR TO THE [REDACTED]

In accordance with Article 141 of the PRC Company Law, the shares issued prior to any listing of shares by a company cannot be transferred within one year from the date on which such publicly offered shares are listed and traded on the relevant stock exchange. As such, the Shares issued by the Company prior to the [REDACTED] will be subject to such statutory restriction on transfer within a period of one year from the [REDACTED]. See “History, Development and Corporate Structure — Principal terms of the Pre-[REDACTED] Investors”.

CIRCUMSTANCES UNDER WHICH GENERAL MEETINGS ARE REQUIRED

Pursuant to the PRC Company Law and the terms of the Articles of Association, our Company may from time to time by special resolution of shareholders, among others, increase its capital or decrease its capital or repurchase of shares. See “Appendix III — Summary of Articles of Association” in this document.

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and the Conversion of Unlisted Shares into H Shares, and assuming the [REDACTED] is not exercised, the following persons will have interests and/or short positions in the Shares or underlying shares of our Company which would fall to be disclosed pursuant to the provisions of Divisions 2 and 3 of Part XV of the SFO, or, directly or indirectly, be interested in 10% or more of the nominal value of any class of share capital carrying the rights to vote in all circumstances at general meetings of our Company:

Name of Shareholder	Nature of Interest	Number and Class of Shares held upon completion of the [REDACTED] ⁽¹⁾	Approximate percentage of shareholding in total/issued share capital of our Company as of the Latest Practicable Date	Approximate percentage of shareholding in the total/issued share capital of our Company immediately after the [REDACTED] ⁽²⁾	Approximate percentage of shareholding in the relevant class of Shares after the [REDACTED]
Ms. Jia	Beneficial owner, and interest of concerted parties ⁽³⁾	[REDACTED]	22.89%	[REDACTED]%	[REDACTED]%
	Beneficial owner, and interest of concerted parties ⁽³⁾	[REDACTED]	44.10%	[REDACTED]%	[REDACTED]%
Mr. Wang	Beneficial owner, and interest of concerted parties ⁽³⁾	[REDACTED]	22.89%	[REDACTED]%	[REDACTED]%
	Beneficial owner, and interest of concerted parties ⁽³⁾	[REDACTED]	44.10%	[REDACTED]%	[REDACTED]%
Ms. Zhang.	Beneficial owner, and interest of concerted parties ⁽³⁾	[REDACTED]	22.89%	[REDACTED]%	[REDACTED]%
	Beneficial owner, and interest of concerted parties ⁽³⁾	[REDACTED]	44.10%	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Nature of Interest	Number and Class of Shares held upon completion of the [REDACTED] ⁽¹⁾	Approximate percentage of shareholding in total/issued share capital of our Company as of the Latest Practicable Date	Approximate percentage of shareholding in the total/issued share capital of our Company immediately after the [REDACTED] ⁽²⁾	Approximate percentage of shareholding in the relevant class of Shares after the [REDACTED]
Mr. Li	Beneficial owner, and interest of concerted parties ⁽³⁾	[REDACTED]	22.89%	[REDACTED]%	[REDACTED]%
	Beneficial owner, and interest of concerted parties ⁽³⁾	[REDACTED]	44.10%	[REDACTED]%	[REDACTED]%
Qingdao Hitech ⁽⁴⁾	Beneficial owner	[REDACTED]	6.00%	[REDACTED]%	[REDACTED]%
	Beneficial owner	[REDACTED]	3.09%	[REDACTED]%	[REDACTED]%
Qingdao Laoshan Science and Technology Innovation Development Group Co. Ltd. (青島崂山科技創新發展集團有限公司) ⁽⁴⁾	Interest in controlled corporation	[REDACTED]	6.00%	[REDACTED]%	[REDACTED]%
	Interest in controlled corporation	[REDACTED]	3.09%	[REDACTED]%	[REDACTED]%
Qingdao Huaren ⁽⁵⁾	Beneficial owner	[REDACTED]	3.60%	[REDACTED]%	[REDACTED]%
	Beneficial owner	[REDACTED]	4.40%	[REDACTED]%	[REDACTED]%
Tang Anqi (唐安琪) ⁽⁵⁾	Interest in controlled corporation	[REDACTED]	3.60%	[REDACTED]%	[REDACTED]%
	Interest in controlled corporation	[REDACTED]	4.40%	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Notes:

- (1) All interests stated are long positions.
- (2) The calculation is based on the total number of [REDACTED] Unlisted Shares in issue and [REDACTED] H Shares to be issued pursuant to the [REDACTED] (including [REDACTED] H Shares to be converted from Unlisted Shares) in issue upon [REDACTED], assuming that the [REDACTED] is not exercised.
- (3) As of the Latest Practicable Date, Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li directly held 19,540,937 Shares, 17,980,000 Shares, 17,475,000 Shares and 12,000,000 Shares in our Company, respectively. By virtue of the Concert Party Agreement, each of Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li is deemed to be interested in such Shares by the other Controlling Shareholders as they are parties acting in concert.
- (4) As of the Latest Practicable Date, Qingdao Hitech directly held a total of 9,090,793 Shares in our Company. It is wholly owned by Qingdao Laoshan Science and Technology Innovation Development Group Co. Ltd. (青島嶗山科技創新發展集團有限公司), which is in turn wholly controlled by Laoshan District Financial Bureau of Qingdao City (青島市嶗山區財政局), a PRC government body. As such, Qingdao Laoshan Science and Technology Innovation Development Group Co. Ltd. (青島嶗山科技創新發展集團有限公司) is deemed to be interested in such Shares held by Qingdao Hitech.
- (5) Qingdao Huaren is a limited partnership established under the laws of the PRC on November 30, 2020 and is one of our Employee Shareholding Platforms. As of the Latest Practicable Date, it was managed by its executive partner, Tang Anqi (唐安琪), who is an employee of our Company, and none of the limited partners of Qingdao Huaren contributed more than one third of the capital to Qingdao Huaren. Accordingly, Tang Anqi is deemed to be interested in such Shares held by Qingdao Huaren.

Saved as disclosed herein, our Directors are not aware of any other person who will, immediately following the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised) and the Conversion of Unlisted Shares into H Shares, have any interest and/or short positions in the Shares or underlying shares of our Company which would fall to be disclosed to the Company pursuant to 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 nominal value of any class of our share capital carrying rights to vote in all circumstances at general meetings of our Company. Our Directors are not aware of any arrangement which may at a subsequent date result in a change of control of our Company or any other member of our Group.

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You should read the following discussion and analysis together with our audited consolidated financial information, including the notes thereto, included in Appendix I to this document. Our consolidated financial information has been prepared in accordance with IFRS.

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 this document, including but not limited to the sections headed “Risk Factors” and “Business.”

OVERVIEW

Founded in 2012, we are a China-based innovative biopharmaceutical company committed to developing breakthrough therapies with an emphasis on protein drugs for indications with unmet medical needs and large market opportunities. We primarily focus on the discovery, development and commercialization of multifunctional therapies for wound healing, currently PDGF drugs. Designed to address both acute and chronic wounds as well as minor and hard-to-heal wounds, our Core Products and other PDGF candidates are currently being developed for a broad spectrum of wound healing indications including (i) thermal burns, (ii) DFUs, (iii) fresh wounds, (iv) pressure ulcers, (v) radiation ulcers, (vi) photodermatitis, (vii) alopecia, (viii) hemorrhoids, (ix) dry eye syndrome, (x) corneal injury and (xi) gastric ulcers. As of the Latest Practicable Date, we had entered the Phase IIb clinical trial of Pro-101-1 in thermal burns in China, and the Phase II clinical trial of Pro-101-2 in DFUs in China. In addition, we submitted a pre-IND communication application to the FDA in December 2021 with respect to Pro-101-1 in thermal burns. Meanwhile, we were also advancing the pre-clinical development of PDGF candidates for nine other indications.

During the Track Record Period, we derived all of our revenue from providing research and development services to a single customer. During the Track Record Period and up to the Latest Practicable Date, we had not generated any revenue from product sales, and we do not expect to generate any revenue from product sales before the commercialization of one or more of our candidates. We were not profitable and incurred operating loss during the Track Record Period. In 2022 and 2023, we had operating loss of RMB85.9 million and RMB105.2 million, respectively. Substantially all of our operating loss resulted from research and development expenses and administrative expenses.

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BASIS OF PREPARATION

Our historical financial information has been prepared in accordance with International Financial Reporting Standards (“**IFRS**”) issued by the International Accounting Standards Board (“**IASB**”). Our historical financial information has been prepared under the historical cost convention, as modified by the revaluation of financial assets and financial liabilities at fair value through profit or loss, which are carried at fair value. We have adopted all applicable new and amended IFRSs consistently throughout the Track Record Period except for any new or interpretation that are not yet effective.

MAJOR FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations have been, and are expected to continue to be, materially affected by a number of factors, including the following:

General Factors

Our business and operating results are affected by general factors affecting the global and PRC wound healing and growth factor markets, which include:

- relevant laws and regulations, governmental policies and initiatives affecting the relevant markets;
- growth and competition environment of the relevant markets; and
- political, economic and social instability of different local markets.

Company Specific Factors

While our business is influenced by general factors affecting the global and PRC wound healing and growth factor markets, our results of operations are also affected by company specific factors, including the following:

Our Ability to Successfully Develop our Candidates

Our business and results of operations depend on the successful development of our candidates. As of the Latest Practicable Date, we had researched and developed three pipelines consisting of ten candidates covering 14 indications, including two clinical-stage indications. See “Business — Our Candidates.” Whether our candidates can demonstrate favorable safety and efficacy results from our pre-clinical studies and clinical trials and whether we can successfully

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complete clinical development and whether we can obtain the requisite regulatory approvals for our candidates, are crucial to our business and results of operations. See “Risk Factors — Risks Relating to the Research and Development of Our Candidates” and “Risk Factors — Risks Relating to Regulatory Approvals and Government Regulations.”

Our Ability to Successfully Commercialize, Manufacture and Market our Candidates

We believe the scale and effectiveness of our commercial operation will be crucial to our business. As of the Latest Practicable Date, none of our candidates have been commercialized and we have not generated any revenue from sales of our candidates. We expect to commercialize at least two innovative drugs independently in the next six years. We intend to commercialize our candidates, if approved, by utilizing both direct sales force and strategic partnerships to achieve geographical and channel coverage. See “Business — Commercialization.” However, the commercialization may require significant marketing efforts and inputs before we are able to generate any revenue from sales of our candidates. Once our candidates are commercialized, our business and results of operations will be driven by the market acceptance and sales of our commercialized candidates, which could be affected by: (i) the extent to which reimbursement for these candidates and related treatments will be available from relevant health administrative authorities, private health insurers and other organizations; (ii) our cooperation with third-party collaborators under our sales network; (iii) our pricing policies and (iv) our biologics manufacturing capacity to meet the commercial demand. See “Risk Factors — Risks Relating to Commercialization of Our Candidates” and “Risk Factors — Risks Relating to Manufacturing of Our Candidates.”

Our Cost Structure

Our results of operations are significantly affected by our cost structure, which primarily consists of research and development expenses and administration expenses.

The development of drugs requires a significant investment of resources over a prolonged period of time, and we intend to continue making sustained investments in this area. We have devoted significant resources on research and development activities and our pipeline of candidates have been steadily advancing and expanding. We incurred research and development expenses of RMB34.8 million and RMB39.9 million in 2022 and 2023, respectively, accounting for 44.1% and 48.7%, respectively, of our total expenses in the same years. We incurred research and development expenses of RMB26.8 million and RMB33.3 million attributable to our Core Products in 2022 and 2023, respectively. Our research and development expenses primarily consist of: (i) employee benefit expenses of our research and development personnel; (ii) share-based payment; (iii) service fee, mainly in relation to CDMO and CRO services; (iv) cost of raw materials, mainly in relation to our research and development activities; (v) depreciation and amortization expenses;

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and (vi) office expenses. See “— Description of Major Components of Our Results of Operations — Research and Development Expenses.” The research and development expenses are affected by factors such as: (i) the expansion of our product pipeline as well as potential indications; (ii) complexities of analytical testing technology; (iii) the size and demographics of the enrolled patients; (iv) the number of clinical trial sites and countries involved; (v) the pre-clinical efforts needed for identifying more molecules with proven or highly potential efficacy and significant market opportunities; (vi) the number of our research and development staff; and (vii) any additional requirements imposed by competent regulatory authorities to our pre-clinical and clinical trials. See “Risk Factors — Risks Relating to the Research and Development of Our Candidates.” We intend to continue to advance the development of our candidates, and the research and development expenses are therefore expected to continue to be a major component of our operating expenses.

In addition, we incurred administrative expenses of RMB44.2 million and RMB42.1 million in 2022 and 2023, which primarily consist of: (i) employee benefit expenses, mainly including salaries and bonuses, and other employee benefits relating to our administrative staff; (ii) share-based payment; (iii) hospitality and traveling expenses; (iv) service fee in relation to consulting service of our financing activities and recruitment; (v) [REDACTED]; (vi) depreciation and amortization expenses; and (vii) office expenses. See “— Description of Major Components of Our Results of Operations — Administrative Expenses.”

We expect to incur significant expenses and operating loss for at least the next several years as we further our pre-clinical and clinical research and development efforts, seek regulatory approval for our candidates, launch commercialization of our pipeline candidates, and add personnel necessary to operate our business. We expect that our financial performance will fluctuate from period to period due to the development status of our candidates, regulatory approval timeline and commercialization of our candidates after approval. Subsequent to the [REDACTED], we expect to incur costs associated with operating as a public company.

Funding for Our Operation

During the Track Record Period, we primarily funded our working capital requirements through capital contributions from our Shareholders and private equity financing. Going forward, in the event of a successful commercialization of one or more of our candidates, we expect to fund our operations in part with revenue generated from sales of our commercialized candidates. However, with the continuing expansion of our business, we may require further funding through public or private offerings, debt financing or other sources. Any fluctuation in the funding for our operations will impact our cash flow plan and our results of operations.

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CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Some of our accounting policies require us to apply estimates and assumptions as well as complex judgments related to accounting items. The estimates and assumptions we use and the judgments we make in applying our accounting policies have a significant impact on our financial position and operational results. Our management continually evaluates such estimates, assumptions and judgments based on past experience and other factors, including industry practices and expectations of future events that are deemed to be reasonable under the circumstances. There has not been any material deviation from our management's estimates or assumptions and actual results, and we have not made any material changes to these estimates or assumptions during the Track Record Period. We do not expect any material changes in these estimates and assumptions in the foreseeable future.

We set forth below those accounting policies that we believe are of critical importance to us or involve the most significant estimates, assumptions and judgments used in the preparation of our financial statements. For details of the critical accounting policies, estimates, assumptions and judgments involved in the preparation of financial statements of our Group, see Notes 2 and 3 in Appendix I to this document.

Critical Accounting Policies

Revenue Recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services.

Provision of research and development services

We recognize revenue only when we satisfy a performance obligation by transferring control of the promised services at a point in time.

Fair Value Measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a

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principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by us. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant's ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

We use valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the Historical Financial Information are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 — based on quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 — based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly.
- Level 3 — based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

For assets and liabilities that are recognized in the Historical Financial Information on a recurring basis, we determine whether transfers have occurred between levels in the hierarchy by reassessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of the Track Record Period.

Intangible Assets (Other than Goodwill)

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least at each financial year end.

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Patents

Patents are stated at cost less any impairment losses and are amortized on the straight-line basis over their estimated useful lives.

Research and Development costs

All research costs are charged to profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalized and deferred only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, our intention to complete and our ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development.

Development expenditure which does not meet these criteria is expensed when incurred.

Deferred development costs are stated at cost less any impairment losses and are amortized using the straight-line basis over the commercial lives of the underlying products, commencing from the date when the products are put into commercial production.

Property, Plant and Equipment and Depreciation

Property, plant and equipment, other than construction in progress, are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalized in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, we recognize such parts as individual assets with specific useful lives and depreciate them accordingly.

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Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal estimated useful lives and estimated residual values used for this purpose are as follows:

Categories	Estimated useful lives	Estimated residual value rate
Machinery	3 to 10 years	5%
Office equipment	5 years	5%
Electronic equipment	3 to 5 years	5%
Leasehold improvements	Calculated on the shorter of estimated useful lives and remaining lease terms	—

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at each financial year end.

An item of property, plant and equipment including any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognized in profit or loss in the year the asset is derecognized is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Impairment of Non-financial Assets

Where an indication of impairment exists, or when annual impairment testing for a non-financial asset is required (other than financial assets), the asset's recoverable amount is estimated. An asset's recoverable amount is the higher of the asset's or cash-generating unit's value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

In testing a cash-generating unit for impairment, a portion of the carrying amount of a corporate asset (e.g., a headquarters building) is allocated to an individual cash-generating unit if it can be allocated on a reasonable and consistent basis or, otherwise, to the smallest group of cash-generating units.

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An impairment loss is recognized only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of the Track Record Period as to whether there is an indication that previously recognized impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognized impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortization) had no impairment loss been recognized for the asset in prior years. A reversal of such an impairment loss is credited to profit or loss in the period in which it arises.

Impairment of Financial Assets

We recognize an allowance for expected credit losses (“ECLs”) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that we expect to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

General approach

ECLs are recognized in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At each reporting date, we assess whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, we compare the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition and consider reasonable

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and supportable information that is available without undue cost or effort, including historical and forward-looking information. We consider that there has been a significant increase in credit risk when contractual payments are more than 30 days past due.

We consider a financial asset in default when contractual payments are 90 days past due. However, in certain cases, we may also consider a financial asset to be in default when internal or external information indicates that we are unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by us. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Financial assets at amortized cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables which apply the simplified approach as detailed below.

- Stage 1 — Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs
- Stage 2 — Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs
- Stage 3 — Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs

Simplified approach

For trade receivables that do not contain a significant financing component or when we apply the practical expedient of not adjusting the effect of a significant financing component, we apply the simplified approach in calculating ECLs. Under the simplified approach, we do not track changes in credit risk, but instead recognize a loss allowance based on lifetime ECLs at each reporting date. We have established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

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Share-based payments

We operate a share incentive plan. Our employees (including directors) receive remuneration in the form of share-based payments, whereby employees render services in exchange for equity instruments (“equity-settled transactions”). The cost of equity-settled transactions with employees for grants is measured by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by an external valuer using back-solve method, further details of which are given in Note 24 in Appendix I to this document.

The cost of equity-settled transactions is recognized in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognized for equity-settled transactions at the end of each period in the Track Record Period until the vesting date reflects the extent to which the vesting period has expired and our best estimate of the number of equity instruments that will ultimately vest. The charge or credit to profit or loss for a period represents the movement in the cumulative expense recognized as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of our best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognized. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognized as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognized for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognized for the award is recognized immediately. This includes any award where non-vesting conditions within the control of either us or the employee

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are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

Leases

We assess at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

We as a lessee

We apply a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. We recognize lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

Right-of-use assets are recognized at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the lease terms as follows:

Categories	Estimated useful lives
Buildings	3 to 7 year

If ownership of the leased asset transfers to us by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

(b) Lease liabilities

Lease liabilities are recognized at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value

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guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by us and payments of penalties for termination of a lease, if the lease term reflects us exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognized as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, we use our incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

(c) Short-term leases

We apply the short-term lease recognition exemption to its short-term leases of buildings and motor vehicles (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option).

Lease payments on short-term leases are recognized as an expense on a straight-line basis over the lease term.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as payables.

All financial liabilities are recognized initially at fair value and, in the case of payables, net of directly attributable transaction costs.

Our financial liabilities include trade and other payables and other financial liabilities.

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Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at amortized cost (trade and other payables and other financial liabilities)

After initial recognition, trade and other payables, and other financial liabilities are subsequently measured at amortized cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognized in profit or loss when the liabilities are derecognized as well as through the effective interest rate amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortization is included in finance costs in the statement of profit or loss.

Significant Accounting Estimates

Impairment of Non-Financial Assets (Other than Goodwill)

We assess whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of the Track Record Period. Development costs, not available for intended use, are tested for impairment annually and at other times when such an indicator exists. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm's length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

Fair value measurement of share-based payments

We have set up a share incentive plan and granted share award to our employees. The fair values of the share award are determined by the back-solve method at the grant dates. Significant estimates on assumptions, including the underlying equity value, are made by management. See Note 24 in Appendix I to this document.

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DESCRIPTION OF MAJOR COMPONENTS OF OUR RESULTS OF OPERATIONS

We have not generated any revenue from product sales. We were not profitable and incurred operating loss during the Track Record Period. In 2022 and 2023, we had operating loss of RMB85.9 million and RMB105.2 million, respectively. Substantially all of our operating loss resulted from research and development expenses and administrative expenses. The following table sets out some details of our consolidated statements of comprehensive loss for the years indicated:

	Year ended December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Revenue	—	472
Cost of sales	—	(255)
Gross profit	—	217
Other income and gains	1,002	271
Administrative expenses	(44,223)	(42,117)
Research and development expenses	(34,818)	(39,915)
Other expenses	(32)	(62)
Finance costs	(7,855)	(23,582)
Loss before tax	(85,926)	(105,188)
Income tax expense	—	—
Loss for the year	(85,926)	(105,188)
Total Comprehensive Loss for the Year	(85,926)	(105,188)

Revenue

During the Track Record Period, all of our revenue was generated from the provision of research services to a single customer in relation to a project on medical devices for wound healing. We conducted research on the relevant pharmaceutical formulations and compiled related technical points and screening proposals. Such business is not part of our core business. However, we may from time to time receive similar requests from potential customers and, depending on our capacity and the extent of relevance of such requests to our research and development activities, we may work on such requests on a commission basis. In 2022 and 2023, our revenue was nil and RMB0.5 million, respectively.

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Cost of sales

During the Track Record Period, our cost of sales represented the staff cost incurred for conducting the research services for the customer of the aforementioned project on medical devices for wound healing. In 2022 and 2023, our cost of sales was nil and RMB0.3 million, respectively.

Gross Profit

Gross profit represents our revenue less our cost of sales. Gross profit margin represents our gross profit as a percentage of our revenue. Our gross profit was nil and RMB0.2 million in 2022 and 2023, respectively, solely relating to the aforementioned project on medical devices for wound healing. Our gross margin was nil and 46.0% in 2022 and 2023, respectively.

Other Income and Gains

Our other income and gains primarily consist of (i) government grants, primarily representing the subsidies we received from local governmental authorities for the purpose of supporting our research and development activities; (ii) bank interest income, primarily representing interest income from bank deposits; and (iii) net foreign exchange differences. The following table sets out a breakdown of our other income and gains for the years indicated:

	Year ended December 31,			
	2022		2023	
	<i>(RMB in thousands, except for percentages)</i>			
Other Income				
Bank interest income	726	72.5%	237	87.5%
Government grants	223	22.3%	—	—
Others	37	3.7%	34	12.5%
Gains				
Foreign exchange differences, net	16	1.6%	—	—
Total	1,002	100.0%	271	100.0%

FINANCIAL INFORMATION

Administrative Expenses

Our administrative expenses primarily consist of: (i) employee benefit expenses, mainly including salaries and bonuses, and other employee benefits relating to our administrative staff; (ii) share-based payment; (iii) hospitality and traveling expenses; (iv) service fee in relation to consulting service of our financing activities and recruitment; (v) [REDACTED]; (vi) depreciation and amortization expenses; and (vii) office expenses. The following table sets out a breakdown of our administrative expenses for the years indicated:

	Year ended December 31,			
	2022			2023
	<i>(RMB in thousands, except for percentages)</i>			
Employee benefit expenses	12,039	27.2%	14,227	33.8%
Share-based payment	20,522	46.4%	9,743	23.1%
Hospitality and traveling expenses . . .	4,640	10.5%	9,196	21.8%
Service fee	1,404	3.2%	1,879	4.5%
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Depreciation and amortization expenses	1,276	2.9%	1,463	3.5%
Office expenses	176	0.4%	1,593	3.8%
Others ⁽¹⁾	1,171	2.6%	2,692	6.4%
Total	44,223	100.0%	42,117	100.0%

Note:

(1) Others mainly include short-term lease payments, vehicle usage fees, training fees and property management fees.

FINANCIAL INFORMATION

Research and Development Expenses

Our research and development expenses primarily consist of: (i) employee benefit expenses of our research and development personnel; (ii) share-based payment; (iii) service fee, mainly in relation to CDMO and CRO services; (iv) cost of raw materials, mainly in relation to our research and development activities; (v) depreciation and amortization expenses; and (vi) office expenses. The following table sets out a breakdown of our research and development expenses by nature for the years indicated:

	Year ended December 31,			
	2022			2023
	<i>(RMB in thousands, except for percentages)</i>			
Employee benefit expenses	13,006	37.4%	10,546	26.4%
Share-based payment	4,311	12.4%	4,927	12.3%
Service fee	6,831	19.6%	11,834	29.6%
Cost of raw materials	4,164	12.0%	5,630	14.1%
Depreciation and amortization expenses	5,171	14.9%	5,280	13.2%
Office expenses	671	1.9%	627	1.6%
Others ⁽¹⁾	664	1.9%	1,071	2.7%
Total	34,818	100.0%	39,915	100.0%

Note:

(1) Others mainly include intellectual property expenses, traveling expenses and conference expenses.

Our research and development expenses attributable to our Core Products were RMB26.8 million and RMB33.3 million in 2022 and 2023, respectively, accounting for 33.9% and 40.6% of our total operating expenses (comprising research and development expenses and administrative expenses) in the same years, respectively. The following table sets forth the clinical development expenses attributable to the Core Products during the Track Record Period by development stage:

	Year ended December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Phase I	813	—
Phase II	25,983	33,339
Total	26,796	33,339

FINANCIAL INFORMATION

Other Expenses

Our other expenses primarily represent (i) net loss on disposal of non-current assets, (ii) service fee in relation to bank service and (iii) exchange losses. The following table sets out a breakdown of our other expenses by nature for the years indicated:

	Year ended December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Net loss on disposal of non-current assets	7	—
Service fee	11	19
Exchange losses	—	19
Others	14	24
Total	32	62

Finance Costs

Our finance costs consist of (i) interest on other financial liabilities relating to the redemption liabilities from Pre-[REDACTED] Investments and (ii) interest on lease liabilities. For details on our lease liabilities, see “— Indebtedness.” The following table sets out a breakdown of our finance costs for the years indicated:

	Year ended December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Interest on other financial liabilities	7,340	23,170
Interest on lease liabilities	515	412
Total	7,855	23,582

FINANCIAL INFORMATION

Income Tax Expense

We did not record income tax expense in 2022 and 2023. 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. Our principal applicable taxes and tax rates are set forth as follows:

Mainland China

Under the Law of the PRC on EIT Law and Implementation Regulation of the CIT Law, the CIT rate of the PRC subsidiary was 25% during the Track Record Period. We were accredited as a “High and New Technology Enterprise” (“HNTTE”) in 2021 and the certificate will expire in December 2024. Therefore, we were entitled to a preferential CIT rate of 15% during the Track Record Period. The qualification as a HNTTE is subject to review by the relevant tax authority in the PRC every three years. The two PRC subsidiaries have met the requirement under the relevant tax rules and regulations for small and low-profit enterprises, and accordingly, were subject to a reduced preferential CIT rate of 20%, and the portion of the annual taxable income not more than RMB1,000,000 was entitled to be included in the actual taxable income at reduced rates of 12.5% in 2022 and 25% in 2023, respectively.

No provision for Mainland China income tax pursuant to the CIT Law has been made as the Group’s subsidiaries which operate in Mainland China are in loss position and have no estimated taxable profits.

Hong Kong

The subsidiary incorporated in Hong Kong is a qualifying entity under the two-tiered profits tax rates regime. No provision for Hong Kong profits tax has been made as subsidiary incorporated in Hong Kong had no assessable profits derived from or earned in Hong Kong during the Track Record Period. See Note 10 in Appendix I to this document.

During the Track Record Period and up to the Latest Practicable Date, we had made all the required tax filings with the relevant tax authorities in the PRC and Hong Kong, and we are not aware of any outstanding or potential disputes with such tax authorities.

FINANCIAL INFORMATION

YEAR-TO-YEAR COMPARISON OF RESULTS OF OPERATIONS

2023 Compared to 2022

Revenue

We recorded revenue of nil and RMB0.5 million in 2022 and 2023, respectively, primarily due to the provision of research services to a single customer in relation to a project on medical devices for wound healing in 2023, which was one-off in nature.

Cost of Sales

We recorded cost of sales of nil in 2022 and RMB0.3 million in 2023, primarily due to the staff cost incurred for conducting the research and development services for the customer in relation to the aforementioned project.

Gross Profit and Gross Profit Margin

As a result of the foregoing, we recorded gross profit of RMB0.2 million in 2023, with a gross profit margin of 46.0% in 2023. We did not have any gross profit in 2022.

Other Income and Gains

Our other income and gains decreased by 73.0% from RMB1.0 million in 2022 to RMB0.3 million in 2023, primarily due to (i) a decrease in government grants of RMB0.2 million in 2023, as the government grants are non-recurring in nature and (ii) a decrease in bank interest income in connection with a decrease in interest rates on bank deposits in 2023.

Administrative Expenses

Our administrative expenses decreased by 4.8% from RMB44.2 million in 2022 to RMB42.1 million in 2023, primarily because we have a relatively large amount of share-based payment in 2022, due to the adjustment to the scope of employees under our employee incentive plan in that year. The decrease in the share-based payment in 2023 compared to 2022 was partially offset by: (i) an increase in employee benefit expenses, primarily as a result of improved employee compensation of our administrative personnel; and (ii) an increase in hospitality and traveling expenses in relation to our increasing financing activities and our office relocation.

FINANCIAL INFORMATION

Research and Development Expenses

Our research and development expenses increased by 14.6% from RMB34.8 million in 2022 to RMB39.9 million in 2023, primarily due to increases in service fee in relation to the CDMO and CRO services and cost of raw materials for continued clinical development of Pro-101-1 for thermal burns and pre-clinical studies of the PDGF candidates for other indications.

Finance Costs

Our finance costs significantly increased from RMB7.9 million in 2022 to RMB23.6 million in 2023, primarily due to an increase in interest on other financial liabilities in relation to the redemption liabilities from Pre-[REDACTED] Investments.

Other Expenses

Our other expenses remained relatively stable at RMB32.0 thousand and RMB62.0 thousand in 2022 and 2023, respectively.

Loss for the Year

As a result of the foregoing, our loss for the year increased by 22.4% from RMB85.9 million in 2022 to RMB105.2 million in 2023.

FINANCIAL INFORMATION

DISCUSSION OF CERTAIN KEY BALANCE SHEET ITEMS

The following table sets out selected data from our consolidated balance sheet as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Total non-current assets	18,986	18,185
Total current assets	16,725	244,904
Total assets	35,711	263,089
Total non-current liabilities	82,581	383,231
Total current liabilities	8,068	11,732
Total liabilities	90,649	394,963
Net liabilities	(54,938)	(131,874)
Equity attributable to owners of the parent:		
Paid-in capital	82,715	91,806
Deficits	(137,653)	(223,680)
Total deficits	(54,938)	(131,874)

We had a net liability position as of December 31, 2022 and 2023, which increased from RMB54.9 million to RMB131.9 million. The increase in our net liabilities was primarily due to a large increase in other financial liabilities primarily related to the redemption liabilities from our Pre-[REDACTED] Investment in 2023. Pursuant to the supplemental agreement to the shareholders agreement dated February 23, 2024 entered into between us and the Shareholders, the redemption right granted to the Pre-[REDACTED] Investors has been terminated on the date of such supplemental agreement. See “History, Development and Corporate Structure — Pre-[REDACTED] Investments.” As such, the financial instruments issued to Pre-[REDACTED] Investors have been reclassified from other financial liabilities to equity, which reversed our net liability position to a net asset position since the termination of the redemption right.

FINANCIAL INFORMATION

Current Assets and Liabilities

The following table sets out our current assets and liabilities as of the dates indicated:

	As of December 31,		As of February 29,
	2022	2023	2024
	<i>(RMB in thousands)</i>		<i>(unaudited)</i>
Current assets			
Prepayments, other receivables and other assets	960	3,392	5,928
Cash and cash equivalents	15,765	241,512	228,395
Total current assets	16,725	244,904	234,323
Current liabilities			
Trade payables	1,682	6,620	4,276
Lease liabilities	3,829	2,211	2,428
Other payables and accruals	2,557	2,901	3,376
Total current liabilities	8,068	11,732	10,080
Net current assets	8,657	233,172	224,243

Our net current assets increased from RMB8.7 million as of December 31, 2022 to RMB233.2 million as of December 31, 2023, mainly because our total current assets increased significantly from RMB16.7 million as of December 31, 2022 to RMB244.9 million as of December 31, 2023, primarily due to an increase in cash and cash equivalents as a result of our Pre-[REDACTED] Investment in 2023. Such increase was partially offset by an increase of our total current liabilities from RMB8.1 million as of December 31, 2022 to RMB11.7 million as of December 31, 2023, primarily due to an increase in trade payables in relation to the payables for purchasing research and development services from CDMOs and CROs.

Our net current assets slightly decreased from RMB233.2 million as of December 31, 2023 to RMB224.2 million as of February 29, 2024, mainly due to a decrease in cash and cash equivalents, as we continued to develop our pipeline candidates.

FINANCIAL INFORMATION

Current Portion of Prepayments, Other Receivables and Other Assets

Our current portion of prepayments, other receivables and other assets primarily represents: (i) prepayments, primarily consisting of prepaid payments of rent for properties and vehicles, property management fees and renovation fees; and (ii) deposits and other receivables, mainly representing deposits for leases of properties. The following table sets out a breakdown of the current portion of our prepayment, other receivables and other assets as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Prepayments	146	2,085
Deposits and other receivables	670	1,032
Deferred [REDACTED]	[REDACTED]	[REDACTED]
Prepayment for a related party	—	24
Total	960	3,392

Our current portion of prepayment, other receivables and other assets increased significantly from RMB1.0 million as of December 31, 2022 to RMB3.4 million as of December 31, 2023, primarily due to an increase of prepayments for short term lease payments as a result of new short term leases of properties in 2023.

As of February 29, 2024, approximately RMB1.7 million, or 51.3% of our current portion of prepayments, other receivables and other assets as of December 31, 2023 was settled.

FINANCIAL INFORMATION

Cash and Cash Equivalents

Our cash and cash equivalents primarily represent cash in hand and at bank and short-term deposits with a maturity of generally less than three months. The following table sets out a breakdown of our cash and cash equivalents as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Cash and bank balances	15,765	241,512
Denominated in:		
RMB	15,737	241,458
HK\$	28	54
Total	15,765	241,512

Our cash and cash equivalents increased significantly from RMB15.8 million as of December 31, 2022 to RMB241.5 million as of December 31, 2023, primarily as a result of the completion of the Pre-[REDACTED] Investment in 2023.

Trade Payables

Our trade payables mainly include purchasing research and development services from CDMOs and CROs. Our trade payables increased from RMB1.7 million as of December 31, 2022 to RMB6.6 million as of December 31, 2023, primarily due to an increase in payables for purchasing services from CDMOs and CROs in relation to the clinical development of our Core Products, which was in line with our continuous research and development activities.

The following table sets out an aging analysis of the trade payables based on their respective invoice and issue dates as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Within one year	1,682	5,332
Over one year	—	1,288
Total	1,682	6,620

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We did not have any material defaults in payment of trade payables during the Track Record Period.

As of February 29, 2024, RMB2.6 million, or 39.1%, of our trade payables as of December 31, 2023 had been settled.

Other Payables and Accruals

Our other payables and accruals primarily consist of (i) payroll payable, (ii) tax payables and (iii) other payables. The following table sets out a breakdown of our other payables and accruals as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Payroll payable	1,546	1,875
Tax payables	125	221
Other payables	886	805
Total	2,557	2,901

Our other payables and accruals increased by 13.5% from RMB2.6 million as of December 31, 2022 to RMB2.9 million as of December 31, 2023, primarily due to an increase in payroll payables, primarily as a result of the improved employee compensation.

As of February 29, 2024, RMB2.7 million or 92.0% of our other payables and accruals as of December 31, 2023 were subsequently settled.

FINANCIAL INFORMATION

Non-current Assets and Liabilities

The following table sets out our non-current assets and liabilities as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Non-current assets		
Property, plant and equipment	5,804	7,068
Right-of-use assets	8,744	6,495
Intangible assets	3,036	1,031
Prepayments, other receivables and other assets	1,402	3,591
Total non-current assets	18,986	18,185
Non-current liabilities		
Lease liabilities	4,635	2,738
Other financial liabilities	77,946	380,493
Total non-current liabilities	82,581	383,231

The total non-current liabilities significantly increased from RMB82.6 million as of December 31, 2022 to RMB383.2 million as of December 31, 2023, primarily due to an increase in other financial liabilities in relation to the redemption liabilities from our Pre-[REDACTED] Investment in 2023.

Property, Plant and Equipment

Our property, plant and equipment primarily consist of (i) machinery and equipment, (ii) office equipment, (iii) electronic equipment and (iv) leasehold improvements. The following table sets out our property, plant and equipment as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Machinery	5,255	4,700
Office equipment	41	281
Electronic equipment	375	405
Leasehold improvements	133	1,682
Total	5,804	7,068

FINANCIAL INFORMATION

Our property, plant and equipment increased by 21.8% from RMB5.8 million as of December 31, 2022 to RMB7.1 million as of December 31, 2023, primarily due to an increase in leasehold improvements resulting from office relocation and renovation.

Right-of-use Assets

Our right-of-use assets are primarily leased properties. Our right-of-use assets decreased by 25.7% from RMB8.7 million as of December 31, 2022 to RMB6.5 million as of December 31, 2023, primarily due to termination of certain of our leases for office space and laboratories in Beijing in 2023.

Intangible Assets

Our intangible assets were primarily patents. Our intangible assets decreased from RMB3.0 million as of December 31, 2022 to RMB1.0 million as of December 31, 2023, primarily due to amortization of patents.

Non-Current Portion of Prepayments, Other Receivables and Other Assets

Our non-current portion of prepayments, other receivables and other assets primarily represents: (i) advance payments for property, plant and equipment; (ii) value-added tax recoverable, representing value-added taxes paid with respect to our procurement that can be credited against future value-added tax payables; and (iii) deposits for long-term leases. The following table sets out a breakdown of the non-current portion of our prepayment, other receivables and other assets as of the dates indicated:

	As of December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Advance payments for property, plant and equipment	26	577
Value-added tax recoverable	829	2,506
Deposits for leases	547	508
Total	1,402	3,591

Our non-current portion of prepayment, other receivables and other assets increased significantly from RMB1.4 million as of December 31, 2022 to RMB3.6 million as of December 31, 2023, primarily due to an increase in the value-added tax recoverable, mainly resulting from our increased procurement.

FINANCIAL INFORMATION

Other Financial Liabilities

Our other financial liabilities primarily represented redemption liabilities from our Pre-[REDACTED] Investments.

We recorded other financial liabilities of RMB77.9 million and RMB380.5 million as of December 31, 2022 and 2023, respectively. The increase was primarily related to the Pre-[REDACTED] Investment of RMB300,000,000 in 2023. Pursuant to the supplemental agreement to the shareholders agreement dated February 23, 2024 entered into between us and the Shareholders, the redemption right granted to the Pre-[REDACTED] Investors has been terminated on the date of such supplemental agreement. See “History, Development and Corporate Structure — Pre-[REDACTED] Investments.”

KEY FINANCIAL RATIO

The following table sets out our key financial ratio as of the dates indicated:

	As of December 31,	
	2022	2023
Current ratio ⁽¹⁾	2.1	20.9

Note:

(1) Represents current assets divided by current liabilities as of the same date.

Our current ratio increased significantly from 2.1 as of December 31, 2022 to 20.9 as of December 31, 2023, mainly as a result of an increase in cash and cash equivalents in 2023, in relation to the completion of the Pre-[REDACTED] Investment in the same year.

LIQUIDITY AND CAPITAL RESOURCES

Working Capital

Our principal uses of liquidity during the Track Record Period were to fund our research and development of our candidates and our clinical trials. During the Track Record Period, we primarily funded our working capital requirements through capital contributions from our Shareholders and private equity financing. We monitor our cash flows and cash balance on a regular basis and strive to maintain an optimal liquidity that can meet our working capital needs.

FINANCIAL INFORMATION

While we had net operating cash outflows and net losses during the Track Record Period, we believe our liquidity requirements will be satisfied by using funds from a combination of our cash and cash equivalents, net [REDACTED] from the [REDACTED] and other funds raised from the capital markets from time to time. As of December 31, 2023, we had cash and cash equivalents of RMB241.5 million. We currently do not have any plans for material external debt financing. Taking into account the above, together with the estimated net [REDACTED] from the [REDACTED], our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs, including research and development expenses, administrative expenses, finance costs and other expenses for at least the next 12 months from the date of this document.

Our cash burn rate refers to the average monthly aggregate amount of (i) net cash used in operating activities; (ii) capital expenditures; and (iii) lease payments. Assuming that the average cash burn rate going forward of [REDACTED] times the level in 2023, we estimate that our total cash balance as of December 31, 2023 will be able to maintain our financial viability for approximately [REDACTED] months or, if taking into account the estimated net [REDACTED] (based on the mid-point of the indicative [REDACTED] of HK\$[REDACTED] per [REDACTED] and assuming the [REDACTED] is not exercised) from the [REDACTED], for at least [REDACTED] months. Our Directors and our management team 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.

Cash Flow

The following table sets out our cash flows for the years indicated:

	Year ended December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Operating cash flows before movements in working capital . .	(47,526)	(60,637)
Movements in working capital	1,873	1,540
Interest received	726	237
Net cash flows used in operating activities	(44,927)	(58,860)
Net cash flows used in investing activities	(3,434)	(3,123)
Net cash flows (used in)/from financing activities.	(3,245)	287,729
Net (decrease)/increase in cash and cash equivalents.	(51,606)	225,746
Cash and cash equivalents at the beginning of the year.	67,370	15,765
Effects of foreign exchange rate changes, net	1	1
Cash and cash equivalents at the end of the year	15,765	241,512

FINANCIAL INFORMATION

Net Cash Flows Used in Operating Activities

Since the commencement of our business operation, we have incurred negative cash flows from our operations. Substantially all of our operating outflows have resulted from our cash used in our operations. Net cash used in operating activities primarily comprises our loss before tax for the year adjusted by: (i) non-operating items and non-cash items; and (ii) movements in working capital.

In 2023, our net cash used in operating activities was RMB58.9 million, which was primarily attributable to our loss before tax of RMB105.2 million, as adjusted by: (i) the add back of non-operating items and non-cash items, primarily comprising net finance costs of RMB23.6 million, equity-settled share award expense of RMB14.7 million and depreciation of property, plant and equipment and right-of-use assets of RMB4.7 million and amortization of intangible assets of RMB2.0 million; and (ii) movements in working capital, including increases in trade payables, and other payables and accruals of RMB5.3 million, partially offset by an increase in prepayments, other receivables and other assets of RMB3.7 million.

In 2022, our net cash used in operating activities was RMB44.9 million, which was primarily attributable to our loss before tax of RMB85.9 million, as adjusted by: (i) the add back of non-operating items and non-cash items, primarily comprising equity-settled share award expense of RMB24.8 million, net finance costs of RMB7.9 million, depreciation of property, plant and equipment and right-of-use assets of RMB4.4 million and amortization of intangible assets of RMB2.0 million; and (ii) movements in working capital, including increases in trade payables, and other payables and accruals of RMB1.5 million, and a decrease in prepayments, other receivables and other assets of RMB0.4 million.

We intend to implement comprehensive strategies to efficiently reduce our cost and operating expenses. Our object is to improve liquidity to obtain a higher return for our Shareholders and maintain adequate risk management. After our product candidates are commercialized, we intend to closely monitor and manage the settlement of our trade receivables to prevent credit losses. We will also closely monitor the settlement of our trade payables to attain a better cash flow situation.

Net Cash Flows Used in Investing Activities

In 2023, our net cash used in investing activities was RMB3.1 million, which was primarily attributable to purchases of property, plant and equipment of RMB3.1 million.

In 2022, our net cash used in investing activities was RMB3.4 million, which was primarily attributable to purchases of property, plant and equipment of RMB3.4 million.

FINANCIAL INFORMATION

Net Cash Flows (Used in)/from Financing Activities

In 2023, our net cash generated from financing activities was RMB287.7 million, which was primarily attributable to proceeds from issuance of financial instruments with preferential rights in the Pre-[REDACTED] Investment in 2023 of RMB293.0 million, partially offset by principal portion of lease payments of RMB5.2 million.

In 2022, our net cash used in financing activities was RMB3.2 million, which was primarily attributable to principal portion of lease payments of RMB3.8 million, partially offset by capital contribution by a shareholder of RMB0.6 million.

CASH OPERATING COSTS

The following table sets out our cash operating costs for the years indicated:

	Year ended December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Research and development costs for Core Products		
Clinical trial expenses	5,270	11,476
Materials consumed	3,703	5,159
Staff costs	8,689	7,494
Others ⁽¹⁾	1,507	1,343
Sub-total	19,169	25,472
Research and development costs for other products		
Pre-clinical studies	1,334	574
Materials consumed	462	471
Staff costs	4,318	3,051
Others ⁽¹⁾	51	139
Sub-total	6,165	4,235
Total research and development expenses	25,334	29,707
Workforce employment costs ⁽²⁾	12,039	14,227

Notes:

- (1) Others mainly include office expenses, traveling expenses and conference expenses.
- (2) Workforce employment costs represent non-research and development staff costs mainly including salaries and benefits.

FINANCIAL INFORMATION

INDEBTEDNESS

As of December 31, 2022 and 2023 and February 29, 2024, our indebtedness comprises lease liabilities. We did not have any bank borrowings during the Track Record Period and as of February 29, 2024.

Our lease liabilities include the net present value of our lease payments as specified in Note 14 in Appendix I to this document. The following table sets out our lease liabilities as of the dates indicated:

	As of December 31,		As of February 29,
	2022	2023	2024
	<i>(RMB in thousands)</i>		
			<i>(Unaudited)</i>
Non-current lease liabilities	4,635	2,738	2,692
Current lease liabilities	3,829	2,211	2,428
Total	8,464	4,949	5,120

Our lease liabilities decreased by 41.5% from RMB8.5 million as of December 31, 2022 to RMB4.9 million as of December 31, 2023, primarily due to termination of certain of our leases for office space and laboratories in Beijing in 2023.

Except as disclosed above, during the Track Record Period and up to February 29, 2024, we did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance leases or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees.

CONTINGENT LIABILITIES

We did not have any material contingent liabilities as of December 31, 2022 and 2023 and the Latest Practicable Date.

FINANCIAL INFORMATION

CAPITAL EXPENDITURES

Our capital expenditures during the Track Record Period were primarily related to our purchases of property, plant and equipment. We funded our capital expenditure requirements during the Track Record Period mainly from capital contributions from our Shareholders and equity financing. The following table sets out the details of our capital expenditure for the years indicated:

	Year ended December 31,	
	2022	2023
	<i>(RMB in thousands)</i>	
Purchases of property, plant and equipment.	3,434	3,123

We plan to fund our planned capital expenditures using cash generated from operations and the net [REDACTED] received from the [REDACTED]. See “Future Plans and Use of [REDACTED].” We may reallocate the fund to be utilized on capital expenditure based on our ongoing business needs. We expect that our capital expenditures for 2024 will primarily be related to the purchase of equipment and instruments for research and development and quality control activities.

CAPITAL COMMITMENTS

As of December 31, 2022 and 2023, we did not have any capital commitments.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet arrangements.

FINANCIAL RISK DISCLOSURE

Our principal financial instruments comprise cash and cash equivalents, financial assets included in prepayments, other receivables and other assets, trade payables, financial liabilities included in other payables and accruals, other financial liabilities. The main purpose of these financial instruments is to raise finance for our operations.

The main risks arising from our financial instruments are credit risk and liquidity risk. The board and senior management meet periodically to analyze and formulate measures to manage our exposure to these risks.

FINANCIAL INFORMATION

Credit Risk

The carrying amounts of cash and cash equivalents and financial assets included in prepayments, other receivables and other assets, represent our maximum exposure equal to credit risk in relation to the financial assets.

We expect that there is no significant credit risk associated with cash and bank balances, financial assets measured at amortized cost since they are substantially held in reputable state-owned banks and other medium or large-sized listed banks. Management does not expect that there will be any significant losses from on-performance by these counterparties.

We trade only with recognized and creditworthy third parties. It is our policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In order to minimize the credit risk, we review the recoverable amount of each individual trade receivable periodically and management also has monitoring procedures to ensure the follow-up action is taken to recover overdue receivables. In this regard, our Directors consider that our credit risk is significantly reduced.

For financial assets included in prepayments, other receivables and other assets relate to receivables for which there was no recent history of default and past due amounts. We seek to maintain strict control over our outstanding receivables to minimize credit risk. Long aging balances are reviewed regularly by senior management. In view of the fact that deposits and other receivables relate to diversified counter parties, there is no significant concentration of credit risk. Our Directors believe that there is no material credit risk inherent in our outstanding balances.

Maximum exposure and year-end staging

The tables below show the credit quality and the maximum exposure to credit risk based on our credit policy, which is mainly based on past due information unless other information is available without undue cost or effort, and year-end staging classification as at 31 December. The amounts presented are gross carrying amounts for financial assets.

FINANCIAL INFORMATION

As of December 31, 2022

	12-month ECLs
	Stage 1
	<i>RMB'000</i>
Financial assets included in prepayments,	
other receivables and other assets — Normal*	1,217
Cash and cash equivalents — Not yet past due	15,765
Total	16,982

As of December 31, 2023

	12-month ECLs
	Stage 1
	<i>RMB'000</i>
Financial assets included in prepayments,	
other receivables and other assets — Normal*	1,564
Cash and cash equivalents — Not yet past due	241,512
Total	243,076

* The credit quality of the financial assets included in prepayments, other receivables and other assets is considered to be “normal” when they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk since initial recognition. Otherwise, the credit quality of the financial assets is considered to be “doubtful”.

FINANCIAL INFORMATION

Liquidity risk

We monitor and maintain a level of cash and cash equivalents deemed adequate by our management to finance the operations and mitigate the effects of fluctuations in cash flows.

The maturity profile of our financial liabilities and lease liabilities as of the end of each of the Track Record Period, based on the contractual undiscounted payments, is as follows:

	<u>Less than 1 year</u>	<u>1 to 5 years</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
December 31, 2022			
Financial liabilities included in other			
payables and accruals	886	—	886
Trade payables	1,682	—	1,682
Other financial liabilities	—	83,071	83,071
Lease liabilities	4,181	5,092	9,273
Total	<u>6,749</u>	<u>88,163</u>	<u>94,912</u>
December 31, 2023			
Financial liabilities included in other			
payables and accruals	805	—	805
Trade payables	6,620	—	6,620
Other financial liabilities	—	399,970	399,970
Lease liabilities	2,360	2,821	5,181
Total	<u>9,785</u>	<u>402,791</u>	<u>412,576</u>

Capital management

The primary objectives of our capital management are to safeguard our ability to continue as a going concern and to maintain healthy capital ratios in order to support our business and maximize Shareholders’ value.

We manage our capital structure and make adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, we may adjust the dividend payment to Shareholders, return capital to Shareholders or issue new shares. We are not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the Track Record Period.

FINANCIAL INFORMATION

MATERIAL RELATED PARTY TRANSACTIONS

For more details about our related party transactions during the Track Record Period, see Note 27 in Appendix I to this document. Our Directors believe that our transactions with related parties during the Track Record Period were conducted on an arm’s length basis, and they did not distort our results of operations or make our historical results not reflective of our future performance.

DIVIDEND

No dividend was paid or declared by our Company or other entities comprising our Group during the Track Record Period.

Any future declarations and payments of dividends will be at the absolute discretion of our Directors and will depend on our actual and expected results of operations, cash flow and financial position, general business conditions and business strategies, expected working capital requirements and future expansion plans, legal, regulatory and other contractual restrictions, and other factors which our Directors consider relevant. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. According to relevant PRC laws, 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. As a result, we may not have sufficient or any distributable profits to make dividend contributions to our Shareholders, even if we become profitable. As of December 31, 2023, we did not have any pre-determined dividend payout ratio.

FINANCIAL INFORMATION

DISTRIBUTABLE RESERVES

As of December 31, 2023, we did not have any distributable reserves.

[REDACTED]

[REDACTED] represent professional fees, [REDACTED] and other fees incurred in connection with the [REDACTED]. We expect to incur [REDACTED] expenses of approximately RMB[REDACTED] million (HK\$[REDACTED] million), comprising: (i) [REDACTED] fees of RMB[REDACTED] million (HK\$[REDACTED] million); and (ii) non-[REDACTED]-related expenses of RMB[REDACTED] million (HK\$[REDACTED] million), which are further categorized into: (a) fees and expenses of legal advisors and accountants of RMB[REDACTED] million (HK\$[REDACTED] million); and (b) other fees and expenses of RMB[REDACTED] million (HK\$[REDACTED] million), assuming the [REDACTED] is not exercised and based on the [REDACTED] of HK\$[REDACTED] per [REDACTED] (being the mid-point of the [REDACTED]), approximately RMB[REDACTED] million (HK\$[REDACTED] million) of which has been charged to our consolidated statements of profit or loss (including RMB[REDACTED] million (HK\$[REDACTED] million) charged during the Track Record Period), approximately RMB[REDACTED] million (HK\$[REDACTED] million) of which is expected to be charged to our consolidated statements of profit or loss, and approximately RMB[REDACTED] million (HK\$[REDACTED] million) of which is expected to be capitalized and will be deducted from equity upon the completion of the [REDACTED]. The [REDACTED] are expected to represent approximately [REDACTED]% of the gross [REDACTED] of the [REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED] (being the mid-point of the indicative [REDACTED]) and that the [REDACTED] is not exercised. The [REDACTED] 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

The following unaudited [REDACTED] adjusted consolidated net tangible assets of our Company have been prepared in accordance with Rule 4.29 of the Listing Rules and with reference to Accounting Guideline 7 *Preparation of Pro Forma Financial Information for Inclusion in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants for illustration purposes only, and is set out here to illustrate the effect of the [REDACTED] on the consolidated net tangible assets of our Company attributable to owners of the parent as if the [REDACTED] had taken place on December 31, 2023.

The unaudited [REDACTED] adjusted consolidated net tangible assets of our Company attributable to owners of the parent has been prepared for illustrative purposes only and because of its hypothetical nature, it may not give a true picture of the financial position of our Company had the [REDACTED] been completed as at December 31, 2023 or any future date.

FINANCIAL INFORMATION

			Unaudited [REDACTED] adjusted		
	Consolidated net tangible assets attributable to owners of the parent as at December 31, 2023	Estimated net [REDACTED] from the [REDACTED]	consolidated net tangible assets attributable to owners of the parent as at December 31, 2023	Unaudited [REDACTED] adjusted consolidated net tangible assets attributable to owners of the parent per Share as at December 31, 2023	
	RMB'000 <i>Note 1</i>	RMB'000 <i>Note 2</i>	RMB'000	RMB <i>Note 3</i>	HK\$ <i>Note 4</i>

Based on an

[REDACTED] of

HK\$[REDACTED] per

Share (132,905) [REDACTED] [REDACTED] [REDACTED] [REDACTED]

Based on an

[REDACTED] of

HK\$[REDACTED] per

Share (132,905) [REDACTED] [REDACTED] [REDACTED] [REDACTED]

Notes:

- (1) The consolidated net tangible assets attributable to owners of the parent as at December 31, 2023 is arrived at after deducting intangible assets of RMB1,031,000 from the consolidated net liabilities attributable to owners of the parent of RMB131,874,000 as at December 31, 2023, as shown in Appendix I to this document.
- (2) The estimated net [REDACTED] from the [REDACTED] are calculated based on the [REDACTED] of HK\$[REDACTED] per Share or HK\$[REDACTED] per Share, being the low-end [REDACTED] and high-end [REDACTED], after deduction of the [REDACTED] fees and related expenses payable by us.
- (3) The unaudited [REDACTED] adjusted consolidated net tangible assets attributable to owners of the parent per Share are calculated based on [REDACTED] Shares ([REDACTED] H Shares to be issued pursuant to the [REDACTED]) in issue assuming that the [REDACTED] has been completed on December 31, 2023.
- (4) The unaudited [REDACTED] adjusted consolidated net tangible assets attributable to owners of the parent per Share are converted into Hong Kong dollars at an exchange rate of RMB0.9070 to HK\$1.00.
- (5) No adjustment has been made to reflect any trading results or other transactions entered into by us subsequent to December 31, 2023.

FINANCIAL INFORMATION

NO MATERIAL ADVERSE CHANGE

After performing sufficient due diligence work which our Directors consider appropriate and after due and careful consideration, our Directors confirm that, up to the date of this document, save as disclosed in “Summary — Recent Development,” there has been no material adverse change in our financial or trading position or prospects since December 31, 2023, being the end date of the periods reported in Appendix I to this document, and there has been no event since December 31, 2023 that would materially affect the information as set out in Appendix I to this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors confirm that, except as otherwise disclosed in this document, 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

See “Business — Our Strategies” in this document for a detailed description of our future plans.

USE OF [REDACTED]

Assuming that the [REDACTED] is not exercised, after deducting the [REDACTED] and other estimated [REDACTED] paid and payable by us in connection with the [REDACTED], and assuming an [REDACTED] of HK\$[REDACTED] per Share (being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] and HK\$[REDACTED]), we estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] million from the [REDACTED].

We intend to use the [REDACTED] from the [REDACTED] for the purposes and in the amounts set forth below, subject to changes in light of our evolving business needs and changing market condition:

- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for carrying out the continual clinical development of our Core Products, Pro-101-1 and Pro-101-2.
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for carrying out the continual clinical development of our Core Product Pro-101-1 in thermal burns in China and the U.S.
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for carrying out the continuous clinical trials activities of our Core Product Pro-101-1 in thermal burns in China. We completed the Phase IIa clinical trial of Pro-101-1 in thermal burns in China in May 2023. We initiated the Phase IIb clinical trial of Pro-101-1 in thermal burns in China in December 2023 and expect to complete the trial in the second quarter of 2025. We intend to initiate the Phase III clinical trial in China in the third quarter of 2025 and complete the trial in the fourth quarter of 2026. We plan to launch Pro-101-1 in China in 2027.
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for payment of the expenses of third-parties’ services of the Phase IIb and Phase III clinical trials in China for Pro-101-1 in thermal burns; and

FUTURE PLANS AND USE OF [REDACTED]

- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for payment of R&D personnel costs of the Phase IIb and Phase III clinical trials in China for Pro-101-1 in thermal burns.
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for carrying out the continual clinical development of our Core Product Pro-101-1 in thermal burns in the U.S. We submitted a pre-IND communication application to the FDA in December 2021 with respect to Pro-101-1 for thermal burns. In their response, the FDA agreed with our proposal to carry out the clinical trials and submit a BLA via section 351(a) pathway (the pathway for approval of innovator biologics) for Pro-101-1 in thermal burns. We expect to submit the IND application to the FDA in the first quarter of 2026 for carrying out multi-center clinical trials of Pro-101-1.
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for payment of expenses of third-parties' services of the clinical trials in the U.S. for Pro-101-1 in thermal burns; and
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for payment of R&D personnel costs of the clinical trials in the U.S. for Pro-101-1 in thermal burns.
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for carrying out the continual clinical development of our Core Product Pro-101-2 in DFUs in China. We initiated the Phase II clinical trial of Pro-101-2 in DFUs in China in February 2022 and expect to complete the trial in the second quarter of 2027. We intend to initiate the Phase III clinical trial in China in the third quarter of 2027 and complete the trial in the second quarter of 2029. We plan to launch Pro-101-2 in 2030.
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for payment of the expenses of third-parties' services of the Phase II and Phase III clinical trials in China for Pro-101-2 in DFUs; and
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for payment of R&D personnel costs of the Phase II and Phase III clinical trials in China for Pro-101-2 in DFUs.

FUTURE PLANS AND USE OF [REDACTED]

- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for payment of the expenses of third-parties' services, R&D personnel costs and raw materials costs of the continual pre-clinical research and development of our PDGF products other than the Core Products for other indications, such as fresh wounds, pressure ulcers and radiation ulcers.
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for payment of the expenses of third-parties' services, R&D personnel costs and raw materials costs of pre-clinical research and development activities of our Mes-201, Oli-101 and Oli-201.
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be used for enhancing our research and development capabilities by purchasing specialized equipment and instruments related to our research and development and quality control activities. Such purchases are expected to enhance our research and development capabilities, accelerate the progress of drug discovery, and enable us to more effectively navigate complex medical innovation pathways, as well as to strengthen our quality control capabilities to ensure that our products meet the stringent safety and efficacy standards required by the relevant industries and jurisdictions.
- approximately [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, as working capital and for general corporate uses.

In the event that the [REDACTED] is set at the maximum [REDACTED] or the minimum [REDACTED] of the indicative [REDACTED] range, the net [REDACTED] of the [REDACTED] will increase by approximately HK\$[REDACTED] million or decrease by approximately HK\$[REDACTED] million.

The additional net [REDACTED] that we would receive if the [REDACTED] were exercised in full would be: (i) HK\$[REDACTED] million (assuming an [REDACTED] of HK\$[REDACTED] per Share, being the maximum [REDACTED] of the indicative [REDACTED] range); (ii) HK\$[REDACTED] million (assuming an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range); or (iii) HK\$[REDACTED] million (assuming an [REDACTED] of HK\$[REDACTED] per Share, being the minimum [REDACTED] of the indicative [REDACTED] range).

To the extent that the net [REDACTED] from the [REDACTED] are either more or less than expected, we will adjust our allocation of the net [REDACTED] for the above purposes on a pro rata basis.

FUTURE PLANS AND USE OF [REDACTED]

If the net [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, and the relevant applicable laws in the relevant jurisdiction for non-Hong Kong based deposits). We will make an appropriate announcement if there is any change to the above proposed use of [REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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HOW TO APPLY FOR [REDACTED]

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HOW TO APPLY FOR [REDACTED]

[REDACTED]

[To insert the firm’s letterhead]

ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF B&K CORPORATION LIMITED, HUATAI FINANCIAL HOLDINGS (HONG KONG) LIMITED AND CITIC SECURITIES (HONG KONG) LIMITED

Introduction

We report on the historical financial information of B&K Corporation Limited (the “**Company**”) and its subsidiaries (together, the “**Group**”) set out on pages [I-4] to [I-71], which comprises the consolidated statements of profit or loss and other comprehensive income, statements of changes in equity and statements of cash flows of the Group for each of the years ended 31 December 2022 and 2023 (the “**Relevant Periods**”), and the consolidated statements of financial position of the Group and the statements of financial position of the Company as at 31 December 2022 and 2023 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-71] forms an integral part of this report, which has been prepared for inclusion in this document of the Company dated 29 April 2024 (the “**Document**”) in connection with the initial [REDACTED] of the shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”).

Directors’ responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information, and for such internal control as the directors determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountants’ responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 *Accountants’ Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants (“**HKICPA**”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

APPENDIX I

ACCOUNTANTS' REPORT

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants' judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity's preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountants' report, a true and fair view of the financial position of the Group and the Company as at 31 December 2022 and 2023 and of the financial performance and cash flows of the Group for each of the Relevant Periods in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page [I-4] have been made.

APPENDIX I

ACCOUNTANTS’ REPORT

Dividends

We refer to note 11 to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

No historical financial statements for the Company

As at the date of this report, no statutory financial statements have been prepared for the Company since its date of incorporation.

[•]

Certified Public Accountants

Hong Kong

29 April 2024

I HISTORICAL FINANCIAL INFORMATION

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The financial statements of the Group for the Relevant Periods, on which the Historical Financial Information is based, were audited by Ernst & Young in accordance with Hong Kong Standards on Auditing issued by HKICPA (the “**Underlying Financial Statements**”).

The Historical Financial Information is presented in Renminbi (“**RMB**”) and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	<i>Notes</i>	Year ended 31 December	
		2022	2023
		<i>RMB’000</i>	<i>RMB’000</i>
REVENUE	5	—	472
Cost of sales		—	(255)
Gross profit		—	217
Other income and gains	5	1,002	271
Administrative expenses		(44,223)	(42,117)
Research and development expenses		(34,818)	(39,915)
Other expenses		(32)	(62)
Finance costs	7	(7,855)	(23,582)
LOSS BEFORE TAX	6	(85,926)	(105,188)
Income tax expense	10	—	—
LOSS FOR THE YEAR		<u>(85,926)</u>	<u>(105,188)</u>
Attributable to:			
Owners of the parent		<u>(85,926)</u>	<u>(105,188)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted			
For loss for the year (<i>RMB per share</i>)	12	<u>(0.95)</u>	<u>(1.11)</u>
OTHER COMPREHENSIVE LOSS			
Other comprehensive loss that may be reclassified to profit or loss in subsequent period:			
Exchange difference on translation of a foreign operation		(27)	(47)
OTHER COMPREHENSIVE LOSS FOR THE YEAR, NET OF TAX		<u>(27)</u>	<u>(47)</u>
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		<u>(85,953)</u>	<u>(105,235)</u>
Attributable to:			
Owners of the parent		<u>(85,953)</u>	<u>(105,235)</u>

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	<i>Notes</i>	As at 31 December	
		2022	2023
		<i>RMB’000</i>	<i>RMB’000</i>
NON-CURRENT ASSETS			
Property, plant and equipment	13	5,804	7,068
Right-of-use assets	14(a)	8,744	6,495
Intangible assets	15	3,036	1,031
Prepayments, other receivables and other assets . .	16	1,402	3,591
Total non-current assets		18,986	18,185
CURRENT ASSETS			
Prepayments, other receivables and other assets . .	16	960	3,392
Cash and cash equivalents	17	15,765	241,512
Total current assets		16,725	244,904
CURRENT LIABILITIES			
Trade payables	18	1,682	6,620
Lease liabilities	14(b)	3,829	2,211
Other payables and accruals	19	2,557	2,901
Total current liabilities		8,068	11,732
NET CURRENT ASSETS		8,657	233,172
TOTAL ASSETS LESS CURRENT			
LIABILITIES		27,643	251,357
NON-CURRENT LIABILITIES			
Lease liabilities	14(b)	4,635	2,738
Other financial liabilities	21	77,946	380,493
Total non-current liabilities		82,581	383,231
Net liabilities		(54,938)	(131,874)
EQUITY			
Equity attributable to owners of the parent			
Paid-in capital	22	82,715	91,806
Deficits	23	(137,653)	(223,680)
Total deficits		(54,938)	(131,874)

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Attributable to owners of the parent					
	Paid-in capital	Capital reserves*	Share award reserves*	Exchange reserves*	Accumulated losses*	Total deficits
	RMB'000 (note 22)	RMB'000 (note 23)	RMB'000 (note 23)	RMB'000 (note 23)	RMB'000	RMB'000
At 1 January 2022	82,078	119,985	3,061	—	(199,579)	5,545
Loss for the year	—	—	—	—	(85,926)	(85,926)
Exchange differences related to a foreign operation	—	—	—	(27)	—	(27)
Total comprehensive loss for the year	—	—	—	(27)	(85,926)	(85,953)
Equity-settled share award arrangement (note 24)	—	10,778	14,055	—	—	24,833
Capital contribution by a shareholder (note 22)	637	—	—	—	—	637
At 31 December 2022 and 1 January 2023	82,715	130,763	17,116	(27)	(285,505)	(54,938)
Loss for the year	—	—	—	—	(105,188)	(105,188)
Exchange differences related to a foreign operation	—	—	—	(47)	—	(47)
Total comprehensive loss for the year	—	—	—	(47)	(105,188)	(105,235)
Equity-settled share award arrangement (note 24)	—	—	14,671	—	—	14,671
Issuance of financial instruments with preferential rights (note 21)	9,091	283,914	—	—	—	293,005
Recognition of financial liabilities recognised for preferential rights issued to an investor (note 21)	—	(279,377)	—	—	—	(279,377)
At 31 December 2023	91,806	135,300	31,787	(74)	(390,693)	(131,874)

* The reserve accounts comprised the deficit of RMB(137,653,000) and RMB(223,680,000) in the consolidated statements of financial position as at the end of each of the Relevant Periods.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

	<i>Notes</i>	Year ended 31 December	
		2022	2023
		<i>RMB’000</i>	<i>RMB’000</i>
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss before tax		(85,926)	(105,188)
Adjustments for:			
Finance costs	7	7,855	23,582
Bank interest income	5	(726)	(237)
Loss on disposal of items of property, plant and equipment	6	7	—
Depreciation of property, plant and equipment . .	13	1,278	1,308
Depreciation of right-of-use assets	14(a)	3,164	3,430
Amortisation of other intangible assets	15	2,005	2,005
Foreign exchange differences, net	6	(16)	19
Derecognition of right-of-use assets and lease liabilities on early termination		—	(227)
Equity-settled share award expenses	24	24,833	14,671
		(47,526)	(60,637)
Decrease/(increase) in prepayments, other receivables and other assets		379	(3,742)
Increase in trade payables		1,438	4,938
Increase in other payables and accruals		56	344
Cash used in operations		(45,653)	(59,097)
Interest received		726	237
Net cash flows used in operating activities		<u>(44,927)</u>	<u>(58,860)</u>
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of items of property, plant and equipment		(3,434)	(3,123)
Net cash flows used in investing activities		<u>(3,434)</u>	<u>(3,123)</u>
CASH FLOWS FROM FINANCING ACTIVITIES			
Payment of [REDACTED]		[REDACTED]	[REDACTED]
Principal portion of lease payments		(3,758)	(5,169)
Capital contribution by a shareholder	22	637	—
Proceeds from issuance financial instruments with preferential rights		—	293,005
Net cash flows (used in)/from financing activities		<u>(3,245)</u>	<u>287,729</u>

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	<i>Notes</i>	Year ended 31 December	
		2022	2023
		<i>RMB’000</i>	<i>RMB’000</i>
NET (DECREASE)/INCREASE IN CASH			
AND CASH EQUIVALENTS		(51,606)	225,746
Cash and cash equivalents at beginning of year . .		67,370	15,765
Effect of foreign exchange rate changes, net		1	1
CASH AND CASH EQUIVALENTS			
AT END OF YEAR		<u>15,765</u>	<u>241,512</u>
ANALYSIS OF BALANCES OF CASH AND			
CASH EQUIVALENTS			
Cash and cash equivalents as stated in			
the consolidated statements of financial			
position	17	<u>15,765</u>	<u>241,512</u>
Cash and cash equivalents as stated in			
the consolidated statements of cash flows		<u>15,765</u>	<u>241,512</u>

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STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

		As at 31 December	
		2022	2023
		<i>RMB’000</i>	<i>RMB’000</i>
NON-CURRENT ASSETS			
Property, plant and equipment		5,804	7,068
Right-of-use assets		8,744	6,176
Intangible assets		3,036	1,031
Investment in subsidiaries	31	2,000	16,000
Prepayments, other receivables and other assets . .	16	1,402	3,545
Total non-current assets		<u>20,986</u>	<u>33,820</u>
CURRENT ASSETS			
Prepayments, other receivables and other assets . .	16	954	3,277
Cash and cash equivalents	17	14,380	236,618
Total current assets		<u>15,334</u>	<u>239,895</u>
CURRENT LIABILITIES			
Trade payables		1,682	6,620
Lease liabilities		3,829	1,947
Other payables and accruals	19	2,476	9,660
Total current liabilities		<u>7,987</u>	<u>18,227</u>
NET CURRENT ASSETS		<u>7,347</u>	<u>221,668</u>
TOTAL ASSETS LESS CURRENT LIABILITIES.		<u>28,333</u>	<u>255,488</u>
NON-CURRENT LIABILITIES			
Lease liabilities		4,635	2,672
Other financial liabilities	21	77,946	380,494
Total non-current liabilities		<u>82,581</u>	<u>383,166</u>
Net liabilities		<u>(54,248)</u>	<u>(127,678)</u>
EQUITY			
Equity attributable to owners of the parent			
Paid-in capital	22	82,715	91,806
Deficits	23	(136,963)	(219,484)
Total deficits		<u>(54,248)</u>	<u>(127,678)</u>

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II NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE INFORMATION

The Company was established in the People’s Republic of China (“**PRC**”) on 24 April 2012. The registered office address of the Company is Room 1507, Building 1 Xiexin Center, No. 19 Qinling Road Laoshan District, Qingdao Shandong Province, PRC. On 1 April 2024, the Company was converted to joint stock company with limited liability and the registered capital of the Company was RMB100,008,722, which was divided into 100,008,722 shares, with a nominal value of RMB1.00 each.

On 26 March 2024, the Company changed its name from Huaren Biotechnology (Qingdao) Limited to B&K Corporation Limited.

During the Relevant Periods, the Company and its subsidiaries were principally engaged in the research and development of platelet-derived growth factor, or PDGF products.

As at the end of the Relevant Periods, the Company had direct interests in its subsidiaries, all of which are private limited liability companies (and has substantially similar characteristics to a private company incorporated in Hong Kong), the particulars of which are set out below:

Name	Place and date of incorporation/ registration and place of operations	Nominal value of registered share capital	Percentage of equity attributable to the Company directly	Principal activities
海南華人生物技術有限公司* Hainan Huaren Biotechnology Co., Ltd. (“ Hainan Huaren ”). . .	PRC/ Chinese Mainland 6 March 2022	RMB1,000,000	100%	Research and development
Beijing Huarene Biotechnology Hongkong Company Limited (“ Hongkong Huarene ”)	PRC/ Hong Kong 8 August 2022	RMB5,000,000	100%	Research and development
華仁益海生物科技(北京)有限公司* Huaren Yihai Biotechnology (Beijing) Co., Ltd. (“ Huaren Yihai ”)	PRC/ Chinese Mainland 21 July 2023	RMB20,000,000	100%	Research and development

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No audited financial statements have been prepared for the three subsidiaries for the years ended 31 December 2022 and 2023, as these three subsidiaries were not subject to any statutory audit requirements under the relevant rules and regulations in their jurisdictions of incorporation/registration.

* The English names of these two companies registered in the PRC represent the best efforts made by the management of the Company to translate the Chinese names of the companies as they do not have official English names.

2. ACCOUNTING POLICIES

2.1 BASIS OF PREPARATION

The Historical Financial Information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which comprise all standards and interpretations approved by the International Accounting Standards Board (the “IASB”).

All IFRSs effective for the accounting period commencing from 1 January 2023, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the Historical Financial Information throughout the Relevant Periods.

The Historical Financial Information has been prepared under the historical cost convention.

The Historical Financial Information has been prepared on the assumption that the Group will continue as a going concern, which assumes that the Group will be able to meet its obligations and continue its operations for the coming twelve months notwithstanding that as at 31 December 2023, the Group had net deficits of RMB131,874,000 as at 31 December 2023. In the opinion of the directors of the Company, the Group will have necessary liquid funds to finance its operating and capital expenditure requirements for the next twelve months after 31 December 2023. This is due to the following considerations:

- (a) The Group had cash and cash equivalents of RMB241,512,000 as at 31 December 2023;
- (b) The Group had net current assets of RMB233,172,000 as at 31 December 2023;
- (c) The Group entered into a supplemental agreement with its investors of series of financing to terminate certain preferential rights on 23 February 2024. According to the supplemental agreement, the financial liabilities with a carrying amount of RMB380,493,000 as at 31 December 2023 were derecognised, and the Company is not required to settle these financial liabilities .

- (d) The Group has performed a cash flow forecast for the next eighteen months and considered that the Group will have sufficient liquid funds to finance its operations and can operate as a going concern in the next twelve months.

Basis of consolidation

The Historical Financial Information includes the financial statements of the Group for the Relevant Periods. A subsidiary is an entity, directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

Generally, there is a presumption that a majority of voting rights results in control. When the Company has, less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- (a) the contractual arrangement with the other vote holders of the investee;
- (b) rights arising from other contractual arrangements; and
- (c) the Group's voting rights and potential voting rights.

The financial information of the subsidiary is prepared for the same reporting period as the Company, using consistent accounting policies. The results of the subsidiary are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

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If the Group loses control over a subsidiary, it derecognises the related assets (including goodwill), liabilities and any non-controlling interest and the exchange fluctuation reserve; and recognises the fair value of any investment retained, and any resulting surplus or deficit in profit or loss. The Group’s share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

2.2 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

The Group has not applied the following revised IFRSs, that have been issued but are not yet effective, in this Historical Financial Information. The Group intends to apply these revised IFRSs, if applicable, when they become effective.

Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ³
Amendments to IFRS 16	<i>Lease Liability in a Sale and Leaseback</i> ¹
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current</i> ¹
Amendments to IAS 1	<i>Non-current Liabilities with Covenants</i> ¹
Amendments to IAS 7 and IFRS 7	<i>Supplier Finance Arrangements</i> ¹
Amendments to IAS 21	<i>Lack of Exchangeability</i> ²

1 Effective for annual periods beginning on or after 1 January 2024

2 Effective for annual periods beginning on or after 1 January 2025

3 No mandatory effective date yet determined but available for adoption

The Group is in the process of making an assessment of the impact of these revised IFRSs upon initial application. So far, the Group has expected that the adoption of them will not have material impact on the Group’s financial position and financial performance.

2.3 MATERIAL ACCOUNTING POLICY INFORMATION

Fair value measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability.

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The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the Historical Financial Information are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 — based on quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2 — based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly
- Level 3 — based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognised in the Historical Financial Information on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the reporting periods.

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for a non-financial asset is required (other than financial assets), the asset’s recoverable amount is estimated. An asset’s recoverable amount is the higher of the asset’s or cash-generating unit’s value in use and its fair value less costs of disposal, and is determined for an individual asset,

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unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

In testing a cash-generating unit for impairment, a portion of the carrying amount of a corporate asset (e.g., a headquarters building) is allocated to an individual cash-generating unit if it can be allocated on a reasonable and consistent basis or, otherwise, to the smallest group of cash-generating units.

An impairment loss is recognised only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of the reporting period as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to profit or loss in the period in which it arises.

Related parties

A party is considered to be related to the Group if:

- (a) the party is a person or a close member of that person's family and that person
 - (i) has control or joint control over the Group;
 - (ii) has significant influence over the Group; or
 - (iii) is a member of the key management personnel of the Group or of a parent of the Group;

or

- (b) the party is an entity where any of the following conditions applies:
 - (i) the entity and the Group are members of the same group;
 - (ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);
 - (iii) the entity and the Group are joint ventures of the same third party;
 - (iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;
 - (v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group;
 - (vi) the entity is controlled or jointly controlled by a person identified in (a);
 - (vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and
 - (viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

Property, plant and equipment and depreciation

Property, plant and equipment are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalised in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognises such parts as individual assets with specific useful lives and depreciates them accordingly.

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Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal estimated useful lives and estimated residual values used for this purpose are as follows:

<u>Categories</u>	<u>Estimated useful lives</u>	<u>Estimated residual value rate</u>
Machinery.	3 to 10 years	5%
Office equipment	5 years	5%
Electronic equipment	3 to 5 years	5%
Leasehold improvements.	Calculated on the shorter of estimated useful lives and remaining lease terms	—

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at each financial year end.

An item of property, plant and equipment including any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in profit or loss in the year the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Intangible assets (other than goodwill)

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortised over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at each financial year end.

Patents

Patents are stated at cost less any impairment losses and are amortised on the straight-line basis over their estimated useful lives of ten years.

Research and development costs

All research costs are charged to profit or loss as incurred.

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Expenditure incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development.

Development expenditure which does not meet these criteria is expensed when incurred.

Deferred development costs are stated at cost less any impairment losses and are amortised using the straight-line basis over the commercial lives of the underlying products, commencing from the date when the products are put into commercial production.

Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Company recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

Right-of-use assets are recognised at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the lease terms as follows:

Categories

Buildings.	3 to 7 years
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If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

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(b) Lease liabilities

Lease liabilities are recognised at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for termination of a lease, if the lease term reflects the Group exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognised as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

(c) Short-term leases

The Group applies the short-term lease recognition exemption to its short-term leases of buildings and motor vehicles (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option).

Lease payments on short-term leases are recognised as an expense on a straight-line basis over the lease term.

Investments and other financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and the Group’s business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially measures a financial asset at its fair value plus in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15 in accordance with the policies set out for “Revenue recognition” below.

In order for a financial asset to be classified and measured at amortised cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest (“**SPPI**”) on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group’s business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortised cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

Purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace are recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset.

Subsequent measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial assets at amortised cost (debt instruments)

Financial assets at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognised in the statement of profit or loss when the asset is derecognised, modified or impaired.

Derecognition of financial assets

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group’s consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a “pass-through” arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of the Group’s continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

The Group recognises an allowance for expected credit losses (“ECLs”) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

General approach

ECLs are recognised in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At each reporting date, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information. The Group considers that there has been a significant increase in credit risk when contractual payments are more than 30 days past due.

The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

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Financial assets at amortised cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables which apply the simplified approach as detailed below.

- Stage 1 — Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs
- Stage 2 — Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs
- Stage 3 — Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs

Simplified approach

For trade receivables that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as payables.

All financial liabilities are recognised initially at fair value and, in the case of payables, net of directly attributable transaction costs.

The Group’s financial liabilities include trade and other payables and other financial liabilities.

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at amortised cost (trade and other payables and other financial liabilities)

After initial recognition, trade and other payables, and other financial liabilities are subsequently measured at amortised cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognised in profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in the statement of profit or loss.

Derecognition of financial liabilities

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in the statement of profit or loss.

Offsetting of financial instruments

Financial assets and financial liabilities are offset and the net amount is reported in the statement of financial position if there is a currently enforceable legal right to offset the recognised amounts and there is an intention to settle on a net basis, or to realise the assets and settle the liabilities simultaneously.

Cash and cash equivalents

Cash and cash equivalents in the statement of financial position comprise cash on hand and at banks, and short-term highly liquid deposits with a maturity of generally within three months that are readily convertible into known amounts of cash, subject to an insignificant risk of changes in value and held for the purpose of meeting short-term cash commitments.

For the purpose of the consolidated statement of cash flows, cash and cash equivalents comprise cash on hand and at banks, and short-term deposits as defined above, less bank overdrafts which are repayable on demand and form an integral part of the Group's cash management.

Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognised outside profit or loss is recognised outside profit or loss, either in other comprehensive income or directly in equity.

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period, taking into consideration interpretations and practices prevailing in the countries in which the Group operates.

Deferred tax is provided, using the liability method, on all temporary differences at the end of the reporting period between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences; and
- in respect of taxable temporary differences associated with investments in subsidiaries, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

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Deferred tax assets are recognised for all deductible temporary differences, and the carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carryforward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences; and
- in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at the end of the reporting period and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at the end of the reporting period and are recognised to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Government grants

Government grants are recognised at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed.

Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to profit or loss over the expected useful life of the relevant asset by equal annual instalments or deducted from the carrying amount of the asset and released to profit or loss by way of a reduced depreciation charge.

Revenue recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognised when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

Provision of research and development services

The Group recognises revenue only when it satisfies a performance obligation by transferring control of the promised services at a point in time.

Other income

Interest income is recognised on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Share-based payments

The Company operates a share incentive plan. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services in exchange for equity instruments (“**equity-settled transactions**”). The cost of equity-settled transactions with employees for grants is measured by reference to the fair

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value of the equity instruments at the date at which they are granted. The fair value is determined by an external valuer using back-solve method, further details of which are given in note 24 to the Historical Financial Information.

The cost of equity-settled transactions is recognised in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognised for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The charge or credit to profit or loss for a period represents the movement in the cumulative expense recognised as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group's best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognised. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. This includes any award where non-vesting conditions within the control of either the Company or the employee are not met. However, if a new award is substituted for the

cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

Other employee benefits

Pension schemes

The employees of the Company and the Group’s subsidiaries which operate in Chinese Mainland are required to participate in a central pension scheme operated by the local municipal government. The Company and the Group’s subsidiaries are required to contribute a certain percentage of their payroll costs to the central pension scheme. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension scheme.

The Group’s subsidiary in Hong Kong operates a defined contribution Mandatory Provident Fund retirement benefit scheme (the “**MPF Scheme**”) under the Mandatory Provident Fund Schemes Ordinance for the eligible employees from Hong Kong. Contributions are made based on a percentage of the employees’ basic salaries and are charged to profit or loss as they become payable in accordance with the rules of the MPF Scheme. The assets of the MPF Scheme are held separately from the subsidiary in an independently administered fund. The subsidiary’s employer contributions vest fully with the employees when contributed into the MPF Scheme.

Housing fund

The Company and the Group’s subsidiaries which operate in Chinese Mainland contribute on a monthly basis to a defined contribution housing fund plan operated by the local municipal government. Contributions to this plan by the Company and these subsidiaries are expensed as incurred.

Foreign currencies

The Historical Financial Information is presented in RMB, which is the Company’s functional currency. Each entity in the Group determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the

transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of the reporting period. Differences arising on settlement or translation of monetary items are recognised in profit or loss.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognised in other comprehensive income or profit or loss is also recognised in other comprehensive income or profit or loss, respectively).

In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of initial transaction is the date on which the Group initially recognises the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of the advance consideration.

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group's Historical Financial Information requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

Judgements

In the process of applying the Group's accounting policies, management has made the following judgements, apart from those involving estimations, which have the most significant effect on the amounts recognised in the financial statements:

Research and development costs

Development expenses incurred on the Group's product 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.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of the reporting period, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Impairment of non-financial assets (other than goodwill)

The Group assesses whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of the reporting period. Non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm's length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

Fair value measurement of share-based payments

The Group has set up a share incentive plan and granted share award to the Group's employees. The fair values of the share award are determined by the back-solve method at the grant dates. Significant estimates on assumptions, including the underlying equity value are made by management. Further details are included in note 24 to the Historical Financial Information.

Deferred tax assets

Deferred tax assets are recognised for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilised. Significant management judgement is required to determine the amount of deferred tax assets that can be recognised, based upon the likely timing and level of future taxable profits together with future tax planning strategies. Further details are contained in note 10 to the Historical Financial Information.

Leases — Estimating the incremental borrowing rate

The Group cannot readily determine the interest rate implicit in a lease, and therefore, it uses an incremental borrowing rate (“**IBR**”) to measure lease liabilities. The IBR is the rate of interest that the Group would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The IBR therefore reflects what the Group “would have to pay”, which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when it needs to be adjusted to reflect the terms and conditions of the lease (for example, when leases are not in the subsidiary’s functional currency). The Group estimates the IBR using observable inputs (such as market interest rates) when available and is required to make certain entity-specific estimates (such as the subsidiary’s stand-alone credit rating).

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4. OPERATING SEGMENT INFORMATION

The Group is engaged in research and development of biopharmaceutical products, which is regarded as a single reportable segment in a manner consistent with the way in which information is reported internally to the Group’s senior management for purposes of resource allocation and performance assessment. Therefore, no further operating segment analysis thereof is presented.

Geographical information

(a) Revenue from external customers

	Year ended 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Chinese Mainland	—	472
Hong Kong	—	—
Total revenue from external customers	<u>—</u>	<u>472</u>

(b) Non-current assets

	Year ended 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Chinese Mainland	18,439	17,312
Hong Kong	—	365
Total non-current assets.	<u>18,439</u>	<u>17,677</u>

The non-current asset information above is based on the locations of the assets and excludes financial instruments.

Information about a major customer

Revenue of approximately RMB472,000 for 2023 was derived from research and development services to a single customer (2022: Nil).

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5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	Year ended 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Revenue from contracts with customers.	—	472

Revenue from contracts with customers

(a) Disaggregated revenue information

	Year ended 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Types of services		
Provision of research and development services . . .	—	472
Geographical market		
Chinese Mainland	—	472
Timing of revenue recognition		
Transferred at a point in time	—	472

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(b) Performance obligations

Information about the Group’s performance obligations is summarised below:

Research and development services

The performance obligation is satisfied at the point as services are rendered and payment is generally due within 30 days from the date of billing.

An analysis of other income and gains is as follows:

	Year ended 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Other income		
Government grants*	223	—
Bank interest income	726	237
Others	37	34
Total other income	<u>986</u>	<u>271</u>
Gains		
Foreign exchange differences, net	16	—
Total gains	<u>16</u>	<u>—</u>
Total other income and gains	<u><u>1,002</u></u>	<u><u>271</u></u>

* Government grants have been received from the PRC local government authorities to support the Group’s research and development activities. There are no unfulfilled conditions related to these government grants.

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6. LOSS BEFORE TAX

The Group’s loss before tax is arrived at after charging:

	<i>Notes</i>	Year ended 31 December	
		2022	2023
		<i>RMB’000</i>	<i>RMB’000</i>
Depreciation of property, plant and equipment*	13	1,278	1,308
Depreciation of right-of-use assets	14(a)	3,164	3,430
Amortisation of intangible assets**	15	2,005	2,005
Research and development expenses		34,818	39,915
Lease payments not included in the measurement of lease liabilities	14(c)	204	1,256
Foreign exchange differences, net		(16)	19
Auditor’s remuneration		390	1,108
Loss on disposal of items of property, plant and equipment	13	7	—
[REDACTED]		[REDACTED]	[REDACTED]
Government grants		(223)	—
Bank interest income		(726)	(237)
Employee benefit expense (excluding directors’ remuneration as set out in note 8):			
Wages and salaries		18,213	16,886
Pension scheme contributions (defined contribution scheme), social welfare and other welfare		4,574	4,126
Equity-settled share award expenses***	24	24,833	14,671
Total		47,620	35,683

* The depreciation of property, plant and equipment is included in “Administrative expenses” and “Research and development expenses” in the consolidated statements of profit or loss and other comprehensive income.

** The amortisation of intangible assets is included in “Research and development expenses” in the consolidated statements of profit or loss and other comprehensive income.

*** Equity-settled share award expenses are included in “Administrative expenses” and “Research and development costs” in the consolidated statements of profit or loss and other comprehensive income.

**** There are no forfeited contributions that may be used by the Group as the employer to reduce the existing level of contributions.

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7. FINANCE COSTS

An analysis of finance costs is as follows:

	<i>Note</i>	Year ended 31 December	
		2022	2023
		<i>RMB’000</i>	<i>RMB’000</i>
Interest on other financial liabilities	21	7,340	23,170
Interest on lease liabilities	14(c)	515	412
Total		<u>7,855</u>	<u>23,582</u>

8. DIRECTORS’ REMUNERATION

The remuneration of the directors as recorded is set out below:

	Year ended 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Fees	—	—
Other emoluments:		
Salaries, bonuses, allowances and benefits in kind	2,264	6,270
Pension scheme contributions	145	129
Subtotal	<u>2,409</u>	<u>6,399</u>
Total fees and other emoluments	<u>2,409</u>	<u>6,399</u>

	Year ended 31 December 2022		
	Salaries, bonuses, allowances and benefits in kind	Pension scheme contributions	Total remuneration
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Executive director:			
Ms. Jia Lijia (i)	<u>530</u>	<u>—</u>	<u>530</u>
Directors:			
Mr. Wang Kelong (ii)	<u>1,192</u>	<u>90</u>	<u>1,282</u>
Mr. Zhai Junhui (iii)	<u>542</u>	<u>55</u>	<u>597</u>
Total	<u>2,264</u>	<u>145</u>	<u>2,409</u>

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	Year ended 31 December 2023		
	Salaries, bonuses, allowances and benefits in kind	Pension scheme contributions	Total remuneration
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Executive director:			
Ms. Jia Lijia	636	—	636
Directors:			
Mr. Wang Kelong	4,191	81	4,272
Mr. Zhai Junhui	543	48	591
Mr. Miao Tianxiang (iv)	900	—	900
Ms. Lin Ying (v)	—	—	—
Mr. Yuan Fei (vi)	—	—	—
Total	<u>6,270</u>	<u>129</u>	<u>6,399</u>

There was no arrangement under which a director waived or agreed to waive any remuneration during the Relevant Periods.

- (i) Ms. Jia Lijia was appointed as the executive director of the Company in April 2012.
- (ii) Mr. Wang Kelong was appointed as a director of the Company in October 2020.
- (iii) Mr. Zhai Junhui was appointed as a director of the Company in December 2020.
- (iv) Mr. Miao Tianxiang was appointed as a director of the Company in April 2023.
- (v) Ms. Lin Ying was appointed as a director of the Company in July 2023.
- (vi) Mr. Yuan Fei was appointed as a director of the Company in June 2023.

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9. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees during the Relevant Periods included nil and one director, respectively, details of whose remuneration are set out in note 8 above. Details of the remuneration for the highest paid employees who are not a director of the Company are as follows:

	Year ended 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Salaries, bonuses, allowances and benefits in kind	1,965	1,674
Equity-settled share award expenses	24,833	14,671
Pension scheme contributions	68	105
Total	<u>26,866</u>	<u>16,450</u>

The number of non-director highest paid employees whose remuneration fell within the following bands is as follows:

	Year ended 31 December	
	2022	2023
HK\$2,500,001 to HK\$3,000,000	1	1
HK\$4,000,001 to HK\$4,500,000	2	2
HK\$7,000,001 to HK\$7,500,000	1	1
HK\$12,500,001 to HK\$13,000,000	1	—
Total	<u>5</u>	<u>4</u>

10. INCOME TAX

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.

Chinese Mainland

Under the Law of the PRC on Corporate Income Tax (the “**CIT Law**”) and Implementation Regulation of the CIT Law, the CIT rate of the PRC subsidiary was 25% during the Relevant Periods. The Company was accredited as a “High and New Technology Enterprise” (“**HNTE**”) in 2021 and the certificate will expire in December 2024. Therefore, the Company was entitled to a preferential CIT rate of 15% during the Relevant Periods. The qualification as a HNTE is subject to review by the relevant tax authority in the PRC every three years. The two PRC subsidiaries have met the requirement under the relevant tax rules

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and regulations for small and low-profit enterprises, and accordingly, were subject to a reduced preferential CIT rate of 20%, and the portion of the annual taxable income not more than RMB1,000,000 was entitled to be included in the actual taxable income at reduced rates of 12.5% in 2022 and 25% in 2023, respectively.

No provision for Chinese Mainland income tax pursuant to the CIT Law has been made as the Group’s subsidiaries which operate in Chinese Mainland are in loss position and have no estimated taxable profits.

Hong Kong

The subsidiary incorporated in Hong Kong is a qualifying entity under the two-tiered profits tax rates regime. No provision for Hong Kong profits tax has been made as subsidiary incorporated in Hong Kong had no assessable profits derived from or earned in Hong Kong during the Relevant Periods.

The Group had no taxable income during the Relevant Periods.

A reconciliation of the tax expense applicable to loss before tax at the statutory rate to the tax expense at the effective tax rate is as follows:

	Year ended 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Loss before tax	(85,926)	(105,188)
Tax at the statutory tax rate of 25%	(21,482)	(26,297)
Lower tax rate applicable to the Group	8,668	10,759
Expenses not deductible for tax	4,930	3,517
Additional deductible allowance for research and development expenses	(3,526)	(3,403)
Tax losses not recognised	11,410	15,424
Tax charge at the Group’s effective tax rate	<u>—</u>	<u>—</u>

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11. DIVIDENDS

No dividends have been declared and paid by the Company during the Relevant Periods.

12. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amounts is based on the loss for the year attributable to ordinary equity holders of the parent and the weighted average numbers of ordinary shares in issue during the Relevant Periods by reference with the conversion rate of share capital as the Company was converted into a joint stock company with limited liability under the Company Law of the PRC on 1 April 2024.

The Group had no potentially dilutive ordinary shares in issue during the Relevant Periods.

The calculation of basic loss per share is based on:

	Year ended 31 December	
	2022	2023
Loss		
Loss attributable to ordinary equity holders of the parent, for the purpose of calculating basic loss per share (<i>RMB'000</i>):	(85,926)	(105,188)
Shares		
Weighted average number of ordinary shares in issue during the Relevant Periods used in the basic loss per share calculation by reference with the conversion rate of share capital	90,105,648	95,057,185
Loss per share (<i>RMB per share</i>)	(0.95)	(1.11)

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13. PROPERTY, PLANT AND EQUIPMENT

Group and Company

31 December 2022

	Machinery	Office equipment	Electronic equipment	Leasehold improvements	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2022:					
Cost	3,546	71	413	594	4,624
Accumulated depreciation . .	(1,531)	(38)	(142)	(348)	(2,059)
Net carrying amount	<u>2,015</u>	<u>33</u>	<u>271</u>	<u>246</u>	<u>2,565</u>
At 1 January 2022, net of accumulated depreciation	2,015	33	271	246	2,565
Additions	4,250	19	255	—	4,524
Disposals	(2)	(1)	(4)	—	(7)
Depreciation provided during the year	<u>(1,008)</u>	<u>(10)</u>	<u>(147)</u>	<u>(113)</u>	<u>(1,278)</u>
At 31 December 2022, net of accumulated depreciation	<u>5,255</u>	<u>41</u>	<u>375</u>	<u>133</u>	<u>5,804</u>
At 31 December 2022:					
Cost	7,744	87	600	594	9,025
Accumulated depreciation . .	(2,489)	(46)	(225)	(461)	(3,221)
Net carrying amount	<u>5,255</u>	<u>41</u>	<u>375</u>	<u>133</u>	<u>5,804</u>

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	<u>Machinery</u>	<u>Office equipment</u>	<u>Electronic equipment</u>	<u>Leasehold improvements</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2023:					
Cost	7,744	87	600	594	9,025
Accumulated amortisation . .	<u>(2,489)</u>	<u>(46)</u>	<u>(225)</u>	<u>(461)</u>	<u>(3,221)</u>
Net carrying amount	<u>5,255</u>	<u>41</u>	<u>375</u>	<u>133</u>	<u>5,804</u>
At 1 January 2023, net of accumulated					
depreciation	5,255	41	375	133	5,804
Additions	337	260	219	1,756	2,572
Depreciation provided					
during the year	<u>(892)</u>	<u>(20)</u>	<u>(189)</u>	<u>(207)</u>	<u>(1,308)</u>
At 31 December 2023, net of accumulated					
depreciation	<u>4,700</u>	<u>281</u>	<u>405</u>	<u>1,682</u>	<u>7,068</u>
At 31 December 2023:					
Cost	8,081	346	819	2,350	11,596
Accumulated depreciation . .	<u>(3,381)</u>	<u>(65)</u>	<u>(414)</u>	<u>(668)</u>	<u>(4,528)</u>
Net carrying amount	<u>4,700</u>	<u>281</u>	<u>405</u>	<u>1,682</u>	<u>7,068</u>

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14. LEASES

The Group as a lessee

The Group has lease contracts for buildings used in its operations. Leases of buildings generally have lease terms between 36 months and 84 months. Generally, the Group is restricted from assigning and subleasing the leased assets outside the Group.

(a) Right-of-use assets

The carrying amounts of the Group’s right-of-use assets and the movements during the Relevant Periods are as follows:

	<u>Buildings</u>
	<i>RMB’000</i>
At 1 January 2022	9,986
Additions	3,035
Revision of lease terms arising from a change of lease payments	(1,113)
Depreciation charges	(3,164)
As at 31 December 2022 and 1 January 2023	8,744
Additions	6,283
Termination of leases	(5,102)
Depreciation charges	(3,430)
At 31 December 2023	<u>6,495</u>

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(b) Lease liabilities

The carrying amounts of lease liabilities and the movements during the Relevant Periods are as follows:

	Year ended 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Carrying amount at 1 January	9,654	8,464
Additions	3,035	6,283
Accretion of interest recognised during the year . . .	515	412
Termination of leases	—	(5,329)
Revision of lease terms arising from a change of lease payments.	(1,113)	—
Payments.	(3,627)	(4,881)
Carrying amount at 31 December	<u>8,464</u>	<u>4,949</u>
Analysed into:		
Current portion	3,829	2,211
Non-current portion	4,635	2,738

The maturity analysis of lease liabilities is disclosed in note 30 to the Historical Financial Information.

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(c) *The amounts recognised in profit or loss in relation to leases are as follows:*

	Year ended 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Interest on lease liabilities	515	412
Depreciation charge of right-of-use assets	3,164	3,430
Expense relating to short-term leases	204	1,256
Total amount recognised in profit or loss	<u>3,883</u>	<u>5,098</u>

(d) The total cash outflow for leases is disclosed in note 26(c) to the Historical Financial Information.

15. INTANGIBLE ASSETS

Group and Company

31 December 2022

	Patents
	<i>RMB’000</i>
At 1 January 2022:	
Cost	20,045
Accumulated amortisation	(15,004)
Net carrying amount	<u>5,041</u>
Cost at 1 January 2022, net of accumulated amortisation	5,041
Additions	—
Amortisation provided during the year	(2,005)
At 31 December 2022	<u>3,036</u>
At 31 December 2022:	
Cost	20,045
Accumulated amortisation	(17,009)
Net carrying amount	<u>3,036</u>

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31 December 2023

	Patents
	<i>RMB’000</i>
At 1 January 2023:	
Cost.	20,045
Accumulated amortisation	(17,009)
Net carrying amount	<u>3,036</u>
Cost at 1 January 2023, net of accumulated amortisation	3,036
Additions.	—
Amortisation provided during the year.	(2,005)
At 31 December 2023	<u>1,031</u>
At 31 December 2023:	
Cost.	20,045
Accumulated amortisation	(19,014)
Net carrying amount	<u>1,031</u>

16. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

Group

	As at 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Current		
Prepayments	146	2,085
Prepayment for a related party	—	24
Deferred [REDACTED]	[REDACTED]	[REDACTED]
Deposits and other receivables	670	1,032
Subtotal.	<u>960</u>	<u>3,392</u>
Non-current		
Advance payments for property, plant and equipment	26	577
Value-added tax recoverable	829	2,506
Deposits for leases	547	508
Subtotal.	<u>1,402</u>	<u>3,591</u>
Total	<u>2,362</u>	<u>6,983</u>

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The financial assets included in the above balances relate to receivables for which there was no recent history of default and past due amounts. In calculating the expected credit loss rate, the Group considers the historical loss rate and adjusts for forward-looking factors and information. As at 31 December 2022 and 2023, the expected credit loss rates and the loss allowances were assessed to be minimal.

Company

	As at 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Current		
Prepayments	146	2,085
Prepayment for a related party	—	24
Deferred [REDACTED]	[REDACTED]	[REDACTED]
Deposits and other receivables	664	917
Subtotal.	954	3,277
Non-current		
Advance payments for property, plant and equipment . . .	26	577
Value-added tax recoverable	829	2,506
Deposits for leases	547	462
Subtotal.	1,402	3,545
Total	2,356	6,822

17. CASH AND CASH EQUIVALENTS

Group

	As at 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Cash and cash equivalents		
Cash and bank balances.	15,765	241,512
Denominated in:		
RMB	15,737	241,458
HK dollars.	28	54
Total	15,765	241,512

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At the end of the reporting period, the cash and bank balances of the Group denominated in RMB amounted to RMB15,737,000 (2022: RMB241,458,000). The RMB is not freely convertible into other currencies. However, under Chinese Mainland’s Foreign Exchange Control Regulations and Administration of Settlement, Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business.

Cash at banks earns interest at floating rates based on daily bank deposit rates. The bank balances are deposited with creditworthy banks with no recent history of default.

Company

	As at 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Cash and cash equivalents		
Cash and bank balances	14,380	236,618
Denominated in:		
RMB	14,380	236,618

18. TRADE PAYABLES

An ageing analysis of the trade payables as at the end of each of the Relevant Periods, based on the invoice date, is as follows:

Group and company

	As at 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Within 1 year	1,682	5,332
Over 1 year	—	1,288
Total	1,682	6,620

The trade payables are non-interest-bearing and are normally settled within one month after the receipt of the invoice.

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19. OTHER PAYABLES AND ACCRUALS

Group

	As at 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Payroll payable	1,546	1,875
Tax payables	125	221
Other payables	886	805
Total	2,557	2,901

Company

	As at 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Payroll payable	1,469	575
Tax payables	125	193
Other payables	882	8,892*
Total	2,476	9,660

* The amounts of RMB8,115,000 as at 31 December 2023 representing the intercompany charges in regards to certain employee benefit expenses paid by Huaren Yihai on behalf of the Company.

Other payables and accruals are non-interest-bearing and have no fixed terms of settlement.

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20. DEFERRED TAX

The movements in deferred tax assets and liabilities during the Relevant Periods are as follows:

Deferred tax liabilities

	Right-of-use assets
	<i>RMB’000</i>
At 1 January 2022.	1,498
Deferred tax credited to profit or loss during the year.	(186)
Gross deferred tax liabilities at 31 December 2022 and 1 January 2023 . . .	1,312
Deferred tax credited to profit or loss during the year.	(362)
Gross deferred tax liabilities at 31 December 2023.	<u>950</u>

Deferred tax assets

	Lease liabilities	Tax losses	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
At 1 January 2022.	1,448	50	1,498
Deferred tax charged to profit or loss during the year	(178)	(8)	(186)
Gross deferred tax assets at 31 December 2022 and 1 January 2023	1,270	42	1,312
Deferred tax (charged)/credited to profit or loss during the year.	(554)	192	(362)
Gross deferred tax assets at 31 December 2023.	<u>716</u>	<u>234</u>	<u>950</u>

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For presentation purposes, certain deferred tax assets and liabilities have been offset in the consolidated statements of financial position. The following is an analysis of the deferred tax balances of the Group for reporting purposes:

	As at 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Net deferred tax assets recognised in the consolidated statement of financial position.	—	—
Net deferred tax liabilities recognised in the consolidated statement of financial position.	—	—
	<u>—</u>	<u>—</u>

Deferred tax assets have not been recognised in respect of the following items:

	As at 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Tax losses arising in Chinese Mainland.	95,749	195,390
Tax losses arising in Hong Kong.	134	3,362
Total	<u>95,883</u>	<u>198,752</u>

The Group had accumulated tax losses in Chinese Mainland of RMB95,749,000 and RMB195,390,000 at the end of each of the Relevant Periods, out of which the tax losses in the PRC are available for a maximum of ten years for offsetting against future taxable profits of the Company and its two PRC subsidiaries in which the losses arose.

The Group also had accumulated tax losses in Hong Kong of RMB134,000 and RMB3,362,000 at the end of each of the Relevant Periods, out of which the tax losses in Hong Kong will be carried forward indefinitely for offsetting against future taxable profits of the subsidiary in which the losses arose.

Deferred tax assets have not been recognised in respect of these losses as it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

21. OTHER FINANCIAL LIABILITIES

Series A Financing

In August 2021, the Company entered into an investment agreement with certain independent investors, pursuant to which these investors paid the amounts of in aggregate of RMB75,000,000 and subscribed for the Company’s paid-in capital of RMB3,374,000 (referred as “**Series A Financing**”).

The investors of the Series A Financing are entitled to the same voting rights and dividend rights as other founding shareholders of the Company. Certain key preferential rights issued to the investors of the Series A Financing are summarised as follows:

Investors’ redemption rights

The investors of the Series A Financing would have the right but not the obligation to request the Company to purchase all or part of the shares of the Company held by them, upon the occurrence of any of the specified contingent events, including but not limited to:

- (i) a qualified initial public offering of the Company has not been consummated by 31 December 2026; or
- (ii) the Company has not been acquired and is valued at a valuation of not less than RMB3,000,000,000 by 31 December 2026.

The redemption price of each share shall equal to the aggregate of the original issue price plus interest at 8% per annum calculated on a simple basis for the period from the payment date of the consideration up to the redemption date, plus all declared but unpaid dividends.

Liquidation preference

In the event of any liquidation or dissolution of the Company, the investors of the Series A Financing shall be entitled to receive the amount equal to investment costs and dividends that have accrued on the paid-in capital or all declared but unpaid dividends (the “**Priority Liquidation Amount**”). After the Priority Liquidation Amount is paid off, if the Company still has net assets legally available for distribution, the investors of the Series A Financing shall be entitled to the residual assets according to its actual investment ratio. If the investors

of the Series A Financing fails to obtain the Priority Liquidation Amount, the founder is obliged to compensate the investors of the Series A Financing for the difference to the extent of the distribution property obtained from all of its equity.

Anti-dilution right

After the closing date, the Company shall ensure that the unit price of each of registered capital subscribed by any new investor other than the strategic investor for the additional registered capital of the Company shall not be less than the cost of each of registered capital investment paid by the Series A Investor in the Series A Financing.

Series B Financing

In May 2023, the Company entered into an investment agreement with an independent investor, pursuant to which the investor paid the amounts of in aggregate of RMB300,000,000 and subscribed for the Company’s paid-in capital of RMB9,091,000 (referred as “**Series B Financing**”). The transaction cost attributable to Series B Financing was RMB6,995,000.

The investor of the Series B Financing is entitled to the same voting rights and dividend rights as other founding shareholders of the Company. Certain key preferential rights issued to the investor of the Series B Financing are summarised as follows:

Investors’ redemption rights

The investor of the Series B Financing would have the right but not the obligation to request the Company to purchase all or part of the shares of the Company held by them, upon the occurrence of any of the specified contingent events, including but not limited to:

- (i) the Company has not obtained the Phase III clinical trial approval for a Class I new drug issued by the Center for Drug Evaluation of the National Medical Products Administration by 31 December 2025;
- (ii) the Company has less than 5 pipelines under development before 31 December 2025;
- (iii) a qualified initial public offering of the Company has not been consummated by 31 December 2026; or
- (iv) the Company has not been acquired and is valued at a valuation of not less than RMB3,500,000,000 by 31 December 2026.

The redemption price of each share shall equal to the aggregate of the original issue price plus interest at 6% per annum calculated on a simple basis for the period from the payment date of the consideration up to the redemption date.

Liquidation preference

In the event of any liquidation or dissolution of the Company, the investor of the Series B Financing shall be entitled to receive the Priority Liquidation Amount. After the Priority Liquidation Amount is paid off, if the Company still has net assets legally available for distribution, the investor of the Series B Financing shall be entitled to the residual assets according to its actual investment ratio.

Presentation and classification

As the occurrence of the specified redemption triggering events such as no qualified initial public offering of the Company consummated by the specified date and change of control, are beyond the Company’s control, the Company recognised financial liabilities for its obligation to buy back as the financial instruments. The financial liabilities are measured at the present value of the redemption amount. The changes in the carrying amount of the financial liabilities were recorded in profit or loss as “finance costs”.

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The movements of the financial liabilities recognised during the Relevant Periods are set out below:

Group and Company

	<i>Note</i>	Year ended 31 December	
		2022	2023
		<i>RMB’000</i>	<i>RMB’000</i>
At beginning of the year		70,606	77,946
Issuance of financial instruments with preferential rights		—	279,377
Changes in carrying amount of the financial liabilities	7	7,340	23,170
At the end of the year		<u>77,946</u>	<u>380,493</u>

22. PAID-IN CAPITAL

Group and Company

	As at 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Issued and fully paid	<u>82,715</u>	<u>91,806</u>

A summary of movements in the Company’s issued paid-in capital is as follows:

	<i>Note</i>	Paid-in capital
		<i>RMB’000</i>
At 1 January 2022		<u>82,078</u>
Capital contributions*		<u>637</u>
At 31 December 2022 and 1 January 2023		<u>82,715</u>
Issuance of financial instruments with preferential rights	21	<u>9,091</u>
At 31 December 2023		<u>91,806</u>

* Hainan Huaren Gongying Corporate Management Consultancy Partnership (Limited Partnership), one of the shareholders of the Company, made capital injection of RMB637,000 to the Company in 2022.

23. RESERVES

The amounts of the Group’s reserves and the movements therein for the Relevant Periods are presented in the consolidated statements of changes in equity.

Capital reserves

Capital reserves comprise contributions by shareholders.

Share award reserves

The share award reserves of the Group represents the fair value of equity-settled share-based payments as details presented in note 24.

Exchange reserves

The exchange reserves comprise all foreign exchange differences arising from the translation of the financial statements of a foreign operation with functional currency other than RMB.

24. SHARE-BASED PAYMENTS

On 25 April 2021, Hainan Huaren Gongying Corporate Management Consultancy Partnership (Limited Partnership) (海南華人共贏企業管理諮詢合夥企業(有限合夥)) (“**Hainan Huaren Gongying LP**”) was established in the PRC as a limited partnership as an employee incentive platform of the Group.

On 26 October 2021, an employee incentive plan (“**2021 incentive plan**”) was implemented to incentivize certain eligible employees of the Group to retain them for the continual operation and development of the Group. The share awards granted representing 4,785,000 paid-in capital of the Company. The vesting condition of the granted share awards would be subject to a listing-based vesting condition and service period vesting condition.

The Group has adopted the back-solve method to determine the fair value of the share awards for the employment incentive plan with reference to the issue price of the Series A Financing. During the Relevant Periods, share award expenses under 2021 incentive plan of RMB24,833,000 and RMB14,671,000 were charged to profit or loss.

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25. COMMITMENTS

- (a) The Group had the following contracted commitments at the end of each of the Relevant Periods:

	As at 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Property, planet and equipment	—	90

- (b) The Group had no lease contracts that have not yet commenced as at 31 December 2022 and 2023.

26. NOTES TO THE CONSOLIDATED STATEMENT OF CASH FLOWS

(a) Major non-cash transactions

During the years ended 31 December 2022 and 2023, the Group had non-cash additions to right-of-use assets and lease liabilities of RMB3,035,000 and RMB6,283,000, in respect of lease arrangements for buildings.

(b) Changes in liabilities arising from financing activities

	Lease liabilities
	<i>RMB’000</i>
At 1 January 2022	9,654
Changes from financing cash flows*	(3,627)
New leases	3,035
Interest expenses	515
Revision of lease terms arising from a change of lease payment	(1,113)
At 31 December 2022	<u>8,464</u>
At 1 January 2023	8,464
Changes from financing cash flows*	(4,881)
New leases	6,283
Interest expenses	412
Termination of leases	(5,329)
At 31 December 2023	<u>4,949</u>

* The amounts of the changes from financing cash flows do not include the value added tax amounts. The amounts of the value added tax were RMB131,000 and RMB288,000 for the Relevant Periods.

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(c) Total cash outflow for leases

The total cash outflow for leases included in the statements of cash flows is as follows:

	Year ended 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Within operating activities.....	204	1,256
Within financing activities.....	3,758	5,169
Total.....	<u>3,962</u>	<u>6,425</u>

27. RELATED PARTY TRANSACTIONS

(a) Name and relationship

The directors of the Group are of the review that the following company and individual are related parties that had transactions or balances with the Company during the Relevant Periods.

Name of related parties	Relationship with the Group
Mr. Wang Kelong	President/Shareholder of the Company
Beijing Houmingde New Material Packaging Co., Ltd. (“ Beijing Houmingde ”) *	Other related party

* Controlled by an immediate family member of the single largest shareholder of the Group.

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(b) Transactions with related parties

	Year ended 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Lease from Beijing Houmingde*	1,053	1,065
Utility charges for Beijing Houmingde	24	44
Out of pocket expenses paid by Mr. Wang Kelong	6	2
Lease of motor vehicle from Mr. Wang Kelong**	—	—
Total	1,083	1,111

* The lease of a building in 2022 and 2023 and the lease of a motor vehicle in 2023 from Beijing Houmingde were made according to the agreed prices. The lease of a motor vehicle in 2022 was made with nil rental charge according to the agreement.

** The lease of motor vehicle from Mr. Wang Kelong was made with nil rental charge according to the agreement.

(c) Outstanding balances with a related party:

	As at 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Current assets		
Prepayments, other receivables and other assets:		
Prepayment for Beijing Houmingde	—	24
Other payables and accruals:		
Due to Mr. Wang Kelong	6	8
Lease liabilities		
Due to Beijing Houmingde	1,602	72

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(d) Compensation of key management personnel of the Group:

	Year ended 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Fees	—	—
Salaries, bonuses, allowances and benefits in kind	1,842	1,926
Equity-settled share award expenses	4,720	4,927
Pension scheme contributions	80	152
Subtotal.	6,642	7,005
Total compensation paid to key management personnel.	<u>6,642</u>	<u>7,005</u>

Further details of directors’ remuneration are included in note 8 to the Historical Financial Information.

28. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of each of the Relevant Periods are as follows:

31 December 2022

Financial assets

	Financial assets at amortised cost
	<i>RMB’000</i>
Financial assets included in prepayments, other receivables and other assets.	1,217
Cash and cash equivalents.	15,765
Total	<u>16,982</u>

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Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB’000</i>
Trade payables	1,682
Financial liabilities included in other payables and accruals	886
Other financial liabilities	77,946
Total	<u>80,514</u>

31 December 2023

Financial assets

	Financial assets at amortised cost
	<i>RMB’000</i>
Financial assets included in prepayments, other receivables and other assets	1,564
Cash and cash equivalents	241,512
Total	<u>243,076</u>

Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB’000</i>
Trade payables	6,620
Financial liabilities included in other payables and accruals	805
Other financial liabilities	380,493
Total	<u>387,918</u>

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29. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

The carrying amounts and fair values of the Group’s financial instruments, other than those with carrying amounts that reasonably approximate to fair values, are as follows:

	Carrying amounts		Fair values	
	As at 31 December		As at 31 December	
	2022	2023	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Financial liabilities				
Other financial liabilities	77,946	380,493	81,933	389,844

Management has assessed that the fair values of cash and cash equivalents, the current portion of financial assets included in prepayments, other receivables and other assets and financial liabilities included in other payables and accruals, approximate to their carrying amounts largely due to the short-term maturities of these instruments.

The Group’s finance department headed by the finance manager is responsible for determining the policies and procedures for the fair value measurement of financial instruments. The finance manager reports directly to the chief financial officer. At each reporting date, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The valuation is reviewed and approved by the chief financial officer.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale.

The following methods and assumptions were used to estimate the fair values:

The fair values of the non-current portion of prepayments, other receivables and other assets have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities.

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Fair value hierarchy

The following tables illustrate the fair value measurement hierarchy of the Group’s financial instruments:

Assets and liabilities measured at fair value:

The Group did not have any financial assets and financial liabilities measured at fair value as at the end of the Relevant Periods.

Assets for which fair values are disclosed:

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 2022 and 2023.

Liability for which fair value is disclosed:

As at 31 December 2022

	Fair value measurement using			Total
	Quoted prices in active markets	Significant observable inputs	Significant unobservable inputs	
	(Level 1)	(Level 2)	(Level 3)	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	
Other financial liabilities.	—	—	81,933	81,933

As at 31 December 2023

	Fair value measurement using			Total
	Quoted prices in active markets	Significant observable inputs	Significant unobservable inputs	
	(Level 1)	(Level 2)	(Level 3)	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	
Other financial liabilities.	—	—	389,844	389,844

During the Relevant Periods, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for financial liabilities.

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The discount rates when estimated the fair value of the redemption amount of other financial liabilities as at the end of each of the Relevant Periods are as follows:

At 31 December 2022	
— Series A Financing	7.67%
At 31 December 2023	
— Series A Financing	7.13%
— Series B Financing	7.50%

30. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group’s principal financial instruments comprise cash and cash equivalents, financial assets included in prepayments, other receivables and other assets, trade payables, financial liabilities included in other payables and accruals, other financial liabilities. The main purpose of these financial instruments is to raise finance for the Group’s operations.

The main risks arising from the Group’s financial instruments are credit risk and liquidity risk. The board of directors and senior management meet periodically to analyse and formulate measures to manage the Group’s exposure to these risks.

Credit risk

The carrying amounts of cash and cash equivalents and financial assets included in prepayments, other receivables and other assets, represent the Group’s maximum exposure equal to credit risk in relation to the financial assets.

The Group expects that there is no significant credit risk associated with cash and bank balances, financial assets measured at amortised cost since they are substantially held in reputable state-owned banks and other medium or large-sized listed banks. Management does not expect that there will be any significant losses from non-performance by these counterparties.

The Group trades only with recognised and creditworthy third parties. It is the Group’s policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In order to minimise the credit risk, the Group reviews the recoverable amount of each individual trade receivable periodically and management also has monitoring procedures to ensure the follow-up action is taken to recover overdue receivables. In this regard, the directors of the Company consider that the Group’s credit risk is significantly reduced.

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For financial assets included in prepayments, other receivables and other assets relate to receivables for which there was no recent history of default and past due amounts. The Group seeks to maintain strict control over its outstanding receivables to minimise credit risk. Long ageing balances are reviewed regularly by senior management. In view of the fact that deposits and other receivables relate to diversified counterparties, there is no significant concentration of credit risk. The directors of the Company believe that there is no material credit risk inherent in the Group’s outstanding balances.

Maximum exposure and year-end staging

The tables below show the credit quality and the maximum exposure to credit risk based on the Group’s credit policy, which is mainly based on past due information unless other information is available without undue cost or effort, and year-end staging classification as at 31 December. The amounts presented are gross carrying amounts for financial assets.

As at 31 December 2022

	<u>12-month ECLs</u>
	<u>Stage 1</u>
	<i>RMB’000</i>
Financial assets included in prepayments, other receivables and	
other assets — Normal*	1,217
Cash and cash equivalents — Not yet past due	<u>15,765</u>
Total	<u><u>16,982</u></u>

As at 31 December 2023

	<u>12-month ECLs</u>
	<u>Stage 1</u>
	<i>RMB’000</i>
Financial assets included in prepayments, other receivables and	
other assets — Normal*	1,564
Cash and cash equivalents — Not yet past due	<u>241,512</u>
Total	<u><u>243,076</u></u>

* The credit quality of the financial assets included in prepayments, other receivables and other assets is considered to be “normal” when they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk since initial recognition. Otherwise, the credit quality of the financial assets is considered to be “doubtful”.

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Liquidity risk

The Company monitors and maintains a level of cash and cash equivalents deemed adequate by the management of the Company to finance the operations and mitigate the effects of fluctuations in cash flows.

The maturity profile of the Company’s financial liabilities and lease liabilities as at the end of each of the Relevant Periods, based on the contractual undiscounted payments, is as follows:

	<u>Less than 1 year</u>	<u>1 to 5 years</u>	<u>Total</u>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
31 December 2022			
Financial liabilities included in			
other payables and accruals . . .	886	—	886
Trade payables	1,682	—	1,682
Other financial liabilities	—	83,071	83,071
Lease liabilities	4,181	5,092	9,273
Total	<u>6,749</u>	<u>88,163</u>	<u>94,912</u>
31 December 2023			
Financial liabilities included in			
other payables and accruals . . .	805	—	805
Trade payables	6,620	—	6,620
Other financial liabilities	—	399,970	399,970
Lease liabilities	2,360	2,821	5,181
Total	<u>9,785</u>	<u>402,791</u>	<u>412,576</u>

Capital management

The primary objectives of the Group’s capital management are to safeguard the Group’s ability to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximise shareholders’ value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the Relevant Periods.

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31. INVESTMENT IN SUBSIDIARIES

	As at 31 December	
	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>
Interests in subsidiaries, at cost.....	2,000	16,000
— Hainan Huaren	1,000	1,000
— Hongkong Huarene	1,000	5,000
— Huaren Yihai	—	10,000

	Hainan Huaren	Hongkong Huarene	Huaren Yihai	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
At 1 January 2022.....	—	—	—	—
Capital increase.....	1,000	1,000	—	2,000
At 31 December 2022 and 1 January 2023	1,000	1,000	—	2,000
Capital increase.....	—	4,000	10,000	14,000
At 31 December 2023.....	1,000	5,000	10,000	16,000

Details of the subsidiaries of the Company are disclosed in note 1 CORPORATE INFORMATION.

32. EVENTS AFTER THE RELEVANT PERIODS

On 7 February 2024, an employee incentive plan was implemented to incentivize certain eligible employees of the Group to retain them for the continual operation and development of the Group. The share awards granted representing the paid-in capital amount of RMB10,003,000 of the Company.

Pursuant to the promoters’ agreement dated 27 March 2024, the then shareholders of the Company agreed to convert the Company into a joint stock company with limited liability. The net asset value of the Company as at 29 February 2024, the conversion base date, was approximately RMB257,229,000, of which (i) the amount of RMB100,008,722 was converted to 100,008,722 shares with par value of RMB1.00 per share; and (ii) the remaining amount of approximately RMB157,220,000 was transferred to capital reserve. The above conversion was completed on 1 April 2024.

33. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Company, the Group or its subsidiary in respect of any period subsequent to 31 December 2023.

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

Setting out below is a summary of the principal provisions of the Articles of Association of B&K Corporation Limited (the “**Huaren**”). The main purpose of this appendix is to provide an overview of the Huaren for prospective investors, and therefore it may not contain all the information that is important to prospective investors.

SHARES AND REGISTERED CAPITAL

Shares of the Company shall take the form of share certificates. The shares issued by the Company shall be denominated in RMB. The par value per share is RMB1.00.

The Company shall issue shares in an open, fair and just manner, and each share of the same class shall have the same rights.

Shares of the same class issued at the same time shall be issued on the same conditions and at the same price. Any entity or individual shall pay the same price for each of the shares for which it or he or she subscribes for.

INCREASE, DECREASE AND REPURCHASE OF SHARES

Capital Increase

The Company may, based on its business and development needs and in accordance with the laws, regulations and the securities regulatory rules of the place where the Company’s shares are listed, increase its capital in the following ways, subject to separate resolutions of the shareholders’ general meeting:

1. Public offering of shares;
2. Non-public issuance of shares;
3. distributing bonus shares to its existing shareholders;
4. Conversion of capital reserve into share capital;
5. other means as is stipulated by laws, administrative regulations, or as approved by securities regulatory rules of the place where the Company’s shares are listed and relevant regulatory authorities.

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Capital reduction

The Company may reduce its registered capital. When the company needs to reduce its registered capital, it must prepare a balance sheet and an inventory of assets.

The Company shall reduce its registered capital in accordance with the procedures stipulated in the Company Law, the Hong Kong Listing Rules and other relevant regulations and the Articles of Association.

Shares repurchase

The Company shall not buy back its shares, except in one of the following circumstances:

1. reducing the registered capital of the Company;
2. merging with another company that holds shares in the Company;
3. using shares for employee stock ownership plan or equity incentives;
4. shareholders who object to resolutions of the general meeting on merger or division of the Company requesting the Company to buy back their shares;
5. to use the shares for conversion of corporate bonds issued by the Company which are convertible into shares;
6. where it is necessary for the Company to preserve its value and shareholders' interest;
7. other circumstances permitted by laws, administrative regulations and relevant provisions of the Hong Kong Listing Rules, etc.

The Company may repurchase its shares through public centralised [REDACTED] or other methods recognised by laws, administrative regulations, the CSRC and the stock exchange where the Company's shares are [REDACTED], and shall comply with applicable laws, administrative regulations, departmental rules and the securities regulatory rules of the place where the Company's shares are listed.

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Where the Company repurchases its shares under the circumstances set out in items 1 and 2 above, a resolution shall be passed at the general meeting of the Company. Where the Company repurchases its shares under the circumstances set out in items 3, 5 and 6 above, a resolution may be passed at a Board meeting attended by more than two-thirds of the directors in accordance with the provisions of the Articles of Association or as authorized by the general meeting.

Where the Company repurchases its shares under the circumstances set out in item 1 above, such shares shall be cancelled within 10 days from the date of repurchase; where the Company repurchases its shares under the circumstances set out in items 2 and 4, such shares shall be transferred or cancelled within 6 months; where the Company repurchases its shares under the circumstances set out in items 3, 5 and 6, the total number of shares held by the Company shall not exceed 10% of the total issued shares of the Company, and such shares shall be transferred or cancelled within 3 years.

Transfer of Shares

Shares of the Company held by the promoters shall not be transferred within one year from the date of establishment of the Company. Shares issued by the Company prior to the public [REDACTED] of shares shall not be transferred within one year from the date on which the Company's shares are listed and traded on the Hong Kong Stock Exchange.

Directors, supervisors and senior management of the Company shall declare to the Company their shareholdings in the Company and any changes thereof, and shall not transfer more than 25% of the total number of shares of the Company held by them each year during their terms of office; the shares of the Company held by them shall not be transferred within one year from the date on which the shares of the Company are [REDACTED]. The above personnel shall not transfer the shares of the Company held by them within half a year after they leave the Company.

If the Company's shareholders holding 5% (excluding the recognized clearing houses or their agents as defined in the relevant ordinances in force under the laws of Hong Kong from time to time) or above shares of the Company, Directors, Supervisors, senior management officers sell shares or other securities with an equity nature within six months after buying the same or buy shares or securities within six months after selling the same, the earnings arising therefrom shall belong to the Company and the Board shall recover such earnings. However, the restriction shall not be applicable to any sale of shares by a securities company holding 5% or above of the Company's shares as a result of its purchase and [REDACTED] of the untaken shares after [REDACTED] or other circumstances stipulated by CSRC.

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The shares or other securities with an equity nature held by Directors, Supervisors, senior management officers and natural person shareholders referred to in the preceding paragraph include the shares or other securities with an equity nature held by their spouses, parents, children, and any of the above which is held by using others' accounts.

If the Company's Board does not comply with the provision of the first paragraph, the shareholders can request the Board to do so within 30 days. If the Board does not enforce such right within the aforesaid period, the shareholders are entitled to commence litigations in the people's court in their own names for the interests of the Company.

If the Company's Board does not enforce the provision of the first paragraph of this Article, the responsible Directors shall assume joint and severally liable in accordance with the laws.

REGISTER OF MEMBERS

The Company shall establish a register of shareholders in accordance with the evidence provided by the securities registration authority. The register of shareholders shall be sufficient evidence of the shareholders' shareholdings in the Company.

The original of register of holders of H Shares shall be maintained in Hong Kong and made available for inspection by shareholders.

When the Company convenes a general meeting, distributes dividends, conducts liquidation or engages in other activities that require the confirmation of the identity of shareholders, the Board or the convener of the general meeting shall determine the record date in accordance with the provisions of the securities regulatory rules of the place where the Company's shares are [REDACTED]. Shareholders whose names appear on the register of shareholders after the close of [REDACTED] on the record date shall be the shareholders entitled to relevant interests.

Rights and Obligations of Shareholders

Shareholders of the Company shall enjoy the following rights:

1. to receive dividends and other distributions in proportion to the number of shares held;
2. to request, summon, preside over, attend or appoint a proxy to attend shareholders' general meetings and speak at the shareholders' general meetings in accordance with the laws, and to exercise the corresponding voting rights (except where a shareholder is required by the securities regulatory rules of the place where the Company's shares are [REDACTED] to abstain from voting on a particular matter);

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3. to supervise the operation of the Company, making suggestions or enquiries;
4. to transfer, give or pledge the shares held by them in accordance with the laws, administrative regulations and the Articles of Association;
5. to review the Articles of Association, the register of members, counterfoils of corporate bonds, minutes of general meetings, resolutions of the Board meetings, resolutions of the Board of Supervisors meetings and financial and accounting reports;
6. in the event of the termination or liquidation of the Company, to participate in the distribution of remaining assets of the Company in proportion to the number of shares held;
7. to request the Company to buy back the shares of shareholders objecting to resolutions of the general meeting concerning merger or division of the Company;
8. other rights stipulated by laws, administrative regulations, departmental rules, regulatory documents and securities regulatory rules of the place where the Company's shares are **[REDACTED]** or the Articles of Association.

Shareholders of the Company shall assume the following obligations:

1. to comply with laws, administrative regulations and the Articles of Association;
2. to pay subscription monies according to the number of shares subscribed and the method of subscription;
3. not to make divestment unless in the circumstances stipulated by laws and regulations;
4. not to abuse the rights of shareholders to damage the interests of the Company or that of other shareholders; not to abuse the independent status of the Company as a legal person and the limited liability of shareholders to damage the interests of the creditors of the Company;
5. other obligations imposed by laws, administrative regulations, securities regulatory rules of the place where the Company's shares are **[REDACTED]** and the Articles of Association.

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Shareholders of the Company who abuse their shareholders' rights and cause losses to the Company or other shareholders shall be liable for compensation in accordance with the law. Shareholders of the Company who abuse the independent status of the Company as a legal person and the limited liability of shareholders to evade debts and seriously damage the interests of the creditors of the Company shall bear joint and several liabilities for the debts of the Company.

RESTRICTIONS ON RIGHTS OF THE CONTROLLING SHAREHOLDERS

The controlling shareholders and de facto controllers of the Company shall not use their connected relations to damage the interests of the Company. If the violation causes losses to the Company, it shall be liable for compensation.

The controlling shareholders and de facto controllers of the Company shall have fiduciary duties towards the Company and its public shareholders. The controlling shareholders shall exercise its rights as a capital contributor in strict compliance with the laws. The controlling shareholder shall not damage the legitimate rights and interests of the Company and public shareholders by means of profit distribution, asset restructuring, external investment, fund appropriation, loan guarantee, etc., and shall not use its controlling status to damage the interests of the Company and public shareholders.

GENERAL MEETING

General Provisions of General Meetings

The shareholders' general meeting is the organ of authority of the Company and shall exercise the following functions and powers:

1. to decide on the Company's business policies and investment plans;
2. to elect and replace directors and supervisors who are not employee representatives and to decide on matters relating to the remuneration of directors and supervisors;
3. to consider and approve the reports of the Board;
4. to consider and approve the report of the Board of Supervisors;
5. to consider and approve the annual financial budgets and final accounts of the Company;
6. to consider and approve the Company's profit distribution plans and loss recovery plans;

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7. to resolve on the increase or reduction of the registered capital of the Company;
8. to resolve on the issuance of corporate bonds and other securities and their listing;
9. to resolve on the merger, division, dissolution, liquidation or change of corporate form of the Company;
10. amendments to the Articles of Association;
11. to resolve on the appointment and dismissal of the accounting firm of the Company;
12. to consider and approve the external guarantees to be approved by the general meeting of shareholders;
13. to consider the purchase or disposal of material assets within one year with an amount exceeding 30% of the latest audited total assets of the Company;
14. to consider and approve the change in use of proceeds;
15. to consider and approve the connected transactions, external investments, pledge of assets, external financing and external donations that should be approved by the shareholders' general meeting as stipulated in the Hong Kong listing rules;
16. to consider share incentive schemes and employee share ownership schemes;
17. to consider other matters required by laws, administrative regulations, departmental rules, regulatory documents and the securities regulatory rules of the place where the Company's shares are listed or the Articles of Association to be decided by the general meeting.

The above-mentioned powers of general meeting shall not be exercised by the Board or other institutions or individuals by way of authorization.

General meetings are divided into annual general meetings and extraordinary general meetings.

The annual general meeting shall be convened once a year within six months after the end of the previous accounting year.

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The Company shall convene an extraordinary general meeting within two months from the date of occurrence of any of the following circumstances:

- (1) the number of directors is less than the number stipulated in the Company Law or less than two-thirds of the number specified in the Articles of Association;
- (2) when the unrecovered losses of the Company amount to one-third of the total amount of its paid-up share capital;
- (3) when requested by shareholders individually or jointly holding 10% or more of the Company's shares;
- (4) when deemed necessary by the Board;
- (5) when proposed by the Board of Supervisors;
- (6) other circumstances stipulated by laws, administrative regulations, departmental rules, securities regulatory rules of the place where the Company's shares are listed or the Articles of Association.

If the extraordinary general meeting is convened in accordance with the securities regulatory rules of the place where the Company's shares are listed, the actual date of the extraordinary general meeting may be adjusted according to the approval progress of the stock exchange where the Company's shares are listed (if applicable).

Summoning of General Meetings

The independent non-executive Directors are entitled to propose to the Board to convene an extraordinary general meeting. The Board shall, in accordance with the laws, administrative regulations, the securities regulatory rules of the place where the Company's shares are listed and the Articles of Association, give a written reply on whether or not to convene the extraordinary general meeting within 10 days after receiving the proposal from the independent non-executive Directors.

If the Board agrees to convene the extraordinary general meeting, a notice of such meeting shall be issued within five days after the resolution of the Board is passed; if the Board does not agree to convene the extraordinary general meeting, it shall explain the reasons and make an announcement. Where the Hong Kong securities regulator provides otherwise, it shall apply accordingly.

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The Board of Supervisors shall have the right to propose to the Board to convene an extraordinary general meeting in writing. The Board shall, in accordance with the laws, administrative regulations, regulatory documents, the securities regulatory rules of the place where the Company's shares are listed and the Articles of Association, give a written reply on whether to convene the extraordinary general meeting or not within 10 days after receiving the proposal.

If the Board agrees to convene the extraordinary general meeting, a notice of such meeting shall be issued within 5 days after the resolution of the Board is passed. Any changes to the original proposal made in the notice shall be approved by the Board of Supervisors.

If the Board does not agree to convene the extraordinary general meeting or fails to give a reply within 10 days after receiving the proposal, the Board shall be deemed to be unable or fail to perform the duty of convening the general meeting, and the Board of Supervisors may summon and preside over the meeting on its own.

Shareholders individually or jointly holding 10% or more of the Company's shares shall have the right to request the Board of Directors in writing to convene an extraordinary general meeting. The Board shall, in accordance with the laws, administrative regulations, the securities regulatory rules of the place where the shares of the Company are [REDACTED] and the Articles of Association, give a written reply on whether to convene the extraordinary general meeting or not within 10 days after receiving the proposal.

If the Board agrees to convene the extraordinary general meeting, a notice of such meeting shall be issued within five days after the resolution of the Board is passed. Any change to the original request made in the notice shall be approved by the relevant shareholders.

If the Board does not agree to convene an extraordinary general meeting or does not reply within 10 days after receiving the proposal, the shareholders individually or jointly holding more than 10% of the Company's shares shall have the right to propose to the Board of Supervisors to convene an extraordinary general meeting, and such proposal shall be made in writing.

If the Board of Supervisors agrees to convene the extraordinary general meeting, it shall issue a notice of general meeting within 5 days after receiving the request. Any changes to the original request in the notice shall be approved by the relevant shareholders.

If the Board of Supervisors fails to issue the notice of the general meeting within the prescribed period, it shall be deemed that the Board of Supervisors will not convene and preside over the general meeting, and shareholders individually or jointly holding 10% or more of the Company's shares for more than 90 consecutive days may summon and preside over the meeting by themselves.

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Proposals at General Meetings

When the Company convenes a general meeting, the Board, the Board of Supervisors and shareholders individually or jointly holding more than 3% of the Company's shares shall have the right to submit proposals to the Company.

Shareholders individually or jointly holding 3% or more of the Company's shares may submit ad hoc proposals in accordance with the Hong Kong Listing Rules before a general meeting is convened. The convener shall issue a supplementary notice of the general meeting in accordance with the Hong Kong Listing Rules after receiving the proposal to announce the contents of the provisional proposal.

Except as provided in the preceding paragraph or the securities regulatory rules of the place where the Company's shares are [REDACTED], the convener shall not amend the proposals set out in the notice of the general meeting or add any new proposals after issuing the notice of the general meeting.

NOTICE OF GENERAL MEETING

The convener shall notify all shareholders by way of announcement 21 days before the annual general meeting and shall notify all shareholders by way of announcement 15 days before the extraordinary general meeting.

Convening of General Meetings

All shareholders registered on the record date or their proxies are entitled to attend the general meeting. They shall exercise their voting rights in accordance with the relevant laws, regulations and the Articles of Association.

Individual shareholders who attend the meeting in person shall produce their identity cards or other effective document or proof of identity and stock account cards. Proxies of individual shareholders shall produce their valid identity cards and the power of attorney of the shareholder.

Shareholder that is a legal person may be represented at the meeting by its legal representative or a proxy appointed by it (which will be regarded as if the legal person shareholder was present in person) to exercise its rights (including the right to vote). If a legal representative attends the meeting, he/she should produce his/her identity card and valid proof that he/she is a legal representative; if a proxy attends the meeting, the proxy should produce his/her identity card and documents proving that he/she has been appointed by such legal person (unless a shareholder

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is a recognised clearing house as defined in the relevant ordinances in force from time to time under the laws of Hong Kong or the securities regulatory rules of the place where the shares of the company are [REDACTED] or its nominee (hereinafter referred to as a “**Recognised Clearing House**”))

If the shareholder is a Recognised Clearing House, the Recognised Clearing House may authorize one or more persons as it thinks fit to act as its representative (s) at any shareholders’ general meeting or any class shareholders’ meeting or any creditors’ meeting; however, if more than one person are so authorized, the power of attorney shall specify the number and class of shares in respect of which each such person is authorized, and the power of attorney shall be signed by the authorized personnel of the Recognised Clearing House. The person so authorized may attend the meeting on behalf of the recognised clearing house (without being required to produce share certificate, notarized authorization and/or further evidence to prove that he/she is duly authorized) to exercise the rights as if he/she was an individual shareholder of the Company.

Resolutions of General Meetings

Resolutions of the general meeting are divided into ordinary resolutions and special resolutions.

Ordinary resolutions shall be passed by votes representing more than half of the voting rights represented by the shareholders (including proxies) present at the meeting.

A special resolution shall be passed by votes representing more than two-thirds of the voting rights represented by the shareholders (including proxies) present at the meeting.

The following matters shall be approved by ordinary resolutions at a general meeting:

1. to decide on the Company’s business policies and investment plans;
2. to elect and replace directors and supervisors who are not employee representatives and to decide on matters relating to the remuneration of directors and supervisors;
3. to consider and approve the reports of the Board;
4. to consider and approve the report of the Board of Supervisors;
5. to consider and approve the annual financial budgets and final accounts of the Company;
6. to consider and approve the Company’s profit distribution plans and loss recovery plans;

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7. to resolve on the appointment and dismissal of the accounting firm of the Company;
8. to consider and approve the external guarantees to be approved by ordinary resolutions at a general meeting;
9. to consider and approve the change in use of proceeds;
10. to consider employee share ownership schemes;
11. to consider and approve the connected transactions, external investments, pledge of assets, external financing and external donations that should be approved by the shareholders' general meeting as stipulated in the Hong Kong listing rules;
12. to consider other matters required by laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association to be decided by ordinary resolutions at a general meeting.

The following matters shall be approved by special resolutions at a general meeting:

1. to resolve on the increase or reduction of the registered capital of the Company;
2. to resolve on the issue of corporate bonds and other securities and their listing;
3. to resolve on the merger, division, dissolution, liquidation or change of corporate form of the Company;
4. amendments to the Articles of Association;
5. to consider the purchase or disposal of material assets within one year with an amount exceeding 30% of the latest audited total assets of the Company;
6. to consider share incentive schemes;
7. to consider and approve the external guarantees to be approved by special resolutions at a general meeting;
8. to consider other matters required by laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association to be decided by the general meeting.

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DIRECTORS AND BOARD OF DIRECTORS

Directors

Directors shall be elected or replaced by the shareholders' general meeting, and may be removed by the shareholders' general meeting before the expiry of their terms of office. The term of office of the Directors shall be 3 years, and they may be re-elected and re-appointed, however, if the term of office of an independent non-executive director exceeds six years, he/she shall be reappointed after the appropriate review process in accordance with the Hong Kong Listing Rules.

The term of office of the Directors shall commence from the date of their appointment until the expiry of the term of the current session of the Board. If the term of office of a director expires but re-election is not made responsively, the said director shall continue fulfilling the duties as director pursuant to laws, administrative regulations, departmental rules and the Articles of Association until a new director is elected.

THE BOARD

The Company shall have a board of directors which shall be accountable to the general meeting.

The Board shall consist of 9 directors, including one chairman and one vice chairman. The number of independent non-executive Directors shall not be less than three and shall represent more than one-third of the total number of Directors at any time.

The Board shall exercise the following powers:

1. to summon general meetings and report its work to the general meetings;
2. to implement the resolutions of the general meeting;
3. to decide on the Company's business plans and investment plans;
4. to formulate the Company's annual financial budgets and final accounts;
5. to formulate the Company's profit distribution plans and loss recovery plans;
6. to formulate proposals for the increase or reduction of the Company's registered capital, the issue of bonds or other securities and listing plans;

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7. to formulate plans for material acquisitions, purchase of shares of the Company or merger, division, dissolution and change of corporate form of the Company;
8. to consider and approve connected transactions, external investments, pledge of assets, external financing and external donations that should be approved by the Board of Directors under the Hong Kong Listing Rules;
9. to decide on external guarantees other than those requiring the approval of the general meeting of shareholders of the Company;
10. to decide on the purchase and sale of assets other than those requiring the approval of the general meeting of shareholders of the Company;
11. to decide on the establishment of the Company's internal management structure;
12. to decide on the appointment or dismissal of the Company's president, general manager, secretary to the Board and other senior management, and decide on their remuneration, rewards and punishments; to decide on the appointment or dismissal of the Company's vice general manager, chief financial officer and other senior management based on the nomination of the general manager, and decide on their remuneration, rewards and punishments;
13. to formulate the basic management system of the Company;
14. to draw up a plan for the establishment of specialized committees of the Board of Directors and submitting it to the General Meeting of Shareholders for approval, and deciding on the selection and recruitment of the personnel of the specialized committees of the Board of Directors;
15. to formulate proposals for any amendment to the Articles of Association;
16. to manage the information disclosure of the Company;
17. to propose to the general meeting the appointment or replacement of the accounting firm that audits the Company;
18. to listen to the work report of the general manager of the Company and inspect the work of the general manager;

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19. other functions and powers conferred by laws, administrative regulations, departmental rules, securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association.

Matters beyond the scope of authorization of the general meeting shall be submitted to the general meeting for consideration.

General Manager

The general manager shall be accountable to the Board and exercise the following powers:

1. to be in charge of the production, operation and management of the Company, 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 structure;
4. to draft the basic management system of the Company;
5. to formulate the specific rules and regulations of the Company;
6. to propose to the Board to appoint or dismiss vice general managers and chief financial officer of the Company;
7. to appoint or dismiss management personnel other than those required to be appointed or dismissed by the Board;
8. to decide on external guarantee, external investment, external financing, purchase or sale of assets, pledge of assets, and connected transactions, that do not need to be submitted to the general meeting of shareholders, the board of directors and the chairman of the board of directors for approval;
9. to exercise other powers conferred by the Articles of Association or the Board.

The general manager attends Board meetings and non-director general manager do not have voting rights on the Board.

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Secretary to the Board

The Company shall have a secretary to the Board, who shall be responsible for the preparation of the general meetings and Board meetings of the Company, keeping of documents, managing shareholders' information of the Company and handling matters such as information disclosure.

The secretary to the Board shall comply with the relevant provisions of laws, administrative regulations, departmental rules and the Articles of Association.

BOARD OF SUPERVISORS

The Company shall have a Board of Supervisors. The Board of Supervisors shall consist of three Supervisors and shall have one chairman. The chairman of the Board of Supervisors shall be elected by more than half of all Supervisors.

The Board of Supervisors shall comprise shareholder representatives and an appropriate proportion of the company's employee representatives, of which the proportion of employee representatives shall not be less than one-third. The employee representatives of the Board of Supervisors shall be democratically elected by the Company's employees at the employee representative assembly, employee meeting or otherwise.

The Board of Supervisors exercises the following powers:

1. it shall review the regular reports of the Company prepared by the Board and to provide written review opinions;
2. to examine the financial affairs of the Company;
3. to supervise the directors and senior management in their performance of their duties and to propose the removal of directors and senior management who have violated laws, administrative regulations, the Articles of Association or 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 general meetings when the Board fails to perform the duty of summoning and presiding over general meetings under the Company Law;

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6. to submit proposals to the general meeting;
7. to initiate proceedings against directors and senior management in accordance with Article 151 of the Company Law;
8. to investigate any irregularities identified in the operation of the Company; if necessary, to engage professional institutions such as accounting firms and law firms to assist its work and the costs shall be borne by the Company;
9. to exercise other powers conferred by these Articles, the general meeting and the Hong Kong Listing Rules.

Resolutions of the Board of Supervisors shall be passed by more than half of the supervisors.

FINANCIAL AND ACCOUNTING SYSTEM

The Company shall establish its financial and accounting system in accordance with the laws, administrative regulations and the requirements of the relevant state authorities.

The annual reports and interim reports of the Company are prepared in accordance with the relevant laws, administrative regulations, the requirements of the CSRC and the stock exchanges where the Company's shares are [REDACTED].

NOTICES

A notice of the Company shall be given in the following manners:

1. by hand;
2. by mail;
3. by fax or e-mail;
4. by publishing on the websites designated by the Company and the Hong Kong Stock Exchange, in accordance with the laws, administrative regulations and the listing rules of the stock exchange where the Company's shares are [REDACTED];
5. by other form as may be prescribed by the Articles of Association;

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6. by other form as may be agreed upon in advance by the Company or the person to be notified or recognized by the person to be notified upon receipt of the notice;
7. other means stipulated by laws, administrative regulations, rules, securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association.

Subject to the securities regulation rules of the place where the Company's shares are [REDACTED], where a notice of the Company is published by way of announcement, the said notice shall be deemed as received by all relevant persons once it is published.

Dissolution and Liquidation of the Company

The Company shall be dissolved for the following reasons:

1. the term of its operations as is stipulated in the Articles of Association has expired or events of dissolution specified in the Articles of Association have occurred;
2. the shareholders' general meeting resolves to dissolve the Company;
3. dissolution is necessary due to merger or division of the Company;
4. the Company's business license is revoked, the Company is ordered to close down or be revoked in accordance with the law;
5. where the Company encounters serious difficulties in its operation and management and its continuous existence will cause significant losses to the interests of shareholders, and such difficulties cannot be resolved through other means, shareholders holding more than 10% of the voting rights of all shareholders of the Company may request the People's Court to dissolve the Company.

Where the Company is dissolved pursuant to items 1, 2, 4 and 5 above, a liquidation committee shall be established and the liquidation shall commence within 15 days after the occurrence of the cause of dissolution. The liquidation committee shall be composed of directors or persons determined by the shareholders' general meeting. If a liquidation committee is not established within the time limit, the creditors may apply to the people's court to designate relevant personnel to form a liquidation committee to carry out liquidation.

The liquidation committee shall notify creditors within 10 days from the date of its establishment, and publish an announcement in a newspaper recognized by the stock exchange where the Company's shares are [REDACTED] within 60 days.

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If the liquidation committee discovers that the Company's assets are insufficient to repay its debts after cleaning up the Company's assets and preparing a balance sheet and an inventory of assets, it shall apply to the People's Court for a declaration of insolvency in accordance with the law.

Upon completion of the liquidation, the liquidation committee shall prepare a liquidation report which shall be submitted to the shareholders' general meeting or the people's court for confirmation, and shall submit the same to the company registration authority, and apply for cancellation of the company's registration, and publish an announcement on the termination of the company.

AMENDMENTS TO THE ARTICLES

The Company shall amend the Articles of Association in any of the following circumstances:

- (1) After the amendments are made to the Company Law or relevant laws, administrative regulations, departmental rules and securities regulatory rules of the place where the shares of the Company are [REDACTED], the provisions of the Articles of Association are in conflict with the amended laws, administrative regulations, departmental rules and securities regulatory rules of the place where the shares of the Company are [REDACTED];
- (2) there is a change in the Company's situation, which is inconsistent with the matters recorded in the Articles of Association;
- (3) the shareholders' general meeting decides to amend the Articles of Association.

The amendments to the Articles of Association passed by the shareholders' general meeting shall be submitted to the competent authorities for approval if they are subject to approval by the competent authorities. If there is any change relating to the registered particulars of the Company, application shall be made for registration of the changes in accordance with the laws.

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A. FURTHER INFORMATION ABOUT OUR GROUP

1. Incorporation of Our Company

Our Company was established as a limited liability company in the PRC on April 24, 2012 and converted into a joint stock company with limited liability on April 1, 2024. Accordingly, 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 the Articles of Association” in Appendix III to this document.

As of the date of this document, our Company’s registered office is at Room 1507, Building 1, Xiexin Center, No. 19 Qinling Road, Laoshan District, Qingdao, Shandong Province, PRC. Our Company has established a principal place of business in Hong Kong at 5/F, Manulife Place, 348 Kwun Tong Road, Kowloon, Hong Kong and has been registered as a non-Hong Kong company under Part 16 of the Companies Ordinance on April 26, 2024 with the Registrar of Companies in Hong Kong. Ms. Wong Wai Yee Ella (黃慧兒) has been appointed as our authorized representative for the acceptance of services of process and notices on behalf of our Company in Hong Kong. The address for service on the Company in Hong Kong is the same as its principal place of business in Hong Kong as set out above.

2. Changes in Share Capital of Our Company

On April 1, 2024, our Company was converted into a joint stock company with limited liability and renamed as B&K Corporation Limited (華芒生物科技(青島)股份有限公司). As of the Latest Practicable Date, our registered capital was RMB100,008,772 divided into 100,008,772 shares with a nominal value of RMB1.00 each.

Save as disclosed in “History, Development and Corporate Structure,” there has been no alteration in the share capital of our Company within two years immediately preceding the date of this document.

3. Changes in Share Capital of Our Subsidiaries

A summary of the corporate information and the particulars of our subsidiaries are set out in Note 1 to the Accountants’ Report in Appendix I to this document.

Beijing Huarene Biotechnology Hongkong Company Limited (香港華人生物技術有限公司) was incorporated as a private company limited by shares in Hong Kong on August 8, 2022.

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Huaren Yihai Biotechnology (Beijing) Co., Ltd. (華仁益海生物科技(北京)有限公司) was established as a limited liability company in the PRC on July 21, 2023 with a registered capital of RMB20 million.

Save as disclosed above, there has been no alteration in the share capital of the subsidiaries of our Company within two years immediately preceding the date of this document.

4. Shareholders’ Resolutions

Pursuant to the resolutions passed at a duly convened general meeting of our Shareholders on April 1, 2024, the following resolutions, among others, were passed by the Shareholders:

- (a) the issue by our Company of H Shares with a nominal value of RMB1.00 each and such H Shares be [REDACTED] on the Stock Exchange;
- (b) the number of H Shares to be issued shall be no more than [REDACTED], representing approximately [REDACTED]% of the total issued share capital of our Company as enlarged by the [REDACTED], and the grant of the [REDACTED] in respect of no more than [REDACTED]% of the number of H Shares issued pursuant to the [REDACTED];
- (c) subject to filing with the CSRC, upon completion of the [REDACTED], [REDACTED] Unlisted Shares will be converted into H Shares on a one-for-one basis;
- (d) authorization of the Board or its authorized individual to handle all matters relating to, among other things, the [REDACTED], the issue and the [REDACTED] of H Shares on the Stock Exchange; and
- (e) subject to the completion of the [REDACTED], the conditional adoption of the Articles of Association, which shall become effective on the [REDACTED].

5. Corporate Reorganization

Our Company has not gone through any corporate reorganization. For details of the history and development of our Company, see “History, Development and Corporate Structure” in this document.

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B. FURTHER INFORMATION ABOUT OUR BUSINESS

1. Summary of Material Contracts

The following contract (not being contracts entered into in the ordinary course of business) was entered into by members of our Group within the two years immediately preceding the date of this document which is or may be material:

- (a) the capital injection agreement dated May 24, 2023 entered into between the Company, Ms. Jia, Mr. Wang, Zhang Hongbo, Li Gewei, Qingdao Huaren, Song Jianqing, Hainan Huaren, Qingdao CDH, Jiaxing CDH, Zhang Hong and Qingdao Hitech, in relation to the investment of RMB300,000,000 by Qingdao Hitech in the Company;
- (b) the shareholders’ agreement dated May 24, 2023 entered into among the Company, Ms. Jia, Mr. Wang, Zhang Hongbo, Li Gewei, Qingdao Hitech, Qingdao Huaren, Song Jianqing, Hainan Huaren, Qingdao CDH, Jiaxing CDH and Zhang Hong, pursuant to which shareholders rights were agreed among the parties;
- (c) the supplemental agreement dated February 23, 2024 entered into among the Company, Ms. Jia, Mr. Wang, Zhang Hongbo, Li Gewei, Qingdao Hitech, Qingdao Huaren, Song Jianqing, Hainan Huaren, Qingdao CDH, Jiaxing CDH and Zhang Hong, regarding termination of certain special rights entitled by certain shareholders; and
- (d) the [REDACTED].

2. Our Material Intellectual Property Rights

(a) Trademarks

As of the Latest Practicable Date, we had registered the following trademarks, which we consider to be material to our Group’s business:

No.	Trademark	Owner	Registration No.	Place of registration	Class	Expiry date
1.	华苾	Our Company	306063237	Hong Kong	05	September 20, 2032
2.	huarene	Our Company	306063228	Hong Kong	05	September 20, 2032
3.	修美瑞	Our Company ⁽³⁾	67207244	PRC	05	April 20, 2033
4.	修普乐	Our Company ⁽⁴⁾	67213514	PRC	05	March 6, 2033
5.	修美平	Our Company ⁽⁵⁾	67213520	PRC	05	March 6, 2033
6.	瑞美平	Our Company ⁽⁶⁾	67225276	PRC	05	April 6, 2033

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(3)–(6) This trademark was registered under the former name of our Company, namely Huaren Biotechnology (Qingdao) Limited (華荃生物科技(青島)有限公司).

(b) Patents

As of the Latest Practicable Date, we had registered the following patents which we consider to be or may be material to our business:

No.	Patent	Patentee	Patent Type	Patent Number	Application	
					Date	Term
1.	A recombinant human platelet-derived growth factor and its encoding gene and presentation method (一種重組人血小板衍生生長因子及其編碼基因與表達方法)	Institute of Bioengineering of AMMS, Our Company ⁽¹⁾	Invention	ZL 200410068993.2	July 15, 2004	20 years
2.	A recombinant human platelet-derived growth factor gel (一種重組人血小板衍生生長因子凝膠劑)	Institute of Bioengineering of AMMS, Our Company ⁽²⁾	Invention	ZL 200510124266.8	November 29, 2005	20 years
3.	A pH-responsive hydrogel biocarrier and its application (一種pH響應型水凝膠生物載體及應用)	Our Company ⁽³⁾	Invention	ZL 202111296151.2	November 3, 2021	20 years

For a discussion of the details of the material patents and patent applications in connection with our clinical and pre-clinical products, please see “Business – Intellectual Property Rights” in this document.

(1)–(2) This patent was registered under the former name of our Company, namely Beijing Zhonghong Saisi Biotechnology Limited (北京中宏賽思生物技術有限公司).

(3) This patent was registered under the former name of our Company, namely Huaren Biotechnology (Qingdao) Limited (華荃生物科技(青島)有限公司).

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(c) Software Copyrights

As of the Latest Practicable Date, we have registered the following software copyrights which we consider to be or may be material in relation to our Group’s business:

No.	Registered Owner	Copyright	Registration Number	Date of Initial Publication
1.	Our Company ⁽¹⁾	Biomedical R&D Supervision System (生物醫藥研發監管系統)	2021SR0536590	Not yet
2.	Our Company ⁽²⁾	Biomedical Innovation R&D Expert Technology System (生物醫藥創新研發專家技術系統)	2021SR0535807	Not yet
3.	Our Company ⁽³⁾	Biomedical Human Cytokine-based R&D Expert Technology System (生物醫藥基於人細胞因子研發專家技術系統)	2021SR0535808	Not yet
4.	Our Company ⁽⁴⁾	Biomedical R&D Review System (生物醫藥研發評審系統)	2021SR0545111	Not yet
5.	Our Company ⁽⁵⁾	Biomedical R&D Review System (生物醫藥研發基因多態差異分析系統)	2021SR0535996	Not yet
6.	Our Company ⁽⁶⁾	Biomedical Experimental Data Intelligent Collection and Analysis Software (生物醫藥實驗數據智能採集分析軟件)	2021SR0536035	Not yet

(1)–(6) This copyright was registered under the former name of our Company, namely Huaren Biotechnology (Qingdao) Limited (華荃生物科技(青島)有限公司).

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(d) Domain Names

As of the Latest Practicable Date, we owned the following domain names which we consider to be or may be material to our business:

No.	Domain Name	Registered Owner	Registration Date
1.	huarenshengwu.com.	Our Company	October 28, 2020
2.	bio-bank.net	Our Company	September 7, 2021

Save as aforesaid, as of the Latest Practicable Date, there were no other trade or service marks, patents, intellectual or industrial property rights which were material in relation to our business.

C. FURTHER INFORMATION ABOUT OUR DIRECTORS AND SUPERVISORS

1. Directors’ and Supervisors’ Service Contracts and Appointment Letters

We [have entered] into a contract with each of our Directors and Supervisors in respect of, among other things, compliance with the relevant laws and regulations, the Articles of Association and applicable provisions on arbitration.

Save as disclosed above, we have not entered, 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 (other than contracts expiring or determinable by the employer within one year without any payment of compensation (other than statutory compensation)).

2. Remuneration of Directors and Supervisors

Save as disclosed in “Directors, Supervisors and Senior Management” and “Appendix I — Accountant’s Report — II. Notes to The Historical Financial Information — 8. Directors’ and chief executive’s remuneration” for the financial years ended December 31, 2022 and 2023, none of our Directors and Supervisors received other remunerations of benefits in kind from us.

3. Employee Incentive Plans

The following is a summary of the principal terms of (i) the employee incentive plan approved and adopted by the Company in December 2020 (the “**Plan I**”); (ii) the employee incentive plan approved and adopted by the Company in October 2021 (the “**Plan II**”); and (iii)

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the employee incentive plan approved and adopted by the Company in February 2024 (the “**Plan III**”, together with Plan I and Plan II, the “**Employee Incentive Plans**”), respectively. The terms of the Employee Incentive Plans are not subject to the provisions of Chapter 17 of the Listing Rules.

As of the Latest Practicable Date, Qingdao Huaren and Hainan Huaren, our Employee Shareholding Platforms, hold 8,000,000 Unlisted Shares (representing approximately [REDACTED]% of total issued shares of our Company upon completion of the [REDACTED], without taking into consideration the exercise of the [REDACTED]) and 4,785,000 Unlisted Shares (representing approximately [REDACTED]% of total issued shares of our Company upon completion of the [REDACTED], without taking into consideration the exercise of the [REDACTED]), respectively, as underlying Shares under the Employee Incentive Plans. For details of Qingdao Huaren and Hainan Huaren, see “History, Development and Corporate Structure — Employee Shareholding Platforms.”

(a) Objectives

The objectives of the Employee Incentive Plans are to further improve the corporate governance of the Company, to build an incentive mechanism for senior management members, core employees and consultants engaged by our Group, among others, to achieve our strategies and to advance development of the Company.

(b) Eligibility

Pursuant to the plan documents (the “**Plan Documents**”), participants of the Employee Incentive Plans include our Company’s and its subsidiaries’ directors, senior management members, core technical personnels, key employees consultants engaged by our Group and other eligible persons as approved by the Board. The Plan Documents further provided that the following employees or other talents may not be selected as participants to the Employee Incentive Plans (as the case may be):

- Persons who have received public reprimand from, or was considered as unfit for his or her position by, relevant regulators in the preceding twelve months;
- Persons who have received administrative penalties or prohibition order for entering into the market from relevant regulators in the preceding twelve months;
- Persons who was penalized by, or received prohibition order for entering into the market from, the CSRC or its relevant branches in the preceding twelve months;

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- Persons who are not allowed to hold the position of director, supervisor or senior management pursuant to the Company Law of the PRC; and
- Persons who have been considered as not eligible by the Board in accordance with the Articles of Association, the Company Law of the PRC and the Securities Law of the PRC.

(c) Administration

The Employee Incentive Plans shall be approved by the Board and Shareholders. Subject to authorization from Shareholders, the Board shall be responsible for the amendment, explanation and implementation of the Employee Incentive Plans.

(d) Shares and Share Price under the Plan

As of the Latest Practicable Date, there were a total of 12,785,000 Shares and 17 individual participants under the Employee Incentive Plans. We do not expect to grant additional partnership interest or Shares as incentive under the Employee Incentive Plans. Immediately following completion of the [REDACTED], the aggregate number of Shares underlying the Employee Incentive Plans remain as 12,785,000 representing [REDACTED]% of the total issued Shares (without taking into consideration the exercise of the [REDACTED]). As a result, the Employee Incentive Plans will not cause any dilution of the shareholding of our Shareholders immediately after the [REDACTED]. For further details on the interest of our core connected persons granted under the Employee Shareholding Platforms, see “History, Development and Corporate Structure — Employee Shareholding Platforms.”

(e) Repurchase of Shares Granted

The partnership interests granted to the participant may be repurchased by the entities designated by the managing partner of the Employee Shareholding Platforms or the Board (as the case may be) in the event of, including but not limited to:

- (i) the death, loses his/her ability to work or loss of civil capacity of the participant;
- (ii) the participant engages in bribery, solicitation of bribes, embezzlement, theft, disclosure of commercial or technical secrets and violation of our Company’s regulations on non-competition or restriction of non-competition during the period of his/her employment, breach of fiduciary duty, or carrying out related parties transaction or other violations of relevant laws, administrative regulations or the provisions of the Articles of Association, causing significant economic losses to our Company;

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- (iii) the participant has seriously neglected his/her duties, dereliction of duty, or committed malpractice for personal gain, which has caused significant damage to our Company;
- (iv) the participant, as resolved by the Board, is directly liable for material adverse effect caused to the Company’s operation, management, production and research and development; and
- (v) for Plan II and Plan III only, the participant resigns, whose terms of service agreement expire and are not renewed, or whose service agreement is terminated.

D. DISCLOSURE OF INTERESTS

1. Disclosure of Interests of Directors, Supervisors and chief executive of our Company

Immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised), the interests or short positions of our Directors, Supervisors and the chief executive of our Company in our Shares, underlying Shares and debentures of our Company and its associated corporations, within the meaning of Part XV of the SFO which will have to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he or she is taken or deemed to have under such provisions of the SFO) or which will be required, pursuant to section 352 of the SFO, to be recorded in the register referred to therein or which will be required to be notified to us and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Companies contained in the Listing Rules, will be as follows:

(a) Interest in Shares of our Company

Name of Director, Supervisor or chief executive	Position	Nature of Interest ⁽¹⁾	Number and class of Shares held	Approximate percentage of shareholding in the total issued Shares immediately prior to the [REDACTED]	Approximate percentage of shareholding in the total issued Shares immediately after the [REDACTED] ⁽²⁾	Approximate percentage of shareholding in the relevant class of Shares after the [REDACTED] ⁽²⁾
Ms. Jia	Chairperson of the Board and executive Director	Beneficial owner and Interest of concert parties ⁽³⁾	[REDACTED]	22.89%	[REDACTED]%	[REDACTED]%
		Beneficial owner and Interest of concert parties ⁽³⁾	[REDACTED]	44.10%	[REDACTED]%	[REDACTED]%

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Name of Director, Supervisor or chief executive	Position	Nature of Interest ⁽¹⁾	Number and class of Shares held	Approximate percentage of shareholding in the total issued Shares immediately prior to the [REDACTED]	Approximate percentage of shareholding in the total issued Shares immediately after the [REDACTED] ⁽²⁾	Approximate percentage of shareholding in the relevant class of Shares after the [REDACTED] ⁽²⁾
Mr. Wang	President, Executive Director and vice chairperson of the Board	Beneficial owner and Interest of concert parties ⁽³⁾	[REDACTED]	22.89%	[REDACTED]%	[REDACTED]%
		Beneficial owner and Interest of concert parties ⁽³⁾	[REDACTED]	44.10%	[REDACTED]%	[REDACTED]%

Notes:

- (1) All interests stated are long positions
- (2) The calculation is based on the total number of [REDACTED] Unlisted Shares in issue and [REDACTED] H Shares to be issued pursuant to the [REDACTED] (including [REDACTED] H Shares to be converted from Unlisted Shares) in issue upon [REDACTED], assuming that the [REDACTED] is not exercised.
- (3) As of the Latest Practicable Date, Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li directly held 19,540,937 Shares, 17,980,000 Shares, 17,475,000 Shares and 12,000,000 Shares in our Company, respectively. By virtue of the Concert Party Agreement, each of Ms. Jia, Mr. Wang, Ms. Zhang and Mr. Li is deemed to be interested in such Shares by the other Controlling Shareholders as they are parties acting in concert.

(b) Interest in associated corporations

None of the Directors, Supervisors or chief executive of the Company will, immediately following completion of the [REDACTED], has any interests and/or short positions in the Shares, underlying Shares and debentures of our Company’s associated corporations (within the meaning of Part XV of the SFO), which will have to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he/she is taken or deemed to have under such provisions of the SFO), or which will be required, pursuant to section 352 of the SFO, to be recorded in the register referred to therein, or which will be required to be notified to our Company and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Companies contained in the Listing Rules.

2. Disclosure of Interests of Substantial Shareholders

For information on the persons who will, immediately following the completion of the [REDACTED], having or be deemed or taken to have beneficial interests or short position in our Shares or underlying shares which would fall to be disclosed to our Company under the provisions

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of 2 and 3 of Part XV of the SFO, or directly or indirectly be interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any other member of our Group, please see “Substantial Shareholders” in this document.

3. Disclaimers

- (a) None of our Directors or any of the parties listed in “Qualifications of Experts” of this Appendix is interested in our promotion, or in any assets which, within the two years immediately preceding the date of this document, have been acquired or disposed of by or leased to us, or are proposed to be acquired or disposed of by or leased to our Company;
- (b) Save in connection with the [REDACTED] and the [REDACTED], none of our Directors or any of the parties listed in “Qualifications of Experts” of this Appendix is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to our business;
- (c) Save in connection with the [REDACTED] and the [REDACTED], none of the parties listed in “Qualifications of Experts” of this Appendix:
 - (i) is interested legally or beneficially in any shares in any member of our Group; or
 - (ii) (has any right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for any securities in any member of our Group; and
- (d) none of our Directors or Supervisors or their close associates (as defined in the Listing Rules) or any shareholders of our Company (who, to the knowledge of our Directors owns more than 5% of our issued share capital) has any interest in our top five customers or suppliers.

E. OTHER INFORMATION

1. Estate Duty

Our Directors have been advised that no material liability for estate duty is likely to fall on our Company or any of our subsidiaries under the laws of the PRC.

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2. Litigation

As of the Latest Practicable Date, we were not engaged in any litigation, arbitration or claim of material importance and no litigation, arbitration or claim of material importance was known to our Directors to be pending or threatened by or against any member of our Group, that would have a material adverse effect on our results of operations or financial conditions, taken as a whole.

3. Preliminary Expenses

As of the Latest Practicable Date, our Company has not incurred material preliminary expenses.

4. Promoters

The promoters of the Company are all of the 11 then shareholders of our Company as of April 1, 2024 immediately before our conversion into a joint stock limited liability company. Save as disclosed in this document, within the two years immediately preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given 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.

5. Taxation of Holders of H Shares

(a) Hong Kong

The sale, purchase and transfer of H shares are subject to Hong Kong stamp duty if such sale, purchase and transfer are effected on the H share register of members of our Company, including in circumstances where such transaction is effected on the Stock Exchange. The stamp duty is charged to each of the seller and purchaser at the ad valorem rate of 0.1% of the consideration for, or (if higher) the fair value of the H Shares being sold or transferred. In other words, a total of 0.2% is currently payable on a typical sale and purchase transaction of the H Shares. In addition, a fixed duty of HK\$5 is charged on each instrument of transfer (if required).

(b) Consultation with professional advisors

Potential investors in the [REDACTED] are urged to consult their professional tax advisors if they are in any doubt as to the taxation implications of subscribing for, purchasing, holding or disposing of or dealing in our H Shares (or exercising rights attached to them). None of us, the Joint Sponsors, [REDACTED], or any other person or party involved in the [REDACTED] accept

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responsibility for any tax effects on, or liabilities of, any person, resulting from the subscription, purchase, holding or disposal of, dealing in or the exercise of any rights in relation to our H Shares.

6. Application for [REDACTED]

The Joint Sponsors have made an application on behalf of our Company to the [REDACTED] Committee of the Stock Exchange for the [REDACTED] of, and permission to [REDACTED], the H Shares to be issued as mentioned in this document (including any H Shares which may be issued pursuant to the exercise of [REDACTED]) and the H Shares to be converted from Unlisted Shares, on the Main Board of the Stock Exchange. All necessary arrangements have been made to enable the securities to be admitted into [REDACTED].

7. No Material Adverse Change

Our Directors confirm that, up to the date of this document, there has been no material adverse change in the financial or trading position or prospect of our Group since December 31, 2023 (being the date to which the latest audited consolidated financial statements of our Group were prepared).

8. Qualification of Experts

The following are the qualifications of the experts (as defined under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance) who have given opinions or advice which are contained in this document:

<u>Name</u>	<u>Qualification</u>
Huatai Financial Holdings (Hong Kong) Limited	Licensed to conduct type 1 (dealing in securities), type 2 (dealing in future contracts), type 4 (advising on securities), type 6 (advising on corporate finance), type 7 (providing automated trading services) and type 9 (asset management) regulated activities as defined under the SFO
CITIC Securities (Hong Kong) Limited	Licensed to conduct Type 4 (advising on securities) and type 6 (advising on corporate finance) regulated activities as defined under the SFO

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<u>Name</u>	<u>Qualification</u>
Commerce & Finance Law Offices	Legal advisor to the Company as to PRC laws and PRC intellectual property law
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co	Independent industry consultant
Ernst & Young	Certified Public Accountants

As of the Latest Practicable Date, none of the experts named above had any shareholding interest in our Company or any of our subsidiaries or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group.

9. Consents of Experts

Each of the experts whose names are set out in paragraph 8 above has given and has not withdrawn its consent to the issue of this document with the inclusion of its report and/or letter and/or legal opinion (as the case may be) and references to its name included herein in the form and context in which it respectively appears.

10. Joint Sponsors' Independence

Each of the Joint 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 Joint Sponsors, the Joint Sponsors' fees payable by us to each of the Joint Sponsors in respect of their services as sponsors in connection with the [REDACTED] on the Stock Exchange is US\$500,000.

11. 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.

12. Bilingual Prospectus

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).

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13. Miscellaneous

- (a) Save as disclosed in "History, Development and Corporate Structure" and "Statutory and General Information" in this document, within the two years immediately preceding the date of this document, no share or loan capital of any member of our Group has been issued or agreed to be issued or is proposed to be issued for cash or as fully or partly paid other than in cash or otherwise.
- (b) No founder, management or deferred shares nor any debentures in any member of our Group.
- (c) No share or loan capital or debenture of any member of our Group is under option or is agreed conditionally or unconditionally to be put under option.
- (d) No commissions, discounts, brokerages or other special terms have been granted in connection with the issue or sale of any share or loan capital of our Company or any of its subsidiaries by our Company for subscribing or agreeing to subscribe, or procuring or agreeing to procure subscriptions, for any shares in or debentures of our Company or any of our subsidiaries.
- (e) None of our Directors or experts (as named in this document), have any interest, direct or indirect, in any assets which have been, within the two years immediately preceding the date of this document, acquired or disposed of by or leased to, any member of our Group, or are proposed to be acquired or disposed of by or leased to any member of our Group.
- (f) No equity or debt securities of any company within our Group is presently listed on any stock exchange or traded on any trading system nor is any listing or permission to deal being or proposed to be sought.
- (g) Our Company has no outstanding convertible debt securities or debentures.
- (h) There is no arrangement under which future dividends are waived or agreed to be waived.
- (i) There has not been any interruption in the business of our Group which may have or has had a significant effect on the financial position of our Group in the 12 months preceding the date of this document.

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 the copy of this Document delivered to the Registrar of Companies in Hong Kong for registration were:

- (a) the written consents referred to in “Statutory and General Information — E. Other Information — 9. Consents of Experts” in Appendix IV to this document; and
- (b) a copy of each of the material contracts referred to in “Statutory and General Information — B. Further Information about our Business — 1. Summary of Material Contracts” in Appendix IV to this document.

DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be available on display on the website of the Stock Exchange at www.hkexnews.hk and our Company’s website at huarenshengwu.com during a period of 14 days from the date of this document:

1. the Articles of Association;
2. the Accountant’s Report prepared by Ernst & Young in respect of the historical financial information of the Group for the years ended December 31, 2022 and 2023, the text of which is set forth in Appendix I to this document;
3. the audited consolidated financial statements of our Company for the financial years ended December 31, 2022 and 2023;
4. the report from Ernst & Young on the unaudited [REDACTED] financial information of our Group, the text of which is set forth in Appendix II to this document;
5. the material contracts in “Statutory and General Information — B. Further Information about our Business — 1. Summary of Material Contracts” in Appendix IV to this document;
6. the written consents referred to in “Statutory and General Information — E. Other Information — 9. Consents of experts” in Appendix IV to this document;

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**DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES IN HONG KONG AND AVAILABLE ON DISPLAY**

7. the service contracts referred to in “Statutory and General Information — C. Further Information about our Directors and Supervisors — 1. Directors’ and Supervisors’ Service Contracts and Appointment Letters” in Appendix IV to this document;
8. the legal opinions issued by Commerce & Finance Law Offices, our PRC Legal Advisor, in respect of, among other things, the general corporate matters and the property interests of our Group under PRC laws;
9. the legal opinions issued by Commerce & Finance Law Offices, our legal advisor as to PRC intellectual property law, in respect of, among other things, certain aspects of the IP matters of our Group;
10. the industry report issued by Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., the summary of which is set forth in “Industry Overview” in this document; and
11. the PRC Company Law, the PRC Securities Law, the Overseas Listing Trial Measures, together with their respective unofficial English translations.