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Application Proof of
VISEN Pharmaceuticals
维昇药业

(Incorporated in the Cayman Islands with limited liability)

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VISEN
VISEN Pharmaceuticals
维昇药业

(incorporated in the Cayman Islands with limited liability)

[REDACTED]

Number of [REDACTED] under the [REDACTED]	[REDACTED] Shares (subject to the [REDACTED])
Number of [REDACTED]	[REDACTED] Shares (subject to [REDACTED])
Number of [REDACTED]	[REDACTED] Shares (subject to [REDACTED] and the [REDACTED])
Maximum [REDACTED]	HK\$[REDACTED] per [REDACTED], plus brokerage of 1%, SFC transaction levy of 0.0027%, Stock Exchange trading fee of 0.00565% and AFRC transaction levy of 0.00015% (payable in full on [REDACTED] in Hong Kong dollars, subject to refund)
Nominal Value [REDACTED]	US\$0.0001 per Share [REDACTED]

Joint Sponsors, [REDACTED], [REDACTED], [REDACTED] and [REDACTED]

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The obligations of the [REDACTED] under the [REDACTED] are subject to termination by the [REDACTED] and the [REDACTED] (for themselves and on behalf of the [REDACTED]) if certain grounds arise prior to 8:00 a.m. on the [REDACTED]. See "[REDACTED]" for further details.

Prior to making an [REDACTED] decision, prospective [REDACTED] should consider carefully all of the information set out in this document, including the risk factors set out in the section headed "Risk Factors."

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[REDACTED]

[REDACTED]

IMPORTANT

[REDACTED]

IMPORTANT

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

CONTENTS

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SUMMARY

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

OVERVIEW

Founded in November 2018, we are a late-stage, near-commercialization biopharmaceutical company focused on providing treatments in selected endocrinology diseases in China (including Hong Kong, Macau and Taiwan). We have one Core Product and two other pipeline drug candidates, all of which were in-licensed from our collaboration partner and one of the Controlling Shareholders, Ascendis Pharma. See “Business – Collaborations” for more details. Since our inception until the date of this document, we have been conducting further research and development of such drug candidates.

Our Core Product, lonapegsomatropin, is a once-weekly long-acting growth hormone replacement therapy for the treatment of pediatric growth hormone deficiency (“PGHD”), a common short stature in patients aged under 18 caused by insufficient growth hormone. TransCon CNP (navepegritide), one of our key drug candidates, is a long-acting prodrug of c-type natriuretic peptide for the treatment of achondroplasia (“ACH”), a short-limbed dwarfism which results in severe skeletal complications and comorbidities. Palopegteriparatide, the other key drug candidate, is a once-daily parathyroid hormone (“PTH”) replacement therapy for the treatment of chronic hypoparathyroidism (“HP”), a syndrome of abnormal calcium and phosphorus metabolism caused by decreased secretion or defective function of PTH.

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

SUMMARY

Our Drug Pipeline

Leveraging our clinical development capabilities, we provide patients in China (including Hong Kong, Macau and Taiwan) with access to the following endocrine solutions: (i) our Core Product, lonapegsomatropin, has completed the Phase 3 pivotal trial in China for the treatment of PGHD; the BLA filing was made on January 18, 2024 and subsequently accepted by the NMPA on March 7, 2024; (ii) TransCon CNP (navepegritide) has completed the double-blind period of Phase 2 clinical trial in China for the treatment of ACH and the last patient last visit of open-label extension (“OLE”) period of this trial was completed in April 2024; and (iii) palopegteriparatide is currently undergoing development in a Phase 3 pivotal trial in China; it has completed the double-blind period in January 2023, and the expected NDA filing to the NMPA will be in the first half of 2025. Below is a pipeline diagram setting forth our drug candidates:

	Drug Candidate*	Indication	Clinical Development and Regulatory Status					Upcoming Milestones of Trials Conducted by VISEN
			IND	Phase 1	Phase 2	Phase 3	BLA / NDA	
Pediatric Endocrinology	★ Lonapegsomatropin	Pediatric Growth Hormone Deficiency	Completed China Phase 3 pivotal trial in April 2022 (BLA accepted by the NMPA in March 2024) ⁽¹⁾					Expected BLA approval date in mid 2025
	➡ TransCon CNP (navepegritide)	Achondroplasia	Ongoing China Phase 2 trial, double-blind period ⁽²⁾ completed in November 2023 ⁽²⁾					Expected NDA submission to the NMPA
Adult Endocrinology	➡ Palopegteriparatide	Hypoparathyroidism	Ongoing China Phase 3 pivotal trial, double-blind period ⁽⁴⁾ completed in January 2023 ⁽³⁾					Expected NDA submission to the NMPA in first half of 2025

★ Core Product ➡ Key drug candidates

* VISEN has gained exclusive licensed rights to develop, manufacture and commercialize all drug candidates in endocrinology in China (including Hong Kong, Macau and Taiwan).

Notes:

- (1) VISEN completed the Phase 3 pivotal trial of lonapegsomatropin in China for the treatment of PGHD in April 2022 which met its primary endpoint according to our published results. We made the BLA filing with the NMPA on January 18, 2024 for our Core Product for the treatment of PGHD, which was subsequently accepted by the NMPA on March 7, 2024.
- (2) The primary analysis of the double-blind period of the Phase 2 clinical trials of TransCon CNP (navepegritide) in China for the treatment of ACH was completed in November 2023, with primary endpoint met according to the topline results. We became the sole sponsor for the OLE period of this trial in January 2023 and the last patient last visit of the OLE period was completed in April 2024.
- (3) VISEN completed the primary analysis of the Phase 3 pivotal trial of palopegteriparatide in China for the treatment of adult HP in January 2023 which met its primary efficacy and key secondary endpoints according to its topline data.
- (4) Double-blind means a phase in clinical trial where neither the patients nor the researchers know who is receiving a placebo and who is getting the treatment in which the objective is primarily to prevent bias and ensure the validity of the results. OLE means a type of clinical study that typically follows a double-blind randomized placebo controlled trial of a new drug in which the objective is primarily to gather information about safety and tolerability of the new drug in long-term, day to day use.

SUMMARY

Our Core Product - Lonapegsomatropin

Lonapegsomatropin is a drug candidate studied by us to treat children aged 3 to 17 years old with GHD in a completed Phase 3 pivotal trial in China, where each subject received treatment for 52 weeks. Lonapegsomatropin demonstrated a greater AHV at 52 weeks for lonapegsomatropin compared to daily human growth hormone (“hGH”), with statistical significance. We in-licensed lonapegsomatropin from Ascendis Pharma in November 2018. Prior to our in-licensing, lonapegsomatropin had been studied by Ascendis Pharma in over 300 children with growth hormone deficiency (“GHD”) across three Phase 3 programs. Leveraging its novel molecular design, lonapegsomatropin is the only long-acting growth hormone (“LAGH”) that releases unmodified hGH *in vivo* consistently in between weekly doses. Such unmodified hGH is identical in the molecular composition to the endogenous growth hormone secreted by pituitary gland and preserves its original mode of action, with direct action by circulating growth hormone on target tissues and indirect action through promoting insulin-like growth factor-1 (“IGF-1”) production in the liver (via growth hormone receptor). In contrast, modified hGH often substantially alters its molecular size, which changes its receptor binding affinity and its ability to reach the target tissue. Our Core Product provides a convenient once-weekly dosing regimen in injection frequency as compared to once-daily hGH, which may foster increased dosing compliance for pediatric patients in daily lives.

We made the BLA filing with the NMPA on January 18, 2024 for our Core Product for the treatment of PGHD, which was subsequently accepted by the NMPA on March 7, 2024.

Addressable Market and Competitive Landscape

China accounted for the largest share of the global hGH market in 2023, surpassing the United States and representing 34% of the global market. The hGH market in China was RMB11.6 billion in 2023 and is expected to grow to RMB28.6 billion by 2030, at a CAGR of 13.7% from 2023 to 2030, according to Frost & Sullivan. The number of patients receiving hGH therapies largely depends on the number of PGHD patients receiving hGH therapies, which is calculated by multiplying the prevalence of PGHD by the treatment rate. As PGHD affects newborn to children as old as 17, the prevalence of PGHD is expected to remain relatively stable from 2023 to 2030, despite the expected decrease of birth rate. On the other hand, the treatment rate for PGHD is expected to significantly increase from 5.3% in 2023 to 10.7% in 2030, leading to a continuous growth in the number of patients receiving hGH therapies.

The hGH market is characterized by intense competition. We are aware of several pharmaceutical and biopharmaceutical companies that have commenced clinical studies of products or have successfully commercialized products addressing areas that we are targeting, including companies marketing or developing LAGH therapies, such as GeneScience Pharmaceutical Co., Ltd., I-Mab Biopharma Co., Ltd., Xiamen Amoytop Biotech Co., Ltd. and Anhui Anke Biotechnology (Group) Co., Ltd, Novo Nordisk A/S, as well as companies marketing daily hGH, such as GeneScience Pharmaceutical Co., Ltd., Anhui Anke

SUMMARY

Biotechnology (Group) Co., Ltd and Shanghai United Cell Biotechnology Co., Ltd., and Novo Nordisk A/S. Currently in China, only one LAGH therapy has received marketing approval and several are currently under clinical development. See “Risk Factors – Competition in the biotechnology and biopharmaceutical industries is intense and our competitors may discover, develop or commercialize products that are safer, more effective, more effectively marketed or cost less than ours, or receive regulatory approval or reach the market earlier. If we are unable to compete effectively, our business, results of operations and prospects will suffer” and “Industry Overview – Human Growth Hormone” for more details.

TransCon CNP (navepegritide)

TransCon CNP (navepegritide) is a disease-modifying therapy studied by us to treat children aged 2 to 10 years old with ACH in China, where there is currently no effective disease-modifying therapy approved. A disease-modifying therapy is a treatment that delays, slows, or reverses the progression of a disease by targeting its underlying cause. We in-licensed the TransCon CNP (navepegritide) from Ascendis Pharma in November 2018. Prior to our in-licensing, TransCon CNP (navepegritide) had been studied by Ascendis Pharma in 45 healthy adult male subjects in a Phase 1 global trial. TransCon CNP (navepegritide) is designed to optimize efficacy with a safe and convenient once-weekly dose, and is the first ACH therapy in clinical development in China to date, according to Frost & Sullivan. TransCon CNP (navepegritide) has completed the double-blind period of Phase 2 clinical trial in China for the treatment of ACH.

Addressable Market and Competitive Landscape

Due to the absence of approved therapy to treat the genetic basis of ACH, according to Frost & Sullivan, it is currently unfeasible to determine the market share and market size for ACH as there have been no corresponding sales generated in China. The prevalence of ACH in China was 51.2 thousand in 2023 and is estimated to reach 51.9 thousand in 2030.

There is currently no effective disease-modifying therapy for ACH approved in China.

Palopegteriparatide

Palopegteriparatide is a treatment solution studied by us to treat adults with HP. We in-licensed the palopegteriparatide from Ascendis Pharma in November 2018. Prior to our in-licensing, palopegteriparatide had been studied by Ascendis Pharma in healthy adult volunteers in a Phase 1 trial. The current treatments for HP are inadequate due to their limited therapeutic benefits and the need for chronic administration of calcium in high doses and increased risks of associated complications. Palopegteriparatide is designed to restore physiologic levels and activity of PTH throughout 24 hours per day, thereby addressing full aspects of the disease, including normalizing serum and urinary calcium and serum phosphate levels. We are studying palopegteriparatide in a China Phase 3 pivotal trial, and have completed its double-blind period in January 2023.

SUMMARY

Addressable Market and Competitive Landscape

Due to the absence of approved PTH replacement therapy for the treatment of HP in China, according to Frost & Sullivan, it is currently unfeasible to determine the market share and market size for HP as there have been no corresponding sales generated in China. The prevalence of HP in China was 410.1 thousand in 2023 and is estimated to reach 495.6 thousand in 2030.

No PTH replacement therapy has been approved for HP treatment in China. Palopegteriparatide is the only PTH replacement therapy that has initiated clinical development in China. As of the Latest Practicable Date, Eneboparatide (developed by Amolyt Pharma) and CLTX-305 (developed by Calcilytix Therapeutics) are being developed in Phase 3 global clinical trials; EB612 (developed by Entera Bio), MBX 2109 (developed by MBX Biosciences) and AMOR-1 (developed by Amorphical) are being developed in Phase 2 global clinical trials; and EXT608 (developed by Extend Biosciences) is being developed in Phase 1 global clinical trials. None of these drug candidates have undergone clinical studies in China.

Our Business Model

We have one Core Product and two other pipeline drug candidates, all of which were in-licensed from our collaboration partner, Ascendis Pharma. Since our inception until the date of this document, we have been conducting further research and development of such drug candidates.

Transient conjugation technology. Our drug pipeline is developed based on transient conjugation technology (TransCon) that enables a prodrug, in which the parent drug is protected in an inactive form, to release unmodified parent drug in a predictable manner after distribution into the body and resume physiologic activity. The effectiveness and vast potential of this transient conjugation technology (TransCon) have been supported by the FDA and EMA approvals of lonapegsomatropin for PGHD – the first marketing approvals obtained by a drug generated from this technology and EMA approval of palopegteriparatide.

R&D execution capabilities. Since our inception, our management and internal R&D teams have carried out extensive R&D activities. In carrying out clinical development operations, our R&D team reviewed all relevant clinical data generated from the global clinical trials of the three drug candidates conducted by our collaboration partner, Ascendis Pharma, and prepared for clinical trial initiations in China. Leveraging strong domain knowledge in the specific disease epidemiology, disease characteristics, local clinical practice as well as the current status of the market for the indications targeted by these drug candidates, our R&D team designed and implemented the study protocol for the clinical trials in China, and has substantially advanced the clinical development of our three drug candidates. See “Business – Our Drug Pipeline” and “Business – Research and Development” for more details.

SUMMARY

Commercialization planning. In anticipation of the upcoming commercial launch of our drug candidates, we started building up a focused and specialized commercialization team with strong expertise in endocrinology. With respect to specific characteristic of each pipeline drug and their respective market conditions, we have designed tailor-made programs for commercialization, patient awareness, and market access. For lonapegsomatropin, we plan to deploy a pediatric endocrine medical representative team to cover public hospitals, establish collaborations with an extensive network of private clinics, and offer a comprehensive service program to cover majority of the potential markets for lonapegsomatropin. For TransCon CNP (navepegritide), the disease-modifying drug for ACH, we plan to leverage lonapegsomatropin team for commercial coverage, build up the awareness of ACH and establish TransCon CNP (navepegritide) as the standard of care for ACH, and participate in the negotiation of National Reimbursement Drug List of China (“NRDL”) to maximize patient access. For palopegteriparatide, the PTH replacement therapy for HP, we plan to deploy a separate adult endocrinology medical representative team, establish HP treatment centers to cover broad geographic areas and a large patient pool via a “hub-and-spoke” model, engage in various activities to improve disease awareness, advance diagnosis and treatment for HP, and participate in the negotiation of NRDL to maximize patient access. Further, we have entered into a strategic collaboration agreement with Shanghai Pharmaceutical Holding Co., Ltd. (上藥控股有限公司), or Shanghai Pharmaceutical, a wholly-owned subsidiary of Shanghai Pharmaceutical Holding Co., Ltd. (上海醫藥集團股份有限公司) (HKEx stock code: 2607), aiming to establish the necessary management framework in line with the good supply practice (“GSP”).

Commercial supply and local manufacturing capability. We plan to implement a three-step plan to source commercial supply for the commercialization of lonapegsomatropin as early as possible and address the vast domestic market potentials in China (including Hong Kong, Macau and Taiwan) effectively and secure sustainable drug supply for local patients. In the short term, we plan to first source the commercial drug supply from our collaboration partner, Ascendis Pharma. We have successfully reached a commercial supply agreement for the commercial supply of the Core Product by Ascendis Pharma in October 2023. In the medium term, we will collaborate with WuXi Biologics (Shanghai) Co., Ltd. (“WuXi Biologics”), a wholly-owned subsidiary of WuXi Biologics (Cayman) Inc. (藥明生物技術有限公司) (HKEx stock code: 2269), or the designated local CDMO, to manufacture lonapegsomatropin for commercial supply in China (including Hong Kong, Macau and Taiwan). In the long term, we plan to establish our in-house manufacturing capabilities. See “Business – Commercial Supply and Manufacturing” for more details.

CMC R&D and Local BLA for local manufacturing. According to the Exclusive License Agreement, we have the contractual right to obtain full knowledge of the Core Product drug substance manufacturing technology knowhow from Ascendis Pharma. As a step towards local manufacturing of our Core Product, in July 2023, we entered into a bilateral Technology Transfer Master Plan of the Core Product with Ascendis Pharma, which has marked the commencement of the technology transfer (the “Technology Transfer”) with respect to the manufacturing of the Core Product from Ascendis Pharma to us and sets forth the obligations of both parties under the Exclusive License Agreement with respect to the Technology Transfer.

SUMMARY

After completion of the Technology Transfer, we will have the full knowledge of the Core Product drug substance manufacturing technology knowhow to independently collaborate with WuXi Biologics or any other chosen CDMO in China. Further, in December 2023, we entered into a bilateral collaboration agreement with WuXi Biologics, pursuant to which WuXi Biologics will serve as the local CDMO of the Technology Transfer to conduct the process development and validation achieving the localization of the manufacturing technology (together with the Technology Transfer, the “Technology Transfer and Localization”). Completion of the Technology Transfer and Localization, which is expected to be in 2026, will confer to us the technical capabilities to manufacture the Core Product drug substance in collaboration with WuXi Biologics. We are also developing the dual chamber device (“DCD”) technology in the form of prefilled syringe as a drug delivery system for the Core Product drug substance. Once this development is finished, WuXi Biologics will have the capability to produce the Core Product. The commercialization of the Core Product produced by WuXi Biologics will start once we obtain the approval of Local BLA, which is expected to occur in 2028. See “Business – Research and Development – CMC Development Programs” for more details. We expect to procure the Core Product from Ascendis Pharma for the commercial supply until 2028 following our anticipated commercialization in 2025.

OUR STRENGTHS

We believe the following strengths have contributed to our success and differentiated us from our competitors.

- late-stage pipeline based on validated technology, fast approaching revenue generation with high degree of certainty;
- lonapegsomatropin as the long-acting hGH replacement therapy for PGHD in China, the largest and fast-growing hGH market in the world;
- TransCon CNP (navepegritide) as the disease-modifying therapy in China (including Hong Kong, Macau and Taiwan) for ACH;
- palopegteriparatide as the PTH replacement therapy in China (including Hong Kong, Macau and Taiwan) addressing the underlying cause of HP;
- strong clinical and regulatory capabilities with proved track-records in developing our drug candidate pipeline products; and
- world-class management team with deep commercialization expertise and strong support from Shareholders and investors.

See “Business – Our Strengths” for more details.

SUMMARY

OUR STRATEGIES

To achieve our mission to become a leading biopharmaceutical company in developing and commercializing endocrine therapies in China (including Hong Kong, Macau and Taiwan), we intend to pursue the following strategies.

- rapidly advance the regulatory approval of our Core Product and the clinical development and regulatory approval of other pipeline candidates;
- build commercialization capabilities backed by patient support and market access in anticipation of the commercial launch of our Core Product and lay the foundation for commercialization of future drug candidates;
- establish localized manufacturing capabilities to secure the supply of our Core Product and future potential drug candidates in China (including Hong Kong, Macau and Taiwan);
- expand the endocrine disease indications covered by our Core Product, two key drug candidates, and new potential drugs based on transient conjugation technology (TransCon);
- further expand our pipeline portfolio through strategic in-licensing, collaborations and partnerships for endocrine therapies looking to enter China (including Hong Kong, Macau and Taiwan); and
- establish a recognized and leading franchise in endocrinology in China (including Hong Kong, Macau and Taiwan).

See “Business – Our Strategies” for more details.

RESEARCH AND DEVELOPMENT

R&D Team and Capabilities

We have a strong China-based in-house clinical R&D team led by a seasoned management team with strong therapeutic area expertise and experience in global biopharmaceutical development, medical practice and strategic planning. In addition, we have assembled senior R&D personnel with extensive expertise in clinical development, clinical operation, regulatory and medical affairs, and chemistry, manufacturing, and controls (“CMC”). Our R&D capabilities are also supported by our scientific advisory board comprising reputable key opinion leaders (“KOLs”) in endocrinology and pediatrics.

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Our R&D team has extensive expertise in medical science, regulatory, clinical operation, quality assurance, pharmacovigilance and data management, statistics, and medical affairs, enabling us to lead and guide the external contract research organization (“CROs”) and collaboration partners in a more efficient and effective manner. As of the Latest Practicable Date, our R&D team consisted of 36 full-time employees, with approximately 41% holding a Ph.D. or an M.D. degree. We expect to grow our R&D team as we continue our development activities. Almost all of our R&D team members have in-depth industry knowledge and clinical development experience in multinational companies. Our R&D team has an average of over 14 years of experience in the clinical development of drugs and/or endocrine therapies and some of them have extensive expertise in endocrinology and related areas and worked on the clinical development of other endocrine drugs.

To date, our R&D team has demonstrated a strong capability to optimize study design and development strategy in China, which has enabled us to advance our drug candidates directly into pivotal studies, work seamlessly with our collaboration partners, and conduct clinical execution in an efficient manner. With our insights and expertise in the endocrinology field, we are able to navigate the research, development, regulatory and commercialization landscape in China and seek opportunities to maximize the value of each of our pipeline assets and future endocrine drug candidates.

Clinical Development Programs

We are dedicated to building a pipeline of endocrine therapies in China (including Hong Kong, Macau and Taiwan). We believe successful clinical development programs covering preparation, design and execution is critical to our future growth and our ability to remain competitive in the biopharmaceutical market in China.

Since the in-licensing of our drug candidates from Ascendis Pharma, our senior management has led an internal clinical R&D team and worked in close collaboration with our scientific advisory board and industry-leading CROs to carry out R&D activities. Our R&D team reviewed all relevant clinical data generated from the global clinical trials of the three drug candidates conducted by Ascendis Pharma and prepared for clinical trial initiations in China. Leveraging strong domain knowledge in the specific disease epidemiology, disease characteristics, local clinical practice as well as the current status of the market for the indications targeted by these drug candidates, our R&D team designed and implemented the study protocol for the clinical trials in China, and has successfully completed the pivotal Phase 3 trial of lonapegsomatropin for PGHD, the double-blind period of pivotal Phase 3 trial of palopegteriparatide for adult HP and the double-blind period of Phase 2 trial of TransCon CNP (navepegtride) for ACH.

The study designs have taken into consideration both: (i) the scientific rationale, such as mechanism of action (“MoA”), well established pre-clinical data, the most updated global clinical data, the global study protocol, and local clinical practice; as well as (ii) market opportunities in China, such as addressable patient population, product positioning and competitive landscape of each of our drug candidates. Our clinical R&D team organized a

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number of meetings with the KOLs on our scientific board to optimize the study designs for our drug candidates. In addition, our R&D team engaged in pre-IND communications with the NMPA, have made multiple IND submissions to the NMPA and have obtained the IND approval for all of our drug candidates.

Our R&D team manages all key aspects of our trials, oversees clinical development work and performs the following functions: (i) clinical development strategy; (ii) market assessment and demand analysis; (iii) trial proposal and protocol design, including study objectives and primary/secondary endpoints; (iv) clinical site selections, initiations, management and monitoring; (v) biostatistics, including data management and programming; (vi) pharmacovigilance; (vii) quality assurance; (viii) investigator and site contracts; (ix) medical and safety monitoring; (x) clinical data collection and statistical analysis; and (xi) regulatory submission and communication. In addition, we leverage our external CROs to perform clinical trials. We implemented a variety of measures to guide our CROs, including comprehensive planning ahead of trial execution, regular communication and quality check of working progress, milestone program based on quality assurance check, and a vendor management system.

CMC Development Programs

See “Business – Research and Development – CMC Development Programs” for more details.

R&D Expenses

During the Track Record Period, our R&D expenses amounted to RMB179.5 million, RMB57.7 million and RMB25.8 million in 2022, 2023 and the four months ended April 30, 2024, respectively, among which, during the respective period, we incurred (i) RMB106.2 million, RMB28.7 million and RMB12.7 million on the development of lonapegsomatropin; (ii) RMB17.8 million, RMB9.4 million and RMB6.2 million on the development of TransCon CNP (navepegritide); and (iii) RMB55.5 million, RMB19.6 million and RMB6.9 million on the development of palopegteriparatide. See “Financial Information – Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income – Research and Development Costs” for details.

During the Track Record Period, we procured R&D consulting services from Ascendis Pharma mainly for the following activities: (i) for lonapegsomatropin, (a) the pharmacovigilance and biometry for data analysis including statistical programming and statistical analysis, and (b) the regulatory strategy advice and documentation support to prepare for our Import BLA submission package with the NMPA; (ii) for TransCon CNP (navepegritide) and palopegteriparatide, the pharmacovigilance and biometry for data analysis including statistical programming and statistical analysis. The amount of R&D consulting services rendered by Ascendis Pharma relating to our three drug candidates was RMB8.0 million, RMB10.0 million and RMB5.1 million in 2022, 2023 and the four months ended April 30, 2024, respectively. In connection with our expected R&D and regulatory activities of three

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drug candidates, we expect to procure R&D consulting services from Ascendis Pharma mainly for the following activities: (i) for lonapegsomatropin, (a) the technology transfer of lonapegsomatropin drug substance from Ascendis Pharma to us, and (b) consulting the technology localization process that involves the lonapegsomatropin drug substance manufacturing scale-up; (ii) for TransCon CNP (navepegritide) and palopegteriparatide, the support of data programming and statistical analysis, and the regulatory strategy advice and documentation support in connection with our expected NDA with the NMPA. See “Connected Transactions – Non-Exempt and Partially-Exempt Continuing Connected Transactions – Exclusive License Agreements” for more details.

COMMERCIALIZATION PLAN, PATIENT SUPPORT AND MARKET ACCESS

We are solely responsible for and take full control over the commercialization of our three drug candidates in China (including Hong Kong, Macau and Taiwan). We build up our in-house commercialization team in line with the overall R&D and commercialization timeline of our drug candidate pipeline. In the past few years, we have built up a specialized commercialization team with strong expertise in endocrinology, to drive medical activities in the market of China (including Hong Kong, Macau and Taiwan) in accordance with local rules and regulations. In April 2021, we added Dr. CHEN Jun, Ph.D., as Chief Commercial Officer to our management team, to enhance our commercialization capabilities. Dr. Chen has over 25 years of experience in the healthcare industry and over 20 years of experience in the commercialization of endocrine products, including growth hormone. Our product launch team also includes key leadership members such as medical affairs and marketing head Mr. GU Qing, who has 18 years of marketing experience in the healthcare industry, and commercial strategy development head Mr. PAN Haifeng, who has 22 years of experience in the commercialization of endocrine products. The addition of Dr. Chen, Mr. Gu and Mr. Pan enabled us to initiate the development of our product launch team including aspects of medical affairs and commercial strategy development. We believe our key commercialization leadership members, who have substantial experience and strong track records relevant to our pipeline drug candidates, can leverage their expertise in launching endocrine drugs in China (including Hong Kong, Macau and Taiwan).

In anticipation of the potential BLA approval of our Core Product in mid-2025 and subsequent commercial launch later that year, we plan to expand our commercial team equipped with field sales, regional marketing, medical affairs and customer service functions starting from early 2025. We also plan to build up our commercial infrastructure for palopegteriparatide and TransCon CNP (navepegritide) based on the respective expected commercial launch timeline. We believe our internal commercialization team with expanded talent pool will be sufficient for the purpose of executing our commercialization plan.

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Lonapegsomatropin

Lonapegsomatropin has the potential to capture a significant share in the highly attractive hGH market in China. China accounted for the largest share of the global hGH market in 2023, reaching RMB11.6 billion in 2023 at a CAGR of 23.9% from 2018 to 2023. The hGH market in China is expected to continue its fast growth to reach RMB28.6 billion in 2030, powered by increasing patient penetration, extending average duration of treatment, and growing acceptance of LAGH treatment. The hGH market in China is characterized with patient payment primarily out-of-pocket and sales primarily from private hospitals and clinics, resulting in hGH product prices being less vulnerable to various price-cutting measures such as price negotiation in NRDL and price cut in volume-based procurement. The future competitive landscape of LAGH is expected to be moderate, as there is currently one LAGH product available and only a handful of products under development. Lonapegsomatropin, with its profiles in efficacy, safety and convenience, is a promising drug candidate among the potential competitors.

Our initial focus of commercialization is patients suffering from short stature and diagnosed with PGHD. The commercial goal for lonapegsomatropin is two-fold: (i) to accelerate market upgrade from short-acting daily growth hormone to long-acting weekly growth hormone; and (ii) to establish lonapegsomatropin as the leading LAGH.

To realize our commercial goals, we have devised a competitive and productive promotional program. The hGH market in China is highly concentrated, with the majority of PGHD diagnoses being made by pediatric endocrinologists in around 200 top-tier hospitals in China. To maximize the coverage of our target customer segment, we have identified around 1,000 public hospitals as our target market, including all major children’s hospitals as well as major Tier 3 hospitals and some Tier 2 hospitals with sizable pediatric departments. We plan to establish a relatively small but elite commercial team in the first few years after our first commercial launch to cover the top-tier hospitals and to establish the brand position, followed by expanding the team to cover most of target market. For hospitals beyond our target market, we plan to establish external partnerships with distributors and/or contract sales organization (“CSOs”) to broaden patient accessibility through incremental coverage across China. In addition to focusing on the target public hospitals that handle the majority of PGHD diagnoses, we also plan to establish extensive coverage of private hospitals/clinics, which are responsible for approximately 67% of hGH sales, where drug listing is relatively simple and patients can have easy access to treatment initiation, prescription refills and quality customer services.

We also plan to deploy a series of programs towards patients undergoing lonapegsomatropin therapy. These programs include providing a comprehensive patient starter kit, offering assistance from a professional service team, and developing a digital patient service platform to enhance patient experience and convenience. The digital patient service platform includes social media and app that offer features such as injection guidance, FAQs, refill-services, and virtual classrooms. This platform creates an ecosystem connecting patients,

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caregivers and physicians, aiming to improve the treatment experience and optimize compliance and treatment outcomes. As PGHD patients have higher annual treatment costs and longer treatment durations compared to many common chronic diseases, we expect such programs will be productive.

We expect the pricing of our Core Product to be determined by various factors such as (i) the competitive landscape of the addressable market at the time of our commercial launch, (ii) the value propositions of our Core Product including the drug efficacy and safety as well as the drug administration convenience, (iii) the supply and production costs, and (iv) our pricing strategies. As the Core Product is currently under the BLA review by the NMPA, we have not formulated concrete pricing strategy at this stage but we expect that the Core Product will be priced at a fair premium compared to its competitors in China (including Hong Kong, Macau and Taiwan), reflecting its value propositions. As the hGH market in China is characterized with patient payment primarily out-of-pocket and sales primarily from private hospitals and clinics, we plan to primarily focus on the self-pay market for the commercialization of our Core Product. We plan to promote our Core Product primarily through our in-house sales and marketing team through various marketing activities focusing on promoting the clinical benefits and accessibility of our Core Product. We may also engage contract sales organizations to promote our Core Product in peripheral cities or regions that are otherwise not covered by our in-house sales and marketing team. We will collaborate with distributors to establish an effective distribution network of our Core Product. For this purpose, we have entered into a strategic collaboration agreement with Shanghai Pharmaceutical aiming to establish the necessary management framework in line with the GSP.

We plan to provide treatments in selected endocrinology diseases by highlighting four key product advantages: (i) lonapegsomatropin preserves the natural dual mode MoA of endogenous growth hormone by releasing unmodified hGH, which includes both a direct effect at the bone plate and the indirect effect mediated by IGF-1 at the liver. With this advantage, lonapegsomatropin demonstrated a greater AHV at 52 weeks for lonapegsomatropin compared to daily hGH, with statistical significance, potentially enabling children with PGHD to achieve treatment goals more effectively within a limited treatment time window; (ii) lonapegsomatropin demonstrates key pharmacological profiles, including a molecular structure of the active drug substance, receptor binding affinity, plasma concentration, tissue distribution, and a safety profile comparable to daily hGH, which has been utilized by clinicians for over 30 years with a high level of confidence in its safety. In contrast, the other LAGHs permanently alter the molecular structure of hGH, resulting in new active drug molecules that have significantly different pharmacological profiles from the daily hGH and limited clinical experience; (iii) lonapegsomatropin offers more than 300 injection-free days per year compared to daily hGH, thus could greatly improve treatment compliance and treatment outcomes; and (iv) lonapegsomatropin can be stored for 54 months at 2-8°C or up to six months at room temperatures of $\leq 30^{\circ}\text{C}$, a more patient-friendly storage requirement than other growth hormone products that typically require constant storage at 2-8°C and for no more than 24 months. This advantage offers great flexibility for children with PGHD and their caregivers, enabling convenient transportation and usage of the medication. By effectively

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communicating the value propositions of lonapegsomatropin to healthcare professionals (“HCPs”), we anticipate successfully persuading prescribing doctors about the product’s benefits and establishing a promising position in the market.

Since the commercial launch of lonapegsomatropin by Ascendis Pharma in the fourth quarter of 2021, Ascendis Pharma has recorded sales revenue of lonapegsomatropin of EUR0.9 million, EUR35.7 million and EUR178.7 million in 2021, 2022 and 2023, respectively, according to its annual reports.

TransCon CNP (navepegritide)

ACH is a widely recognized condition that can be readily diagnosed by experienced pediatricians, resulting in a high awareness and diagnosis rate. Patients with ACH have normal mental development and a pressing need for treatment prior to reaching puberty. There is no available disease-modifying drug to treat ACH in China. TransCon CNP (navepegritide) is the only disease-modifying drug under clinical development in China with positive efficacy results in clinical trials. Once approved, TransCon CNP (navepegritide) is expected to be utilized by patients over several years during the growth period from two to 15 years old. In addition, TransCon CNP (navepegritide) has a long half-life of 120 hours porting once-weekly dose administration.

Once TransCon CNP (navepegritide) is commercially available, our main commercial goals are to build up the awareness of ACH among key stakeholders, establish TransCon CNP (navepegritide) as the standard of care for ACH, and establish patient access. The successful execution of this commercial strategy holds the potential to achieve a rapid revenue uptake from TransCon CNP (navepegritide).

We expect TransCon CNP (navepegritide) to be included in the NRDL soon after its approval by undergoing the pricing negotiation process with relevant governmental authorities. To optimize resources and maximize the effectiveness of our commercial efforts for TransCon CNP (navepegritide), we have devised a comprehensive and productive program. Given that the group of HCPs specialized in endocrinology or genetic diseases who treat ACH largely overlaps with the target HCPs for lonapegsomatropin, we plan to leverage the promotional synergy between TransCon CNP (navepegritide) and lonapegsomatropin. This includes utilizing the shared field medical representative team, patient service infrastructure, channel and distribution network, thereby minimizing the required promotion resources for TransCon CNP (navepegritide).

Palopegteriparatide

HP is a chronic disease characterized by the deficiency of PTH, which plays a crucial role in calcium and phosphate metabolism. HP affects a significant patient population, with approximately 410 thousand individuals affected in 2023. Patients with HP experience daily challenges related to both physical and mental well-being and often require lifelong treatment. The optimal approach for managing HP involves PTH replacement therapy to compensate for

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the insufficient physiological levels of PTH in the body. Currently, there is no available PTH replacement therapy for HP due to the extremely short half-life of native PTH, which lasts only a few minutes. Palopegteriparatide, by leveraging the ability of the transient conjugation technology (TransCon) to generate long-acting prodrugs of unmodified parent drugs, successfully extends the half-life of PTH to 60 hours, and is potentially the first PTH replacement therapy for HP treatment over multi-year or even lifetime. Palopegteriparatide possesses many advantages over conventional therapy as demonstrated in the Phase 3 clinical trials, and is the most advanced PTH replacement drug under clinical development in China with few competing products.

The commercial goal for palopegteriparatide includes market development, patient access and establishing HP treatment centers. Once commercially launched, we expect a rapid revenue uptake of palopegteriparatide.

We expect palopegteriparatide to be included in the NRDL soon after its approval by undergoing the pricing negotiation process with relevant governmental authorities. We plan to deploy an effective and productive commercial program for palopegteriparatide. We plan to deploy our commercial resources in a “hub-and-spoke” model. We plan to support dozens of major hospitals with HP treatment expertise to establish HP Center of Excellence across China as “hubs.” HP patients can receive high-quality diagnosis and key therapy decisions at these “hubs.” In addition, we plan to cover a few hundred regional hospitals as “spokes.” The “spoke” hospitals can identify potential HP patients, channel them to “hubs” for key therapy decisions, while providing easy access for patients’ prescription refills and ongoing HP management. As most HP patients are treated by adult endocrinologists, we plan to deploy a separate adult endocrinology medical representative team and medical science liaison (“MSL”) team to cover these hospitals. The “hub-and-spoke” model may allow us to leverage a small but elite medical representative team and productive promotion program to cover broad geographic areas and a large patient pool.

COLLABORATIONS

Exclusive License Agreements with Ascendis Pharma

We own the intellectual property rights to exclusively develop, manufacture, and commercialize our Core Product and other drug candidates in China (including Hong Kong, Macau and Taiwan). In November 2018, we entered into three Exclusive License Agreements with Ascendis Pharma relating to lonapegsomatropin, TransCon CNP (navepegritide) and palopegteriparatide, respectively, which were subsequently amended in January 2021 due to the necessity to reflect the evolving cooperation progress between the parties in terms of technology transfer and Joint Commercialization Committee. Pursuant to the terms of each agreement, Ascendis Pharma granted us an exclusive (including as to Ascendis Pharma), royalty-free license under its applicable owned patents and other intellectual property for the purposes of developing, manufacturing and commercializing the applicable drug candidates in endocrinology in China (including Hong Kong, Macau and Taiwan). In addition, during the

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term of the Exclusive License Agreements, Ascendis Pharma is required to notify us prior to engaging in substantive discussions with a third party regarding the license to such third party by Ascendis Pharma or its affiliates of rights to develop or commercialize endocrine drugs in China (including Hong Kong, Macau and Taiwan) covered by the relevant Exclusive License Agreement, which we will refer to as a ROFN Opportunity. If we inform Ascendis Pharma that we wish to negotiate an agreement for such ROFN Opportunity, Ascendis Pharma and us shall enter into good faith negotiations to finalize the relevant license agreement. See “Business – Collaborations – Exclusive License Agreements with Ascendis Pharma” for more details regarding the collaboration between us and Ascendis Pharma. We are not obligated to make any royalty or milestone payments under the relevant Exclusive License Agreements, but have instead issued to three wholly-owned subsidiaries of Ascendis Pharma A/S an aggregate of 40,000,000 Series A Preferred Shares as consideration for them to enter into these agreements. Ascendis Pharma is one of our Founding Shareholders. See “History, Development and Corporate Structure – Major Corporate Development and Shareholding Changes of Our Group” for more details.

The interests of Ascendis Pharma are highly aligned with ours. See “Relationship with the Controlling Shareholders” for more details regarding the mutual complementary relationship between us and Ascendis Pharma.

Strategic Cooperation with China Alliance on Rare Diseases on A National Patient Registry and Diagnosis Consensus of ACH in China

We supported the founding of Achondroplasia Advisory Board in June 2019 under the governance of CHARD, a national, non-profit, cooperative exchange platform for rare diseases by entering into a donation agreement with CHARD, and subsequently entered into a five-year strategy cooperation with CHARD on a national patient registry and diagnosis consensus of ACH in China in December 2020.

Strategic Cooperation with Peking University Health Science Center On A Cohort Study on HP

On July 15, 2021, we entered into a strategic cooperation agreement with Peking University Health Science Center to initiate the PaTHway R study, the first registry study for HP patients in China and one of the largest epidemiological surveys for this disease worldwide. The PaTHway R study aims to enhance the understanding among the public and professionals regarding the etiology, treatment options, disease burdens of HP and was kicked off in January 2022.

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Key Arrangements in relation to Our Local Manufacturing Capabilities for the Core Product

On December 18, 2023, we entered into a collaboration agreement with WuXi Biologics to strengthen our commercialization capabilities and establish localized manufacturing capabilities to secure the supply of our Core Product and future potential drug candidates. The commercialization of the Core Product produced by WuXi Biologics will start once we obtain the approval of Local BLA, which is expected to occur in 2028.

Entry into Strategic Collaboration Agreement with Shanghai Pharmaceutical

On October 30, 2023, to advance the expected commercialization of our Core Product and other products, we entered into a strategic collaboration agreement with Shanghai Pharmaceutical. Pursuant to such agreement, Shanghai Pharmaceutical will leverage its expertise and capabilities to assist us to establish the necessary management framework in line with the GSP.

Entry into Strategic Collaboration Agreement with United Family Healthcare

On August 5, 2024, we entered into the strategic collaboration with the United Family Healthcare, one of the leading private healthcare providers in China with a network of over ten hospitals and over 20 clinics across China. This collaboration will focus on jointly developing capabilities in diagnosis, treatment and services for children with medical needs in growth and development.

BUSINESS DEVELOPMENT

We will continue to select, develop, and market paradigm-shifting therapeutic drugs that have the potential to fulfill current unmet medical needs. We aim to bridge global innovation to bring endocrine therapies to Chinese patients, and plan to become the partner of choice in endocrinology for China (including Hong Kong, Macau and Taiwan). Thus far, we have a proven track record of collaborating with Ascendis Pharma, which underscores our credibility with global biopharmaceutical and biotechnology companies and paves the way for long-term collaborations. We intend to expand our pipeline portfolio through strategic in-licensing, collaborations and partnerships with Ascendis Pharma and other biopharmaceutical companies. Under the Exclusive License Agreements with Ascendis Pharma, we hold a right of first negotiation on certain future Ascendis Pharma products within the endocrine disease area for China (including Hong Kong, Macau and Taiwan). This will enable us to source, develop and commercialize additional drug candidates that are based on the unique transient conjugation technology (TransCon) and have the potential to be highly differentiated endocrine therapies. We plan to collaborate with Ascendis Pharma to evaluate future potential drug candidates and exercise our right for those products who address unmet medical need and possess strong commercial potential in China (including Hong Kong, Macau and Taiwan). See “Business – Collaborations – Exclusive License Agreements with Ascendis Pharma” for more details.

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Beyond Ascendis Pharma, we plan to leverage our platform and network to pursue business development opportunities with other potential biopharmaceutical partners with endocrine drugs, drug candidates or technologies and platforms that may be synergistic or complementary to our portfolio and/or our capabilities. We believe our relationships with our Shareholders and a group of strategic and life sciences focused Sophisticated Investors will contribute to our success in building value-creating partnerships. In the long-term, we plan to leverage our infrastructure in endocrinology to become the partner of choice for endocrine treatment looking to enter China (including Hong Kong, Macau and Taiwan).

We plan to fully exploit our extensive knowledge in endocrinology and our deep understanding of the medical need and technology, and through identifying and executing attractive licensing and collaboration opportunities or through mergers and acquisitions, we seek to pursue business development opportunities to further expand our portfolio with other potential biopharmaceutical partners with endocrine drugs, drug candidates or technologies that may be synergistic or complementary to our portfolio.

Our scaled operation and platform, integrated with a commercial team that targets the same group of doctors and call points in the endocrinology specialty, is highly synergistic with strong operating leverage to maximize the value of additional endocrine products looking to enter China (including Hong Kong, Macau and Taiwan):

- *Synergistic clinical stage products with potential.* We prioritize bringing in drugs or drug candidates based on their clinical profile, degree of novelty and validation, technology differentiation, the unmet medical needs of the target disease and respective commercial potential in China (including Hong Kong, Macau and Taiwan).
- *Marketed endocrine products with only light commercialization effort required and attractive cashflow or margin.* We are strategically seeking to in-license or acquire rights to drugs that are either already launched or in late-stage development in regulated markets such as the United States and the European Union that may be synergistic or complementary to our portfolio.

As a complementary measure, we will opportunistically look to establish internally developed pipeline of promising therapies, with local CDMO support or through mergers and acquisitions of research-driven biotech companies, when the products’ target or MoA fit with our overall product offering suite and target large market opportunities.

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INTELLECTUAL PROPERTY

We own the intellectual property rights to exclusively develop, manufacture, and commercialize our Core Product and other drug candidates in China (including Hong Kong, Macau and Taiwan). As of the Latest Practicable Date, we have exclusive licenses from Ascendis Pharma to 36 issued patents (including a platform patent which covers Lonapegsomatropin, TransCon CNP (navepegritide) and Palopegteriparatide) in China (including Hong Kong, Macau and Taiwan), and 47 pending patent applications in China (including Hong Kong, Macau and Taiwan). Our patent and patent application portfolio includes the following:

Lonapegsomatropin. We have exclusively licensed from Ascendis Pharma eight issued patents and four patent applications in China (including Hong Kong, Macau and Taiwan) relating to lonapegsomatropin. The issued patents are projected to expire in 2035.

TransCon CNP (navepegritide). We have exclusively licensed from Ascendis Pharma 19 issued patents and 12 patent applications in China (including Hong Kong, Macau and Taiwan) relating to TransCon CNP (navepegritide). The issued patents are projected to expire in 2040.

Palopegteriparatide. We have exclusively licensed from Ascendis Pharma 10 issued patents and 24 patent applications in China (including Hong Kong, Macau and Taiwan) relating to palopegteriparatide. The issued patents are projected to expire in 2037.

Auto-Injector. We have exclusively licensed from Ascendis Pharma two issued patents and seven patents applications in China (including Hong Kong, Macau and Taiwan) relating to the auto-injector. The issued patents are projected to expire in 2038.

We currently do not own or have any exclusive license to any patents or patent applications in any jurisdictions outside of China (including Hong Kong, Macau and Taiwan) for lonapegsomatropin, TransCon CNP (navepegritide), and palopegteriparatide.

See “Business – Collaborations – Exclusive License Agreements with Ascendis Pharma” for more details regarding our exclusive license arrangements with Ascendis Pharma. We performed due diligence on Ascendis Pharma’s intellectual property rights before entering into the license agreements with them, but we cannot guarantee that such rights will not be challenged or that they will provide meaningful exclusivity or competitive advantage or otherwise enable us to successfully exploit the licensed drug candidates. See “Risk Factors – Key Risks Related to Our Business, Business Operations, Intellectual Property, Regulatory Approval of Our Drug Candidates, Commercialization and Financial Prospects – Our in-licensed patents and patent applications or any patents and patent applications that we own or in-license in the future may be subject to priority disputes or to inventorship disputes and similar proceedings. If we or our licensors are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the development, manufacture and commercialization of one or more of our drug candidates.”

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The term of a patent depends upon the laws of the country in which it is issued. Generally, a patent term is 20 years from the earliest filing date of a non-provisional patent application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to inventions are effective for 20 years, and utility models are effective for 10 years and designs are effective for 15 years from the date of application. The patent compensation system has been effective from June 1, 2021, which may benefit issued patents in China. For patents relating to new drugs approved for marketing in the PRC, the patent term may be extended upon request of the patent holder by up to five years as determined by the competent patent authorities, in order to compensate for the time spent for drug marketing registration and approval procedures, and with such compensation the patent term after the relevant new drug marketing authorization is approved shall not exceed 14 years.

We conduct our business mainly under the brand name of “VISEN Pharmaceuticals” (维昇药业). As of the Latest Practicable Date, we had 124 registered trademarks and 3 pending trademark applications in China (including Hong Kong, Macau and Taiwan). We have one domain name, which is *www.visenpharma.com*.

See “Risk Factors – Other Risks Related to Our Intellectual Property” for other risks related to our intellectual property, and “Appendix IV – Statutory and General Information – B. Further Information about Our Business” and “Business – Intellectual Property” for more details regarding our intellectual property rights.

Our Directors confirm that, as of the Latest Practicable Date, we were not a party to any material legal or administrative proceedings in connection with intellectual property rights or otherwise, and we are not aware of any claims or proceedings contemplated by Governmental Authorities or third parties which could materially and adversely affect our business. See “Business – Legal Proceedings and Compliance.”

SUPPLIERS

Our major suppliers primarily provide us (i) the clinical supplies of our endocrine drug candidates; (ii) operational services such as patient registry; (iii) certain research and development services which we outsource to third-party CROs; and (iv) lessors of our leased properties. We have established stable relationships with many of our key suppliers.

Purchases from our five largest suppliers, for 2022, 2023 and the four months ended April 30, 2024 were RMB87.4 million, RMB30.0 million and RMB8.2 million, respectively, representing 53%, 45% and 48% of our total purchase cost for the respective period. Purchases from our largest supplier for 2022, 2023 and the four months ended April 30, 2024 were RMB63.5 million, RMB17.7 million and RMB3.9 million, respectively, representing 39%, 26% and 23% of our purchase cost for the respective period.

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Save for Ascendis Pharma, all of our five largest suppliers during the Track Record Period are Independent Third Parties, and none of our Directors, their respective associates nor any Shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as at the Latest Practicable Date, has 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, we order supplies and services on a purchase order basis and have set up CRO bidding and management processes to enable us to obtain better terms and conditions.

SHAREHOLDER INFORMATION

As at the Latest Practicable Date, Ascendis Pharma A/S, through its wholly-owned subsidiaries, Ascendis Pharma Endocrinology Division, Ascendis Pharma Growth Disorders and Ascendis Pharma Bone Diseases (collectively, the “Ascendis Subsidiaries”), was indirectly interested in an aggregate of approximately 39.95% of the Shares in the Company. Immediately after the completion of the [REDACTED] (assuming the [REDACTED] is not exercised and no Shares are issued under the [REDACTED] Share Award Scheme), Ascendis Pharma A/S, through the Ascendis Subsidiaries, will be indirectly interested in approximately [REDACTED] of the Shares in the Company. As at the Latest Practicable Date, Vivo Plenilune IX Limited, or Vivo Capital, was interested in approximately 35.09% of the Shares in the Company. Immediately after the completion of the [REDACTED] (assuming the [REDACTED] is not exercised and no Shares are issued pursuant to the [REDACTED] Share Award Scheme), Vivo Capital will be interested in [REDACTED] of the total issued share capital of our Company. Vivo Capital is a wholly-owned subsidiary of Vivo Capital Fund IX (Cayman), L.P., which is in turn controlled by its general partner, Vivo Capital IX (Cayman), LLC. (collectively, “Vivo Funds”). Accordingly, Ascendis Pharma A/S, the Ascendis Subsidiaries, and Vivo Funds will be the Controlling Shareholders of the Company after the [REDACTED]. See “Relationship with the Controlling Shareholders” for details.

Since the establishment of our Company, we have completed two rounds of [REDACTED] Investments from our Founding Shareholders and [REDACTED] Investors including a group of strategic and life sciences focused institutional investors who support our mission. The total funds raised by the Company from the [REDACTED] Investments were approximately US\$190 million. We utilized the proceeds for the principal business of our Group as approved by the Board, including, but not limited to, R&D activities, the growth and expansion of our Group’s business and general working capital purposes in accordance with the budget approved by the Board. As at the Latest Practicable Date, approximately 79.7% of the net proceeds from the [REDACTED] Investments have been utilized. We intended to use the rest net proceeds from the [REDACTED] investment for further research and development activities, working capital, and other general corporate purposes. The Sophisticated Investors

SUMMARY

of our Company include Vivo Capital, Sofinnova, HongShan Growth, OrbiMed and Sherpa Healthcare Partners holding [REDACTED], [REDACTED], [REDACTED], [REDACTED] and [REDACTED], respectively, of the total issued share capital of the Company upon completion of the [REDACTED] (assuming the [REDACTED] is not exercised and no Shares are issued under the [REDACTED] Share Award Scheme). See “History, Development and Corporate Structure – [REDACTED] Investments” for more details.

CONTINUING CONNECTED TRANSACTION

Our Company has entered into and will continue to engage in certain transactions with our Controlling Shareholders, which will constitute continuing connected transactions upon the [REDACTED]. In connection with these continuing connected transactions, we have applied for, and the Stock Exchange [has granted] us, waivers from strict compliance with certain requirements set out in Chapter 14A of the Listing Rules, including waivers of continuing connected transactions with terms of more than three years. See “Connected Transactions” for more details.

RISK FACTORS

We believe that there are certain risks involved in our operations, many of which are beyond our control. See “Risk Factors” for further details. Some of the major risks we face include:

- Our rights to develop, manufacture and commercialize our drug candidates are subject to the terms and conditions of licenses granted to us by Ascendis Pharma. If we fail to comply with our obligations in our Exclusive License Agreements with Ascendis Pharma, we could lose the rights to develop, manufacture and commercialize our drug candidates and be required to pay monetary damages, which could materially and adversely affect our business operations.
- We expect to procure the Core Product from Ascendis Pharma for the commercial supply until 2028 following our anticipated commercialization in 2025, which may expose us to risks such as potential disruptions in the supply chain and a lack of control over the quality and timing of product supply, and may adversely affect our business and profitability.
- We have a limited operating history, no products approved for commercial sale, never generated any revenue and may incur significant losses in the future, which makes it difficult to assess our future viability. The risks involved in our business may cause potential [REDACTED] to lose substantially all of their [REDACTED] in us.
- We have incurred losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

SUMMARY

- None of our drug candidates has received a marketing approval in China (including Hong Kong, Macau and Taiwan). If we are unable to advance our drug candidates through clinical development, obtain regulatory approval and/or ultimately commercialize our drug candidates, or experience significant delays in doing so, our business and profitability will be materially harmed.

SUMMARY OF KEY FINANCIAL INFORMATION

This summary historical data of financial information set forth below is derived from, and should be read in conjunction with, our consolidated financial statements, including the accompanying notes, set forth in the Accountants’ Report in Appendix I to this document, as well as the information set forth in “Financial Information.” Our financial information was prepared in accordance with IFRS.

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

We currently have no product approved for commercial sale and have not generated any revenue from product sales. We have incurred operating losses in each year since inception and during the Track Record Period. Our total comprehensive losses were RMB288.9 million, RMB249.5 million and RMB60.3 million in 2022, 2023 and the four months ended April 30, 2024, respectively, the change of which was primarily due to the decrease of RMB121.8 million in R&D expenses in relation to our drug candidates for the year ended December 31, 2023, and the loss from a discontinued procurement contract recorded in the amount of RMB109.0 million for the year ended December 31, 2023 in relation to our cancellation of the commitment to purchase the previously reserved drug substance under the commitment and pre-payment agreement in February 2023. Substantially all of our operating losses resulted from R&D expenses, administrative expenses, and other gains and losses, net. See our consolidated statements of profit or loss and other comprehensive income set forth in the Accountants’ Report in Appendix I to this document for details of the fluctuation in our total comprehensive losses.

We expect to incur significant expenses and operating losses for at least the next several years as we further our clinical R&D efforts, continue the clinical development of and seek regulatory approval for our drug candidates, launch commercialization of our pipeline products, and add personnel necessary to operate our business. Subsequent to the [REDACTED], we expect to incur costs associated with operating as a [REDACTED]. We expect that our financial performance will fluctuate from period to period due to the development status of our drug candidates, regulatory approval timeline and commercialization of our drug candidates after approval.

SUMMARY

The table below sets forth our consolidated statements of profit or loss and other comprehensive income for the periods indicated derived from our consolidated statements of profit or loss and other comprehensive income set forth in the Accountants’ Report in Appendix I to this document:

	Year Ended December 31,		Four Months Ended April 30,	
	2022	2023	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(unaudited)</i>	
Other income	5,764	11,356	2,567	5,835
Other gains and losses, net	77,184	(106,695)	(113,590)	805
Research and development costs	(179,546)	(57,690)	(3,805)	(25,771)
Administrative expenses	(177,449)	(79,944)	(22,248)	(35,146)
Finance costs	(619)	(317)	(126)	(66)
[REDACTED]	<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]</u>
Loss before tax	(288,967)	(249,570)	(138,997)	(60,131)
Income tax expense	—	—	—	—
Loss for the year/period	(288,967)	(249,570)	(138,997)	(60,131)
Exchange differences on translation of the financial statements of subsidiaries	69	106	(63)	(189)
Total comprehensive loss for the year/period	<u>(288,898)</u>	<u>(249,464)</u>	<u>(139,060)</u>	<u>(60,320)</u>

SUMMARY

Summary of Our Consolidated Statements of Financial Position

The table below sets forth selected information from our consolidated statements of financial position as of the dates indicated, which have been derived from the Accountants’ Report in Appendix I to this document:

	As of December 31,		As of April 30,
	2022	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
NON-CURRENT ASSETS			
Property, plant and equipment	2,352	876	551
Right-of-use assets	14,812	12,379	11,158
Intangible assets	1,415	567	301
Amount advanced to a related party	–	39,193	39,193
Prepayments and other receivables	11,103	16,660	17,596
Total non-current assets	29,682	69,675	68,799
CURRENT ASSETS			
Prepayments and other receivables	15,961	16,972	16,418
Amount advanced to a related party	69,171	9,367	9,375
Cash and cash equivalents	626,458	347,782	299,683
Total current assets	711,590	374,121	325,476
CURRENT LIABILITIES			
Trade and other payables	49,460	37,582	33,366
Deferred income	2,900	2,900	–
Amounts due to related parties	30,311	8,790	6,344
Lease liabilities	4,668	2,552	1,785
Total current liabilities	87,339	51,824	41,495
Net current assets	624,251	322,297	283,981
Total assets less current liabilities	653,933	391,972	352,780

SUMMARY

	As of December 31,		As of April 30,
	2022	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
NON-CURRENT			
LIABILITIES			
Lease liabilities	1,328	1,097	554
Total non-current liabilities	1,328	1,097	554
Net assets	652,605	390,875	352,226
EQUITY			
Equity attributable to owners of the Company			
Share capital	70	70	70
Treasury shares	(6)	(6)	(6)
Reserves	652,541	390,811	352,162
Total equity	652,605	390,875	352,226

We had net current assets of RMB250.9 million as of July 31, 2024, being the latest practicable date for the purpose of liquidity disclosure in this document, which decreased from RMB284.0 million as of April 30, 2024, primarily due to a decrease of RMB29.7 million in cash and cash equivalents as a result of the operating costs associated with our R&D and administrative activities.

Our net current assets decreased from RMB322.3 million as of December 31, 2023 to RMB284.0 million as of April 30, 2024, primarily due to a decrease of RMB48.1 million in cash and cash equivalents as a result of the operating costs associated with our R&D and administrative activities.

Our net current assets decreased from RMB624.3 million as of December 31, 2022 to RMB322.3 million as of December 31, 2023, primarily due to a decrease of RMB278.7 million in cash and cash equivalents as a result of the operating costs associated with our R&D and administrative activities and a decrease of RMB59.8 million in amount advanced to a related party.

Our net assets decreased from RMB390.9 million as of December 31, 2023 to RMB352.2 million as of April 30, 2024, primarily due to our loss for the period of RMB60.1 million in the four months ended April 30, 2024, partially offset by our recognition of equity-settled share-based payment of RMB21.7 million in the same period.

SUMMARY

Our net assets decreased from RMB652.6 million as of December 31, 2022 to RMB390.9 million as of December 31, 2023, primarily due to our loss for the year of RMB249.6 million in 2023.

Summary of Our Consolidated Statements of Cash Flow

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

	Year Ended		Four Months Ended	
	December 31,		April 30,	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i>
Net cash flows used in operating activities	(246,549)	(271,310)	(88,467)	(46,534)
Net cash flows used in investing activities	(1,766)	(520)	(245)	–
Net cash flows used in financing activities	(7,949)	(6,952)	(2,266)	(1,376)
Net decrease in cash and cash equivalents	(256,264)	(278,782)	(90,978)	(47,910)
Cash and cash equivalents at beginning of the year/period	882,653	626,458	626,458	347,782
Cash and cash equivalents at end of the year/period	626,458	347,782	535,417	299,683

During the Track Record Period, we incurred negative cash flows from our operations. Substantially all of our operating cash outflows have resulted from our R&D costs and administrative expenses. During the Track Record Period, our primary uses of cash included funding the R&D of our drug candidates, expenses for regulatory filing activities of the Core Product, purchasing quality control testing samples for the Core Product, prepayments for future commercial supply of drug products, losses from discontinued procurement contracts, as well as other working capital needs. During the Track Record Period, we funded our operations through private equity financing. 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. Going forward, we believe our liquidity requirements will be satisfied by a combination of [REDACTED] from the [REDACTED] and cash generated from our operations.

Our cash burn rate refers to the average monthly (i) net cash used in operating activities, including clinical development and business development activities; (ii) capital expenditures; and (iii) lease payments. We had cash and cash equivalents of RMB299.7 million as of April 30, 2024. We estimate that we will receive [REDACTED] of approximately HK\$[REDACTED] million, equivalent to RMB[REDACTED] million, after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], assuming no

SUMMARY

[REDACTED] is exercised and assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the low-end of the [REDACTED] in this document. We estimate that our cash and cash equivalents as of April 30, 2024 will be able to maintain our financial viability for [REDACTED] months or, if we take into account [REDACTED]% of the estimated [REDACTED] from the [REDACTED] (namely, the portion allocated for our working capital and other general corporate purposes), [REDACTED] months or, if we also take into account the estimated [REDACTED] from the [REDACTED], [REDACTED] months. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing, if needed, with a minimum buffer of 12 months.

KEY FINANCIAL RATIO

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

	As of December 31,		As of April 30,
	2022	2023	2024
Current ratio ⁽¹⁾	8.15	7.22	7.84

Note:

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

Our current ratio increased from 7.22 as of December 31, 2023 to 7.84 as of April 30, 2024, mainly due to a decrease in our current liabilities from RMB51.8 million as of December 31, 2023 to RMB41.5 million as of April 30, 2024, which was primarily due to (i) a decrease of RMB4.2 million in trade and other payables; (ii) a decrease of RMB2.9 million in deferred income; and (iii) a decrease of RMB2.4 million in amounts due to related parties.

Our current ratio decreased from 8.15 as of December 31, 2022 to 7.22 as of December 31, 2023, mainly due to a decrease in our current assets from RMB711.6 million as of December 31, 2022 to RMB374.1 million as of December 31, 2023, which was primarily due to a decrease of RMB278.7 million in cash and cash equivalents. See “Financial Information – Discussion of Certain Selected Items from the Consolidated Statements of Financial Position – Net Current Assets.”

RECENT DEVELOPMENTS

BLA Filing of Our Core Product

We made the BLA filing with the NMPA on January 18, 2024 for our Core Product for the treatment of PGHD, which was subsequently accepted by the NMPA on March 7, 2024.

SUMMARY

Entry into Strategic Collaboration Agreement with United Family Healthcare

On August 5, 2024, we entered into the strategic collaboration with the United Family Healthcare, one of the leading private healthcare providers in China with a network of over ten hospitals and over 20 clinics across China. This collaboration will focus on jointly developing capabilities in diagnosis, treatment and services for children with medical needs in growth and development.

Expected Significant Increase in Net Loss

We expect a significant increase in net loss in the year ending December 31, 2024, primarily because we expect to incur increasing R&D expenses and administrative expenses as we continue to carry out the Technology Transfer and Localization and establish localized manufacturing capabilities of the Core Product.

No Material Adverse Change

Our Directors confirm that, up to the date of this document, there has been no material adverse change in our financial or trading position since April 30, 2024 (being the date on which the latest consolidated financial information of our Group was prepared) and there has been no event since April 30, 2024 which would materially affect the information shown in our consolidated financial statements included in the Accountants’ Report in Appendix I to this document.

Impact of the COVID-19 Outbreak

The outbreak of a novel strain of coronavirus causing COVID-19 since early 2020 has materially and adversely affected the global economy. The COVID-19 pandemic and its recurrence have caused temporary disruption to our business operations to the extent that necessary on-site operations and R&D activities had to be put on hold temporarily and transportation of consumables and other supplies necessary for our operations had to be reduced during the affected period. However, the outbreak of COVID-19 had not caused any early termination or suspension of our clinical trials, and during the Track Record Period and up to the Latest Practicable Date, the COVID-19 pandemic did not have any material adverse effect on our results of operations and financial position. With most restrictive measures lifted since December 2022, we did not experience any disruption to our business operations in 2023 and the four months ended April 30, 2024 due to the COVID-19 pandemic, and our Directors are of the view that it is unlikely that there will be any material delays in regulatory affairs regarding our drug candidates in the future or any long-term impact on our operations or deviations from our overall development plans due to the COVID-19 pandemic. However, we cannot assure you that the COVID-19 pandemic will not further escalate or have material adverse effect on our performance in the future. See “Risk Factors — An occurrence of a natural disaster, widespread health epidemic or other outbreaks could have a material adverse effect on our business, financial condition and results of operations.”

SUMMARY

[REDACTED]

SUMMARY

DIVIDENDS

We have never declared nor paid any dividends on our ordinary shares or any other securities during the Track Record Period. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. [REDACTED] should not purchase our ordinary shares with the expectation of receiving cash dividends.

Any future determination to pay dividends will be made at the discretion of our Directors or the Shareholders in general meeting, and may be based on a number of factors, including our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors may deem relevant. As advised by our Cayman Islands counsel, under the Cayman Islands law a company may declare and pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be declared or paid if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business. [REDACTED] should not purchase our shares with the expectation of receiving cash dividends.

[REDACTED]

[REDACTED] mainly comprise legal and other professional fees paid and payable to the professional parties, commissions payable to the [REDACTED], and printing and other expenses for their services rendered in relation to the [REDACTED] and the [REDACTED]. [REDACTED] for the [REDACTED] are estimated to be approximately HK\$[REDACTED] million, including (i) [REDACTED] (including but not limited to commissions and fees) of approximately HK\$[REDACTED] million and (ii) [REDACTED] of approximately HK\$[REDACTED] million, comprising (a) fees and expenses of legal advisors and accountants of approximately HK\$[REDACTED] million and (b) other fees and expenses of approximately HK\$[REDACTED] million, at an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the [REDACTED], which represents approximately [REDACTED]% of the gross [REDACTED] we expect to receive from this [REDACTED] assuming no Shares are issued pursuant to the [REDACTED] and no Shares are issued under the [REDACTED] Share Award Scheme. RMB[REDACTED] million (HK\$[REDACTED] million) was recognized and charged to our consolidated statements of profit or loss and other comprehensive income as of April 30, 2024. After April 30, 2024, approximately HK\$[REDACTED] million is expected to be charged to our consolidated statements of profit or loss and other comprehensive income, and approximately HK\$[REDACTED] million is expected to be charged against equity upon the [REDACTED]. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

SUMMARY

USE OF [REDACTED]

Assuming an [REDACTED] of HK\$[REDACTED], being the mid-point of the [REDACTED], and after deducting estimated [REDACTED] fees and the estimated [REDACTED] in connection with the [REDACTED] and [REDACTED], and the [REDACTED] is not exercised, we estimate that the aggregate [REDACTED] from the [REDACTED] will be approximately HK\$[REDACTED] million, or HK\$[REDACTED] million if the [REDACTED] is exercised in full.

In line with our strategies, we intend to use the [REDACTED] we will receive from the [REDACTED] for the following purposes, subject to changes in light of our evolving business needs and changing market conditions:

<u>Allocation of the estimated [REDACTED]</u>	<u>Proposed main purposes</u>
[REDACTED]%, or HK\$[REDACTED] million	To fund the ongoing BLA registration of imported Core Product, ongoing and planned research and development and BLA registration of locally manufactured Core Product, planned clinical trial on new indication expansion, and planned commercial launch of our Core Product, lonapegsomatropin;
[REDACTED]%, or HK\$[REDACTED] million	To fund the ongoing China Phase 3 pivotal trial and planned commercial launch of palopegteriparatide;
[REDACTED]%, or HK\$[REDACTED] million	To fund the ongoing open-label portion of China Phase 2 trial of TransCon CNP (navepegritide) for the treatment of ACH; and
[REDACTED]%, or HK\$[REDACTED] million	To fund our working capital and other general corporate purposes.

See “Future Plans and Use of [REDACTED]” for more details.

DEFINITIONS

In this document, unless the context otherwise requires, the following terms shall have the meanings set out below.

“Accountants’ Report”	the accountant’s report of our Company, the text of which is set out in Appendix I to this document
“affiliate(s)”	with respect to any specified person, any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“AFRC”	the Accounting and Financial Reporting Council of Hong Kong
“Articles” or “Articles of Association”	the articles of association of our Company conditionally adopted by a special resolution passed on [●] with effect from the [REDACTED], a summary of which is set forth in “Summary of the Constitution of the Company” in Appendix III to this document
“Ascendis Pharma”	a group of entities comprised of Ascendis Pharma A/S, Ascendis Pharma Bone Diseases, Ascendis Pharma Endocrinology Division and Ascendis Pharma Growth Disorders (or certain member/members of the group, where the context otherwise requires)
“Ascendis Pharma A/S”	a company registered in Denmark on September 21, 2006, a biopharmaceutical company listed on the Nasdaq (Ticker Symbol: ASND) since January 2015, and one of our Controlling Shareholders
“Ascendis Pharma Bone Diseases”	Ascendis Pharma Bone Diseases A/S, a company registered in Denmark on June 29, 2012, a wholly-owned subsidiary of Ascendis Pharma A/S, and one of our Controlling Shareholders
“Ascendis Pharma Endocrinology Division”	Ascendis Pharma Endocrinology Division A/S, a company registered in Denmark on June 29, 2012, a wholly-owned subsidiary of Ascendis Pharma A/S, and one of our Controlling Shareholders

DEFINITIONS

“Ascendis Pharma Growth Disorders”	Ascendis Pharma Growth Disorders A/S, a company registered in Denmark on June 29, 2012, a wholly-owned subsidiary of Ascendis Pharma A/S, and one of our Controlling Shareholders
“associate(s)”	has the meaning ascribed to it under the Listing Rules
“Board”	the board of Directors
“business day”	any day (other than a Saturday, Sunday or public holiday in Hong Kong) on which banks in Hong Kong are generally open for normal banking business
“BVI”	the British Virgin Islands
“CAGR”	compound annual growth rate

[REDACTED]

“Cayman Companies Act” or “Companies Act”	the Companies Act, Cap. 22 (Law 3 of 1961, as consolidated and revised) of the Cayman Islands
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[REDACTED]

“CRF Investment”	CRF Investment Holdings Company Limited, an exempted company incorporated in the Cayman Islands on November 14, 2017, a [REDACTED] Investor
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“CHARD”	China Alliance for Rare Disease (中國罕見病聯盟), a national, non-profit, cooperative exchange platform for rare disease, approved by the national health authority and supported by multiple hospital associations and universities
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“China” or “the PRC”	the People’s Republic of China, and for the purposes of this document only, except where the context requires otherwise, references to China or the PRC exclude the special administrative regions of Hong Kong and Macau and Taiwan
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DEFINITIONS

“Clinical Supply Agreements”	three supply agreements entered into between our Company and Ascendis Pharma Endocrinology Division, Ascendis Pharma Growth Disorders and Ascendis Pharma Bone Diseases, respectively, on November 7, 2018, each a Clinical Supply Agreement
“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
“Company,” “our Company,” or “the Company”	VISEN Pharmaceuticals, an exempted company with limited liability incorporated in the Cayman Islands on November 1, 2018
“connected person(s)”	has the meaning ascribed to it under the Listing Rules
“connected transaction(s)”	has the meaning ascribed to it under the Listing Rules
“Controlling Shareholder(s)”	has the meaning ascribed to it under the Listing Rules and unless the context otherwise requires, refers to the entities as mentioned in the section headed “Relationship with the Controlling Shareholders” in this document, namely, Ascendis Pharma A/S and its wholly-owned subsidiaries, Ascendis Pharma Endocrinology Division, Ascendis Pharma Growth Disorders and Ascendis Pharma Bone Diseases and Vivo Capital, Vivo Capital IX (Cayman), LLC., Vivo Capital Fund IX (Cayman), L.P.
“Cormorant”	our [REDACTED] Investors, including Cormorant Global Healthcare Master Fund, LP, Cormorant Private Healthcare Fund III, LP and CRMA SPV, L.P.
“Director(s)”	the director(s) of our Company
“EMA”	European Medicines Agency

DEFINITIONS

“Equity Incentive Plan”	the equity incentive plan as adopted by the Board on April 29, 2019 and approved by the Shareholders on June 26, 2019, as amended on January 8, 2021 and March 10, 2021
“Euro”, “EUR” or “€”	the lawful currency of the European Union
“Exclusive License Agreements”	three exclusive license agreements entered into between our Company and Ascendis Pharma Endocrinology Division, Ascendis Pharma Growth Disorders and Ascendis Pharma Bone Diseases, respectively, on November 7, 2018 (as amended, respectively, on January 4, 2021), each an Exclusive License Agreement
“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the government of Hong Kong
“FDA”	U.S. Food and Drug Administration

[REDACTED]

“Founding Shareholder(s)”	Ascendis Pharma A/S, Vivo Capital and Sofinnova
“Frost & Sullivan”	Frost & Sullivan International Limited
“Frost & Sullivan Report”	the report prepared by Frost & Sullivan
“FTE”	a full time equivalent person year of work (consisting of 1,673 hours per year for work in Denmark, 1,768 hours per year for work in Germany, or 1,840 hours per year for work in the US), prorated on a daily or hourly basis as necessary

[REDACTED]

DEFINITIONS

“Governmental Authority(ies)”	any governmental, regulatory, or administrative commission, board, body, authority, or agency, or any stock exchange, self-regulatory organization, or other non-governmental regulatory authority, or any court, judicial body, tribunal, or arbitrator, in each case whether national, central, federal, provincial, state, regional, municipal, local, domestic, foreign, or supranational
“Group,” “our Group,” “the Group,” “we,” “us,” or “our”	the Company and its subsidiaries from time to time, and where the context requires, in respect of the period prior to our Company becoming the holding company of its present subsidiaries, such subsidiaries as if they were subsidiaries of our Company at the relevant time
“HBM Healthcare Investments”	HBM Healthcare Investments (Cayman) Ltd., a company established under the laws of Cayman Islands on May 8, 2001, a [REDACTED] Investor
“HongShan”	a leading venture capital and private equity firm investing across technology, healthcare and consumer sectors
“HongShan Growth”	HSG Growth VI Holdco F LTD., a company established under the laws of the Cayman Islands on July 2, 2020, a [REDACTED] Investor
“HK” or “Hong Kong”	the Hong Kong Special Administrative Region of the People’s Republic of China
“HKSCC”	Hong Kong Securities Clearing Company Limited, a wholly-owned subsidiary of Hong Kong Exchanges and Clearing Limited

[REDACTED]

“HKSCC Nominees”	HKSCC Nominees Limited, a wholly-owned subsidiary of HKSCC
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DEFINITIONS

“HKSCC Participant”	a person admitted to participate in CCASS as a direct clearing participant, a general clearing participant, a custodian participant or an investor participant
“Hong Kong dollars” or “HK\$”	Hong Kong dollars, the lawful currency of Hong Kong

[REDACTED]

“IFRS(s)”	International Financial Reporting Standards, as issued from time to time by the International Accounting Standards Board
“Independent Third Party(ies)”	any entity or person who is not a connected person of our Company or an associate of such person within the meaning ascribed to it under the Listing Rules

DEFINITIONS

[REDACTED]

“Joint Sponsors”	Morgan Stanley Asia Limited and Jefferies Hong Kong Limited
“KOL”	key opinion leader
“Latest Practicable Date”	September 19, 2024, being the latest practicable date for ascertaining certain information in this document before its publication
“laws”	all laws, statutes, legislation, ordinances, rules, regulations, guidelines, opinions, notices, circulars, directives, requests, orders, judgments, decrees, or rulings of any Governmental Authority (including the Stock Exchange and the SFC) of all relevant jurisdictions

[REDACTED]

DEFINITIONS

“Listing Committee”	the Listing Committee of the Stock Exchange
	[REDACTED]
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
“Logos Capital”	Logos Opportunities Fund II LP, a limited partnership established under the laws of the State of Delaware on March 26, 2020, a [REDACTED] Investor
“Macau”	the Macau Special Administrative Region of the People’s Republic of China
“Main Board”	the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operates in parallel with the Growth Enterprise Market of the Stock Exchange
“Memorandum” or “Memorandum of Association”	the memorandum of association of our Company conditionally adopted by a [special resolution] passed on [●], with effect from the [REDACTED]
“MOFCOM”	the Ministry of Commerce of the PRC (中華人民共和國商務部)
“NDA”	new drug application, submission of which is the vehicle through which drug sponsors formally propose that the relevant drug regulatory authority approve a new pharmaceutical for sale and marketing in accordance with local rules and regulations
“NMPA”	National Medical Products Administration (國家藥品監督管理局), the successor of the China Food and Drug Administration (國家食品藥品監督管理總局) (the “CFDA”), the State Food and Drug Administration (國家食品藥品監督管理局) (the “SFDA”) and the State Drug Administration (國家藥品監督管理局) (the “SDA”)
“NPC”	National People’s Congress (全國人民代表大會)

DEFINITIONS

“NRDL” National Reimbursement Drug List of China (《國家基本醫療保險、工傷保險和生育保險藥品目錄》)

[REDACTED]

“OrbiMed” our [REDACTED] investors, including Worldwide Healthcare Trust PLC, OrbiMed Genesis Master Fund, L.P. and OrbiMed New Horizons Master Fund, L.P.

[REDACTED]

DEFINITIONS

“Pivotal bioVenture Partners China”	Cosmic Clover Limited, a company established under the laws of BVI on August 2, 2017, a [REDACTED] Investor
“[REDACTED] Share Award Scheme”	the [REDACTED] share award scheme as adopted by the Board on November 8, 2022 and approved by the Shareholders on November 16, 2022
“PRC Legal Adviser”	JunHe LLP, our legal adviser on PRC law
“PRDL”	Provincial Reimbursement Drug List of China (《省級基本醫療保險、工傷保險和生育保險藥品目錄》)
“Preferred Share(s)”	the Series A Preferred Shares and the Series B Preferred Shares
“[REDACTED] Investment(s)”	the investment(s) in our Company undertaken by the Series A Preferred Shareholders and Series B Preferred Shareholders prior to this [REDACTED], the details of which are set forth in “History, Development and Corporate Structure”
“[REDACTED] Investor(s)”	HongShan Growth, OrbiMed, Sherpa Healthcare Partners, Cormorant, HBM Healthcare Investments, Pivotal bioVenture Partners China, Logos Capital and CRF Investment

[REDACTED]

“QIB”	a qualified institutional buyer within the meaning of Rule 144A
“Regulation S”	Regulation S under the U.S. Securities Act
“RMB” or “Renminbi”	Renminbi, the lawful currency of China
“Rule 144A”	Rule 144A under the U.S. Securities Act
“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)
“SAMR”	the State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局)
“SAT”	State Administration of Taxation (國家稅務總局)
“Series A Preferred Share(s)”	the series A-1 preferred share(s) of our Company with a par value of US\$0.0001 each
“Series A Preferred Shareholder(s)”	the holder(s) of Series A Preferred Shares as detailed in “History, Development and Corporate Structure”
“Series B Preferred Share(s)”	the series B preferred share(s) of our Company with a par value of US\$0.0001 each
“Series B Preferred Shareholder(s)”	the holder(s) of Series B Preferred Shares as detailed in “History, Development and Corporate Structure”
“Series A Share Purchase Agreement”	the share purchase agreement entered into between our Company and the Series A Preferred Shareholders dated November 7, 2018
“Series B Share Purchase Agreement”	the share purchase agreement entered into between our Company and the Series B Preferred Shareholders dated January 8, 2021
“SFC”	Securities and Futures Commission of Hong Kong
“SFO” or “Securities and Futures Ordinance”	Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Share(s)”	ordinary share(s) in the share capital our Company with a par value of US\$0.0001 each
“Shareholder(s)”	holder(s) of our Share(s)
“Shareholders’ Agreement”	the amended and restated shareholders agreement entered into by the Company and [REDACTED] Investors on January 8, 2021

DEFINITIONS

“Sherpa Healthcare Partners”	our [REDACTED] Investors, including Sherpa Healthcare Fund I, L.P. and Sherpa Healthcare Co-Investment Fund, L.P.
“Sofinnova”	Sofinnova Venture Partners IX, L.P., a limited partnership established under the laws of the State of Delaware on July 11, 2014, a Founding Shareholder of the Company
“Sophisticated Investor(s)”	has the meaning ascribed to it under Chapter 2.3 of the Guide for New Listing Applicants issued by the Stock Exchange
“Share Schemes”	the Equity Incentive Plan and the [REDACTED] Share Award Scheme
	[REDACTED]
“State Council”	the State Council of the PRC (中華人民共和國國務院)
“Stock Exchange” or “Hong Kong Stock Exchange”	The Stock Exchange of Hong Kong Limited
“subsidiary” or “subsidiaries”	has the meaning ascribed to it in section 15 of the Companies Ordinance
“substantial shareholder(s)”	has the meaning ascribed to it in the Listing Rules
“Takeovers Code”	Code on Takeovers and Mergers and Share Buy-backs issued by the SFC, as amended, supplemented or otherwise modified from time to time
“Track Record Period”	the periods comprising the two years ended December 31, 2022 and 2023 and the four months ended April 30, 2024
	[REDACTED]
“U.S.” or “United States”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction

DEFINITIONS

“US dollars”, “U.S. dollars”, “US\$” or “USD”	United States dollars, the lawful currency of the United States
“U.S. SEC”	the Securities and Exchange Commission of the United States
“U.S. Securities Act”	the United States Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder
“VISEN BVI”	VISEN Pharmaceuticals (BVI) Limited, a company incorporated under the laws of the BVI on November 9, 2020, and a wholly-owned subsidiary of the Company
“VISEN HK”	VISEN Pharmaceuticals HK Limited, a company incorporated under the laws of Hong Kong on November 13, 2018, and a wholly-owned subsidiary of the Company
“VISEN Shanghai”	VISEN Pharmaceuticals (Shanghai) Co., Ltd. (維昇藥業(上海)有限公司), a company established in the PRC with limited liability on February 15, 2019 and an indirectly wholly-owned subsidiary of our Company
“VISEN Suzhou”	VISEN Pharmaceuticals (Suzhou) Co., Ltd. (維昇藥業(蘇州)有限公司), a company established in the PRC with limited liability on June 11, 2021 and an indirectly wholly-owned subsidiary of our Company
“VISEN Taiwan”	VISEN Pharmaceuticals (Taiwan) Ltd. (台灣維昇藥業有限公司), a company established in Taiwan with limited liability on December 28, 2021 and an indirectly wholly-owned subsidiary of our Company
“Vivo Capital”	refers to Vivo Plenilune IX Limited, a company incorporated under the laws of the Cayman Islands on September 11, 2018, a Founding Shareholder of the Company. Vivo Capital, Vivo Capital IX (Cayman), LLC. and Vivo Capital Fund IX (Cayman), L.P., are our Controlling Shareholder as a group

DEFINITIONS

[REDACTED]

“%”

per cent

GLOSSARY OF TECHNICAL TERMS

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

“ACH”	Achondroplasia, a form of short-limbed dwarfism, manifested by the disorder of bone growth that prevents the changing of cartilage, particularly in the long bones of the arms and legs, to bone
“AE”	adverse event, any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product
“AGV”	annualized growth velocity
“AHV”	annualized height velocity
“ANCOVA”	analysis of covariance, a method to test the main and interaction effects of categorical variables on a continuous dependent variable, controlling for the effects of selected other continuous variables, which co-vary with the dependent
“antibody”	a blood protein produced in response to and binding a specific antigen. Antibodies bind non-chemically with substances which the body recognizes as alien, such as bacteria, viruses, and foreign substances in the blood
“biologics”	class of drug products derived from a variety of natural sources – human, animal, or microorganism – that may be produced by biotechnology methods and other cutting-edge technologies (in contrast to small molecule drugs that are chemically synthesized). They can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities, such as cells and tissues

GLOSSARY OF TECHNICAL TERMS

“BLA”	biologics license application used to apply for regulatory approval to market and commercialize a biologic product
“CDE”	Center for Drug Evaluation of NMPA (國家藥品監督管理局藥品審評中心), a division of the NMPA mainly responsible for review and approval of IND and NDA
“CDMO”	contract development and manufacturing organization
“clinical trial” or “clinical study”	any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy
“C _{max} ”	highest or peak blood/plasma concentration
“CMC”	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
“CNP”	C-type natriuretic peptide, the paracrine element of the natriuretic peptide axis which complements the endocrine actions of atrial natriuretic peptide and brain natriuretic peptide
“cohort”	in epidemiology, refers to a group of people who share experiences or states
“Core Product”	our “core product” as defined under Chapter 18A of the Listing Rules, namely lonapegsomatropin
“CRO”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“CSO”	contract sales organization, a company that provides various services and solutions related to pharmaceutical marketing and commercial activities under contracts with pharmaceutical or biotech companies

GLOSSARY OF TECHNICAL TERMS

“designated local CDMO” or “WuXi Biologics”	WuXi Biologics (Shanghai) Co., Ltd. (上海藥明生物技術有限公司), a limited liability company established in the PRC on January 6, 2015, a wholly-owned subsidiary of WuXi Biologics (Cayman) Inc. (藥明生物技術有限公司), an exempted company incorporated with limited liability in the Cayman Islands on February 27, 2014, with its shares being listed on the Main Board of the Stock Exchange (HKEx stock code: 2269)
“disease-modifying therapy”	a treatment that delays, slows, or reverses the progression of a disease by targeting its underlying cause
“double-blind”	a phase in clinical trial where neither the patients nor the researchers know who is receiving a placebo and who is getting the treatment in which the objective is primarily to prevent bias and ensure the validity of the results
“endpoint”	with respect to a clinical study or trial, the outcome that is measured, whether referring to occurrence of disease, symptom, sign or laboratory abnormality constituting a target outcome, in which case “endpoint” will be preceded by the outcome term, such as in “clinical remission endpoint” or “maintenance therapy endpoint”
“FGFR3”	fibroblast growth factor receptor 3. A FGFR3 gene is a gene that makes a protein that is involved in cell division, cell maturation, formation of new blood vessels, wound healing, and bone growth, development, and maintenance. A mutation in the FGFR3 gene may cause the FGFR3 protein to become overactive in certain bone disorders, genetic conditions, and cancers
“GAMA”	government affairs and market access
“GCP”	a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected
“GHD”	growth hormone deficiency, a condition caused by insufficient amounts of growth hormone in human body

GLOSSARY OF TECHNICAL TERMS

“GLP”	good laboratory practice, a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of products in development for human or animal health
“GMP”	good manufacturing practice, a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product
“HCP”	healthcare professional
“hGH”	human growth hormone, a small protein that is made by the pituitary gland and secreted into the bloodstream. hGH production is controlled by a complex set of hormones produced in the hypothalamus of the brain and in the intestinal tract and pancreas
“homeostasis”	a state of balance among all the body systems needed for the body to survive and function correctly. In homeostasis, body levels of acid, blood pressure, blood sugar, electrolytes, energy, hormones, oxygen, proteins, and temperature are constantly adjusted to respond to changes inside and outside the body, to keep them at a normal level
“HP”	Hypoparathyroidism, a syndrome of abnormal calcium and phosphorus metabolism caused by underproduction or defective function of PTH
“IGF-1”	insulin-like growth factor-1, a form of insulin-like growth factor which is a protein made by the body that stimulates the growth of many types of cells. Insulin-like growth factor is similar to insulin, a hormone made in the pancreas
“Import BLA”	biologics license application used to apply for regulatory approval to market and commercialize a biologic product manufactured and imported from overseas
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China

GLOSSARY OF TECHNICAL TERMS

“INN”	International Nonproprietary Names, which identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property
“indication”	a known disease or condition/symptoms which makes a particular prevention, diagnosis, or medicinal product advisable
“LAGH”	long-acting growth hormone
“MAD”	multiple-ascending doses escalation is a study to obtain drug tolerance data, which is generally carried out after completing a single-ascending doses escalation trial in which the drug first enters the human body in order to determine the maximum tolerated dose of multiple doses in humans
“MAA”	Marketing Authorization Application, an application made to a European regulatory authority for approval to market a medicine within the European Union
“Local BLA”	biologics license application used to apply for regulatory approval to market and commercialize a biologic product manufactured locally
“MoA”	mechanism of action, which, in pharmacology, refers to the specific biochemical interaction through which a drug substance produces its pharmacological effect. A mechanism of action usually includes mention of the specific molecular targets to which the drug binds, such as an enzyme or receptor
“NPR-B receptor”	Natriuretic Peptide Receptor B receptor, a guanylyl cyclase receptor encoded on the ninth chromosome in humans that is activated by CNP. It is expressed at high levels in the brain, heart, bones, ovaries, and lungs
“NPR-C receptor”	Natriuretic Peptide Receptor C receptor, a non-guanylyl cyclase receptor that is coupled to adenylyl cyclase inhibition or phospholipase C activation through inhibitory guanine nucleotide regulatory protein

GLOSSARY OF TECHNICAL TERMS

“OLE”	open-label extension, a type of clinical study that typically follows a double-blind randomized placebo controlled trial of a new drug in which the objective is primarily to gather information about safety and tolerability of the new drug in long-term, day to day use
“p” or “p-value”	with respect to clinical trials or studies, the probability of obtaining a result at least as extreme as the one that was actually observed in the biological or clinical experiment or epidemiological study, given that the null hypothesis (which is the hypothesis to be nullified that there is no association between the investigated factors or characteristics) is true. A result is said to be “statistically significant” if there is the likelihood that a relationship between two or more variables is caused by something other than chance (so it allows for rejection that the null hypothesis is true) whereas “clinically meaningful” is the practical importance of a treatment effect – whether it has a real genuine, palpable, noticeable effect on daily life
“PEG”	polyethylene glycol, a polymer made by joining molecules of ethylene oxide and water together in a repeating pattern. PEG can be a liquid or a waxy solid
“PEGylation”	a process through which PEG chains are conjugated to proteins (therapeutic proteins), peptides, or any molecule, and the resulting substance is “PEGylated.” Through the PEGylation process, the molecular mass of the therapeutic protein is increased. Therefore, it guards the therapeutic protein from proteolytic enzymes and degradation of the protein
“PGHD”	pediatric growth hormone deficiency
“pharmacodynamics” or “PD”	the study of how a drug affects an organism, which, together with pharmacokinetics, influences dosing, benefit, and adverse effects of the drug
“pharmacokinetics” or “PK”	the study of how the body interacts with administered substances for the entire duration of exposure. The four main parameters generally examined by this field include absorption, distribution, metabolism, and excretion (ADME)

GLOSSARY OF TECHNICAL TERMS

“Phase 1”	it is usually a human pharmacological test during early clinical studies. The first administration of the investigational product to humans is at this stage. These studies may be performed in healthy volunteers or in patient populations affected by a condition or disease, depending on the characteristics of the drug and the purpose of the development program. Such studies are generally intended to address one or more of the following: preliminary safety and tolerability assessments, pharmacokinetics, pharmacodynamics, and early determination of drug activity
“Phase 2”	to investigate the safety and efficacy of the drug in specific patient groups as an exploratory study. In addition, the objectives of the exploratory studies were to refine the effective dose and regimen, refine the definition of the target population, ensure robustness of the drug safety profile, and include evaluation of potential study endpoints adopted in subsequent studies. Exploratory studies can provide information on identifying and identifying factors that influence treatment effectiveness, combined with modeling and simulation, and help support subsequent confirmatory study designs
“Phase 3”	also called confirmatory studies, they are intended to confirm preliminary evidence accumulated in early clinical studies about the safety and effectiveness of a drug in the intended use and population. Confirmatory studies are generally designed to provide a sufficient basis for marketing approval of a drug and to provide adequate instructions for the use of the drug and officially published drug product information
“pivotal trial” or “pivotal study”	a clinical study seeking to demonstrate the efficacy of a new drug in order to obtain its marketing approval by regulatory authorities
“popPK”	population pharmacokinetics, popPK analysis is a well-established, quantitative method that can quantify and explain the variability in drug concentrations among individuals

GLOSSARY OF TECHNICAL TERMS

“pre-clinical study”	also called non-clinical study. The nonclinical assessment usually includes toxicology, carcinogenicity, immunogenicity, pharmacology, pharmacokinetics, and other evaluations to support clinical studies (and may encompass evidence generated in in vivo and in vitro models, and by modelling and simulation)
“primary endpoint”	with respect to a clinical study or trial, the main predefined result that is measured at the end of a study (e.g., the number of deaths or the difference in survival between the treatment group and the control group)
“PRO”	patient reported outcome
“PTH”	Parathyroid hormone, a polypeptide that is synthesized and cleaved into an active form within the parathyroid gland
“receptor”	a region of tissue, or a molecule in a cell membrane, which responds specifically to a particular signal, that is any of a neurotransmitter, hormone, antigen, or other substance. “Receptor modulator” or a “selective receptor modulator” (SRM) is a type of drug that has different effects in different tissues, as it may behave as an agonist in some tissues but as an antagonist in others
“renal”	of or pertaining to the kidney, as with renal pelvis cancer
“SAD”	single-ascending dose (SAD), a study in which the maximum recommended starting dose (MRSD) is used as the starting dose for clinical administration when the drug first enters the human body, and the dose is gradually increased in the form of a single dose to obtain the maximum tolerated dose in humans
“SAE”	serious adverse event, any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect
“SDS”	standard deviation scores

GLOSSARY OF TECHNICAL TERMS

“secondary endpoint”	with respect to a clinical study or trial, a secondary objective that was measured. For example, a drug designed to prevent allergy-related deaths might also have a measure of whether quality of life is improved
“SMO”	site management organization, an organization that contractually provides clinical trial related services to a study sponsor, CRO or clinical investigator
“standard of care”	treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. It is also called best practice, standard medical care, and standard therapy
“TEAE”	treatment-emergent adverse events, an AE that emerges during treatment having been absent pre-treatment, or worsens relative to the pre-treatment state
“tolerability”	the degree to which overt AEs of a drug can be tolerated by a patient. Tolerability of a particular drug can be discussed in a general sense, or it can be a quantifiable measurement as part of a clinical study

FORWARD-LOOKING STATEMENTS

Certain statements in this document are forward-looking statements that are, by their nature, subject to significant risks and uncertainties. Any statements that express, or involve discussions as to, expectations, beliefs, plans, objectives, assumptions, future events, or performance (often, but not always, through the use of words or phrases such as "will," "expect," "anticipate," "estimate," "believe," "going forward," "ought to," "may," "seek," "should," "intend," "plan," "projection," "could," "vision," "goals," "aim," "aspire," "objective," "target," "schedules," and "outlook") are not historical facts, are forward-looking and may involve estimates and assumptions and are subject to risks (including but not limited to the risk factors detailed in this document), uncertainties and other factors some of which are beyond our control and which are difficult to predict. Accordingly, these factors could cause actual results or outcomes to differ materially from those expressed in the forward-looking statements.

Our forward-looking statements have been based on assumptions and factors concerning future events that may prove to be inaccurate. Those assumptions and factors are based on information currently available to us about the businesses that we operate. The risks, uncertainties and other factors, many of which are beyond our control, that could influence actual results include, but are not limited to:

- our operations and business prospects;
- our business and operating strategies and our ability to implement such strategies;
- our ability to develop and manage our operations and business;
- our ability to control costs and expenses;
- our expectations regarding the potential market size and the size of the patient populations for our drug candidates, if approved for commercial use;
- our expectations regarding the potential advantages of our drug candidates over existing therapies;
- our ability to maintain good relationships with business partners;
- the actions and developments of our competitors;
- changes to regulatory and operating conditions in the industry and geographical markets in which we operate;
- our ability to obtain, maintain, protect and enforce intellectual and proprietary rights for our drug candidates;
- our development plans with respect to our drug candidates;

FORWARD-LOOKING STATEMENTS

- our ability to develop, acquire and advance drug candidates into, and successfully complete, clinical trials;
- the timing or likelihood of regulatory filings and approvals for our drug candidates;
- the commercialization of our drug candidates, if approved;
- our commercialization, marketing and manufacturing capabilities of our drug candidates and associated devices;
- developments and projections relating to our competitors and our industry; and
- all other risks and uncertainties described in “Risk Factors.”

Since actual results or outcomes could differ materially from those expressed in any forward-looking statements, we strongly caution [REDACTED] against placing undue reliance on any such forward-looking statements. Any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by the Listing Rules, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. Statements of, or references to, our intentions or those of any of our Directors are made as of the date of this document. Any such intentions may change in light of future developments.

All forward-looking statements in this document are expressly qualified by reference to this cautionary statement.

RISK FACTORS

We are a biotechnology company seeking [REDACTED] on 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. Given the nature of our industry, there are a number of risks involved in our operations, many of which are beyond our control. As a result of these risks, you may lose all of your [REDACTED] in our Company.

You should carefully consider all of the information set out in this document before making an [REDACTED] in the Shares, including the risks and uncertainties described below in respect of our business and our industry and the [REDACTED]. You should pay particular attention to the fact that we are a company incorporated in the Cayman Islands and that our principal operations are conducted in China and are governed by a legal and regulatory environment that in some respects differs from what prevails in other countries. Our business could be affected materially and adversely by any of these risks.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) key risks related to our business, business operations, intellectual property, regulatory approval of our drug candidates, commercialization and financial prospects; (ii) other risks related to our limited operating history, financial position and need for additional capital; (iii) other risks related to the development of our drug candidates; (iv) other risks related to our intellectual property; (v) other risks related to obtaining regulatory approval of our drug candidates and other legal compliance matters; (vi) other risks related to manufacturing and commercialization of our drug candidates; (vii) risks related to our business operations; and (viii) risks related to the [REDACTED].

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

KEY RISKS RELATED TO OUR BUSINESS, BUSINESS OPERATIONS, INTELLECTUAL PROPERTY, REGULATORY APPROVAL OF OUR DRUG CANDIDATES, COMMERCIALIZATION AND FINANCIAL PROSPECTS

These are the key risks that are specific and critical to biopharmaceutical companies in general and to us specifically.

RISK FACTORS

Our rights to develop, manufacture and commercialize our drug candidates are subject to the terms and conditions of licenses granted to us by Ascendis Pharma. If we fail to comply with our obligations in our Exclusive License Agreements with Ascendis Pharma, we could lose the rights to develop, manufacture and commercialize our drug candidates and be required to pay monetary damages, which could materially and adversely affect our business operations.

We rely on the exclusive licenses granted to us by Ascendis Pharma to develop, manufacture and commercialize our drug candidates in China (including Hong Kong, Macau and Taiwan). We also rely on licenses to certain patent rights from Ascendis Pharma that are important or necessary to the development of our drug candidates, as we do not currently own all of the underlying intellectual properties and the transfer of patents related to these drug candidates will occur only upon the first regulatory approval for marketing of the corresponding drug candidate. See “Business – Collaborations – Exclusive License Agreements with Ascendis Pharma” for more details regarding our license agreements with Ascendis Pharma. As a result, our rights are subject to the continuation of, and compliance with the terms of, those agreements. If we fail to comply with our obligations under our current or future license agreements with Ascendis Pharma, Ascendis Pharma may have the right to terminate these agreements and, upon the effective date of such termination, may have the right to terminate our exclusive rights or all of our rights and acquire rights to certain of our developed intellectual property. If Ascendis Pharma terminates any license we rely upon, we might not be able to develop, manufacture or commercialize any drug or drug candidate related to the intellectual property licensed under these agreements and we may face other additional penalties or costs. In such case, we may have to negotiate new agreements or agreement amendments with terms less favorable to us including, potentially, licenses that are non-exclusive, if we are able to do so at all, and other parties, including our competitors, may be able to gain access to the applicable licensed technology. We may also face claims for monetary damages or other penalties. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach we commit if permitted, and otherwise seek to preserve our rights under the intellectual property rights licensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. If Ascendis Pharma breaches our license agreements, we may not be able to enforce such agreements or obtain remedies that are sufficient or adequate.

Our licenses may not include rights to all intellectual property relevant to our drug candidates, and disputes may arise in these Exclusive License Agreements, including (i) the scope of rights granted under the license agreements and other interpretation-related issues; (ii) the extent to which the conduct of our business, including any relevant technology and processes, infringe, misappropriate or otherwise violate the intellectual property right of the licensor that is not subject to the license agreements; (iii) the sublicensing of patent and other intellectual property or proprietary rights under the license agreements; (iv) our diligence obligations under the license agreements and what activities satisfy such obligations; and (v) the inventorship and ownership of patents, inventions, know-how and other intellectual property and proprietary rights resulting from activities performed by us and/or our counterparties.

RISK FACTORS

The resolution of any dispute relating to such agreements could narrow the scope of our rights to the relevant intellectual property or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may need to obtain additional licenses from Ascendis Pharma, which may not be available on an exclusive basis, commercially reasonable terms or at all, or expend significant time and resources to redesign our drug candidates or the methods for manufacturing them, all of which may not be feasible on a technical or commercial basis.

Furthermore, in the future, Ascendis Pharma may rely on third-party consultants or collaborators or on funds, resources or expertise from third parties, including governmental bodies, such that Ascendis Pharma may not be the sole and exclusive owners of the patents that we in-license. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors or other third parties, who could then market equivalent or substantially equivalent products and technologies. In addition, if Ascendis Pharma has not obtained adequate rights and licenses from these third parties, we may need to obtain additional rights from these third parties, which might not be available on reasonable terms or at all, or we could be prevented from developing and commercializing, or face competition with respect to, the related drug candidates.

Over time, there exists possibility that we seek additional rights to intellectual property from Ascendis Pharma and, in connection with the related negotiations, we may agree to amend our existing licenses in a manner that are more favorable to Ascendis Pharma.

In addition, there exists possibility that we need to obtain additional licenses from third parties to advance our research or development or allow commercialization of our current and any future drug candidates, and we cannot assure you that third-party patents or other intellectual property or proprietary rights which might be enforced against our current and any future drug candidates in the absence of such a license do not exist. We may fail to obtain any of these licenses on commercially reasonable terms, or at all. Other companies in our industry may have much greater resources than us and be able to effectively compete with us for access to licensed intellectual property. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or in-license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected drug candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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We expect to procure the Core Product from Ascendis Pharma for the commercial supply until 2028 following our anticipated commercialization in 2025, which may expose us to risks such as potential disruptions in the supply chain and a lack of control over the quality and timing of product supply, and may adversely affect our business and profitability.

We expect to procure the Core Product from Ascendis Pharma for the commercial supply until 2028 following our anticipated commercialization in 2025. In anticipation of the potential BLA approval and subsequent commercial launch of our Core Product, we entered into a commercial supply agreement with Ascendis Pharma in October 2023, pursuant to which we agreed to purchase, and Ascendis Pharma agreed to sell, lonapegsomatropin drug package, auto-injectors and additional certain drug items intended for marketing display purposes. For auto-injectors to be purchased from Ascendis Pharma, the import medical device registration application for the auto-injector was submitted by a third-party marketing authorization holder to the NMPA in June 2023 and has been approved in April 2024. Since the Core Product is used exclusively with the auto-injector produced by such marketing authorization holder, we expect to rely on its auto-injector supply before we establish our collaborative local manufacturing capability with local CDMO. See “Business – Commercial Supply and Manufacturing – Step 1: Commercial Drug Procurement from Importation” for details. Our anticipated reliance on Ascendis Pharma and its manufacturing suppliers (collectively, the commercial suppliers) in the short term may expose us to risks including but not limited to the following:

- our commercial suppliers may increase their prices over time, which can directly impact our cost of goods sold and reduce profitability;
- our commercial suppliers may be subject to potential issues such as production disruptions, labor strikes or financial difficulties, which may disrupt the supply chain and lead to delays in product availability; and
- we may have less control over the quality of the products supplied by our commercial suppliers. Inconsistent or inferior product quality may in turn lead to product recalls, product returns or exchanges, product liability, increased costs and damage to our reputation, thereby adversely affect our business, financial condition and results of operations.

Any of these occurrences may result in higher costs or adversely affect our commercialization plan, business operations and profitability.

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None of our drug candidates has received a marketing approval in China (including Hong Kong, Macau and Taiwan). If we are unable to advance our drug candidates through clinical development, obtain regulatory approval and/or ultimately commercialize our drug candidates, or experience significant delays in doing so, our business and profitability will be materially harmed.

Our business will depend on the successful development, regulatory approval and commercialization of our drug candidates for the treatment of patients with our currently targeted and new indications. Our Core Product, lonapegsomatropin, has received the acceptance letter for its BLA filing from the NMPA after the completion of Phase 3 pivotal trial in China and the other two of our pipeline drug candidates are being studied in clinical trials in China. However, we make no guarantee that we will be able to obtain additional regulatory approvals for our drug candidates in a timely manner, or at all, or advance any of our drug candidates through the clinical development.

The developmental success of our drug candidates will depend on several factors, including but not limited to the successful completion of clinical trials or studies, receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or drug registrations, establishing adequate manufacturing capabilities, commercialization of our existing drug candidates with respect to current and new indications and compliance with all relevant safety requirements. If we do not achieve one or more of these in a timely manner or at all, due to reasons either within or outside our control, including a change in our development strategy, we may not successfully obtain regulatory approval for our drug candidates, which would materially harm our business and may prevent us from generating sufficient revenues and cash flows to continue our operations. As a result, our financial condition, results of operations and prospects would be materially and adversely harmed.

Our drug candidates may cause undesirable AEs or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if any. If any of our drug candidates receives marketing approval and subsequently causes undesirable side effects, the ability to market the drug candidates could be compromised.

Although results from the global and China clinical development of our drug candidates, lonapegsomatropin, TransCon CNP (navepegritide) and palopegteriparatide, have supported that these drug candidates are generally safe and well-tolerated, there is no guarantee that our current or future drug candidates would not cause undesirable side effects. Any such undesirable side effects could potentially cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the NMPA or similar authorities. In the event that trials conducted by us or Ascendis Pharma reveal a high and unacceptable severity and prevalence of side effects, such trials could be suspended or terminated and the NMPA or similar regulatory authorities could order us to cease further development of or deny approval of our drug candidates for any

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or all targeted indications. The drug-related side effects could affect patient enrollment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, in the event that any of our drug candidates receives regulatory approval and we or others later identify undesirable side effects caused by one of our products, a number of potentially significant negative consequences could occur, including:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof, including requirements such as patient education, certification of health care professionals or specific monitoring;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a warning or a contraindication;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- we may suffer reputational damage.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of a particular drug candidate, if approved, and could result in the loss of significant revenue to us, which would harm our results of operations and business.

We may not be able to identify, discover or in-license new products or drug candidates to successfully expand our drug candidate portfolio, which could materially and adversely affect our future growth and prospects.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval, and commercialization of our existing drug candidates, the success of our business in the long-term depends in part upon our ability to identify, in-license, discover, develop, or commercialize additional drug candidates to expand our drug candidate portfolio.

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Our research programs or licensing efforts may fail to identify, discover or in-license new products or drug candidates for clinical development and commercialization for a number of reasons, including, without limitation, the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential drug candidates; and
- our potential drug candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; and we may lack sufficient human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which would limit our ability to diversify and expand our drug candidate portfolio.

Accordingly, there can be no assurance that we will be able to identify new products or drug candidates or additional therapeutic opportunities for our existing drug candidates or to develop suitable potential drug candidates through internal research programs. We may therefore not be able to successfully expand our drug candidate portfolio, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

Our success depends upon our and Ascendis Pharma's ability to obtain, maintain, protect and enforce intellectual property protection for our drug candidates and their underlying technologies. If we or Ascendis Pharma are unable to obtain and maintain intellectual property protection for our drug candidates, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any product or technology may be adversely affected. The patents and patent applications in-licensed to us covering one or more of our drug candidates could be found invalid or unenforceable if challenged in court or before a regulatory authority.

Our success depends in significant part on Ascendis Pharma's ability to establish and maintain patent, trade secret and other intellectual property and proprietary right protection with respect to the drug candidates we plan to develop, and on our ability to develop these drug candidates and commercialize the products resulting therefrom without infringing, misappropriating or otherwise violating the intellectual property or proprietary rights of others. In the future, we may apply for our own patents with claims covering our technologies, processes and drug candidates when and where we deem it appropriate to do so. There can be no assurance that the claims of any existing or future patent application that we or Ascendis Pharma file will issue as a patent, and if it does issue or has issued, will exclude others from making, using or selling our existing or future drug candidates or products similar or identical to those drug candidates or otherwise provide us with any meaningful competitive advantage. We also rely on trade secrets to protect aspects of our business, especially where we or

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Ascendis Pharma do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect and even with trade secret protection, companies may be able to independently develop equivalent knowledge, methods and know-how. As a result, in jurisdictions where we or Ascendis Pharma have not sought and do not seek patent protection, third parties may be able to manufacture and sell products similar or identical to ours in the future without our permission and compete directly against us, and we may not be able to stop them from doing so, even if our products are protected by trade secrets.

Even with respect to issued patents, issuance is not conclusive as to their scope, validity or enforceability, and the patents we have rights to may be challenged or invalidated in the courts or patent offices in China or other jurisdictions. For example, if we or Ascendis Pharma were to initiate legal proceedings against a third party to enforce a patent covering any of our drug candidates, the defendant could counterclaim that the patent is invalid or unenforceable. In patent litigation, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the applicable intellectual property office, or made a misleading statement or committed other inequitable conduct, during prosecution. Mechanisms for challenging patents include re-examination, post-grant review, interference, derivation, opposition, invalidation and other proceedings. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we or Ascendis Pharma and the patent examiner were unaware during prosecution. If we or Ascendis Pharma were not to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a drug candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our or Ascendis Pharma's ability to enforce such claims against the defendant and others. Any efforts to defend intellectual property rights against such challenges are also likely to be costly, and we or Ascendis Pharma may not have sufficient funds to defend against any such claims or may otherwise decide not to defend them for commercial or other reasons. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability of or prevent us from stopping others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates.

With respect to patent rights, we do not know whether any of the pending patent applications to which we currently or in the future will have rights will result in the issuance of patents that effectively protect our drug candidates, or if current or future issued patents will effectively prevent others from developing and commercializing technologies, processes and products similar or identical to ours and competing directly against us. Publications of discoveries in the scientific literature often lag behind the actual discoveries. Therefore, we cannot be certain that we or Ascendis Pharma or any future licensors were the first to make or file on the inventions claimed in our current or future owned or licensed patents or pending

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patent applications. There is also no assurance that all of the potentially relevant prior art relating to the patents and patent applications covering our drug candidates has been identified and disclosed to the relevant patent office during the prosecution of the related patent application, and such prior art could be used by a third party to challenge the validity or enforceability of such patents, should they issue, or prevent a patent from issuing from a pending patent application. Although we seek to enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our R&D output, such as our employees, contractors, collaborators and CROs, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Any changes we make to our drug candidate or any future drug candidates, including formulations that may be required for commercialization or that cause them to have what we view as more advantageous properties, may not be covered by our patents and patent applications, and we may be required to file new patent applications and/or seek other forms of protection for any such altered drug candidates if any such protection is available. The patent landscape surrounding the technology underlying our current and any future drug candidates is crowded, and there can be no assurance that we would be able to secure patent protection that would adequately cover an alternative to our current or any future drug candidates.

In addition, the patent prosecution process is expensive, time-consuming and complicated and we and Ascendis Pharma may not be able to prepare, file, prosecute and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or Ascendis Pharma will fail to identify patentable aspects of inventions before it is too late to obtain patent protection for them. Similar to the patent rights of other biopharmaceutical companies, the scope, validity and enforceability of our patent rights generally are highly uncertain and involve complex legal and factual questions. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in China or elsewhere. Our and Ascendis Pharma's pending and future patent applications may not result in patents being issued that protect our drug candidates, their underlying technologies, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or Ascendis Pharma to narrow the scope of the claims of pending and future patent applications, which would limit the scope of patent protection that is obtained, if any. Our and Ascendis Pharma's patent applications cannot currently prevent third parties from applying the technology that is claimed in such applications unless and until a patent is issued from such applications, and then only to the extent the claims that issued are broad enough to cover the technology being practiced by those third parties.

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Claims that our drug candidates or the exploitation of our products in the future infringe upon, misappropriate or otherwise violate the patents or other intellectual property or proprietary rights of third parties could result in costly litigation, the outcome of which would be uncertain and could have a material adverse effect on our business, or could require substantial time and monetary expenditure to resolve, even if litigation is avoided.

Our commercial success depends upon our ability to develop, manufacture, market, and sell any drug candidates without infringing, misappropriating, or otherwise violating the intellectual property and proprietary rights of third parties. We cannot guarantee that our drug candidates or the sale or use of our future products do not and will not in the future infringe, misappropriate or otherwise violate third-party patents or other intellectual property or proprietary rights. Litigations involving patents and other intellectual property rights are common in the biotechnology and biopharmaceutical industries. Numerous issued patents and pending patent applications owned by third parties exist in the fields in which we are developing drug candidates. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others. Third parties may also allege that we misappropriated their trade secrets, or that we are otherwise violating their intellectual property or proprietary rights, whether with respect to the manner in which we have conducted our research or development, or with respect to the sale, use or manufacture of the drug candidates we have developed or are developing. Such third parties might resort to litigation against us or Ascendis Pharma or other parties we have agreed to indemnify.

It is also possible that we or Ascendis Pharma have failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties with claims to compositions, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Because patent applications can take many years to issue, there may be pending patent applications that we are not aware of and which may later result in issued patents that our drug candidates may infringe. We or Ascendis Pharma also may have incorrectly concluded, or may in the future incorrectly conclude, that third-party patents are invalid or that our activities do not infringe, misappropriate or otherwise violate a third party's intellectual property. In addition, third parties may obtain patents in the future and claim that the development, manufacture or commercialization of our drug candidates infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover our drug candidates, our manufacturing process or any molecules formed during the manufacturing process, any final drug itself, the holders of any such patents may be able to prevent us from developing or commercializing such drug candidates unless we obtain a license under the applicable patents or until such patents expire or are finally determined to be invalid or unenforceable. Such a license may not be available on commercially reasonable 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 or other third parties gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a drug candidate, or be forced, by court order or otherwise, to cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms.

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Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages and attorneys' fees in the case of willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing drug candidates, which may be impossible or require substantial time and monetary expenditure. Third parties who bring successful claims against us for infringement, misappropriation or other violation of their intellectual property or proprietary rights may obtain injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates. Defending against claims of infringement, misappropriation or other violations of patents, intellectual property rights or proprietary rights of third parties, regardless of merit or outcome, would involve substantial expense, be time-consuming and distract our management and employees, and our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Uncertainties resulting from the initiation and continuation of patent litigation, trade secret litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our in-licensed patents and patent applications or any patents and patent applications that we own or in-license in the future may be subject to priority disputes or to inventorship disputes and similar proceedings. If we or our licensors are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the development, manufacture and commercialization of one or more of our drug candidates.

Although we are not currently aware of any pending challenges, we, Ascendis Pharma or any future licensors may be subject to claims that former employees, collaborators or other third parties have an interest in the intellectual property we use in our business, whether as an inventor, co-inventor or otherwise, including derivation, interference or other proceedings brought or declared in applicable patent offices. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our owned or in-licensed patents and other intellectual property. Even if we are successful in defending against any such claims, it could result in substantial costs and be a distraction to our management and other employees. If we or Ascendis Pharma fail in defending any such claims, in addition to paying monetary damages, we may lose valuable rights to the concerned intellectual property and could be required to cease using the related technology or to seek license of rights to it from the prevailing party, which may not be available on commercially reasonable terms or at all. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, and prospects.

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The regulatory approval processes of the NMPA and its regulatory authorities responsible for review and approval are uncertain and time-consuming and may evolve over time. If we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed and you may lose your [REDACTED] in us.

Although the BLA filing of our Core Product was accepted by the NMPA in March 2024, we currently do not have any products that have gained regulatory approval for marketing. The time required to obtain the approval of the NMPA and its regulatory authorities responsible for review and approval is inherently uncertain and depends on numerous factors, including the substantial discretion of the regulatory authorities. Our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize our Core Product, lonapegsomatropin, and our other pipeline programs. We cannot commercialize drug candidates in China or other jurisdictions without obtaining regulatory approval from regulatory authorities in relevant jurisdictions, such as the NMPA in China. Before obtaining regulatory approvals for the commercial sale of any drug candidate for a particular indication, we must demonstrate with substantial evidence gathered in clinical studies that the drug candidate is safe and effective for that indication and that the manufacturing facilities, processes and controls comply with regulatory requirements with respect to such drug candidate. Prior to seeking approval for any of our drug candidates, we will need to confer with the NMPA and its regulatory authorities responsible for review and approval regarding the design of our clinical trials and the type and amount of clinical data necessary to seek and gain approval for our drug candidates. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's R&D and may vary among jurisdictions. It is possible that none of our existing drug candidates or any future drug candidates will ever obtain regulatory approval.

Any of the following instances during clinical trials could cause our drug candidates to fail to receive regulatory approval from the NMPA or its regulatory authorities responsible for review and approval:

- disagreement with the design, protocol or conduct of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its risks;
- disagreement with our interpretation of data from clinical trials;
- insufficiency of data collected from clinical trials of our drug candidates;

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- changes in the approval policies or regulations that render our clinical data insufficient for approval; or
- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the applicable regulatory authority.

The NMPA or a comparable regulatory authority may require us to provide more information, including additional pharmaceutical, non-clinical or clinical data, to support a regulatory approval. To obtain such data, we may need to perform additional clinical trials, or modify our manufacturing processes, or both, which may delay or prevent regulatory approval and our commercialization plans, or force us to abandon the development program. If we change our manufacturing processes, we may also be required to conduct additional clinical trials or other studies, which equally could delay or prevent the approval of our drug candidates.

Under China’s regulatory framework, in addition to obtaining marketing approval for commercializing imported drug products, a separate marketing approval from the NMPA is required to commercialize locally manufactured drug products. If we are unable to obtain marketing approval to commercialize locally manufactured drug products, our business prospects will be adversely affected, which will ultimately affect our long-term profitability.

Under China’s regulatory framework, two separate BLAs are required for a biopharmaceutical company to commercialize imported drug products (“Import BLA”) and locally manufactured drug products (“Local BLA”). The Import BLA only allows us to import and commercialize drug products that are manufactured overseas, whereas the Local BLA will allow us to commercialize locally manufactured drug products.

Pursuant to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (“Registration Measures”) and the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (“Drug Administration Law”), in order for the Company to sell its locally manufactured drug products in China, the Local BLA application for registration will be required. As part of the Local BLA application for registration, we are required to furnish, among other materials, a drug manufacturing certificate, which certifies the local manufacturing capabilities of the manufacturing facility. Failure to obtain the approval of Local BLA suggests we did not receive the drug registration certificate from the NMPA, which will consequently hinder our ability to commercialize our locally manufactured drug products in China. And while we may continue to rely on our Import BLA to commercialize imported drug products from Ascendis Pharma, our long-term profitability will be adversely affected as we lose one main stream of revenue.

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Even if our drug candidates obtain regulatory approval, they may never achieve market acceptance or commercial success, which will depend, in part, upon the degree of acceptance among physicians, patients, third-party payors and the medical community.

Even if our drug candidates obtain NMPA or other regulatory approvals, and are ultimately commercialized, our drug candidates may not achieve market acceptance among physicians, patients, third-party payors, patient advocacy groups and the medical community. For example, we are aware of several global LAGH drug products that reached the commercial stage but were later withdrawn from the market due to factors such as market development strategies, cost considerations, competitive advantages and disadvantages of the product and other relevant factors. The degree of market acceptance, if any, for our most advanced drug candidates for which marketing approval is obtained will depend on a number of factors, including:

- the efficacy of the products as demonstrated in clinical trials;
- the prevalence and severity of any side effects and overall safety profile of the product;
- the perceived safety of the transient conjugation technology (TransCon);
- the convenience and features of the auto-injector or drug delivery device used to administer the drug;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment and their willingness to pay for such product;
- relative convenience and ease of administration of our products;
- the potential and perceived advantages of our drug candidates over current treatment options such as standard of care or alternative treatments, including future alternative treatments;
- the availability of supply of our products and their ability to meet market demand;
- marketing and distribution support for our drug candidates;
- product labeling or product insert requirements of the NMPA or other comparable regulatory authorities;
- the timing of market introduction of our drug candidates as well as competing products;

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- the affordability of our drug candidates and the cost of treatment in relation to alternative treatments;
- the quality of our relationships with patient advocacy groups; and
- coverage and reimbursement policies of government and other third-party payors.

If our drug candidates that obtain regulatory approval do not achieve significant market acceptance or commercial success, this could harm our business, results of operations and prospects, and the value of our Shares. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies introduced are more favorably received than our products, are more cost-effective and render our products obsolete.

Competition in the biotechnology and biopharmaceutical industries is intense and our competitors may discover, develop or commercialize products that are safer, more effective, more effectively marketed or cost less than ours, or receive regulatory approval or reach the market earlier. If we are unable to compete effectively, our business, results of operations and prospects will suffer.

The markets in which we intend to compete are undergoing, and are expected to continue to undergo, rapid and significant technological changes. Some of our drug candidates are for fields in which competing products already exist and are established. We expect competition to intensify as technological advances are made or new drugs and biopharmaceutical products are introduced. New developments by competitors may render our current or future drug candidates and/or technologies non-competitive, obsolete or not economical. Our competitors' products may be more efficacious or marketed and sold more effectively than any of our drug candidates. Many of our competitors have:

- significantly greater name recognition, financial, marketing, research, drug development and technical and human resources than we have at every stage of the discovery, development, manufacturing and commercialization process and additional mergers and acquisitions in the biopharmaceutical industries may result in even more resources being concentrated in our competitors;
- more extensive experience in commercializing drugs, conducting pre-clinical testing, conducting clinical studies, obtaining regulatory approvals, challenging patents and manufacturing and marketing pharmaceutical products;
- more expansive patent and other intellectual property and proprietary rights than us;
- products that have been approved or are in late stages of development; and
- collaboration arrangements in our target markets with leading companies and research institutions.

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We are aware of several pharmaceutical and biopharmaceutical companies that have commenced clinical studies of products or have successfully commercialized products addressing areas that we are targeting. There are a variety of experimental growth hormone therapies based on different stages of clinical development by various companies, including Novo Nordisk A/S, Xiamen Amoytop Biotech Co., Ltd. and Anhui Anke Biotechnology (Group) Co., Ltd. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competing products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

It is also possible that our competitors will commercialize competing drugs or treatments before we launch our drug candidates. We also anticipate that we will face increased competition in the future as new companies enter into the endocrine drugs market. For example, unmodified LAGH therapies approved overseas may enter China's market in the future, and we may therefore face increased challenges in effectively competing with them. Furthermore, to the extent we are developing endocrine drug candidates that incorporate already approved drugs, we face competition from the pharmaceutical companies which are currently marketing such approved products. These pharmaceutical companies can generally be expected to seek to delay the introduction of competing products through a variety of means including:

- filing new formulation patent applications on drugs whose original patent protection is about to expire;
- filing an increasing number of patent applications that are more complex and costly to challenge;
- filing suits for alleged patent infringement to delay regulatory approval;
- developing patented controlled-release or other "next-generation" products, which may compete with endocrine drug candidates;
- establishing exclusive contracts with third-party payors; or
- changing product claims and product labeling.

Any one of these strategies may increase the costs and risks associated with our efforts to introduce any of our drug candidates and may delay or altogether prevent such introduction. Our competitors may develop or commercialize products with significant advantages in regard to any of these factors. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our business, results of operations and prospects, and the value of our Shares.

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

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

We have no experience in launching and marketing drug candidates in China (including Hong Kong, Macau and Taiwan). If we are unable to effectively build and manage our commercial network or benefit from third-party collaborators' sales network, we may be unable to generate any revenue.

Even though our senior management members are experienced in launching and marketing drug candidates, our Company currently has no sales, marketing or commercial product distribution capabilities and has no experience in marketing drugs. We are developing an in-house marketing organization and commercialization team in alignment with the updated timeline of BLA registration and commercial launch of the Core Product, which will require significant capital expenditures, management resources and time. We will have to compete with other biopharmaceutical companies to recruit, hire, train and retain marketing personnel and medical representatives.

Although we are currently focused on establishing internal sales, marketing and commercial distribution capabilities, we may in the future pursue collaborative arrangements regarding the sales and marketing of some of our drug candidates and there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or, if we are able to do so, that they will have effective medical representative team. Relevant part of the revenue we receive will depend on the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties in accordance with local rules and regulations, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We will also face competition in our search for third parties to assist us with the sales and marketing efforts of our drug candidates.

There can be no assurance that we will be able to develop in-house medical representative team and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, especially given the limited experience generally in marketing recently approved drugs in China (including Hong Kong, Macau and Taiwan). As a result, we may not be able to generate product sales revenue.

RISK FACTORS

We have incurred losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

We have no products approved for commercial sale, have not generated any revenue from commercial sales of our drug candidates, and have incurred net losses each year since we commenced operations in 2018. In 2022, 2023 and the four months ended April 30, 2024, our total comprehensive losses were RMB288.9 million, RMB249.5 million and RMB60.3 million, respectively.

We have been devoting the majority of our financial resources and efforts to our R&D activities, including clinical development of our drug candidates. None of our drug candidates have received marketing approval and we may never be successful in obtaining marketing approval and commercializing our drug candidates. We expect to continue to incur expenses and increase operating losses for the foreseeable future. We anticipate that our expenses will increase as we:

- continue our ongoing and planned clinical development of our drug candidates;
- collaborate with WuXi Biologics to strengthen our commercialization capabilities and establish localized manufacturing capabilities;
- seek regulatory approvals for our drug candidates;
- commercialize those of our drug candidates for which we have obtained marketing approval;
- hire additional clinical, operational, financial, quality control and scientific personnel;
- expand our commercialization team for any future products that have obtained regulatory approval; or
- incur additional legal, accounting and other expenses associated with operating as a [REDACTED].

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials of our drug candidates, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering, developing or in-licensing additional drug candidates. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

RISK FACTORS

Because of the numerous risks and uncertainties associated with the development and commercialization of the drug candidates, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our drug candidates, our expenses could increase and profitability could be further delayed.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our Shares and could impair our ability to raise capital, expand our business, maintain our R&D efforts or continue our operations. A decline in the value of our Shares could also cause you to lose part or all of your [REDACTED].

We have net operating cash outflow during the Track Record Period.

We had net cash used in operating activities of RMB246.5 million, RMB271.3 million and RMB46.5 million in 2022, 2023 and the four months ended April 30, 2024, respectively. While we believe we have sufficient working capital to fund our current operations for the next few years, we expect that we will continue to experience net cash outflows from our operating activities for the foreseeable future. If we are unable to maintain adequate working capital, we may default on our payment obligations and may not be able to meet our operating cash and capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations, and prospects.

We will need to obtain funding from time to time to complete the development and any commercialization of our drug candidates, which may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially during the next few years. The development of biopharmaceutical drug candidates is capital intensive. As our drug candidates enter and advance through clinical trials, we will require substantial additional funding to meet our financial needs and to pursue our business objectives.

RISK FACTORS

As of April 30, 2024, we had RMB299.7 million in cash and cash equivalents. We believe that the [REDACTED] from this [REDACTED], together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for the next 12 months. However, we will need to raise additional capital to complete the development and/or commercialization of our drug candidates, lonapegsomatropin for the treatment of PGHD, TransCon CNP (navepegritide) for the treatment of ACH, and palopegteriparatide for the treatment of adult patients with HP, and in connection with our continuing operations and other planned activities. Our future capital requirements will depend on many factors, including:

- the progress, results and costs of laboratory testing, manufacturing, and clinical development for our current drug candidates;
- the scope, progress, results and costs of laboratory testing and clinical trials of other drug candidates that we may pursue;
- the development requirements of other drug candidates that we may pursue;
- the timing and amounts of any milestone or royalty payments we may be required to make under any future license agreements, if we enter into such agreements;
- the costs of expanding our R&D capacities, including hiring additional R&D, clinical, quality control and manufacturing personnel;
- the costs, timing and outcome of regulatory review of our drug candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our drug candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, obtaining, maintaining, protecting and enforcing our intellectual property and proprietary rights and defending against any intellectual property-related claims;
- the costs of operating as a [REDACTED]; and
- the extent to which we acquire or in-license additional drug candidates and technologies.

RISK FACTORS

Identifying potential drug candidates and conducting clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our drug candidates, if approved, may not achieve commercial success. To date, we have no products approved for commercial sale, nor have we generated any revenue from product sales. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish some rights to our drug candidates on terms that are not favorable to us. Any additional capital-raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future drug candidates, if approved. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce or altogether cease our R&D programs or future commercialization efforts.

OTHER RISKS RELATED TO OUR LIMITED OPERATING HISTORY, FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have a limited operating history, no products approved for commercial sale, never generated any revenue and may incur significant losses in the future, which makes it difficult to assess our future viability. The risks involved in our business may cause potential [REDACTED] to lose substantially all of their [REDACTED] in us.

We are a late-stage, near-commercialization biopharmaceutical company. To date, we have focused the majority of our efforts on our R&D activities and, in particular, developing lonapegsomatropin, our Core Product, for the treatment of PGHD, TransCon CNP (navepegritide) for the treatment of ACH, and palopegteriparatide for HP. We have not yet successfully obtained marketing approvals for, manufactured or commercialized our drug candidates. We have no products approved for commercial sale and have not generated any revenue from product sales. We expect that our annual operating expenses may increase over the next several years as we expand our R&D efforts and prepare for commercialization.

Our limited operating history, particularly in light of the rapidly evolving drug development industry in which we operate and the changing environments we encounter, may make it difficult to evaluate our current business and prospects for future performance. As a result, any assessment of our future performance or viability is subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by clinical-stage companies in rapidly evolving fields as we seek to transition into a company capable of supporting commercial activities. If we do not address these risks and difficulties successfully, our business will suffer and may cause potential [REDACTED] to lose substantially all of their [REDACTED] in us.

RISK FACTORS

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

We adopted the Equity Incentive Plan and granted restricted share units to certain employees, directors, consultants and other eligible persons to motivate and reward the eligible persons who had contributed and would continue to contribute to the success of our Company. In 2022, 2023 and the four months ended April 30, 2024, we recorded non-cash share-based payments of RMB93.5 million, RMB(12.3) million and RMB21.7 million, respectively. For further details of the share-based payments, please see the section headed “Financial Information” in this document. To further motivate our employees, directors, consultants and other eligible persons and align their interests with ours, we may grant additional share-based compensation in the future. Expenses incurred with respect to such share-based payments may increase our operating expenses and therefore have an adverse effect on our financial performance. Issuance of additional Shares with respect to such share-based payments may also dilute the shareholding percentage of our existing Shareholders.

Raising additional capital may cause dilution to the interests of our Shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the value of your [REDACTED] 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 in-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 [REDACTED] of our Shares to decline.

In the event we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party our rights to drug candidates, which may include without limitation the exclusive licensed rights in China (including Hong Kong, Macau and Taiwan) that we obtained from Ascendis Pharma and rights to potentially future drug candidates, on unfavorable terms, which we would have otherwise sought to develop or commercialize ourselves or reserve for future potential arrangements when we are more likely to achieve more favorable terms.

RISK FACTORS

OTHER RISKS RELATED TO THE DEVELOPMENT OF OUR DRUG CANDIDATES

Safety issues with the parent drugs or other components of our drug candidates, or with approved products of third parties that are similar to our drug candidates, could give rise to delays in the regulatory approval process.

Our product development portfolio consists of prodrugs that are new molecular entities that incorporate existing parent drug molecules, many of which have been previously approved by the EMA, the FDA or other regulatory authorities. Discovery of previously unknown problems with any of the parent drugs that we use in our drug candidates may result in restrictions on its permissible uses, including withdrawal of the product from the market. Additionally, problems with approved parent drugs marketed by third parties that utilize the same therapeutic target as the parent drug we use in our drug candidates could adversely affect the development of our drug candidates.

Any failure or delay in commencing or completing clinical trials or obtaining regulatory approvals for our drug candidates would delay the commercialization of the drug candidates and severely harm our business and financial condition.

We may not make the best resource allocation decision or collaboration decision to pursue the in-licensed drug candidate or indication with the best commercial potential.

We are currently focusing on the three drug candidates in our pipeline, lonapegsomatropin for PGHD, TransCon CNP (navepegritide) for ACH and palopegteriparatide for HP. As a result, we may forego or delay pursuit of opportunities with other potential drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future R&D programs and drug candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through licensing, royalty or other collaboration arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

Clinical trials are difficult to implement, involve uncertain outcomes and may not be successful and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The initial or interim results of a trial may not be predictive of the final results, and the results from the global trials of a particular drug candidate may not be predictive of the results to be generated from the trials we are conducting or will conduct for the same drug candidate in China (including Hong Kong, Macau and Taiwan). Drug candidates in later stages of clinical trials in China (including Hong Kong, Macau and Taiwan) may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies, initial clinical trials and global clinical trials.

RISK FACTORS

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials conducted by Ascendis Pharma due to various factors, including the difference in clinical practice and various uncertainties in trial conduction. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding positive results in earlier trials. Our future clinical trial results may not be favorable, regardless of earlier results from the global clinical trials conducted by Ascendis Pharma and China clinical trials conducted by us. If so, we would have expended a significant amount of capital to progress the relevant drug candidates to that stage, and would not realize any revenue on such drug candidate if it then ultimately failed to receive regulatory approval due to poor clinical trial results. Such an uncompensated expenditure could materially adversely affect our business, financial condition, results of operations and prospects.

We rely and will continue to rely on investigators and third parties to conduct clinical trials for our drug candidates in China (including Hong Kong, Macau and Taiwan). If we lose our relationships with them or if they do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We have relied on and plan to continue to rely on investigators and third-party CROs to monitor and manage data for our ongoing clinical programs. We rely on these parties for the execution of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of the studies sponsored by us is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the investigators and CROs does not relieve us of our regulatory responsibilities.

We, our investigators and CROs are required to comply with GCP, GLP, and other regulatory regulations and guidelines enforced by the NMPA and comparable regulatory authorities for all of our drug candidates in clinical development. Regulatory authorities enforce these GCP, GLP or other regulatory requirements through periodic inspections of trial sponsors, investigators and trial sites. If we or any of our investigators and CROs fail to comply with applicable GCP, GLP or other regulatory requirements, the relevant data generated in our clinical trials may be deemed unreliable and the NMPA or other comparable regulatory authorities may require us to perform additional clinical studies before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP and GLP requirements. In addition, our clinical trials must be conducted with drug candidates or products produced under GMP requirements. Failure to comply with these regulations may require us to repeat pre-clinical and clinical trials, which would delay the regulatory approval process.

RISK FACTORS

Our CROs have the right to terminate their agreements with us in the event of a material breach that is not substantially cured. If any of our relationships with our third-party CROs is terminated, we may not be able to (i) enter into arrangements with alternative CROs or do so on commercially reasonable terms or (ii) meet our desired clinical development timelines. In addition, there is a natural transition period when a new CRO commences work, and the new CRO may not provide the same type or level of services at the same pace as the original provider and data from our clinical trials may be compromised as a result. There is also a need for relevant technology to be transferred to the new CRO, which may take time and further delay our development timelines.

Except for remedies available to us under our agreements with investigators and third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If our investigators and third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to their 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 approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed and our costs could increase. In turn, our ability to generate revenues could be delayed or compromised.

We rely on third parties to carry out many of our activities, which may lead to uncertainties with respect to the deliverables despite our efforts in managing our third-party vendors. Outsourcing these functions involves certain risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these third parties, which could increase the risk of such information being misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party service providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our investigators and third parties, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

RISK FACTORS

We currently purchase our drug candidates from our collaboration partner, Ascendis Pharma, for clinical development in China and purchase our drug candidates from them for commercial supply in the future. Our business could be harmed if our collaboration partner fails to provide us with sufficient quantities of drug candidates or trial materials or fail to do so at an acceptable quality levels or prices.

We currently purchase our drug candidates from our collaboration partner, Ascendis Pharma, for clinical development in China, and purchase our drug candidates from them for commercial supply of lonapegsomatropin in China before the establishment of local manufacturing capabilities. The current and future supply arrangement may expose us to certain risks, including the following:

- our collaboration partner may have limited capacity or limited manufacturing slots, which may affect the timeline for the production of our drugs;
- they might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- they may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- they may not perform as agreed, may not devote sufficient resources to our drugs, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our drugs;
- they are subject to ongoing periodic unannounced inspections to ensure strict compliance with GMP and other government regulations. We do not have control over their compliance with these regulations and requirements;
- they may be unable to sustain their business and become bankrupt as a result;
- raw materials and components used in the manufacturing process, particularly those for which we or Ascendis Pharma 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;
- products and components from them may be subject to additional customs and import charges, which may cause us to incur delays or additional costs as a result;
- they may be subject to inclement weather, as well as natural or man-made disasters; and
- they may have unacceptable or inconsistent product quality success rates and yields.

RISK FACTORS

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates by the NMPA or other comparable regulatory authorities, result in higher costs or adversely impact the commercialization of our drug candidates. In addition, we may rely on third parties to perform certain specification tests on our product. If these activities are not appropriately done and the data is not reliable, the NMPA or other comparable regulatory authorities could place restrictions on us until deficiencies are remedied.

Manufacturers of biopharmaceutical products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process, including the absence of contamination. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error and availability of qualified personnel, as well as compliance with strictly enforced regulations in the PRC and other applicable jurisdictions. Further, if contaminants are discovered in the supply of our drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time for us to investigate and remedy the contamination. There can be no assurance that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future. Additionally, Ascendis Pharma may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environment. If Ascendis Pharma were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drug candidate would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

We depend on enrollment of patients in our clinical trials for our drug candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical trials of our drug candidates is critical to our success. The timely completion of clinical trials in accordance with the protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the number of patients with the disease or condition being studied;
- the understanding of risks and benefits of the drug candidate in the trial;

RISK FACTORS

- clinicians’ and patients’ perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- the size and nature of the patient population who meet inclusion criteria;
- the proximity of patients to study sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapies;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment.

We may not be successful in developing, acquiring, enhancing or adapting to new technologies and methodologies to enhance the scope and quality of our clinical trials.

We must keep pace with new technologies and methodologies to maintain our competitive position. In 2022, 2023 and the four months ended April 30, 2024, our research and development costs were RMB179.5 million, RMB57.7 million and RMB25.8 million, respectively. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our clinical trials. We also intend to continue to enhance our technical capabilities in product research and discovery, development and manufacturing, which are capital and time-intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may make our techniques obsolete, which could harm our business and prospects.

RISK FACTORS

OTHER RISKS RELATED TO OUR INTELLECTUAL PROPERTY

Patent and other intellectual property litigation may lead to unfavorable publicity which may harm our reputation and cause the [REDACTED] of our Shares to decline, and any unfavorable outcome from such litigation could limit our R&D activities and/or our ability to commercialize our drug candidates.

During the course of any intellectual property litigation involving us or Ascendis Pharma, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or [REDACTED] regard these announcements, or the announcement of the litigation, as negative, the perceived value of our drug candidates, future drugs, programs or intellectual property could be diminished. Accordingly, the [REDACTED] of our Shares may decline. Such announcements could also harm our reputation or the market for our drug candidates, which could have a material adverse effect on our business. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, in-license needed technology, or enter into strategic partnerships that would help us bring our drug candidates to market.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we or Ascendis Pharma do not comply with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on a patent and patent application are due to be paid to the patent offices and agencies in several stages each year lifetime of the patent and patent application. Patent agencies in the PRC and other jurisdictions require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, including for patent rights licensed from Ascendis Pharma, we may be required to rely on our partners to take the necessary action to comply with these requirements with respect to patents or other intellectual property they have licensed to us. While 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 noncompliance, which could include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents, can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Upon such an event, our competitors and other third parties may be able to enter the market and compete with our drug candidates, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

RISK FACTORS

If we are unable to protect the confidentiality of trade secrets and other confidential information, including unpatented know-how upon which we rely, our business and competitive position would be harmed.

In addition to patent rights, we rely on trade secret and other confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them.

However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, courts in some jurisdictions are less willing or unwilling to protect trade secrets. Adequate remedies may not exist in the event of unauthorized use or disclosure of our trade secrets or confidential information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition, results of operations and prospects.

We may be subject to claims that we or our employees have misappropriated the intellectual property, including know-how or trade secrets, of a third party, or claiming ownership of what we regard as our own intellectual property, or are in breach of non-competition or non-solicitation agreements with competitors or other third parties.

Many of our employees were previously employed at or engaged by other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property, including know-how, trade secrets or other proprietary information or are in breach of non-competition or non-solicitation agreements with competitors or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and scientific personnel.

RISK FACTORS

In addition, while we typically require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own and the agreements may be breached or may not be self-executing, which may result in claims by or against us related to the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

The degree of protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and they may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to any drug candidates we may develop or utilize similar technology that are not covered by the claims of the patents that we own or are licensed now or in the future;
- we or our licensors might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or in-license, which could result in the patents applied for not being issued or being invalidated after issuing;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- pending patent applications may not lead to issued patents;
- we may obtain or in-license patents for certain compounds many years before we receive NDA or other approval for drugs containing such compounds, and because patents have a limited life, which may begin to be invalid prior to the commercial sale of the related drugs, the commercial value of our patents may be limited;
- our competitors might conduct R&D activities in jurisdictions where we do not have rights to patents and then use the information learned from such activities to develop competitive drugs for commercialization in our major markets;
- we may fail to develop or acquire rights to additional proprietary technologies that are patentable;

RISK FACTORS

- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate;
- third parties may gain unauthorized access to our intellectual property due to potential lapses in our information systems;
- the patents of others may have an adverse effect on our business, for example by preventing us from commercializing one or more of our drug candidates for one or more indications; 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.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Our registered and unregistered trademarks or trade names are valuable assets and may be challenged, infringed, circumvented or declared generic or determined to infringe a third party's marks. We may not be able to protect our rights to these trademarks and trade names, which may be necessary to build name recognition among potential collaborators 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 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. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In the event that our trademarks or trade names are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and cause substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations and prospects.

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The absence of patent linkage, patent term extension and data and market exclusivity for NMPA-approved pharmaceutical products could increase the risk of early generic competition with our products in China.

The life of a patent and the protection it affords are limited. Even if we in-license valid patents covering our drug candidates, we may still be open to competition once the patent life has expired for a drug. In the United States, competing generic products are prevented from entering the market for a certain period of time after the FDA grants marketing approval for the innovative products in certain circumstances. In China, the latest Patent Law of the PRC and other relevant regulations on drug registration contains provisions on extension of patent terms, linking of patents to products to delay generic entry, and granting of data exclusivity in certain circumstances. However, our competitors may obtain approval of competing products prior to or following our patent expiration, our business, financial condition, results of operations, and prospects could be materially harmed.

OTHER RISKS RELATED TO OBTAINING REGULATORY APPROVAL OF OUR DRUG CANDIDATES AND OTHER LEGAL COMPLIANCE MATTERS

All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated.

All jurisdictions in which we intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We intend to focus our activities on China (including Hong Kong, Macau and Taiwan). These jurisdictions strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like ours that plans to operate in these regions.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process and approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include 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, disgorgement of profits, or other civil or criminal penalties. Changes in government regulations or in practices relating to the pharmaceutical and biopharmaceutical industries, including healthcare reform in China, and compliance with new regulations may result in additional costs. Failure to comply with these regulations could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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Even if we obtain regulatory approval for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.

If the NMPA or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion and record-keeping for the drug will be subject to extensive and ongoing regulatory requirements on pharmacovigilance. These requirements include submissions of safety and other post-marketing information and reports, registration, random quality control testing, adherence to any CMC specifications, continued compliance with current GMPs, and GCPs and potential post-approval studies for the purposes of license renewal.

Even if a drug candidate were to successfully obtain marketing approval from the NMPA or other comparable regulatory authorities in other jurisdictions, any approval might contain significant limitations related to use restrictions for specified indications, specified age groups, warnings, precautions, distribution or contraindications, may be subject to burdensome and costly post-approval trials, risk management requirements or other post-marketing commitments, or may be subject to requirement of a liable that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. If we are unable to obtain regulatory approval for one of our drug candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenue attributable to that drug candidate. Also, any regulatory approval of our current or future drug candidates, even if obtained, may be withdrawn.

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

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on our clinical trials;
- refusal by the NMPA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us;
- suspension or revocation of existing approvals;
- refusal by the NMPA or comparable regulatory authorities to accept any of our other IND approvals, BLAs and/or NDAs;

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

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could significantly harm our business, financial condition, results of operations and prospects.

Our employees, management, Directors, principal investigators and consultants may engage in misconduct or other improper activities, including bribery, money laundering, corrupt practices, or noncompliance with regulatory standards and requirements.

We are subject to anti-bribery, anti-corruption and anti-money laundering laws in China and other applicable jurisdictions. As our business expands, the applicability of these laws to our operations has increased. We could be liable for actions taken by our employees, management or Directors that violate anti-bribery, anti-corruption, anti-money laundering or other related laws and regulations in China and other applicable jurisdictions. We may be subject to claims, fines, or suspension of our operations. Our reputation, our future commercial activities or the price of our Shares could be adversely affected if our Company is associated with any negative publicity as a result of illegal or improper actions, or allegations of illegal or improper actions, taken by our employees, management or Directors.

We are also exposed to the risk of employee, management, Directors and third-party fraud or other misconduct or failure to comply with applicable regulatory requirements. Misconduct by employees could include failures to comply with regulations of the NMPA and other comparable regulatory authorities, to provide accurate information to such regulators, to comply with manufacturing standards we have established, to comply with healthcare fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

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Legal, regulatory and administrative proceedings against any of our employees, management, Directors, independent contractors, commercial partners and vendors, even if they do not involve our Company, may have a material adverse effect on our reputation, business prospects and financial results. For example, Dr. YAO Zhengbin is our independent non-executive Director. Dr. Yao, in his capacity as the then chairman/chief executive officer/president of Viela Bio, Inc. (“Viela”, Nasdaq: VIE), along with each of the former board members of Viela, one of Viela’s large shareholders and others, was named as a co-defendant in a class action initiated in February 2023 by certain former shareholders of Viela which alleges various breaches of fiduciary duties in connection with the purchase of all outstanding shares of Viela by Horizon Therapeutics PLC (Nasdaq: HZNP). As of the latest Practicable Date, the case was dismissed with prejudice by the Court of Chancery of the State of Delaware. Such former shareholders of Viela have appealed the decision to the Delaware Supreme Court, where the case is currently pending.

It is not always possible to identify and deter employee, management or Directors misconduct, and any precautions we take to detect and prevent improper activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with relevant laws. If any such actions are initiated against us, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement of profits, imprisonment, possible exclusion from participation in government supported healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to anti-bribery laws in China and other applicable jurisdictions that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Although we have policy and procedures designed to ensure that we, our employees and our business partners comply with anti-bribery laws, there is no assurance that such policy and procedures will prevent our business partners, employees and intermediaries from engaging in bribery activities. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and exclusion from participation in government supported healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential

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personnel changes and disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

Any failure to comply with applicable regulations and industry standards or obtain various licenses and permits could harm our reputation and our business, results of operations and prospects. Additionally, our and/or others' failure to obtain or renew certain approvals, licenses, permits and certificates required for our business may materially and adversely affect our business, financial condition and results of operations.

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

Pursuant to the relevant laws, regulations and relevant regulatory practice by governmental agencies, we and/or other parties related to our operations, such as landlords or managers of premises on or local industrial parks in which we operate, are required to obtain and maintain various approvals, licenses, permits and certificates from relevant authorities so that we can operate our business. Some of these approvals, permits, licenses and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain 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 causing operations to cease, and may include corrective measures requiring capital expenditure or remedial actions, which in the future could materially and adversely affect our business, financial condition and results of operations. There is also no assurance that the relevant authorities would not take any enforcement action against us. In the event that such enforcement action is taken, our business operations could be materially and adversely disrupted.

Furthermore, if the interpretation or implementation of existing laws and regulations changes, or new regulations come into effect requiring us and/or other such relevant parties to obtain any additional approvals, permits, licenses or certificates that were previously not required to operate our existing businesses, we cannot assure you that we and/or other such relevant parties will successfully obtain such approvals, permits, licenses or certificates. Our or these parties' failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, decrease our revenues and/or increase our costs, which could materially reduce our profitability and prospects.

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Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, limit their use or adoption, and otherwise negatively affect our operating results and business.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving. Regulatory authorities in China have implemented a number of legislative and regulatory proposals concerning data protection. For example, the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》), which became effective in June 2017, created China’s first national-level data protection for “network operators,” which may include all organizations in China that provide services over the internet or another information network. On July 7, 2022, the CAC released the Measures on Security Assessment of Cross-border Data Transfer (數據出境安全評估辦法) (the “Data Export Measures”), which came into effect on September 1, 2022. The Data Export Measures require that any data processor provide abroad any important data collected and generated in their business operation within the territory of the PRC and any personal information for which security assessment is required shall apply for security assessment by the national cyberspace administration authorities before transferring any such important data or personal information abroad. The security assessment requirement also applies to any transfer of important data outside of China. In addition, certain industry-specific laws and regulations govern the collection and transfer of personal data in China. For example, the Regulations on the Administration of Human Genetic Resources (《人類遺傳資源管理條例》), promulgated by the State Council in May 2019 and became effective in July 2019, require approval from or filing with the Ministry of Science and Technology of the People’s Republic of China where human genetic resources (“HGR”) are involved in any international collaborative project and additional approval or filing procedures for any export or cross-border transfer of HGR samples or associated data. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, potentially resulting in confiscation of HGR samples and associated data and administrative fines. In addition, the interpretation and application of data protection laws in China and elsewhere are often uncertain and in flux. Further, the Biosecurity Law of the PRC (《中華人民共和國生物安全法》), which was enacted on October 17, 2020 and became effective on April 15, 2021, aims to strengthen the administration and supervision of the collection, preservation, utilization and external provision of HGR and biological resources in China so as to safeguard the security of HGR and biological resources.

On June 10, 2021, the Standing Committee of the NPC 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 on September 1, 2021. The Data Security Law mainly sets forth specific provisions regarding establishing basic systems for data security management, including graded data classification management system, risk assessment system, monitoring and early warning system, and emergency disposal system. In addition, it clarifies the data security protection obligations of organizations and individuals carrying out data processing activities and implements data security protection responsibilities. On August 20, 2021, the Standing Committee of the NPC promulgated the Personal Information Protection Law of the PRC (《中

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華人民共和國個人信息保護法》) (the “PIPL”) which came into effect in November 2021. In addition to other rules and principles of personal information processing, the PIPL specifically provides rules for processing sensitive personal information. Sensitive personal information refers to such personal information that, once leaked or illegally used, may easily lead to the infringement of human dignity of a natural person or may endanger such person’s personal safety or property, including information such as biometrics, religious belief, specific identity, medical health status, financial accounts, personal location and other information of a natural person, as well as any personal information of a minor under the age of 14. Only where there is a specific purpose and sufficient necessity, and under circumstances where strict protection measures are taken, may personal information processors process sensitive personal information. A personal information processor shall inform the individual of, in addition to other matters prescribed by the PIPL, the necessity of processing such sensitive personal information and the impact thereof on the individual’s rights and interests. We may store and process sensitive personal information of our employees. If there are any changes regarding the interpretation and implementation of the PIPL, we cannot assure you that we will comply with the PIPL in all respects, and regulatory authorities may order us to rectify or terminate our current practice of collecting and processing sensitive personal information. We may also become subject to fines and/or other penalties which may have material adverse effect on our business, operations and financial condition.

Despite our currently in place policies, standard operating procedures and in-house trainings with respect to cyber security, data security and personal data protection, we expect that we will continue to face uncertainty as to whether our efforts to comply with evolving obligations under global data protection, privacy and security laws will be sufficient. Any failure or perceived failure by us to comply with applicable laws and regulations could result in reputational damage or proceedings or actions against us by governmental entities, individuals or others. These proceedings or actions could subject us to significant civil or criminal penalties and negative publicity, result in the delayed or halted transfer or confiscation of certain personal information, require us to change our business practices, increase our costs and materially harm our business, prospects, financial condition and results of operations. In addition, our current and future relationships with customers, vendors, pharmaceutical partners and other third parties could be negatively affected by any proceedings or actions against us or current or future data protection obligations imposed on them under applicable law. In addition, a data breach affecting personal information, including health information, could result in significant legal and financial exposure and reputational damage that could potentially have an adverse effect on our business. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

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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 took effect on February 15, 2022. Pursuant to Article 2 of the Cyber Review Measures, critical information infrastructure operators purchasing internet products and services and online platform operators engaging in data processing activities, which affect or may affect national security, shall be subject to the cybersecurity review. Pursuant to the Cyber Review Measures, an online platform operator which possesses personal information of over one million users and intends to “list in a foreign country (國外上市)” shall be subject to cybersecurity review. For more details, see “Regulatory Environment – Other Significant Regulations of the PRC Affecting Our Business – Information Security and Privacy Protection.” 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 processing 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 Adviser is of the view that it is unlikely that we would be determined or identified as a critical information infrastructure operator as long as there is no material change to the current PRC legal system and regulatory framework in terms of cyber security and data security and the Group’s current business, and thus we have no obligation to proactively apply for cybersecurity review under the Cyber Review Measures.

However, the Cyber Review Measures provides no further explanation or interpretation for “online platform operator”, and does not stipulate that an online 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 in a foreign country” and Hong Kong is not a country or region outside of the PRC, our PRC Legal Adviser 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.

However, 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 processing 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

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products, services or data processing 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, stipulates 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, 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.”

As advised by our PRC Legal Adviser, the PRC Governmental Authorities may have wide discretion in the interpretation of “affect or may affect national security.” Further, 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 face allegations of non-compliance with laws and encounter sanctions, our reputation, revenues and liquidity may suffer, and our drug candidates and future products could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of laws could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from our drug candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our Company and our operating results will be adversely affected. Additionally, if we are unable to generate revenues from our product sales, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines, penalties or damages 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.

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So far, our operations have not produced any hazardous waste products, however we may produce or be in connection with these materials in the future and we may not be able to eliminate the risk of contamination or injury from these materials. We could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations and any harms or damages resulting therefrom. In addition, pursuant to applicable PRC laws and regulations, if we do not complete all required approval, filings, and related procedures in connection with fire prevention, environmental protection, construction and safety production in a timely manner, we could be subject to investigations, suspension of operations, fines and other administrative penalties by competent authorities.

Furthermore, we are subject to numerous international, national, municipal and local environmental, health and safety laws and regulations relating to, among other matters, safe working conditions, product stewardship and environmental protection. However, environmental, health and safety laws and regulations have tended to become increasingly stringent and, to the extent regulatory changes occur in the future, they could result in, among other things, increased costs to our Company.

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

We are subject to changing law and regulations regarding regulatory matters, corporate governance and public disclosure that have increased both our costs and the risk of non-compliance.

We are or will be subject to rules and regulations by various governing bodies, including, for example, once we have become a [REDACTED], the Stock Exchange and the SFC, which are charged with the protection of [REDACTED] and the oversight of companies whose securities are publicly traded, as well as the various regulatory authorities in China and the Cayman Islands, and to new and evolving regulatory measures under applicable law. Our efforts to comply with new and changing laws and regulations have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Moreover, because these laws, regulations and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these regulations and any subsequent changes, we may be subject to penalties and our business may be harmed.

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We are subject to changing law and regulations regarding advertising and promotion of pharmaceutical products, and the increasing use of social media platforms presents new risks and challenges of non-compliance with regulations applicable to our business.

Drug advertisements are subject to strict content restrictions, which prohibit recommendations by doctors and hospitals and guarantees of effectiveness. Advertising that includes content that is outside of the drug's approval documentation, off-label content, is prohibited. False advertising can result in civil suits from end users and administrative liability, including fines. In addition to advertisements, non-promotional websites that convey information about a drug must go through a separate approval process by a local drug regulatory authority.

Social media are increasingly being used to communicate about the diseases that our drug candidates are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of non-compliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged AE. In order to collect potential AEs reported via social media, we intends to set up a program, which involves review of user generated content, such as comments posted on message boards, social media channels, or blogs. Nevertheless, when such an incident occurs, there is a risk that we fail to monitor and comply with applicable reporting obligations or we may not be able to defend our own or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our drug candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. While we are not aware of any such events, if any of these events occur in the future or we otherwise fail to comply with applicable regulations, we may incur liability, face overly restrictive regulatory actions or incur other harm to our business.

OTHER RISKS RELATED TO MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES

Coverage and adequate reimbursement may not be available for our current or any future drug candidates which could make it difficult for us to sell profitably, if approved. Even if reimbursement is available, we may need to significantly concede on prices for our future approved drugs in China and face uncertainty of profitability.

Our ability to commercialize any drug candidates successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by

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limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement in China or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Even if favorable coverage and reimbursement status is attained for one or more drug candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. As the regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from jurisdiction to jurisdiction, we might obtain regulatory approval for a drug candidate in a particular jurisdiction, but then be subject to price regulations that delay our commercial launch of the same drug candidate and reduce the revenues we are able to generate from the sale of the drug candidate in that jurisdictions. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future drug candidates that we develop.

Additionally, there may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the approved indications. 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 not be made permanent. 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 lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any weakening of laws that restrict imports of drugs from countries where they may be sold at lower prices than in the markets we address. Inability to promptly obtain coverage and profitable payment rates from both government-funded healthcare programs and private payors for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

In China, the National Healthcare Security Administration, the Ministry of Human Resources and Social Security of the PRC (the “MHRSS”) or provincial or local human resources and social security authorities, together with other Governmental Authorities, review the inclusion or removal of drugs from the China’s National Drug Catalogue for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, the NRDL, or provincial or local medical insurance catalogues for the PRDL, regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. There can be no assurance that any of our future approved drug candidates will be included in the NRDL or the PRDL. If we were to successfully launch commercial sales of our products in China but fail in our efforts to have our products included in the NRDL or PRDL, our revenue from commercial sales in China will be highly dependent

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on patient self-payment or private insurance coverage, which can make our products less competitive. Additionally, even if the MHRSS or any of its local counterparts and other Governmental Authorities accept our application for the inclusion of products in the NRDL or PRDL, our potential revenue from the sales of these products in China could still decrease as a result of changes in pricing regulations that could potentially restrict or significantly lower the prices we are able to charge for our products to be included in the NRDL or PRDL.

The manufacture of biopharmaceutical products is a complex process which requires significant expertise and capital investment. We may not be able to successfully establish collaboration with local CDMO as planned or develop our own manufacturing infrastructure for supply of our requirements of our drug candidates for commercial sale.

We plan to establish localized manufacturing capabilities for lonapegsomatropin in China to address the vast domestic market potentials in China (including Hong Kong, Macau and Taiwan) effectively and secure sustainable drug supply for local patients. In the short term, we plan to source the commercial drug supply from our collaboration partner, Ascendis Pharma. We have successfully reached a commercial supply agreement for the commercial supply of the Core Product by Ascendis Pharma in October 2023. Please refer to “Connected Transactions” for more details. In the medium term, we intend to collaborate with WuXi Biologics, our designated local CDMO in China, for the commercial production of lonapegsomatropin. In July 2023, we entered into the Technology Transfer Master Plan of the Core Product with Ascendis Pharma, signifying the commencement of Technology Transfer from Ascendis Pharma to us for the manufacturing of the Core Product. In December 2023, we entered into a collaboration agreement with the WuXi Biologics, pursuant to which WuXi Biologics will serve as the local CDMO of the Technology Transfer to conduct the process development and validation achieving the localization of the manufacturing technology. Completion of the Technology Transfer and Localization, which is expected to be in 2026, will confer to us the technical capabilities to manufacture the Core Product drug substance in collaboration with WuXi Biologics. We are also developing the DCD technology in the form of prefilled syringe as a drug delivery system for the Core Product drug substance. Once this development is finished, WuXi Biologics will have the capability to produce the Core Product. For more information regarding the DCD, please refer to “Business – Research and Development – CMC Development Programs – Dual Chamber Device Technology Development.” The commercialization of the Core Product produced by WuXi Biologics will start once we obtain the approval of Local BLA, which is expected to occur in 2028. We expect to procure the Core Product from Ascendis Pharma for the commercial supply until 2028 following our anticipated commercialization in 2025. In the long term, we plan to establish our in-house manufacturing capabilities.

However, we have limited experience as a company in designing and operating a commercial manufacturing facility and may never be successful in developing new manufacturing capability either on our own or together with a third-party on a commercial scale. If our technology transfer from Ascendis Pharma in connection with CMC is delayed, our efforts in collaborating with the designated local CDMO establishing manufacturing and commercialization capacity may also be delayed. In terms of cooperation with local CDMO,

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the designated local CDMO might be unable to timely set up the capabilities necessary for the manufacture and delivery of our drug candidates. Also, our designated local CDMO might face issues (including problems with manufacturing, supply chain, infringement, compliance with GMP and capacity) or failure to comply with relevant laws and regulations in the future, which may have an adverse impact on us. In addition, the investment for building our in-house manufacturing facilities in the future may also be a significant upfront cost for us. In turn, this could materially harm our commercialization plans. If construction or regulatory approval of our manufacturing facilities is delayed, we may not be able to manufacture sufficient quantities of our drug candidates, which would limit our development activities and our opportunities for growth.

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 related to the construction of new facilities or expansion of any future manufacturing facilities, including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, increases in the prices of raw materials, physical limitations that could inhibit continuous supply, man-made or natural disasters, environmental factors or other factors that may be beyond our control. If problems arise during the production of a batch of future products, that batch of future products may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before such product is released to the market, recall and product liability costs may also be incurred. We may also from time to time optimize our method of manufacturing, including CMC processes, and such changes carry the risk that they will not achieve intended objectives. Any of these changes could cause our drug candidates to perform differently and affect the results of future clinical trials conducted with the altered materials manufactured in-house. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our drug candidates and jeopardize our ability to commercialize our drug candidates and generate revenue. Even if we are successful, the manufacturing operations could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors which may be beyond our control, or we may not be successful in establishing sufficient capacity to produce our drug candidates in sufficient quantities to meet the requirements for the potential launch or to meet potential future demand, all of which could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

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As we may in the future establish in-house manufacturing facilities, delays in completing and receiving regulatory approvals for such facilities could delay our development plans or commercialization efforts, which could harm our business.

In the future, we may establish our in-house manufacturing facilities, such facilities will be subject to ongoing, periodic inspection by various regulatory authorities, including the FDA, the EMA, the NMPA or other comparable regulatory agencies to ensure compliance with GMP. Our failure to follow and document our adherence to such GMP or other regulatory requirements may lead to significant delays in the availability of products for clinical or, if approved, commercial use, and may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or the commercialization of our drugs, if approved. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet FDA, EMA, NMPA, or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with GMP and other requirements of the FDA, EMA, NMPA, or other comparable regulatory agencies.

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, suspension of or halt on one or more of our clinical trials, failure to receive from regulatory authorities marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures, or recalls of our drug candidates, operating restrictions and civil or criminal prosecutions, any of which could harm our business.

We may not be successful in achieving cost of goods at commercial scale that provides for an attractive margin.

We have entered into the Technology Transfer Master Plan of lonapegsomatropin with Ascendis Pharma in July 2023 which outlines the implementation plan to transfer the manufacturing technology of lonapegsomatropin from Ascendis Pharma to our Company. Completion of the Technology Transfer and Localization, which is expected to be in 2026, will confer us the technical capabilities to manufacture the lonapegsomatropin drug substance in collaboration with WuXi Biologics. We expect the transitioning of our supply chain to local production will enable us to better control the quality and consistency of the supply of our drug candidates and improve the certainty and cost-effectiveness of production. However, we make no guarantee that we can successfully obtain necessary drug manufacturing licenses or establish a manufacturing capacity at sufficient commercial scale or at all. Local production of drug products will be subject to standards and requirements by various regulatory authorities, including the FDA, the EMA, the NMPA or other comparable regulatory agencies to ensure

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compliance with GMP. We may underestimate the cost and time required to establish the manufacturing facility, or overestimate cost reductions from economies of scale that can be realized with our manufacturing processes. We may not be able to ultimately manage the cost of goods for our drug candidates to levels that will allow for a margin in line with our expectations and return on investment if and when those drug candidates are commercialized.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our drug candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any drug candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

While we maintain clinical trial insurance, which covers certain bodily injury or damage in connection with our clinical trials for our drug candidates, our insurance coverage may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our drug candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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The incidence and prevalence for target patient populations of our drug candidates are based on estimates and third-party sources. If the market opportunities for our drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

We currently focus our drug development on drug candidates for the treatment of endocrine diseases in China (including Hong Kong, Macau and Taiwan). Our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our drug candidates. Our estimates of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and analyses. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the diseases we are targeting. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our drug candidates may be limited or may not be receptive to treatment with our drug candidates, and new patients may become increasingly difficult to identify or access. If the market opportunities for our drug candidates are smaller than we estimate, we may not be able to achieve our forecasted revenue, which could hinder our business plan and adversely affect our business and results of operations.

RISKS RELATED TO OUR BUSINESS OPERATIONS

Changing PRC regulatory framework on overseas approved products may have negative impact on companies adopting in-licensing business model.

The drug market is heavily regulated in China. Changes in government regulations or in practices relating to the pharmaceutical and biopharmaceutical industries, such as a relaxation in regulatory requirements, or the introduction of simplified approval procedures which will lower the entry barrier for potential competitors, or an increase in regulatory requirements which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations and prospects. In particular, under current PRC regulatory requirements, to introduce a drug approved overseas to the China market, the drug must repeat a registrational study in China that is either a fully powered study or a bridging study. By engaging us, foreign pharmaceutical or biopharmaceutical companies will be able to conduct a parallel registrational study in China or a global study that includes China, thereby substantially reducing the time and cost required to introduce drugs to the China market. If China streamlines, expedites or simplifies such regulatory procedures, foreign pharmaceutical or biopharmaceutical companies' demand for collaboration partnerships with local partners with an in-licensing business model like us may decrease, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

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We may be unable to attract and retain senior management and retain qualified and highly skilled employees especially R&D and clinical related staff.

We are highly dependent on the expertise of our senior management as well as our other key employees. Although we have entered into employment agreements with all of our executive officers, each of them may terminate their employment with us at any time with 30 days' prior written notice.

Recruiting and retaining qualified management, scientific, clinical, manufacturing and medical personnel will also be critical to our success. Loss of the services of our executive officers or other key employees could impede the achievement of our research, development, manufacturing and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Further, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, especially given the R&D climate for innovative medicines in China, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous biopharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities, research institutions and hospitals. In addition, our management will be required to devote significant time to new compliance initiatives after we become a [REDACTED], which may require us to recruit more management personnel.

Our business and reputation may be adversely affected by negative publicity involving us, our Shareholders, Directors, officers, employees, suppliers or other third parties that we work with or rely on. Our ability to maintain our reputation is critical to the success of our business, and the failure to do so may materially and adversely affect our business and the value of our Shares.

Our reputation is a valuable component of our business. We, our Shareholders, Directors, officers, employees, partners, or other third parties we cooperate with or rely on may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our employees, partners or other third parties we work with or rely on were non-compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity that may or may not directly related to us, and may not be able to diffuse them to the satisfaction of our current or future [REDACTED], customers, patients and business partners. Any negative publicity and allegations regarding our clinical trials, operations, Shareholders, Directors, officers, employees or partners, with or without merit, may result in a material adverse impact on our operations, prospects and Shares.

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We may not realize the benefits of existing and future collaborations, strategic alliances or licensing arrangements, and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future.

We have entered into exclusive license agreements with Ascendis Pharma with respect to our current drug candidates. We may form or seek additional alliances, create joint ventures or collaborations or enter into additional licensing agreements with third parties in the future that we believe will complement or augment our development and commercialization efforts with respect to our existing and potential future drug candidates. Any of these relationships may require us to incur recurring or non-recurring expenses and other charges, increase our near and long-term expenditures, issue securities that dilute the value of our Shares, or disrupt our management and business.

We may face significant competition in seeking appropriate strategic partners and the negotiation process can be time-consuming and complex. Moreover, we may not be successful in our efforts to establish strategic partnerships or other arrangements for our current and future drug candidates for various reasons, including that we may not have the necessary expertise or resources for the partner to grant us the rights we are seeking, whether related to a new or existing drug candidate we are developing. If and when we collaborate with a third-party for the development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third-party.

Further, collaborations involving our drug candidates are subject to specific risks, such as:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue the development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus, changes in their pricing strategy, availability of funding, or other factors, such as a business combination or change of control that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, discontinue a clinical trial, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drug candidates or future drugs;
- collaborators with development, marketing and distribution rights to one or more of our drug candidates or future drugs may not commit sufficient resources to these activities;

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- collaborators may not properly maintain, enforce or defend our owned or in-licensed 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 such intellectual property or other proprietary information or expose us to potential liability;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability;
- collaborators may not always be cooperative or responsive in providing their services in a clinical trial;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators may enter into change of control and other transactions, which may divert the attention of their management from ordinary operating matters and disrupt their business related to our drug candidates;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates;
- the collaboration may result in increased operating expenses or the assumption of indebtedness or contingent liabilities; and
- collaborators may own or co-own intellectual property covering our drug candidates or future drugs that results from us collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements, license agreements or other strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate these agreements or partnerships with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business.

We also cannot be certain that, following a collaboration, license or other strategic transaction, we will be able to achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any medical activities in

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accordance with local rules and regulations, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on a timely basis, on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations and prospects.

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

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

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

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

An occurrence of a natural disaster, widespread health epidemic or other outbreaks could have a material adverse effect on our business, financial condition and results of operations.

Our business could be materially and adversely affected by natural disasters, such as snowstorms, earthquakes, fires or floods, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, SARS, Ebola, Zika, COVID-19 or other events, such as wars, acts of terrorism, environmental accidents, power shortage or communication interruptions. The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments in China or elsewhere in the world could materially disrupt our business and operations.

For example, there has been an outbreak of COVID-19. The disease quickly spread globally and materially and adversely affected the global economy. The outbreak and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses: supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked. Our patient enrollment was temporarily put on hold for a few months during the clinical trial sites lockdown as a result of COVID-19. Although we quickly resumed patient enrollment and brought our patient enrollment plan back on track after the spread of COVID-19 was contained in China without any early termination or suspension of our clinical trials, there is no guarantee that we would not in the future experience disruptions that could severely impact our business and clinical trials for our current and future drug candidates.

Securities litigation or other litigation against Ascendis Pharma or other collaboration partners could cause substantial damages to them and may impact our collaboration.

All of our current drug candidates are in-licensed from Ascendis Pharma, a company listed on the Nasdaq Stock Market in the United States. Public companies, especially those in the United States, often face securities class action litigation for alleged material misstatements and omissions relating to public disclosure following a decline in the share price of their securities. From time to time, Ascendis Pharma or our future public company collaboration partners may be targets of such litigations. The outcome of such litigations is necessarily uncertain and any of Ascendis Pharma and our future collaboration partners may have to pay substantial monetary damages in relation to such lawsuits. In the extreme scenario where any of our collaboration partners becomes insolvent and faces liquidation as a result of the lawsuits against them, its business and collaboration with us may be negatively affected.

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We will need to increase the size and capabilities of our organization, and we may experience difficulties in managing our growth.

As of the Latest Practicable Date, we employed a total of 59 full-time employees. As our development and commercialization plans and strategies to expand and develop, and as we transition into operating as a [REDACTED], we expect to need additional managerial, operational, financial and other personnel, including personnel to support our product development and planned future commercialization efforts. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal product development efforts effectively, including the clinical and NMPA, review processes for our drug candidates; and
- improving our operational, financial and management controls, reporting systems and procedures.

There are a small number of individuals with experience in endocrine therapies and the competition for these individuals is high. Our future financial performance and our ability to commercialize our drug candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees, we may not be able to successfully implement the tasks necessary to further develop and commercialize our drug candidates and, accordingly, may not achieve our research, development and commercialization goals.

In addition to expanding our organization, we are increasing the size of our facilities and building out our development and manufacturing capabilities through collaborating with the designated local CDMO, which requires significant capital expenditures and technology. If these capital expenditures are higher than expected, it may adversely affect our financial condition and capital resources. In addition, if the increase in the size of our facilities is delayed, it may limit our ability to rapidly expand the size of our organization in order to meet our corporate goals.

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We may in the future be subject to disputes, legal proceedings or arbitration claims in the ordinary course of our business, and the court ruling or arbitration award may not be favorable to us.

We are subject to a variety of dispute risks, including, but not limited to, license agreement disputes, personal-injury claims, environmental claims, employee allegations of improper termination, land and property rights disputes. Such claims may increase our cost of operations and adversely affect our profitability, and may therefore limit the funds available to us for our business operations, which in turn could adversely affect our operating results and negative impact our brand image. In some instances, we may elect or be forced to pay substantial damages if we are unsuccessful in our efforts to defend against these disputes, which could harm our business.

For example, in connection with our prior plan to build our in-house manufacturing capabilities, we entered into a Supervision Agreement on Investment and Development (蘇州工業園區投資發展監管協議) (the “Supervision Agreement”) with the Suzhou Industrial Park Administration Committee in December 2021, and a State-owned Construction Land Use Right Transfer Agreement (國有建設用地使用權出讓合同) (the “Land Use Right Transfer Agreement”, together with the Supervision Agreement, collectively as the “Land Related Agreements”) with the Suzhou Industrial Park Planning and Construction Committee in January 2022. Pursuant to the foregoing agreements, we made payment of RMB9.2 million (including the land deposit of RMB1.8 million) and acquired land use rights of approximately 25,000 square meters in Suzhou and the terms of such land use rights are 30 years. In light of the challenging fundraising environment, and considering the potential capital needs to build an in-house factory, we decided to adjust our commercial supply strategy by initially establishing local production capacity through cooperation with WuXi Biologics, the local CDMO in China, which would be faster and require less upfront capital investment than building an in-house manufacturing facility. By doing so, we can realize local production earlier while substantially reducing the initial capital investment. As such, on November 2, 2023, we exercised the termination right under the Land Use Right Transfer Agreement and submitted an application of land return with relevant governmental authorities of Suzhou Industrial Park, requesting the termination of the Land Related Agreements and returning of the land use rights to Suzhou Industrial Park Administration Committee. In relation to the land return, upon approval of land return by relevant governmental authorities, we may incur a termination loss of approximately RMB1.8 million due to the non-refundable nature of the land deposit, and after communication, we have been informed by the relevant governmental authorities that land reclamation is needed to get the approval of land return. In relation to the land reclamation, we expect that we may incur an estimated cost of approximately RMB13.6 million based on the assessment of land reclamation work as of the Latest Practicable Date and that the relevant work is expected to be completed by the end of 2024. In July 2024, we entered into a construction agreement with a vendor for land reclamation, setting a tentative completion deadline of December 2024. As of the Latest Practicable Date, the land reclamation project was on track. We cannot assure you that we will not incur additional costs in relation

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to the land reclamation. We have not made provision in relation to the land reclamation cost during the Track Record Period and up to the Latest Practicable Date. We cannot assure you that we will not become subject to disputes, claims or legal proceedings in relation to the foregoing land return matter.

The results of any potential disputes, litigation, investigations and legal proceedings are inherently unpredictable and expensive. Any claims against us, whether meritorious or not, could be time consuming, costly, and harmful to our reputation, and could require significant amounts of management time and corporate resources. If any of these legal proceedings were to be determined adversely to us, or we were to enter into a settlement arrangement, we could be exposed to monetary damages or be forced to change the way in which we operate our business, which could have a material and adverse effect on our business, financial condition, and operating results.

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

We maintain insurance policies that are required under PRC laws and regulations as well as insurance based on our assessment of our operational needs and industry practice. We also maintain clinical trial insurance in all the regions where we conduct clinical trials. In line with industry practice in the PRC, we have elected not to maintain certain types of insurances, such as business interruption insurance or key-man insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in us incurring substantial costs and a diversion of resources.

Our internal information technology systems, or those of our CROs or third-party vendors, may fail or suffer security breaches or other unauthorized or improper access, which could result in a significant disruption of our product development programs, give rise to significant liability, subject us to costly and protracted litigation, compromise sensitive information related to our business, cause significant reputational harm and impact our ability to operate our business effectively.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information (including but not limited to intellectual property, proprietary business information, and sensitive and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information.

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Despite our efforts, our internal information technology systems and those of our current and any future third-party vendors and collaborators may be vulnerable to a variety of disruptive elements, including data breaches, cyber-attacks by malicious third parties (including the deployment of computer viruses, harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), unauthorized access, natural disasters, fires, terrorism, war, telecommunication and electrical failures and breaches or disruptions caused by persons with access to systems inside our organization. In particular, the risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. Because the techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates or terrorist organizations, we and our partners may be unable to anticipate these techniques or implement adequate preventative measures.

While we have not experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or a loss of, or damage to, our data or applications, or those of our third-party vendors, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other confidential, personal or proprietary information, significant delays or setbacks in our research, or other similar disruptions. For example, the loss of clinical trial data from our ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential, personal or proprietary information, we could incur significant liability, our competitive position could be harmed, our reputation could be damaged, and the further development and commercialization of our drug candidates could be delayed.

Unauthorized disclosure of sensitive or confidential data, including personal information, whether through a breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, significant liabilities (including under applicable data privacy and security laws and regulations), damage to our reputation and/or enforcement actions against us. For example, competent authorities could compel us to comply with China's cybersecurity and data protection laws and analogous laws of other jurisdictions, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. The costs related to significant security breaches or disruptions could be material. If the information technology systems of our third-party vendors and other collaborators become subject to disruptions or security breaches, we may be exposed to material liability and have insufficient recourse against such third parties and we may have

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to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. The financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we may maintain, and there can be no assurance that the limitations of liability in any of our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

A severe or prolonged downturn in the global economy could materially and adversely affect our business and financial condition.

The global macroeconomic environment is facing numerous challenges. In particular, there is significant uncertainty about the future relationship between the United States and its major trading partners, including China, with respect to trade policies, treaties, government regulations and tariffs. The growth rate of the Chinese economy has generally been slowing since 2012 and the trend may continue. There is considerable uncertainty over the long-term effects of the expansionary monetary and fiscal policies adopted by the central banks and financial authorities of some of the world's leading economies, including the United States and China. There have been concerns over unrest and terrorist threats in the Middle East, Europe and Africa, which have resulted in market volatility. There have also been concerns on the relationship between China and other countries, including the surrounding Asian countries, which may potentially have economic effects. Economic conditions in China are sensitive to global economic conditions, as well as changes in domestic economic and political policies and the expected or perceived overall economic growth rate in China. Any severe or prolonged slowdown in the global or Chinese economy may materially and adversely affect our business, results of operations and financial condition.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our vendors and suppliers, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions or other factors that may be beyond our control, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We currently rely on Ascendis Pharma to produce and supply all of our drug candidates for clinical development and commercial supply in the short term and our ability to obtain clinical and commercial supplies of our drug candidates could be disrupted if the operations of Ascendis Pharma are affected by any business interruption.

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

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain NMPA or other regulatory authority approval for any of our drug candidates and begin commercializing those products in China, our operations may be subject to various PRC fraud and abuse laws, including, without limitation, the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》), the Criminal Law of the PRC (《中華人民共和國刑法》). These laws may impact, among other things, our proposed commercialization programs. In addition, we may be subject to patient privacy laws and requirements, including, without limitation, the Civil Code of the PRC (《中華人民共和國民法典》) and the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》).

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the PRC government.

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

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

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We may not be able to renew our current leases or locate desirable alternatives for our offices and laboratories.

We lease properties for our offices and may in the future lease land and properties for our expanded manufacturing sites. We may not be able to obtain, extend or renew such leases on commercially reasonable terms, or if at all, as we will have to compete with other businesses for premises at desired locations. Rental payments may significantly increase as a result of high demand for the leased properties. Moreover, we may not be able to extend or renew such leases upon expiration of their terms and may therefore be forced to relocate the affected operations. This could disrupt our operations and result in significant relocation expenses. We may not be able to locate desirable alternative sites for our offices and manufacturing sites. The occurrence of such events could materially and adversely affect our business, financial condition, results of operations and prospects.

The PRC’s economic, political and social conditions, as well as governmental policies, could affect the business environment and financial markets in China, our ability to operate our business, our liquidity and our access to capital.

Substantially all of our operations are conducted in China. Accordingly, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China and our PRC subsidiaries are governed by PRC laws and regulations. China’s economy has experienced significant growth in the past few decades. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. Such changes in the PRC economy and relevant markets in the future may materially and adversely affect our business, financial position and results of operations. In addition, the PRC legal system is a civil law system based on written statutes and governmental policies are constantly evolving. We may face challenges in complying with such evolving regulatory landscapes, which could impact our business operations.

Government control of currency conversion of and regulations on loans to, and direct investment in, PRC entities by offshore holding companies may delay or prevent us from making loans or additional contributions to our PRC subsidiary, which could limit our ability to utilize the [REDACTED] from the [REDACTED] effectively and affect our ability to fund and expand our business.

Our PRC subsidiaries’ ability to obtain foreign exchange is subject to foreign exchange regulations. In particular, if we finance our PRC subsidiaries by means of foreign debt from us or other foreign lenders, the amount is not allowed to exceed the statutory limits and such loans must be registered with the local counterpart of SAFE. If we finance our PRC subsidiaries by means of additional capital contributions, the amount of these capital contributions must first be approved by or filed with the relevant government approval authority. Please refer to the paragraphs headed “Regulatory Environment – Other Significant Regulations of the PRC Affecting Our Business – Foreign Exchange Control” in this document for more information.

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In the light of such requirements imposed by PRC regulations on loans to, and direct investment in, PRC entities by offshore holding companies, we cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on timely basis, if at all, with respect to future loans or capital contributions by us to our PRC subsidiaries. If we fail to complete such registrations or obtain such approval, our ability to capitalize or otherwise fund our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

We face foreign exchange risks. Fluctuations in exchange rates could have a material and adverse effect on our results of operations and financial performance.

Change in exchange rates may materially and adversely affect our results of operations and financial performance. The value of the Renminbi against the US dollar and other currencies is affected by a number of factors, such as regulatory updates and developments in the PRC’s and international political and economic conditions. As we have transactional currency exposures, arising from purchases by operating units in currencies other than the units’ functional currencies, and held most of our cash and cash equivalents in US dollars, any appreciation of the Renminbi against the U.S. dollar may result in the decrease in the value of our foreign currency denominated assets. In addition, We currently do not have a foreign currency hedging policy to reduce our foreign currency exposure. We recorded net foreign exchange gains of RMB79.8 million, RMB4.7 million and RMB0.9 million in 2022, 2023 and the four months ended April 30, 2024, respectively. Please refer to Note 6 of the Accountants’ Report in Appendix I to this document for detailed foreign exchange exposure during the Track Record Period. We cannot assure you that we will be able to minimize or reduce our foreign currency risk exposure relating to our foreign currency denominated assets.

As a holding company, we rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have.

We are a holding company incorporated in the Cayman Islands, and we operate our business through our operating subsidiaries in China. We rely on the distribution to us by our Chinese subsidiaries for funding, including to pay dividends to our Shareholders and to service any debt we may incur. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of its accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, our PRC subsidiaries are required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. At its discretion, our PRC subsidiaries may allocate a portion of its after-tax profits based on PRC accounting standards to a discretionary reserve fund.

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We may be deemed as a PRC tax resident under the Enterprise Income Tax Law and be subject to PRC taxation on our worldwide income.

Under the Enterprise Income Tax Law of the People’s Republic of China, or the EIT Law, enterprises established under the laws of jurisdictions other than China may be considered PRC tax residents provided that their “de facto management body” are located within China. Supplementary rules of the EIT Law interpret “de facto management body” as a body that exercises substantial management or control over the business, personnel, finance and properties of an enterprise. Through a circular promulgated in April 2009, the PRC State Administration of Taxation further clarified the criteria for determining whether an enterprise has a “de facto management body” within China. As most of our management is currently based in China and many may remain in China in the future, we and our non-PRC subsidiaries may be treated as PRC tax residents. If we or our non-PRC subsidiaries were treated as PRC tax residents, we or such non-PRC subsidiaries may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income and to PRC enterprise income tax reporting obligations. Any income sourced by us from outside China would be subject to PRC enterprise income tax at a rate of 25%. While the EIT Law provides that dividend income between “qualified resident enterprises” is exempt from PRC enterprise income tax, it is not clear whether our Company and our non-PRC subsidiaries would be eligible for such exemption were we considered to be PRC tax residents. In addition, if we are treated as PRC tax residents under Chinese laws, capital gains realized from sales of our Shares and dividends we pay to non-PRC resident Shareholders may be treated as income sourced within China. Accordingly, dividends we pay to non-PRC resident Shareholders and transfers of Shares by these Shareholders may be subject to PRC income tax. The tax on this income of non-PRC resident enterprise Shareholders would be imposed at a rate of 10% (and may be imposed at a rate of 20% in the case of non-PRC resident individual Shareholders). In the case of dividends, this tax would be withheld by us at source. Any PRC tax liability may ultimately be reduced under an applicable tax treaty. However, it is uncertain whether our shareholders, if deemed PRC tax residents, would be able to obtain the benefits of any income tax treaties or agreements between their country or jurisdiction of tax residence and the PRC. If we are required to withhold PRC income tax on dividends payable to you, or if you are required to pay PRC income tax on the transfer of our Shares, the value of your [REDACTED] in our Shares may be materially and adversely affected.

Transfers of equity interests in a PRC resident enterprise by a non-resident enterprise are regulated by the Chinese tax authorities.

On February 3, 2015, the PRC State Administration of Taxation issued the Announcement on Several Issues concerning Enterprise Income Tax for Indirect Transfer of Assets by Non-Resident Enterprises (關於非居民企業間接轉讓財產企業所得稅若干問題的公告) (“Circular 7”). This regulation repealed certain provisions in the Notice on Strengthening the Administration of Enterprise Income Tax on Non-Resident Enterprises’ Equity Transfer Income (關於加強非居民企業股權轉讓所得企業所得稅管理的通知) (“Circular 698”) and certain rules clarifying Circular 698. Circular 698 was issued by the PRC State Administration of Taxation on December 10, 2009.

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Circular 7 provides comprehensive guidelines relating to, and heightened the Chinese tax authorities’ scrutiny on, indirect transfers by a non-resident enterprise of assets (including equity interests) of a PRC resident enterprise (“PRC Taxable Assets”). For example, when a non-resident enterprise transfers equity interests in an overseas holding company that directly or indirectly holds certain PRC Taxable Assets and if the transfer is believed by the Chinese tax authorities to have no reasonable commercial purpose other than to evade enterprise income tax, Circular 7 allows the Chinese tax authorities to reclassify this indirect transfer of PRC Taxable Assets into a direct transfer and impose on the non-resident enterprise a 10% rate of PRC enterprise income tax. Circular 7 exempts this tax, for examples, (i) where a non-resident enterprise derives income from an indirect transfer of PRC Taxable Assets by acquiring and selling shares of a listed overseas holding company in the public market, and (ii) where a non-resident enterprise transfers PRC Taxable Assets that it directly holds and an applicable tax treaty or arrangement exempts this transfer from PRC enterprise income tax. It remains unclear whether any exemptions under Circular 7 will be applicable to transfers of our Shares by our Shareholders. If the Chinese tax authorities impose PRC enterprise income taxes on these activities, the value of your [REDACTED] in our Shares may be adversely affected.

It may be difficult to effect service of process upon us or our management or to enforce any judgments obtained from foreign courts.

We are a company incorporated in the Cayman Islands with substantially all of our assets located within China. Some of our Directors and senior management reside in China and substantially all of their assets are within China. Judgments of courts of another jurisdiction may be reciprocally recognized or enforced if the jurisdiction has a treaty on that with China. Currently, China does not have treaties providing for the reciprocal enforcement of judgments of courts with Japan, the United States, the United Kingdom or most other western countries. On July 14, 2006, Hong Kong and China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》), pursuant to which reciprocal recognition and enforcement of the judgment may be possible between these two jurisdictions provided that the judgment is rendered by a final court of these two jurisdictions and the parties has a expressly written choice of court. On January 18, 2019, the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “2019 Arrangement”) was signed between the Supreme People’s Court of China and Hong Kong and effective on January 29, 2024, and the 2006 Arrangement has been superseded. The 2019 Arrangement establishes a bilateral legal mechanism with greater clarity and certainty for reciprocal recognition and enforcement of judgments between Hong Kong and the PRC in civil and commercial matters under both Hong Kong and PRC law. The 2019 Arrangement sets forth, among others, the scope, specific types of matters to be covered or excluded, jurisdictional grounds for the purpose of recognition and enforcement as well as grounds for refusal of recognition and enforcement. However, the 2006 Arrangement will remain applicable to a “choice of court

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agreement in writing” as defined in the 2006 Arrangement which is entered into before the 2019 Arrangement taking effect. As the 2019 Arrangement went effective relatively recently and its implementation and interpretation are still evolving, further, China does not have treaties providing for the reciprocal enforcement of judgments of courts with Japan, the United States, the United Kingdom or most other western countries, as a result, [REDACTED] may have limited resources when they seek recognition and enforcement of judgments obtained from non-PRC courts against us or our Directors or officers who live in the PRC.

Failure by our Shareholders or beneficial owners who are PRC residents to make required applications and filings pursuant to regulations relating to offshore investment activities by PRC residents may prevent us from distributing dividends and could expose us and our Shareholders who are PRC residents to liability under Chinese laws.

In 2014, the SAFE promulgated the Circular of the State Administration of Foreign Exchange on Relevant Issues concerning Foreign Exchange Control on Domestic Residents’ Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (“SAFE Circular 37”). SAFE Circular 37 requires PRC residents to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such PRC residents’ legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a “special purpose vehicle.” The term “control” under SAFE Circular 37 is broadly defined as the operation rights, beneficiary rights or decision-making rights acquired by the PRC residents in the offshore special purpose vehicles or PRC companies by such means as acquisition, trust, proxy, voting rights, repurchase, convertible bonds or other arrangements. SAFE Circular 37 further requires amendment to the registration in the event of any changes with respect to the basic information of or any significant changes with respect to the special purpose vehicle. If the shareholders of the offshore holding company who are PRC residents do not complete their registration with the local SAFE branches, the PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the offshore company, and the offshore company may be restricted in its ability to contribute additional capital to its PRC subsidiaries. Moreover, failure to comply with SAFE registration and amendment requirements described above could result in liability under PRC law for evasion of applicable foreign exchange restrictions. We are committed to complying with and to ensuring that our Shareholders who are subject to these regulations will comply with the relevant SAFE rules and regulations.

We are not aware of any PRC residents who hold direct or indirect interests in our Company and are required to make the filings and registrations pursuant to SAFE Circular 37 and other related rules. However, we may not be informed of the identities of all the PRC residents holding direct or indirect interests in our Company, and we cannot provide any assurance that these PRC residents will comply with our request to make or obtain any applicable registrations or comply with other requirements under SAFE Circular 37 or other related rules. In addition, we cannot assure you that all of our Shareholders or beneficial

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owners who are PRC residents have complied with, and will in the future make or obtain any applicable registrations or approvals required by, SAFE regulations. The failure or inability of our PRC resident Shareholders to comply with the registration procedures set forth in these regulations may subject us to fines and legal sanctions, restrict our cross-border investment activities, and limit the ability of our PRC subsidiaries to distribute dividends and the proceeds from any reduction in capital, share transfer or liquidation to us, and we may also be prohibited from injecting additional capital into the PRC subsidiaries. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC law for circumventing applicable foreign exchange restrictions. As a result, our business operation and our ability to distribute profits to you could be materially and adversely affected.

Any failure to comply with PRC regulations regarding the registration requirements may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition and results of operations.

In February 2012, the SAFE promulgated the Notices of the State Administration of Foreign Exchange on Issues concerning the Foreign Exchange Administration of Domestic Individuals' Participation in Equity Incentive Plans of Overseas Listed Companies (《國家外匯管理局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》). In accordance with these rules and other 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, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. Any failure of our PRC individual beneficial owners and holders of share options or shares to comply with the SAFE registration requirements may subject them to fines and legal sanctions and may limit the ability of our PRC subsidiaries to distribute dividends to us.

Certain of our leasehold interests in leased properties have not been registered with the relevant PRC Governmental Authorities as required by relevant PRC laws. The failure to register leasehold interests may expose us to potential fines.

Pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC on December 1, 2010 and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, we did not register all six of our lease agreements as tenant, and such leased properties were primarily used as office space and registered address. We may be required by relevant Governmental Authorities

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to file these lease agreements for registration within a time limit, and may be subject to a fine for non-registration exceeding such time limit, which may range from RMB1,000 to RMB10,000 for each non-registered lease if we fail to complete the registration within the prescribed timeframe.

RISKS RELATED TO THE [REDACTED]

No [REDACTED] market currently exists for our Shares; an active [REDACTED] market for our Shares may not develop and the [REDACTED] and [REDACTED] of our Shares may decline or become volatile, which could lead to substantial losses to [REDACTED].

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

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

Immediately upon the completion of the [REDACTED] without taking into account any Shares which may be issued pursuant to the exercise of the [REDACTED], our Controlling Shareholders will collectively control approximately [REDACTED] voting power at general meetings of our Company. Our Controlling Shareholders will, through their voting power at the Shareholders' meetings and their delegates on the Board, have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional Shares or other equity securities, timing and amount of dividend payments, and our management. Our Controlling Shareholders may not act in the best interests of our minority Shareholders. For example, we obtain exclusive licenses from Ascendis Pharma for the development, manufacture and commercialization of our drug candidates and procure the clinical supplies of our endocrine drug candidates from Ascendis Pharma. While we do not foresee any reason that Ascendis Pharma may determine our exclusive licenses with it to cease manufacturing our drug candidates, there is no guarantee that our Controlling Shareholders' interests will always be aligned with us or our other Shareholders. In addition, without the consent of our Controlling Shareholders, we could be prevented from entering into transactions that could be beneficial to us. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for the Shares as part of a sale of our Company and may significantly reduce the price of our Shares.

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

Prior to the [REDACTED], there has not been a [REDACTED] market for our Shares. Future sales or perceived sales by our existing Shareholders of our Shares after the [REDACTED] could result in a significant decrease in the prevailing [REDACTED] of our 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 Shares in the [REDACTED] market or the perception that these sales may occur could significantly decrease the prevailing [REDACTED] of our Shares and our ability to raise equity capital in the future.

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

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

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

We currently intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the development and commercialization of our pipeline drug candidates near future. As a result, we do not expect to pay any cash dividends in the near future and you should not rely on an [REDACTED] in our Shares as a source for any future dividend income.

The Shareholders in general meeting may declare dividends, but no dividends shall exceed the amount recommended by the Board. Our Board has discretion as to whether to distribute interim dividends. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions (if any) received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on your [REDACTED] in our Shares will likely depend entirely upon any future price appreciation of our Shares. There

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is no guarantee that our Shares will appreciate in value after the [REDACTED] or even maintain the price at which you purchased the Shares. You may not realize a return on your [REDACTED] in our Shares and you may even lose your entire [REDACTED] in our Shares.

We cannot make fundamental changes to our business without the consent of the Stock Exchange.

Under Rule 18A.10 of the Listing Rules, without the prior consent of the Stock Exchange, we will not be able to effect any acquisition, disposal or other transaction or arrangement or any series of acquisitions, disposals or other transactions or arrangements, which would result in a fundamental change in our principal business activities as set forth in this document. As a result, we may be unable to take advantage of certain strategic transactions that we might otherwise choose to pursue in the absence of Rule 18A.10. Were any of our competitors that are not listed on the Stock Exchange to take advantage of such opportunities in our place, we may be placed at a competitive disadvantage, which could have a material adverse effect on our business, financial condition and results of operations.

We are a Cayman Islands exempted company and, because judicial precedent regarding the rights of shareholders is more limited under the laws of the Cayman Islands than other jurisdictions, you may have difficulties in protecting your shareholder rights.

Our corporate affairs are governed by our Memorandum and Articles and by the Cayman Companies Act and common law of the Cayman Islands. The rights of shareholders to take legal action against our Directors and us, actions by minority shareholders and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those established under statutes and judicial precedent in existence in the jurisdictions where minority shareholders may be located. See "Appendix III – Summary of the Constitution of Our Company and Cayman Islands Company Law" for more details.

As a result of all of the above, minority shareholders may enjoy different remedies when compared to the laws of the jurisdiction in which such shareholders are located in.

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

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

WAIVERS AND EXEMPTION

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

MANAGEMENT PRESENCE IN HONG KONG

Pursuant to Rule 8.12 of the Listing Rules, an issuer must have sufficient management presence in Hong Kong. This normally means that at least two of its executive directors must be ordinarily resident in Hong Kong. We do not have sufficient management presence in Hong Kong for the purposes of satisfying the requirements under Rule 8.12 of the Listing Rules.

The Group's management, business operations and assets are primarily based outside Hong Kong. The headquarters and its business operations are based, managed and conducted in the PRC. Currently, the executive Director of the Company, who is our Chief Executive Officer, ordinarily resides in the PRC. All of the senior management team principally reside in the PRC and they manage the Group's business operations from the PRC. As our executive Director and the senior management team play very important roles in the Company's business operations, the Company considers that it is in the best interests of the Company for the executive Director and the majority of senior management team to be based in the places where the Group has significant operations. As such, the Company does not, and will not for the foreseeable future, have a sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rule 8.12 of the Listing Rules. Accordingly, we have applied for, and pursuant to paragraph 10 of Chapter 3.10 of the Guide, the Stock Exchange [has granted], a waiver from strict compliance with the requirements under Rule 8.12 of the Listing Rules. We will ensure that there is an effective channel of communication between us and the Stock Exchange by way of the following arrangements:

- (a) pursuant to Rule 3.05 of the Listing Rules, we have appointed and will continue to maintain two authorized representatives, namely Mr. LU An-bang, our executive Director and Chief Executive Officer, and Ms. Chan Sze Ting, our company secretary, to be the principal communication channel at all times between the Stock Exchange and the Company. Each of our authorized representatives will be readily contactable by the Stock Exchange based on information provided to the Stock Exchange for the contact details of the authorized representatives. Both of our authorized representatives are authorized to communicate on our behalf with the Stock Exchange and shall be authorized to accept service of process and notices on behalf of our Company in Hong Kong under the Companies Ordinance;
- (b) pursuant to Rule 3.20 of the Listing Rules, each Director will provide his/her contact information (including their mobile phone numbers, office phone numbers and e-mail addresses (if available)) to the Stock Exchange and to the authorized representatives. This will ensure that the Stock Exchange and the authorized representatives should have means for contacting all Directors promptly at all times as and when required;

WAIVERS AND EXEMPTION

- (c) we will ensure that all Directors who are not ordinarily resident in Hong Kong have valid travel documents to visit Hong Kong and will be able to come to Hong Kong to meet with the Stock Exchange within a reasonable period of time when required;
- (d) we have retained the services of the Compliance Advisor, in accordance with Rule 3A.19 of the Listing Rules. The Compliance Advisor, among other things, will serve as an additional channel of communication in addition to the authorized representatives of our Company. The Compliance Advisor will provide our Company with professional advice on ongoing compliance with the Listing Rules and will be available to respond to enquiries from the Stock Exchange. We will ensure that the Compliance Advisor has prompt access to our Company's authorized representatives and Directors who will provide to the Compliance Advisor such information and assistance as the Compliance Advisor may need or may reasonably request in connection with the performance of the Compliance Advisor's duties. The Compliance Advisor will also provide advice in compliance with Rule 3A.23 of the Listing Rules; and
- (e) meetings between the Stock Exchange and the Directors could be arranged through the authorized representatives or the Compliance Advisor, or directly with the Directors within a reasonable time frame. Our Company will inform the Stock Exchange as soon as practicable in respect of any change in the authorized representatives and/or the Compliance Advisor in accordance with the Listing Rules.

EXEMPTION IN RESPECT OF FINANCIAL INFORMATION IN THIS DOCUMENT

Section 342(1) 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, and to set out the reports specified in Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

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

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

WAIVERS AND EXEMPTION

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

We are a late-stage, near-commercialization biopharmaceutical company focused on providing treatments in selected endocrinology diseases in China (including Hong Kong, Macau and Taiwan). Our Company is a biotech company as defined under Chapter 18A of the Listing Rules and is seeking the [REDACTED] under Chapter 18A of the Listing Rules. Rule 18A.03(3) of the Listing Rules requires that a biotech company must have been in operation in its current line of business for at least two financial years prior to [REDACTED] under substantially the same management. Rule 18A.06 of the Listing Rules further requires that a biotech company must comply with Rule 4.04 of the Listing Rules, modified so that references to “three financial years” or “three years” in Rule 4.04 of the Listing Rules shall instead reference to “two financial years” or “two years,” as the case may be.

Further, pursuant to Rule 8.06 of the Listing Rules, the latest financial period reported on by the reporting accountants for a new applicant must not have ended more than six months before the date of the [REDACTED] document.

In compliance with the above-mentioned requirements under the Listing Rules, the Accountants’ Report of the Company set out in Appendix I to this document is currently prepared to cover the two financial years ended December 31, 2022 and 2023 and the four months ended April 30, 2024.

As such, we have applied to the SFC for a certificate of exemption from strict compliance with paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance regarding the inclusion of the Accountants’ Report covering the full three financial years immediately preceding the issue of this document, and on the following grounds:

- (a) the Company is primarily engaged in R&D, application and commercialization of biotech products, and falls within the scope of Biotech Company as defined under Chapter 18A of the Listing Rules. Our Company will fulfill the additional conditions for [REDACTED] applicable to a company seeking the [REDACTED] under Chapter 18A of the Listing Rules;
- (b) as at 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 [REDACTED] Investments, the details of which have been fully disclosed in the section headed “History, Development and Corporate Structure” in this document;

WAIVERS AND EXEMPTION

- (c) the Accountants’ Report for each of the two financial years ended December 31, 2022 and 2023 and the four months ended April 30, 2024 has been prepared and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules; and
- (d) notwithstanding that the financial results set out in this document are only for the two financial years ended December 31, 2022 and 2023 and the four months ended April 30, 2024 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 to the Companies (Winding Up and Miscellaneous Provisions) Ordinance would be unduly burdensome as this would require additional work to be performed by our Company and the Company’s reporting accountants; and
- (e) the Accountants’ Report covering the two financial years ended December 31, 2022 and 2023 and the four months ended April 30, 2024 as set out in Appendix I to this document, together with other disclosure in this document, has 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] 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].

CONTINUING CONNECTED TRANSACTIONS

We have entered into and will continue to engage in certain transactions which would potentially constitute continuing connected transactions for our Company under the Listing Rules following completion of the [REDACTED]. [We have applied to the Stock Exchange for, and the Stock Exchange has granted us], waivers from strict compliance with certain requirements set out in Chapter 14A of the Listing Rules for certain continuing connected transactions. For further details of such potential non-exempt continuing connected transactions and the waivers, please see “Connected Transactions – Continuing Connected Transactions.”

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

<u>Name</u>	<u>Address</u>	<u>Nationality</u>
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Executive Director

Mr. LU An-Bang (盧安邦)	Unit 705, Building No. 4 No. 6 Chaowai Dajie Chaoyang District Beijing, PRC	Taiwan, PRC
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Non-Executive Directors

Mr. Michael Wolff JENSEN	Slotsvej 62 DK-2920 Charlottenlund Denmark	Denmark
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Mr. Jan Møller MIKKELSEN	543 Seale Avenue Palo Alto CA 94301 U.S.A.	Denmark
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Mr. FU Shan (付山)	Flat D, 9/F, BLK 7, The Visionary 1 Ying Hong Street Tung Chung, NT Hong Kong	PRC
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Mr. Michael J. CHANG	1 Jiak Kim Street #21-07 Singapore 169423	USA
----------------------	--	-----

Mr. CAO Yibo (曹弋博)	Suite no. 2-3619, Harbourview Horizon All-Suite Hotel 12 HungLok Road Hung Hom Bay Kowloon Hong Kong	PRC
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DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
Independent Non-Executive Directors		
Dr. YAO Zhengbin (Bing)	2002 Stanwich Drive, Berwyn, PA19312, U.S.A.	USA
Mr. CHAN Peng Kuan (陳炳鈞)	Flat B8, 14/F, Block B Viking Garden 40-42 Hing Fat Street Tin Hau Hong Kong	Hong Kong, PRC
Ms. NI Hong (倪虹)	Shouson Hill Road No 9 House 17b Deep Water Bay Hong Kong	Hong Kong, PRC

See "Directors and Senior Management" for further details.

PARTIES INVOLVED IN THE [REDACTED]

Joint Sponsors

Morgan Stanley Asia Limited

46/F, International Commerce Centre
1 Austin Road West
Kowloon
Hong Kong

Jefferies Hong Kong Limited

26/F, Two International Finance Centre
8 Finance Street Central
Hong Kong

[REDACTED]

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

Legal Advisers to our Company

As to Hong Kong and U.S. laws:

Cooley HK
35/F, Two Exchange Square
8 Connaught Place
Central
Hong Kong

As to PRC law:

JunHe LLP
26/F HKRI Centre One, HKRI Taikoo Hui
288 Shimen Road (No. 1)
Shanghai 200041
PRC

As to Cayman Islands law:

Travers Thorp Alberga
Harbour Place, 2nd Floor
PO Box 472
103 South Church Street
Grand Cayman, KY1-1106
Cayman Islands

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

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

As to Hong Kong and U.S. laws:

Davis Polk & Wardwell

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

As to PRC law:

Commerce & Finance Law Offices

13F, China World Office 2
No. 1 Jianguomenwai Avenue
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 International Limited

3006, Two Exchange Square
8 Connaught Place
Central
Hong Kong

[REDACTED]

CORPORATE INFORMATION

Head Office and Principal Place of Business in China	Room 2605, 1788 Square 1788 Nan Jing Road West Shanghai 200040 China
Principal Place of Business in Hong Kong	5/F, Manulife Place 348 Kwun Tong Road Kowloon Hong Kong
Registered office in the Cayman Islands	International Corporation Services Ltd. Harbour Place 2nd Floor PO Box 472 103 South Church Street Grand Cayman KY1-1106 Cayman Islands
Company website	<u>www.visenpharma.com</u> <i>(the information contained on this website does not form part of this document)</i>
Company Secretary	Ms. Chan Sze Ting (陳詩婷) (FCG, HKFCG) 5/F, Manulife Place 348 Kwun Tong Road Kowloon Hong Kong
Authorized representatives	Mr. LU An-bang (盧安邦) Unit 705, Building No. 4 No. 6 Chaowai Dajie Chaoyang District Beijing, PRC Ms. Chan Sze Ting (陳詩婷) (FCG, HKFCG) 5/F, Manulife Place 348 Kwun Tong Road Kowloon Hong Kong
Audit committee	Mr. CHAN Peng Kuan (陳炳鈞) (chairman) Mr. FU Shan (付山) Dr. YAO Zhengbin (Bing)

CORPORATE INFORMATION

Remuneration committee

Ms. NI Hong (倪虹) (chairwoman)
Mr. CHAN Peng Kuan (陳炳鈞)
Mr. LU An-Bang (盧安邦)

Nomination committee

Mr. Michael Wolff JENSEN (chairman)
Dr. YAO Zhengbin (Bing)
Ms. NI Hong (倪虹)

[REDACTED]

Principal bank

Bank of China
3rd Floor, Tower I, Kerry Centre
1515 Nanjing West Road, Jing'an District
Shanghai, China

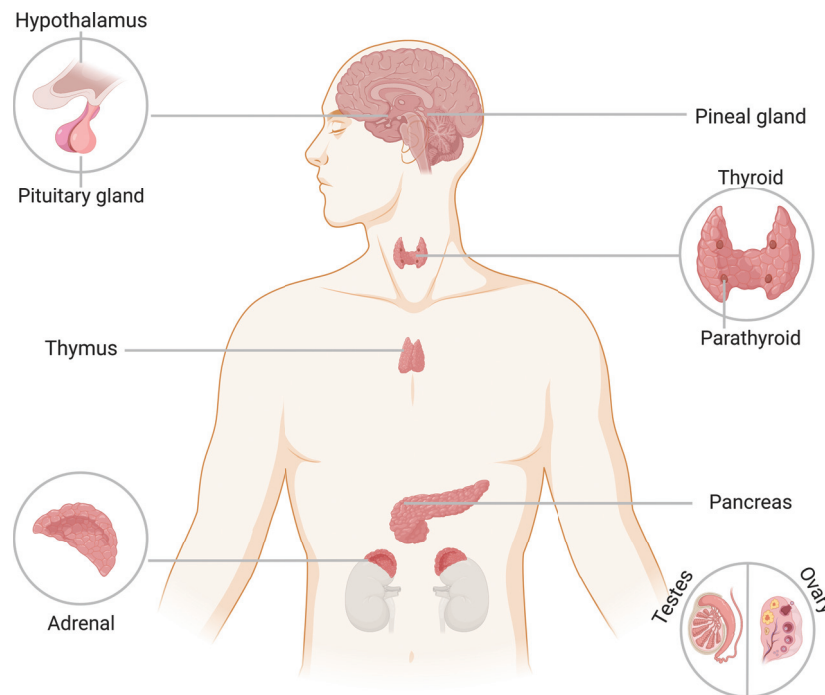
INDUSTRY OVERVIEW

Certain information and statistics set out in this section have been extracted from various official government publications, market data providers and a report commissioned by us and prepared by an independent third party, Frost & Sullivan. The information from official government sources has not been independently verified by us, the [REDACTED], Joint Sponsors, [REDACTED], [REDACTED], [REDACTED], any of the [REDACTED], any of their respective directors and advisers, or any other persons or parties involved in the [REDACTED], and no representation is given as to its accuracy.

ENDOCRINE SYSTEM AND DISEASES

The endocrine system is a network of glands that produces and releases hormones to regulate body processes, such as energy control, reproduction, immunity, behavior, growth and development. This system includes major glands throughout the body, as illustrated below. Hormones produced by these glands enter the bloodstream and are regulated by feedback loops of the endocrine system. In particular, the balance of hormones in the bloodstream is controlled by negative feedback loops.

Endocrine System Includes Major Glands Throughout the Body



Source: Frost & Sullivan Analysis, Created with BioRender.com

INDUSTRY OVERVIEW

Endocrine diseases and disorders result from the improper function of the endocrine system, which can be categorized into hormone overproduction, hormone underproduction, altered tissue responses to hormones and others. Most endocrine disorders progress steadily and complications of untreated or poorly controlled endocrine disorders can be serious, even life-threatening. Contrary to acute cancer or acute infectious diseases that develop rapidly and require urgent or short-term care, endocrine diseases are typically chronic and often require life-long treatment, especially in patients with complex pathology and high associated morbidity. Patients with chronic disease may experience complicated treatment plans requiring significant compliance efforts that may result in reduced productivity, inability to work and low quality of life – this has been termed as the “treatment burden,” which often leads to poor adherence and ultimately suboptimal treatment outcomes.

Endocrinology is a large therapeutic area spanning over 170 types of diseases, among which 79, or nearly half, still lack disease-specific drugs, indicating significant unmet medical needs. The total prevalence of the top five non-diabetic endocrine diseases in China, namely hypothyroidism, polycystic ovary syndrome, constitutional tall stature, hyperaldosteronism and hyperthyroidism, was 191.8 million in 2021.

Endocrine diseases may occur at all ages, affecting newborn to elderly patients. They can be generally categorized into pediatric endocrine diseases and adult endocrine diseases, with each group having its unique characteristics. Children are not just small adults when it comes to endocrine disorders and treatment. As growing individuals, pediatric patients have special needs related to growth and development, and hence they often face a limited treatment window and an urgent need for timely treatment. Hormone problems affecting growth or development can have significant effects on a child’s lifelong physical and emotional well-being. In addition, treatment compliance for children often requires parent/caregiver supervision and discomfort and pain in treatment may affect children’s compliance, calling for more convenient treatment options with simplified drug regimens and better experience. Adult endocrine disorders often require lifelong treatment, creating significant needs for treatment options with reduced burden and favorable long-term safety profiles. Endocrine diseases are often associated with significant disease and socioeconomic burden including time lost from work, burden on caregivers, etc. For example, patients with GHD report more sick leave from work and increased healthcare utilization, including more frequent hospital days and provider visits, and the need for assistance with daily activities, according to Frost & Sullivan.

OVERVIEW OF NON-DIABETIC ENDOCRINE DRUG MARKET

The Non-Diabetic Endocrine Drug Market in China

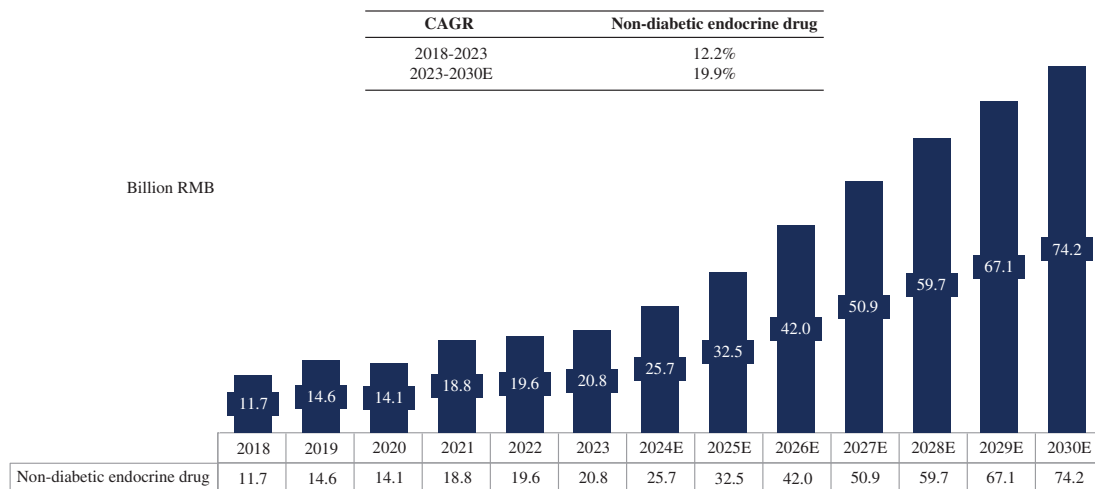
The non-diabetic endocrine drug market in China witnessed strong growth from RMB11.7 billion in 2018 to RMB20.8 billion in 2023, at a CAGR of 12.2%. It is estimated to further grow to RMB74.2 billion by 2030, at a CAGR of 19.9% from 2023 to 2030, according to Frost & Sullivan.

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The non-diabetic endocrine drug market in China has been growing and is expected to continue to grow at a significantly higher rate than the global non-diabetic endocrine drug market. According to Frost & Sullivan, the market size of the latter decreased at a CAGR of 6.6% from 2018 to 2023 due to the negative impact of COVID-19 pandemic on sales volume, the lack of relevant new drug or formulation approvals from 2016-2019, and increased competition from generic drugs. The global non-diabetic endocrine drug market is expected to grow at a CAGR of 12.9% from 2023 to 2030, according to Frost & Sullivan.

The chart below illustrates the historical and forecast size of the non-diabetic endocrine drug market in China:

Non-Diabetic Endocrine Drug Market in China, 2018-2030E

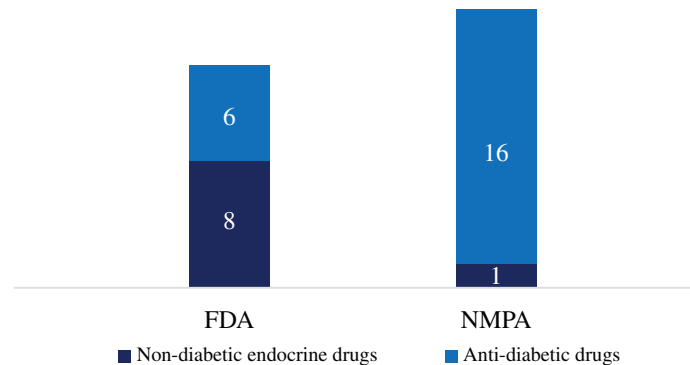


Source: Expert Interview, Annual Report, Frost & Sullivan Analysis

The endocrine drug market in China, including the non-diabetic endocrine drug market, is well-positioned for strong potential market growth. The endocrine drugs innovation in China, especially for non-diabetic endocrine drugs, is still catching up to the developed markets, creating significant opportunities for introducing innovative drug candidates with proven clinical benefits from developed markets. From 2016 to 2023, the FDA approved 14 novel endocrine drugs, including six for diabetes and eight for non-diabetic endocrine diseases such as PGHD. 17 novel endocrine drugs were approved by the NMPA during the same period, including 16 for diabetes and one for non-diabetic endocrine diseases.

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FDA and NMPA Approved Novel Endocrine Drugs,* 2016-2023



* Novel drugs refer to new molecular entities and new therapeutic biological products

Source: FDA, NMPA, Frost & Sullivan Analysis

Significant Unmet Medical Needs in China

- *Large patient pool.* Endocrine diseases affect a large patient population in China. The total prevalence of the top five non-diabetic endocrine diseases in China, namely hypothyroidism, polycystic ovary syndrome, constitutional tall stature, hyperaldosteronism and hyperthyroidism, was 191.8 million in 2021.
- *Lack of awareness and underdiagnosis.* In contrast to acute diseases, most endocrine diseases may progress over years with few or no signs at their early stage of development. Common symptoms of endocrine diseases may be too mild to raise patient awareness. Therefore, many patients undergo a long journey before being diagnosed and receiving the appropriate treatment. Additionally, diagnosis of endocrine diseases with more complex conditions often requires highly specialized clinicians, restricting the diagnosis rate of patients with limited access to appropriate healthcare resources.
- *Lack of guidelines on diagnosis and treatment.* Even for patients who are aware of their developed symptoms and incentivized to visit physicians, they may not be able to receive precise diagnosis and timely treatment due to the lack of guidelines on diagnosis and treatment that identifies and describes diagnosis criteria, treatment goals, courses of intervention, etc. The development of guidelines requires considerable resources. In addition, guidelines need to be continuously updated in light of change in evidence or new interventions. However, the less common a disease, the harder it is to gather resources to develop or update guidelines.
- *Lack of effective treatments.* There is generally a lack of effective treatments for non-diabetic endocrine diseases. In China, partially due to a lag in drug innovation as compared to regions such as the United States and Europe, effective treatments of non-diabetic endocrine diseases are also in great need. For example, there is

INDUSTRY OVERVIEW

currently no effective disease-modifying therapy for ACH approved in China. While some local hGH drugs have expanded their indications to include short stature caused by ACH, such as Jintropin (marketed by GeneScience Pharmaceuticals) and Ansomone (marketed by Anhui Anke), none of these drugs are disease-modifying.

- *Lack of convenient options for long-term treatment.* As many endocrine diseases require treatment over the course of many years, the currently available daily long-term treatment places heavy burden on patients. A high treatment burden is associated with poor adherence. According to the World Health Organization, for example, the average adherence rate to long-term therapy for chronic illnesses in developed countries is only around 50%. Low adherence to long-term treatment often results in suboptimal treatment outcomes, creating a significant need for convenient treatment options, which are currently less available in China as compared to regions such as the United States, Europe and Japan. For example, there are innovative endocrine drugs that recently have been approved in the United States but are not yet approved in China, including lonapegsomatropin, which is the first once-weekly LAGH replacement therapy approved by both the FDA and the EMA for treating PGHD.

Favorable Healthcare Policies

Recent government policies in the healthcare sector have made China an attractive market for the development of innovative endocrine drugs.

- *Policies to prioritize the prevention and treatment of endocrine diseases.* As part of a national effort to fight chronic disease, the State Council issued in 2017 the Medium-to-Long Term Plan of China for the Prevention and Treatment of Chronic Diseases (2017-2025) (《中國防治慢性病中長期規劃(2017-2025年)》), which designated endocrine diseases as a category of chronic diseases that is of high national priority.
- *Policies to encourage the development of pediatric drugs.* Since 2015, several policy documents were endorsed to improve the drug approval process and better the distribution of pediatric-friendly drugs, with key policies outlined as follows:
 - In January 2020, the Drug Registration Regulation issued by the SAMR announced that priority review and approval may be available to the application of drug marketing authorization for new varieties, dosage forms and specifications of pediatric drugs.
 - In November 2021, the National Health Commission issued the Administrative Measures for the National Essential Drugs List (Draft Revision) (《國家基本藥物目錄管理辦法(修訂草案)》) for public comments, which adds a special category for pediatric drugs.

INDUSTRY OVERVIEW

- The CDE has also in recent years issued a number of technical guidelines on the pharmacy, clinical pharmacology and clinical development of pediatric drugs, and to encourage pharmaceutical companies to develop new pediatric drugs.
- *Policies to promote children’s health.* In July 2019, the Healthy China Action Promotion Committee issued the Healthy China Action (2019-2030) (《健康中國行動(2019-2030年)》), announcing a national goal to reduce the rate of stunting in children aged under five from 8.1% in 2013 to below 7% by 2022 and below 5% by 2030. In line with the Healthy China Action (2019-2030), in September 2021, the State Council issued the Outline on the Development of Chinese Children (2021-2030) (《中國兒童發展綱要(2021-2030年)》), also setting target to reduce the rate of stunting in children aged under five to below 5% by 2030. In June 2021, the CPC Central Committee and the State Council jointly issued the Decision on Optimizing the Birth Policy to Promote the Long-term Balanced Development of the Population (《關於優化生育政策促進人口長期均衡發展的決定》), namely, the “three-child policy,” representing a major turn of China’s birth policies. Under this policy, the government will attach great importance to children’s health.
- *Policies to encourage innovation and accelerate new drug approval.* China has established a number of policies to promote innovation and improve the accessibility of new drugs, including through fast track and priority review system, breakthrough therapy designation and conditional approval as well as the acceptance of foreign clinical data. Such policies include the Drug Administration Law of the PRC last amended in 2019 (《中華人民共和國藥品管理法》) and the Opinions of the State Council on Reforming the Evaluation and Approval System for Drugs and Medical Devices (《國務院關於改革藥品醫療器械審評審批制度的意見》) and the Opinions on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》).
- *Policies to enhance accessibility through pricing and reimbursement.* The PRC government has been taking steps to improve the accessibility of innovative drugs through expanding the NRDL and national essential drug list (“NEDL”) at an increasing frequency. Specifically, NRDL is to be updated annually and NEDL is to be updated every three years in principle. Innovative drugs addressing urgent clinical needs are increasingly admitted into the NRDL scheme through a mechanism named “dynamic adjustment.” 36 drugs were incorporated into the NRDL through the dynamic adjustment mechanism in 2017, 17 were included in 2018, 70 were included in 2019, 119 were included in 2020, 67 were included in 2021, 111 were included in 2022, and 126 were included in 2023.

INDUSTRY OVERVIEW

- *Measures to combat rare diseases.* Some endocrine diseases are also rare diseases. In a country of around 1.4 billion people, “rare” translates to millions of people who suffer from these diseases. To combat rare diseases, the PRC authorities published the first and second rare disease catalogue in May 2018 and September 2023 covering 121 and 86 diseases, respectively. According to the Procedure on Formulation of Rare Disease Catalogue (《罕見病目錄制訂工作程序》), the catalogue will be updated from time to time, with each update taking no less than two years to complete. Additionally, 14 rare disease drugs were added to the NRDL in total in 2021 and 2022, and it is expected that more will be included in following years.
- *Policies to facilitate the review and approval process of Local BLA.* According to the Announcement on the Relevant Matters of Optimizing the Application for Market Registration of Foreign-manufactured Drugs Transferred to Domestic Production for Marketing (《關於優化已在境內上市的境外生產藥品轉移至境內生產的藥品上市註冊申請相關事項的公告》), the NMPA will prioritize the evaluation and approval process for marketing registration applications of overseas-original chemical pharmaceuticals and biological products that have obtained marketing approval for shifting to domestic manufacture.

These favorable government initiatives will continue to encourage drug innovation and drive the growth of the endocrine drug market in China. See “Regulatory Environment – Regulations on Pharmaceutical Product Development, Approval and Registration in the PRC – Regulations on the Clinical Trials and Registration of Drugs” for more details regarding favorable government policies and ongoing healthcare reforms.

HUMAN GROWTH HORMONE

Functions of Growth Hormone

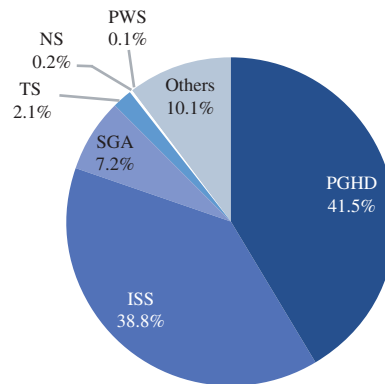
Growth hormone is produced by the pituitary gland. It has many functions including maintaining normal body structure, cardiovascular activities and metabolism. While PGHD is one of the primary causes of poor growth in children, adult GHD is characterized by a number of variable symptoms including reduced energy levels, altered body composition, reduced bone mineral density, reduced muscle strength and impaired cardiac function. GHD is mainly caused by insufficient growth hormone due to factors such as congenital genetic variation, certain diseases, injuries or surgical removal of the anterior pituitary gland, and most of them are not preventable. As advised by Frost & Sullivan, there is only one treatment option for GHD, which is the hGH treatment.

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Short Stature in Children

Short stature refers to individuals of the same race, sex and age who are less than two standard deviations (-2SD) or lower than the third percentile (-1.88SD) of the average height of the normal population in similar living environments. The prevalence of short statures in patients aged below 18 was 8.1 million in 2023 in China. PGHD, idiopathic short stature (“ISS”), and small for gestational age (“SGA”) are the most common types of short stature, representing 41.5%, 38.8% and 7.2% of the total short stature patients aged below 18 in China. The chart below summarizes the estimated prevalence of various types of short statures and their breakdown.

Prevalence Breakdown of Different Types of Short Statures in Patients Aged Below 18 in China, 2023



Notes: TS = Turner Syndrome; NS = Noonan Syndrome; PWS = Prader-Willi Syndrome; Others include multiple pituitary hormone deficiency, hypothyroidism, malnutrition, pituitary tumor, Russel-Silver syndrome, chronic kidney disease and some other diseases, for most of which hGH has no approved indications

Source: Literature Review, Frost & Sullivan Analysis

PGHD represents the most common short stature in patients aged under 18. PGHD is a medical condition of noticeable short height in children due to insufficient growth hormone. Growth hormone produces its effects both directly in peripheral tissues, such as epiphyseal chondrocytes and adipocytes, and indirectly via stimulation of local and hepatic IGF-1 production. Growth hormone and IGF-1 work in concert, with IGF-1 augmenting the anabolic actions of growth hormone while opposing the hyperglycemic and lipolytic effects of growth hormone. PGHD can be (i) congenital, resulting from genetic mutations or from structural defects in the brain; (ii) acquired later in life as a result of trauma, infection, radiation therapy, or tumor growth within the brain; or (iii) idiopathic with no known or diagnosable cause. The burden of PGHD is considerable and not limited to short stature. The severity of PGHD impact on children appears to be variable and individualized, but early diagnosis and growth hormone treatment may lead to fewer long-term complications. The prevalence of PGHD in China was 3.4 million in 2023, indicating significant unmet medical needs.

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Prevalence and Estimated Treatment Rate of PGHD in China, 2018-2030E

	2018	2019	2020	2021	2022	2023	2024E	2025E	2026E	2027E	2028E	2029E	2030E
	<i>in thousands except percentage</i>												
Prevalence	3,370.8	3,371.3	3,393.1	3,385.5	3,374.6	3,364.7	3,352.0	3,339.1	3,321.5	3,303.3	3,281.0	3,261.7	3,244.3
Estimated													
Treatment Rate	3.7%	3.9%	4.2%	4.5%	4.8%	5.3%	5.8%	6.5%	7.2%	8.0%	8.8%	9.7%	10.7%

Source: Expert Interview, Literature Review, Frost & Sullivan Analysis

Besides PGHD, there are other pathological short stature diseases that may be eligible for hGH treatment, as set forth below. These diseases are distinguished from PGHD in respect of specific conditions and causations.

- Idiopathic Short Stature.* ISS is a condition in which the height of the individual is more than two standard deviations (“SD”) below the corresponding mean height for a given age, sex and population group, and in whom no identifiable disorder is present. ISS is primarily caused by genetic and environmental factors, and is a diagnosis arrived after other recognizable causes of short stature have been excluded. Therefore, ISS children represent a highly heterogeneous population with multiple potential pathophysiological mechanisms. It is likely that more identifiable clinical conditions that nowadays are still resting under the cover of the term “idiopathic” will be discovered in the upcoming years. The prevalence of ISS children in China was 3.1 million in 2023.
- Small for Gestational Age.* SGA is a condition in which birth weight and/or length are at least two SDS below the mean for gestational age. Most children who are SGA experience catch-up growth and achieve a height over two SDS below the mean. The catch-up process is usually completed by the time the subject reaches two years old. The prevalence of SGA children in China was 582.9 thousand in 2023.
- Turner Syndrome.* TS results when one of the X chromosomes is completely or partially missing. TS can cause a variety of medical and development problems, including short stature, failure of the ovaries to develop and heart defects. Adults with TS are on average 20 cm shorter than the normal female population. hGH has been approved by the FDA for the treatment of short stature associated with TS. The prevalence of TS children in China was 171.8 thousand in 2023.
- Noonan Syndrome.* NS is an autosomal dominant condition or a genetic mutation. The pathogenesis of NS is mainly related to the abnormal Ras-MAPK signal pathway which involves more than 16 genes. NS prevents the normal development of different parts of the body and is commonly characterized by short stature. There is currently a lack of experience in the diagnosis and treatment of NS in China. The prevalence of NS children in China was 19.5 thousand in 2023.

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- *Prader-Willi Syndrome.* PWS is a genetic disorder caused by the lack of expression of genes on the paternally inherited chromosome 15q11.2-q13 region, affecting approximately one in 15,000 to 30,000 live births. The gender ratio of the patients is approximately one to one. PWS is characterized by infantile hypotonia, failure to thrive and other conditions, due to growth and other hormone deficiencies. The prevalence of PWS children in China was 8.1 thousand in 2023.

The hGH Market in China

The hGH market in China grew rapidly from RMB4.0 billion in 2018 to RMB11.6 billion in 2023, at a CAGR of 23.9%, and is expected to continue to grow to RMB28.6 billion by 2030, at a CAGR of 13.7% from 2023 to 2030, according to Frost & Sullivan. The foregoing projection of the hGH market growth in China is based on the following underlying assumptions:

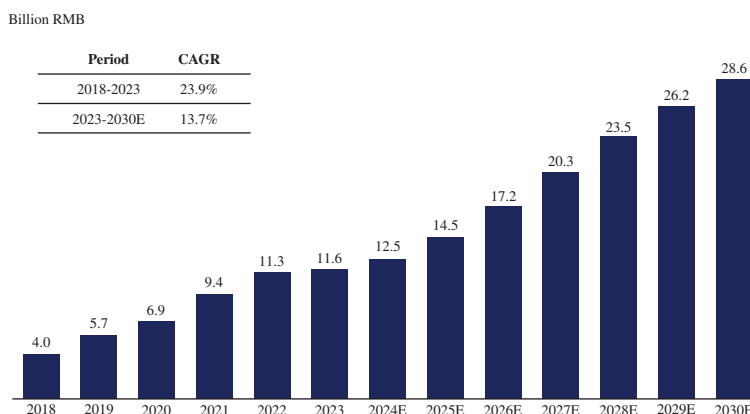
- *Increasing demand of hGH treatment.* There exists market demand generated by the continuous increase in the incidence of GHD and the limitation of existing treatments. A number of indications can be addressed by hGH treatment, including PGHD, ISS, SGA, NS, TS and PWS, which lead to the total prevalence in China reaching 7.3 million in 2023. Further, the treatment rate for PGHD in China is expected to increase from 5.3% in 2023 to 10.7% in 2030.
- *Emergence of hGH treatment.* Formulation of hGH treatment such as LAGH improves compliance and treatment outcomes, which will lead to an increase of hGH penetration of patients. By 2030, the LAGH market is expected to reach RMB21.1 billion and account for approximately 73.8% of the total hGH market in China.
- *Increasing awareness of GH deficiency and increasing patient affordability.* With the development of society and economy, people’s health awareness has gradually increased. The per capita disposable income of China was US\$5,444.8 in 2021 and is expected to continue to grow rapidly to US\$7,325.5 by 2025, based on historical data released by the National Bureau of Statistics of China (中華人民共和國國家統計局), growth rate of the Chinese economy and foreign exchange fluctuations. The increase in per capita disposable income will enhance patients’ willingness and ability to pay for hGH therapy, even at a higher cost for novel medications. With more attention and patient affordability of hGH treatment, the diagnosis and treatment rate will raise, which will propel the hGH market growth.

From 2018 to 2023, the hGH market in China achieved a higher CAGR than the hGH market in the United States, according to Frost & Sullivan. China accounted for the largest share of the global hGH market in 2023, surpassing the United States and representing 34% of the global market. Despite the already large market size for hGH in China, the country’s potential for market growth remains high, primarily due to the expected continuous growth in the treatment rate of short statures, early initiation and extending of GH treatment durations and therapy upgrade from daily to weekly GH treatment.

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In addition to its significant market size and vast growth potential, the hGH market in China is also less vulnerable to potential governmental cost-cutting measures (e.g., NRDL negotiations, volume-based procurement) that may affect reimbursed drugs, given the sales paid by the national healthcare system only account for a small portion of the overall hGH market in China. Specifically, 67.1% of the hGH market in China is covered by private hospitals and clinics, where drugs are not eligible for reimbursement; the remaining 32.9% is covered by public hospitals, where only a fraction of patients are eligible for governmental reimbursement, and may not be reimbursed in full. The chart below illustrates the historical and forecast size of the hGH market in China.

China hGH Market Size and Forecast, 2018-2030E



Source: Expert Interview, Annual Report, Frost & Sullivan Analysis

Formulations of hGH Treatments – Short-acting Growth Hormone and Long-acting Growth Hormone

By frequency of administration, hGH therapies can be categorized into short-acting growth hormone treatments and LAGH treatments.

Short-acting Growth Hormone

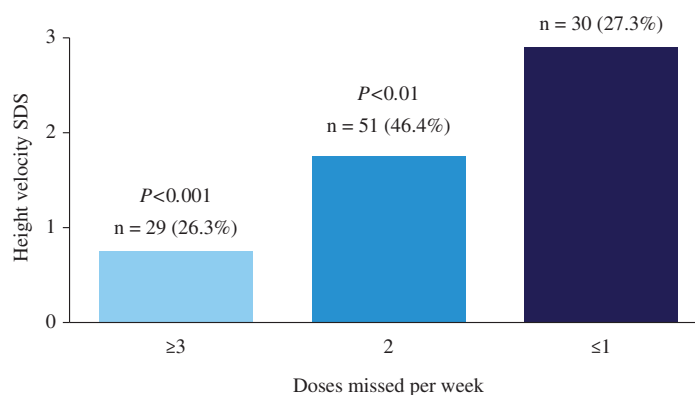
Short-acting growth hormone treatments require daily administration and come in either powder or liquid form, customarily referred to as “short-acting powder” and “short-acting liquid.” Launched in 1998, short-acting powder was the first short-acting growth hormone treatment available in China. Short-acting powder was administered with a standard syringe instead of easy injection device, as its freeze-dried nature would require reconstitution before use, making it less convenient than prefilled devices. The administration of short-acting powder was often associated with a complex injection process and patient discomfort. Such administration can be distressing for patients, resulting in non-adherence and reduction of treatment outcomes, and therefore had limited market acceptance and commercial success.

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Short-acting liquid was the second formulation of hGH treatment available in China, which was less complex to administer with the introduction of easy injection devices. As a result, its market share gained traction quickly and is currently the most popular treatment for PGHD.

However, the burden of daily injections over the course of many years caused missing doses during treatment and premature discontinuation of therapy for many patients, which affected treatment outcomes. According to Frost & Sullivan, in a 2021 study, up to 82% of patients with PGHD missed at least one daily injection per week. In a separate study of 110 children, two out of three patients missed more than one injection per week on average. For patients who missed over one dose per week, there was a clinically relevant reduction in their change in height velocity standard deviation score (“HVSDS”) as compared to patients that missed no more than one dose on average. A greater HVSDS indicates more rapid growth.

Height Velocity Standard Deviation Score According to the Level of Compliance with Four-Month hGH Treatment



Source: Cutfield WS, Derraik JG, Gunn AJ, et al. Non-compliance with growth hormone treatment in children is common and impairs linear growth. *PLoS One*. 2011 Jan 31;6(1):e16223

Long-acting Growth Hormone

To overcome the limitations associated with short-acting growth hormone treatments, LAGH was introduced as a new formulation, aiming to reduce injection frequency and thereby improve compliance and treatment outcomes. Due to the potential significant advantages of LAGH over short-acting growth hormone treatment in terms of increased acceptance, tolerability, and therapeutic flexibility to patients, LAGH is expected to gradually replace short-acting growth hormone treatment as the go-to treatment for PGHD. The LAGH market is projected to continue to grow significantly and overtake the short-acting growth hormone treatment markets, according to Frost & Sullivan.

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The table below sets forth a comparison of hGH treatments in China.

Comparison of Different Formulations of hGH Treatments in China

	Original Launch Year in China	Injection and Compliance	Estimated Average Annual Treatment Cost in China in 2023 Per Patient (RMB)*
Short-acting Growth Hormone (Powder)	1998	<ul style="list-style-type: none"> • Complex injection preparation with multiple steps to operate due to the lack of injection devices in China • Daily injection leads to poor adherence and compromised treatment outcomes 	23,813 to 28,612 ⁽¹⁾
Short-acting Growth Hormone (Liquid)	2005	<ul style="list-style-type: none"> • Less complex than short-acting powder, but still requires daily injection which affects treatment outcomes 	60,845 to 69,974 ⁽¹⁾
LAGH	2014	<ul style="list-style-type: none"> • Weekly injection that largely improves compliance and thereby potentially maximizes clinical efficacy 	121,333 ⁽²⁾

* Only includes annual cost of major players whose market share is more than 5%.

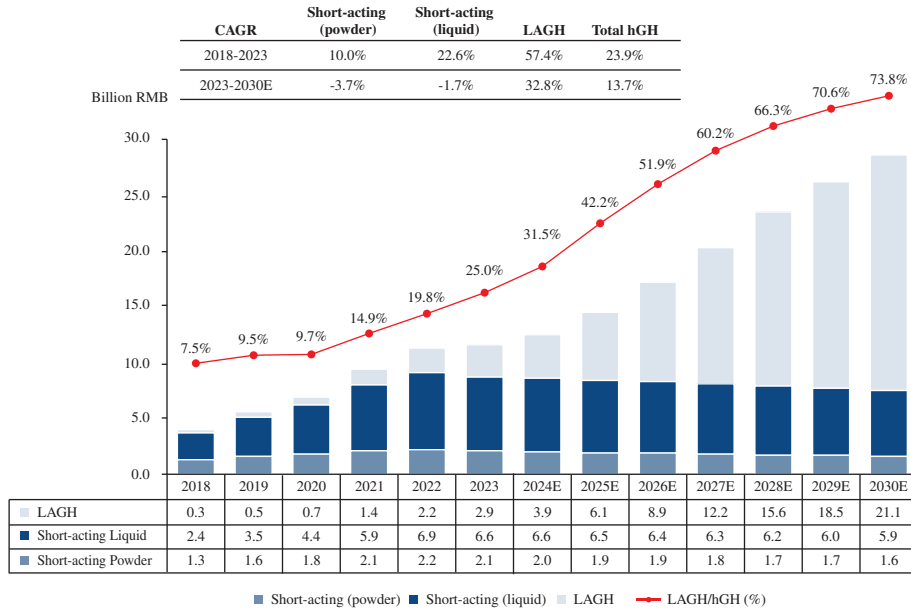
(1) The calculation of annual cost for Short-acting Growth Hormone assumes: (i) the average weight of patients is 30kg; and (ii) the dose of Shorting-acting Hormone is 0.15 IU/kg per day.

(2) The calculation of annual cost for LAGH assumes: (i) the dose of LAGH is 0.2 mg/kg per week; (ii) there are 52 weeks in a year; and (iii) the average weight of patients is 30kg.

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The table below sets forth a breakdown of the market sizes of hGH treatments by formulation.

China hGH Market Breakdown by Formulation, 2018-2030E*



Source: Expert Interview, Literature Review, NMPA, Frost & Sullivan Analysis

* In general, the hGH market size in China is derived from a bottom-up approach by studying the historical revenues of marketed products. The future market size is primarily forecasted by estimating the prevalence of PGHD and other diseases requiring hGH therapies, treatment rates, treatment costs and patient compliance in China during the forecast period. The following key assumptions are used for the purpose of estimating hGH market size in China, as a whole and by formulation:

- (i) The number of patients receiving hGH therapies largely depends on the number of PGHD patients receiving hGH therapies, which is calculated by multiplying the prevalence of PGHD by the treatment rate. As PGHD affects newborn to children as old as 17, the prevalence of PGHD is expected to remain relatively stable from 2023 to 2030, despite the expected decrease of birth rate. The treatment rate, on the other hand, is expected to more than double from 2023 to 2030, which is expected to drive the increase of the number of treated PGHD patients during the same period.
- (ii) The annual treatment cost for short-acting growth hormone is lower than that of LAGH. Short-acting powder costs RMB20,000 to RMB30,000 and short-acting liquid costs RMB60,000 to RMB70,000, while LAGH costs approximately RMB120,000.
- (iii) It is estimated that at least four LAGH products will be approved and commercially launched in China within the next five years, given that it typically takes approximately one to five years to advance Phase III- and Phase II-staged LAGH candidates to market approval stage.
- (iv) It is estimated that LAGH will be associated with longer treatment cycles compared to that of short-acting growth hormone, as patient compliance with LAGH is expected to be significantly higher than with short-acting growth hormone.
- (v) It is estimated that LAGH, with improved efficacy and patient compliance, will attract more patients to undergo treatment. Advances in medical care and economic conditions will enable more patients with PGHD to access and afford LAGH treatment, thereby increasing the overall treatment rate. Supportive government policies and expanded health insurance coverage are likely to make LAGH treatment more accessible to a larger patient population, which will drive the LAGH market growth.

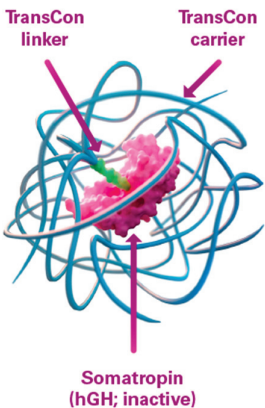
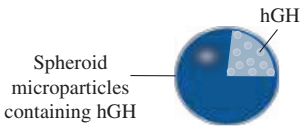
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Development of Long-acting Growth Hormone Treatments

Various technical approaches are being employed to develop LAGH drugs, some of which may come with inherent limitations. The chart below sets forth the technologies currently employed to develop LAGH, their formations, pros and cons and structures.

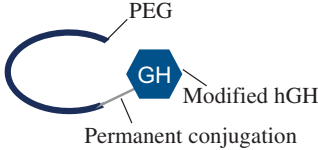
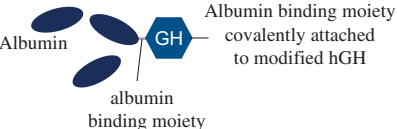
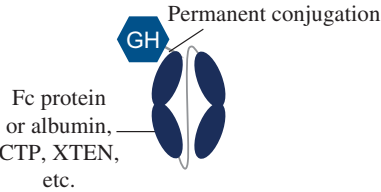
Technologies Currently Employed to Develop Long-acting Growth Hormones

Approach – Unmodified hGH

Formulation	Representative Products (Companies)	Pros	Cons	Illustration
Pro-drug formulation	<ul style="list-style-type: none"> • Lonapegsomatropin (Ascendis Pharma, VISEN) 	<ul style="list-style-type: none"> • Predictable release of hGH • Unmodified hGH, full activity • Same binding affinity and tissue distribution as endogenous growth hormone 	<ul style="list-style-type: none"> • More sophisticated manufacturing technology required 	 <p style="text-align: center;">TransCon linker TransCon carrier</p> <p style="text-align: center;">Somatropin (hGH; inactive)</p>
Depot formulation (currently withdrawn from the United States market)	<ul style="list-style-type: none"> • Nutropin Depot (Genentech) • LB03002 (LG Life Sciences) 	<ul style="list-style-type: none"> • Unmodified hGH, full activity 	<ul style="list-style-type: none"> • Limited by loading efficiency of carrier • High initial burst release, and delay of release after the initial burst • Incidence of non-neutralizing antibodies 5x higher than daily hGH • Injection site reactions 	 <p style="text-align: center;">Spheroid microparticles containing hGH</p> <p style="text-align: center;">hGH</p>

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Approach – Modified hGH

Formulation	Representative Products (Companies)	Pros	Cons	Illustration
PEGylated formulation	<ul style="list-style-type: none"> Jintrolong (GeneScience Pharmaceuticals) PHA-794428 (Pfizer) NNC126-0083 (Novo Nordisk) ARX201 (Ambrx) 	<ul style="list-style-type: none"> Adjustable half-life based on PEG size 	<ul style="list-style-type: none"> Increased risk of lipoatrophy Compromised tissue distribution causing metabolic imbalance Decreased growth hormone receptor affinity 	
Non-Covalent Albumin Binding hGH	<ul style="list-style-type: none"> Sogroya®/ Somapacitan/ NNCO195-0092 (Novo Nordisk) 	<ul style="list-style-type: none"> Adjustable half-life based on binding affinity of fatty acid to albumin 	<ul style="list-style-type: none"> Lipoatrophy reported in Sogroya Phase 2 study Compromised tissue distribution causing metabolic imbalance 	
hGH fusion protein	<ul style="list-style-type: none"> Albutropin/ TV-1106 (Teva) Somavaratan/VRS-317 (Versartis) NGENLA/ Somatrogen/ MOD-4023 (Pfizer and OPKO Health) Eftansomatropin/GX-H9/TJ101 (Genexine, and Handok) LAPS-hGH/HM10560A (Hanmi Pharmaceutical) 	<ul style="list-style-type: none"> Increased half-life 	<ul style="list-style-type: none"> Increased risk of lipoatrophy Decreased growth hormone receptor affinity Increased risk of inducing neutralizing antibodies Injection site reactions Compromised tissue distribution causing metabolic imbalance 	

Source: Literature Review, Frost & Sullivan Analysis

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Global hGH Market Landscape

The global hGH market is a dynamic sector which can be categorized into short-acting growth hormone treatments and LAGH treatments based on the frequency of administration. The LAGH treatments in the global hGH market have seen both unmodified hGH and modified hGH approaches being employed to develop LAGH drugs. In terms of short-acting growth hormone treatments in the global hGH market, daily administration of growth hormone treatment has been in clinical use for treatment for GHD for years. Due to the long-term proven effectiveness and economy of short-acting growth hormone, the current treatment of GHD mainly relies on short-acting growth hormone. There are currently more than 30 short-acting growth hormones drugs approved in the global hGH market.

In terms of LAGH treatments in the global hGH market, out of the nearly 20 LAGH drug candidates that were once in the clinical-stage, or even approved, most did not reach commercial stage primarily due to clinical trial data issue, including high rate of lipoatrophy at injection site, unsatisfactory IGF-1 profile peak, duration and presumed unfavorable benefit risk profile ratio, such as PHA-794428 (developed by Pfizer) and NNC126-0083 (developed by Novo Nordisk) both utilizing PEGylated hGH formulation and TV-1106 utilizing growth hormone fusion protein (developed by Teva), and some reached commercial stage but were subsequently removed from the market primarily due to factors including market development strategies, cost considerations and competitive advantages and disadvantages of the product, such as Nutropin Depot utilizing Depot formulation (developed by Genentech). Due to technological limitations, there remains a significant unmet need for safe and effective LAGH therapies and long-acting technologies. Enabled by the flexible, versatile and reliable transient conjugation technology (TransCon), lonapegsomatropin is the first once-weekly LAGH replacement therapy for PGHD approved both in the United States and the European Union, receiving marketing approvals from the FDA and the EMA on August 25, 2021 and January 12, 2022, respectively. The tables below set forth an overview of the development attempts of LAGH formulations for the treatment of PGHD.

Marketed LAGH Therapies for PGHD Globally, as of the Latest Practicable Date

<u>Approach</u>	<u>Product</u>	<u>Company</u>	<u>Region(s) Approved for Marketing</u>
Unmodified hGH	Lonapegsomatropin (Transiently PEGylated hGH prodrug (22 kDa as released active drug))	Ascendis Pharma	<ul style="list-style-type: none"> • Approved in the United States and the European Union

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Approach	Product	Company	Region(s) Approved for Marketing
	Nutropin Depot [®] (Encapsulated in biocompatible, biodegradable, polylactide-coglycolide polymer microsphere (22 kDa))	Genentech	<ul style="list-style-type: none"> Approved in the United States; later withdrawn⁽¹⁾
	Eutropin Plus [™] /LB03002 (Microparticles containing hGH incorporated into sodium hyaluronate and dispersed in an oil base of medium-chain triglycerides (22 kDa))	LG Life Sciences	<ul style="list-style-type: none"> Approved but not marketed in the European Union Marketed in South Korea
Modified hGH	Jintrolong [®] (40-kDa PEG attached to hGH (62 kDa))	GeneScience Pharmaceuticals	<ul style="list-style-type: none"> Approved in China
	Sogroya (Single-point mutation in hGH, with albumin binding moiety attached (non-covalent albumin-binding properties) (23 kDa))	Novo Nordisk	<ul style="list-style-type: none"> Approved mainly in the United States and the European Union
	Ngenla (recombinant hGH fused to three copies of carboxyl-terminal peptide (CTP) of hGH b-subunit (41 kDa))	Pfizer and OPKO Health	<ul style="list-style-type: none"> Approved mainly in the European Union and United States

(1) Withdrawn due to manufacturing issues and inferior efficacy reported during post-marketing follow-up trials.

Source: FDA, EMA, NMPA, Frost & Sullivan Analysis

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LAGH Therapies for PGHD in Clinical Development Globally, as of the Latest Practicable Date

Approach	Product	Company	Development status	Year*
Modified hGH	Eftansomatropin/GX-H9/TJ101 (recombinant hGH fused to hybrid noncytolytic immunoglobulin Fc portions of IgD and IgG4 (100 kDa))	Genexine and Handok	Phase 2 globally	2017
		I-Mab Biopharma and JumpCan	Phase 3 in China	2020

* Refers to the year when the latest clinical trials started

Source: *ClinicalTrials.gov., CDE, Literature Review, Frost & Sullivan Analysis*

Discontinued Clinical Development of LAGH Therapies for PGHD, as of the Latest Practicable Date

Approach	Product	Company	When the clinical development was discontinued	Reasons for discontinuation
Unmodified hGH	ALTU-238 (Long-extended release formulation using protein crystallization technology (22 kDa))	Altus	2009	The manufacturer had run out of funds
Modified hGH	PHA-794428 (Branched 40 kDa PEG on N-terminus of hGH (62 kDa))	Pfizer	2009	High rate of lipoatrophy at injection site
	NNC126-0083 (43-kDa PEG residue attached to glutamine 141 (65 kDa))	Novo Nordisk	2011	Unsatisfactory IGF-1 profile peak and duration
	ARX201 (30-kDa PEG added to unnatural amino acid incorporated into hGH (52 kDa))	Ambrx	2009	PEGylated-containing vacuoles in the epithelial cells of the choroid plexus in monkeys

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Approach	Product	Company	When the clinical development was discontinued	Reasons for discontinuation
	Albutropin/TV-1106 (Human serum albumin fused to N-terminus of hGH (88 kDa))	Teva	2016	The development of potentially inactivating antibodies; studies in adult growth hormone deficiency (“AGHD”) discontinued for unknown reason; presumed unfavorable benefit risk profile ratio
	Somavaratan/VRS-317 (Fusion protein of recombinant hGH and the pharmacologically inactive portion of long chains of natural hydrophilic amino acids (XTEN technology) (119 kDa))	Versartis	2017	The Phase 3 study did not meet its primary endpoint for non-inferiority comparison against daily recombinant hGH for height velocity in children with PGHD

Source: *ClinicalTrials.gov., Literature Review, Frost & Sullivan Analysis*

China hGH Market Landscape

Most marketed hGH therapies in China are short-acting powder and short-acting liquid. These daily hGH therapies are marketed by local biopharmaceutical companies, such as GeneScience Pharmaceuticals, Anhui Anke and Shanghai United Cell, as well as Novo Nordisk. Many of these marketed therapies target multiple indications, including GHD, severe burns, Noonan and/or Turner syndrome. The table below sets forth an overview of the marketed daily hGH therapies in China as of the Latest Practicable Date.

Marketed Daily hGH Therapies in China, as of the Latest Practicable Date

Manufacturer	Generic Name	Brand Name	Approval Status/Date	Formation
Changchun GeneScience	hGH for Injection	Jintropin	1998	Powder
Anhui Anke	Recombinant Human Growth Hormone (rhGH) for Injection	Ansomone	1999	Powder

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Manufacturer	Generic Name	Brand Name	Approval Status/Date	Formulation
Shanghai United Cell Biotechnology	rhGH for Injection	Genheal	1999	Powder
Zhongshan Sinobioway Hygene Biomedicine	rhGH for Injection	Haizhiyuan	1999	Powder
Kexing Biopharm	rhGH for Injection	Saigaolu	2002	Powder
Changchun GeneScience	rhGH Injection	Jintropin	2005	Liquid
LG Chem	rhGH for Injection	Eutropin	2012	Powder
Novo Nordisk	hGH Injection	Norditropin	2018	Liquid
Anhui Anke	rhGH Injection	Ansomone (Ansomone)	2019	Liquid
Zhongshan Sinobioway Hygene Biomedicine	hGH Injection	Haizhiyuan	2023	Liquid

Currently in China, only one LAGH therapy has received marketing approval and several are currently under clinical development, as outlined in the tables below.

Marketed LAGH Therapies in China, as of the Latest Practicable Date*

Brand Name	Company	Formulation	Development Approach	NMPA Approval Time	Indication(s)
Jintrolong ⁽¹⁾	GeneScience Pharmaceuticals	PEGylated hGH	Modified hGH	2014	PGHD

Clinical Stage Pipeline LAGH Therapies in China, as of the Latest Practicable Date*

Investigational Drug	Drug Form	Development Approach	Company	Global Status	China Status	Date**	Indication(s)
Lonapegsomatropin	Transiently conjugated hGH	Unmodified hGH	VISEN ⁽²⁾	FDA & EMA approved ⁽³⁾	BLA	March 7, 2024	PGHD
Y-shaped pegylated somatropin	PEGylated hGH	Modified hGH	Xiamen Amoytop	Not yet initiated	BLA	January 11, 2024	PGHD
Somapacitan-beco	Mutated hGH attached to an albumin affinity tag	Modified hGH	Novo Nordisk	FDA & EMA approved	BLA	September 5, 2024	PGHD
PEG-recombinant hGH	PEGylated hGH	Modified hGH	Anhui Anke	Not yet initiated	Phase 3	November 23, 2017	PGHD

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Investigational Drug	Drug Form	Development Approach	Company	Global Status	China Status	Date**	Indication(s)
Eftansomatropin GX-H9/TJ101	Hy-Fc (Fc fusion- protein)	Modified hGH	Genexine/ I-Mab Biopharma	Phase 2 completed	Phase 3	December 8, 2020	PGHD
HSA-recombinant hGH	HSA/ recombinant hGH	Modified hGH	Uniongen	Not yet initiated	Phase 3	May 22, 2024	PGHD
QHRD211/ZHB111	PEGylated hGH	Modified hGH	Qianhong Biopharma	Not yet initiated	Phase 2/3	August 13, 2024	PGHD
AK2017	Fc fusion protein	Modified hGH	Anhui Anke	Not yet initiated	Phase 2	December 27, 2023	PGHD
F-899 (Fc fusion protein)	Fc fusion protein	Modified hGH	Yifan	Not yet initiated	Phase 1	May 28, 2021	N/A
GB08	Fc fusion protein	Modified hGH	Kexing	Not yet initiated	Phase 1	June 7, 2024	PGHD

* All marketed and clinical-stage pipeline LAGH therapies were and/or are being studied in active-controlled and parallel-group trial comparisons with daily hGH. Pricing information for the marketed LAGH in China varies across different geographic areas and depends on body weight of the patients. Pricing information is not available for LAGH therapies in clinical development in China. The route of administration for all marketed and clinical-stage LAGH therapies in China is in the form of injection.

** Refers to date when the clinical trial information was first publicly posted.

Notes:

- (1) In 2023, the median unit price of Jintrolong in China is RMB3,500/(1ml:54IU). As of the Latest Practicable Date, Jintrolong has not been included in the NRDL.
- (2) VISEN has gained exclusive licensed rights to develop, manufacture and commercialize in China (including Hong Kong, Macau and Taiwan); Ascendis Pharma retains the rights to develop, manufacture and commercialize outside of China (including Hong Kong, Macau and Taiwan).
- (3) Lonapegsomatropin is the first once-weekly LAGH approved by both the FDA and EMA for PGHD.

Source: CDE, NMPA, FDA, Clinicaltrials.gov, Frost & Sullivan Analysis

The criteria for a successful LAGH include not just weekly dosing regimen, but also at least non-inferior efficacy and safety to daily hGH. Many LAGH development projects failed because of either insufficient or inconsistent efficacy or unwanted safety issues.

Lonapegsomatropin is designed based on the transient conjugation technology (TransCon). The “conjugation” enables extended half-life and therefore a weekly dosing scheme, while the “transient” feature enables the release of unmodified hGH in controlled manner into the bloodstream which is identical to the endogenous growth hormone.

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Due to these unique features, somatropin released from lonapegsomatropin retains the same mode of action and the same physiological volume of distribution as the endogenous growth hormone. Endogenous growth hormone has dual modes of action, with direct action by circulating growth hormone on target tissues and indirect action through promoting IGF-1 production in the liver (via growth hormone receptor). In contrast, modified hGH often substantially alters its molecular size, which changes its receptor binding affinity and its ability to reach the target tissue. The active component of lonapegsomatropin is the released hGH, which is identical in molecular structure to the endogenous growth hormone, the safety profile of which has been clinically proven for almost four decades. In contrast, the modified LAGH is a new active drug molecule, with no prior clinical safety experience outside of its clinical trials. Before the hGH is released in the bloodstream, lonapegsomatropin exists as an inactive prodrug, it therefore presents no biological activities and is well tolerated at the injection site-subcutaneous tissue. In contrast, some modified LAGH has shown severe injection site reactions or even lipoatrophy due to high dose and long exposure of active molecule at the injection site.

Due to the design advantages of lonapegsomatropin, it has proven, in the global Phase 3 active-controlled, parallel-group comparison trial, non-inferiority, as well as superior efficacy to daily hGH, as evidenced by an annual height velocity of 11.2 cm/year compared to 10.3 cm/year for daily hGH, with a p-value of 0.0088, at 52 weeks. It has also demonstrated similar safety to daily hGH, and became the first once-weekly LAGH approved by both the FDA and EMA for PGHD. The completed China Phase 3 pivotal trial continued to support lonapegsomatropin's superior growth profile and comparable safety profile in comparison to daily hGH, where lonapegsomatropin was associated with an AHV of 10.66 cm/year at 52 weeks compared to 9.75 cm/year for daily hGH, with a p-value of 0.0010. These trials proved that weekly lonapegsomatropin is the first and only LAGH with data demonstrating superior efficacy compared to a daily somatropin.

In addition, lonapegsomatropin is coupled with an auto-injector device that offers easy injection, hidden needle, small injection volume, and six-month room temperature storage features, all of which can dramatically improve patient injection experience and become competitive advantages. The FDA approval of lonapegsomatropin includes the new auto-injector and cartridges, which allow families to store the medicine at room temperature for up to six months as compared to other daily or weekly recombinant growth hormones launched in China, which typically require storage at temperatures between 2-8°C.

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Key Drivers of the hGH Drug Market in China

- *Increasing patient penetration.* The diagnosis rate and treatment rate of short stature in children will be driven by a variety of factors including government policy on improving children’s health, increased health awareness and the advancement of clinical diagnosis capabilities. The treatment rate for PGHD in China is expected to increase from 5.3% in 2023 to 10.7% in 2030, according to Frost & Sullivan. The increasing diagnosis rate, along with the development of safer and more easily administered treatment regimens, will also directly improve treatment rate. The increasing patient penetration is expected to fuel the growth of the hGH market in China.
- *Earlier diagnosis and initiation of treatment.* As growing individuals, children have special needs related to growth and development, and hence they often face a limited treatment window and an urgent need for timely treatment. While children in China are currently suffering from late diagnosis, which delays the initiation of treatment, early and precise diagnosis and effective treatment solutions for PGHD will be available with the establishment of standardized diagnosis and treatment guidelines, increasing affordability, disease awareness and technological development. Earlier diagnosis and treatment will also increase the number of younger patients in China who are more sensitive to discomfort and pain, thus boosting the demand for more convenient treatment options.
- *The increasing acceptance of LAGH treatments.* The increasing market acceptance of premium-valued LAGH will drive a treatment paradigm shift towards LAGH and the organic growth of the hGH drug market in China. Based on progress in both pre-clinical and clinical science, particularly in areas of endocrinology and biotechnology, LAGH has been achieving significant development. LAGH can create a more convenient growth hormone dosing profile while retaining the excellent safety, efficacy and tolerability of daily hGH. Many life circumstances can interfere with adherence to daily injections, thus compromising therapeutic outcomes. A national survey from New Zealand showed there were 66% patients missing doses more than 1 time per week and significantly compromised linear growth (HV SDS). Research suggests less frequent injections would be patient-friendly and are able to reduce non-adherence and subsequently improve growth outcomes. The LAGH market will continue to grow significantly and overtake the daily hGH market, according to Frost & Sullivan’s projection. According to Frost & Sullivan, by 2030, the LAGH market is expected to reach RMB21.1 billion and account for approximately 73.8% of the total hGH market in China.
- *Increase in the average duration of treatment.* The average duration of treatment (“DoT”) for PGHD is less than 1.7 years in China, as compared to over 3.5 years in developed countries, according to Frost & Sullivan. The average DoT for short stature in China is expected to increase in the upcoming years due to a number of factors, including the development of improved drug administration, introduction of more convenient injections and expected earlier diagnosis and treatment, according to Frost & Sullivan. An increase in the average DoT is expected to drive the growth of the hGH market in China.

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Entry Barriers for the hGH Drug Market in China

Despite the market potential and opportunities in the hGH drug market, the barriers to entry remain high, primarily due to a combination of factors as highlighted below:

- *Innovation in hGH treatment is capital intensive with heavy R&D capabilities and costs.* Many hGH drugs treat chronic conditions, and therefore require significant resources and investments over a long period of clinical studies in order to obtain regulatory approval for commercialization.
- *Technical barriers to enter into the hGH drug market remain high.* Growth hormone is a product of genetic engineering which applies advanced molecular biology technology and requires biological fermentation production line subject to strict manufacturing standards. Further, recombinant human growth hormone liquid injection that acts long-term applies permanent modification technologies such as PEGylation and fusion protein, which calls for high requirements on strain development, fermentation process management, and product purification.
- *Physician awareness and patient education leading to drug adoption require substantial efforts.* Physician awareness, patient education and drug adoption are critical components of launching a new hGH drug, in particular because the demand for a particular hGH drug is largely driven by the prescription habits of physicians who diagnose and treat endocrine patients. Since the GHD diseases are chronic in nature and require long-term treatment as compared to acute diseases, it is critical to establish a system for patient management and other follow-up services after commercialization.
- *Marketing of hGH drugs requires specialized professional team.* Marketing of hGH drugs often involves communication with HCPs and regulators, as well as insight into therapeutic areas or indications, which requires a specialized professional team to successfully execute commercialization strategies.

ACHONDROPLASIA

ACH is the most common form of dwarfism, occurring with a frequency of one in 30,000 to 10,000 among live birth and affecting approximately 250,000 people worldwide. ACH results in severe skeletal complications and comorbidities, including foramen magnum and spinal stenosis, sleep apnea and chronic ear infections. Patients often face multiple surgeries to alleviate its many complications. Due to the absence of approved therapy to treat the genetic basis of ACH in China, according to Frost & Sullivan, it is currently unfeasible to determine the market share and market size for ACH as there have been no corresponding sales generated in China. The prevalence of ACH in China was 51.2 thousand in 2023 and is estimated to reach 51.9 thousand in 2030. Since ACH is mainly caused by genetics as a congenital disease, normally there is no prevention method available. As advised by Frost & Sullivan, there is only one treatment option for ACH, which is the CNP treatment.

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Competitive Landscape of the ACH Market in China

Currently, there is no approved therapy available in China to treat the genetic basis of ACH, with medical and surgical interventions limited to addressing some of the symptoms, including spinal stenosis, hydrocephalus and obstructive sleep apnoea. Some local hGH drugs have expanded their indications to include short stature caused by ACH, such as Jintropin (marketed by GeneScience Pharmaceuticals) and Ansomone (marketed by Anhui Anke). However, none of these drugs are disease-modifying. According to the International Achondroplasia Consensus Statement Group, the effect of growth hormone treatment in children with ACH has been controversial and its long-term effect remains unclear. The chart below sets forth ACH therapy in clinical development in China.

ACH Therapies with Clinical Activities in China, as of the Latest Practicable Date

<u>Product</u>	<u>Drug Structure</u>	<u>Company</u>	<u>Clinical Status</u>
TransCon CNP (navepegritide)	Prodrug of CNP	VISEN ⁽¹⁾	Phase 2
SAR442501	FGFR3 antibody	Sanofi	Phase 2

(1) VISEN has gained exclusive licensed rights to develop, manufacture and commercialize in China (including Hong Kong, Macau and Taiwan); Ascendis Pharma retains the rights to develop, manufacture and commercialize outside of China (including Hong Kong, Macau and Taiwan).

Source: CDE, Frost & Sullivan Analysis

Global ACH Market Landscape

Outside of China, as of the Latest Practicable Date, Voxzogo (vosoritide) (developed by BioMarin) received marketing approvals from the FDA and the EMA, and Infigratinib/BGJ398 (developed by QED Therapeutics) is being developed in Phase 3 trials and SAR442501 (developed by Sanofi) is being developed in Phase 2 trials.

Administration of CNP to patients with ACH and in animal models of ACH has been found to stimulate growth. Voxzogo (vosoritide), as a CNP analogue, has been developed to provide better stability of CNP and is approved by the FDA and EMA for the treatment of ACH in the United States and the European Union, respectively. Due to the natural form of CNP having a short half-life of only one to two minutes, which makes it unsuitable as a drug product for maintaining stable CNP plasma concentrations, there is a need for the development of a long-acting CNP formulation. Voxzogo (vosoritide) is a CNP-39 analogue that extends the half-life of CNP to 20 to 45 minutes, but it still requires daily injections. In contrast, TransCon CNP extends the half-life to approximately 120 hours, allowing for a more convenient once-weekly dosing regimen.

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Unlike Voxzogo (vosoritide), TransCon CNP (navepegritide) is an investigational long-acting prodrug of CNP designed to provide continuous CNP exposure at therapeutic levels with a well-tolerated and convenient once-weekly dose. Leveraging the transient conjugation technology (TransCon), TransCon CNP (navepegritide) provides a sustained exposure of active CNP, allowing an optimal PK profile for use in pediatric patients with ACH, demonstrated by observed apparent mean elimination half-life of 120 hours in adults (Phase 1 trial TCC-101) supporting once-weekly dose administration. In addition to limited efficacy, short-acting CNP and CNP analogues that result in high C_{max} levels may cause adverse cardiovascular events. As ACH is caused by an FGFR3 mutation that chronically inhibits growth, a more constant CNP exposure at lower C_{max} enabled by TransCon CNP (navepegritide) is expected to correlate with better therapeutic outcomes, with lower cardiovascular risk. According to the topline results from TransCon CNP’s (navepegritide) completed global Phase 2 clinical trial, the primary endpoint, AHV at 52 weeks, demonstrated a greater AHV of 5.42 cm/year at 100 µg/kg/week compared to AHV of 4.35 cm/year for placebo, with a p-value of 0.0218. The data showed robust and consistent results in pre-specified analyses across age groups and dose levels, supporting continued development at the selected dose of 100 µg/kg/week. TransCon CNP (navepegritide) was generally well tolerated with low frequency of injection site reactions.

The table below sets forth a comparison between TransCon CNP (navepegritide) and Voxzogo (vosoritide).

	TransCon CNP (navepegritide)	Voxzogo (vosoritide)
Drug structure	Prodrug of unmodified CNP-38	Modified CNP-39 analog
Technology	38 C terminal amino acids of the human CNP53 transiently conjugated to releasable PEG carrier	37 C-terminal residues of the human CNP53 sequence
Clinical Development Status	<ul style="list-style-type: none"> • Phase 2 in China • Global pivotal Phase 3 	<ul style="list-style-type: none"> • Approved by FDA and EMA • No clinical activities in China
Half-life	120 hours	20-45 minutes
Administration	Weekly injection	Daily injection

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	TransCon CNP (navepegritide)	Voxzogo (vosoritide)
Estimated Average Annual Treatment Cost Per Patient	N/A	Approximately US\$350,000/year (WAC) in the United States
Efficacy	The primary endpoint, annualized height velocity at 52 weeks, demonstrated a greater AHV of 5.42 cm/year at 100 CNP µg/kg/week compared to AHV of 4.35 cm/year for pooled placebo, with p=0.0218 (Global Phase 2 trial data).	The primary endpoint adjusted mean difference in annualized growth velocity (AGV) between patients in the Voxzogo (vosoritide) group and placebo group was 1.57 cm/year in favor of Voxzogo (vosoritide). Mean AGV at week 52 of 5.61 cm/year in the Voxzogo group vs. 3.94 cm/year in placebo.
Indications	Under development for the treatment of ACH (pivotal Phase 3 in ages 2-11 years old)	Treatment of ACH in patients aged 5 or older with open epiphyses for FDA and aged 2 or older with open epiphyses for EMA

Source: Literature review, Frost & Sullivan

Key Drivers of the ACH Therapeutic Market in China

- Lack of effective treatment and the development of emerging therapies.* There is currently no effective disease-modifying therapy for ACH approved in China, indicating ACH patients’ urgent need for treatment. As the first ACH therapy that is under clinical development in China, TransCon CNP (navepegritide), licensed to VISEN, is designed to provide continuous CNP exposure at therapeutic levels with a well-tolerated and convenient once-weekly dose, in order to continuously inhibit abnormal FGFR3 signaling, restore proliferation and differentiation of chondrocytes to rebalance bone growth, and therefore has the potential to be a truly effective disease-modifying therapy available in China. The rising development of drugs combined with the growing awareness of this abnormality is expected to create growth opportunities for the ACH therapeutic market in the coming years.

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- *Favorable policies.* To encourage the R&D of rare disease drugs, the PRC government has initiated a series of actions, such as the implementation of an accelerated review system and a priority review system for rare disease drugs and new drugs under the Drug Administration Law of the People's Republic of China 2019 (《中華人民共和國藥品管理法》, 2019). Other policies increasing the affordability of orphan drugs, reducing taxes and introducing related drugs to the national medical insurance were also issued.

Entry Barriers for the ACH Therapeutic Market in China

Despite the market potential and opportunities in the ACH therapeutic market, the barriers to entry remain high, primarily due to a combination of factors as highlighted below:

- *Technical and requisite R&D capability barriers to enter into the ACH therapeutic market remain high.* Although the mode of action of CNP and its treatment potential for ACH have been known for a long time, the extremely short half-life of endogenous CNP, lasting only approximately two minutes, poses a significant challenge in developing drugs that can maintain a sustained and stable drug concentration in the blood. Furthermore, there is currently no effective disease-modifying drug commercially available in China for ACH. Further, the lack of patient data support for the pathogenesis, diagnosis and treatment methods of ACH due to the limited number of cases and dispersed patients has created high scientific research barriers for drug research and development.
- *Marketing of ACH drugs requires substantial efforts.* Providing sufficient physician and patient education is important for launching new drugs into the market, especially for drugs for the treatment of rare disease such as ACH, due to the relatively limited number of patients and dispersed distribution. Therefore, substantial efforts are needed for commercializing the ACH drugs.
- *ACH drug development is capital intensive with substantial R&D costs.* Developing drugs for the treatment of rare diseases, such as ACH, entails substantial R&D costs, including preclinical studies, clinical trials, regulatory submissions and post-marketing surveillance.

HYPOPARATHYROIDISM

HP is a syndrome of abnormal calcium and phosphorus metabolism caused by decreased secretion or defective function of PTH. It is characterized by hypocalcemia, hyperphosphatemia and inappropriately low serum levels of PTH. HP may be due to congenital or acquired disorders. The most common cause of acquired HP is surgery, accounting for approximately 75% of all cases. Postsurgical HP occurs after thyroidectomy and parathyroidectomy due to injury of parathyroid glands and/or their blood supply. Nonsurgical causes of HP include autoimmune diseases or genetic abnormalities, invasive parathyroid disease, and external beam therapy and radioactive iodine treatment of thyroid disease.

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Patients with HP cannot adequately regulate calcium and phosphate metabolism and suffer from low calcium and elevated phosphate levels in the blood. The condition results in a diverse range of physical, cognitive and emotional symptoms. Specifically, patients experience fatigue, muscle pain or cramping, paresthesia, tetany, pain, heaviness or weakness in extremities. HP-related hypocalcemia can cause laryngospasm or grand seizures in severe cases. Over 70% of patients report cognitive disorders including brain fog/mental lethargy, sleep disturbance and memory loss. Around 60% patients experienced anxiety and depression. Other emotional symptoms include emotional sensitiveness, hyperirritability, feeling misunderstood and isolated. Due to the absence of approved PTH replacement therapy for the treatment of HP in China, according to Frost & Sullivan, it is currently unfeasible to determine the market share and market size for HP as there have been no corresponding sales generated in China. The prevalence of HP in China was 410.1 thousand in 2023 and is estimated to reach 495.6 thousand in 2030, representing a significant market.

Current Treatments

Since HP is caused by surgery or genetics, normally there is no prevention method available. Treatment of HP is aimed at correcting hypocalcemia and hyperphosphatemia, reducing symptoms, and preventing chronic complications resulting from the disease or its treatment. Due to the limitations of currently available treatment options, the generally accepted target serum calcium concentration for HP patients is in the lower end of the normal range. According to the Chinese HP guideline, HP was the last remaining classic endocrine deficiency disease for which the missing hormone was not an approved therapy. Current treatments generally fall into two categories: conventional therapy and PTH therapy.

- *Conventional therapy.* Conventional therapy consists of calcium in combination with active vitamin D and sometimes other supplements. While conventional therapy can increase serum calcium level, it is hard to restore the serum calcium level to the normal range. Additionally, conventional therapy often requires the use of very high doses of calcium and active vitamin D, which cause serum calcium fluctuation, high urine calcium and high serum phosphate, potentially putting HP patients at risk for many complications such as impaired renal function and extraskeletal calcifications. Some individuals remain symptomatic or fail to meet treatment goals even after conventional therapy, with some requiring multiple hospitalizations for hypocalcemia or HP complications.
- *PTH therapy.* PTH therapy, as a feasible alternative to conventional treatment, has been shown to maintain normocalcemia with reduced need for concurrent treatment with the therapeutic dosage of calcium and active vitamin D analogs. To date, once-daily Natpara (PTH (1-84)) is the only PTH therapy that has been approved in the United States and the European Union, although merely indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with HP. Natpara (PTH (1-84)) received marketing approval from the FDA in 2015 and a conditional marketing authorization from the EMA in 2017, respectively, but was later recalled from the United States market in 2019. In October 2022, it was announced that the

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manufacturing of Natpara globally will end at the end of 2024. Because Natpara (PTH (1-84)) was approved as an adjunct to calcium and vitamin D, it does not eliminate the inherent risks associated with conventional therapy. In addition, PTH (1-84) has not been able to show meaningful benefits on clinical episodes of hypocalcemia or hypercalcemia or effect on 24-hour urine calcium excretion.

Competitive Landscape of the HP Market in China

No PTH replacement therapy has been approved for HP treatment in China. Palopegteriparatide, licensed to VISEN, is the only PTH replacement therapy that has initiated clinical development in China. The following chart sets forth the PTH replacement therapy that is in clinical development in China.

PTH Replacement Therapy with Clinical Activities in China, as of the Latest Practicable Date

<u>Investigational Drug</u>	<u>Drug Structure</u>	<u>Company</u>	<u>Clinical Status</u>
Palopegteriparatide	Prodrug of PTH	VISEN ⁽¹⁾	Phase 3

- (1) VISEN has gained exclusive licensed rights to develop, manufacture and commercialize in China (including Hong Kong, Macau and Taiwan); Ascendis Pharma retains the rights to develop, manufacture and commercialize outside of China (including Hong Kong, Macau and Taiwan).

Source: CDE, Frost & Sullivan Analysis

Global HP Market Landscape

Outside of China, Natpara (PTH (1-84)) (developed by NPS Pharmaceuticals, which was later acquired by Takeda Pharmaceutical Company (“Takeda”) in 2019) received marketing approval from the FDA in 2015 for once-daily subcutaneous injection as an adjunct to calcium and vitamin D to control HP. Additionally, as of the Latest Practicable Date, Eneboparatide (developed by Amolyt Pharma) and CLTX-305 (developed by Calcilytix Therapeutics) are being developed in Phase 3 global clinical trials; EB612 (developed by Entera Bio), MBX 2109 (developed by MBX Biosciences) and AMOR-1 (developed by Amorphical) are being developed in Phase 2 global clinical trials; and EXT608 (developed by Extend Biosciences) is being developed in Phase 1 global clinical trials. None of these drug candidates have undergone clinical trials in China.

Natpara (PTH (1-84)) is the only available PTH therapy, but is unable to achieve the physiological level and activities of PTH due to its short half-life, and therefore does not have an ideal PK profile. Natpara (PTH (1-84)) has not demonstrated the ability to reduce incidences of hypercalcemia (elevated serum calcium levels), hypocalcemia (low serum calcium) or hypercalciuria (elevated urinary calcium) relative to conventional therapy in treated patients. In September 2019, Natpara (PTH (1-84)) was recalled from the United States market due to the potential for rubber particulate formation. To address this potential issue, Takeda submitted

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a prior approval supplement to the FDA for Natpara (PTH (1-84)) in 2021, which the FDA did not approve pursuant to its complete response letter issued in March 2022. In October 2022, Takeda announced that it will discontinue manufacturing Natpara globally at the end of 2024 due to unresolved supply issues that are specific to the product, and will not re-commercialize Natpara in the United States.

Unlike Natpara (PTH (1-84)), palopegteriparatide is designed as a once-daily PTH replacement therapy with a long half-life to address the fundamental cause of HP by restoring physiological and stable levels of PTH 24 hours throughout the day. PK data from MAD cohorts in Ascendis Pharma’s Phase 1 clinical trial of palopegteriparatide in healthy subjects demonstrated a half-life of approximately 60 hours, supporting an infusion-like profile of free PTH. This substantial half-life extension of PTH would reflect more closely the physiological levels of PTH observed in healthy individuals, maintain normal blood calcium levels, normalize urinary calcium excretion, reduce clinical hypercalcemia, reduce clinical hypocalcemia, normalize serum phosphate and normalize bone turnover. This infusion-like PK profile of palopegteriparatide translates into a predictable serum calcium response, suggesting the ability to titrate patients with HP into the normal calcemic range. See “Business – Our Drug Pipeline – Palopegteriparatide – A PTH Replacement Therapy Addressing the Underlying Cause of HP” for more details. By providing steady levels of PTH in the physiological range, palopegteriparatide has the potential to address the fundamental limitations of short-acting PTH molecules, such as PTH (1-84) and PTH (1-34) and become a highly differentiated therapy for HP. Palopegteriparatide was approved by the EMA and the FDA in November 2023 and August 2024, respectively, for the treatment of adult patients with chronic HP and was commercially launched in certain European countries in January 2024.

The table below sets forth a comparison between palopegteriparatide and Natpara (PTH (1-84)). Compared to Natpara (PTH (1-84)), palopegteriparatide shows more promising clinical results, with longer half-life and better efficacy.

	<u>Palopegteriparatide</u>	<u>Natpara (PTH (1-84))</u>
Formulation	<ul style="list-style-type: none">• Prodrug of unmodified PTH (1-34)• Restore physiological and stable levels of PTH 24 hours throughout the day	PTH (1-84)
Clinical Development Status	<ul style="list-style-type: none">• Phase 3 in China• Approved by FDA and EMA	<ul style="list-style-type: none">• Approved by FDA and EMA; approval subsequently recalled in the United States• No clinical activities in China
Half-life	60 hours	3 hours
Administration	Daily injection	Daily injection

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	<u>Palopegteriparatide</u>	<u>Natpara (PTH (1-84))</u>
Estimated Average Annual Treatment Costs Per Patient	N/A	N/A
Efficacy	<ul style="list-style-type: none"> • 91% patients stopped Vitamin D and reduced calcium to ≤ 500 mg/day • 76% patients stopped Vitamin D and calcium supplementation entirely • QoL*: SF-36 improved from baseline* <ul style="list-style-type: none"> • PCS*: 44 to 51 • MCS*: 44 to 52 	<ul style="list-style-type: none"> • 43% patients stopped Vitamin D and reduced calcium to ≤ 500 mg/day • QoL: SF-36 improved from baseline* <ul style="list-style-type: none"> • PCS: 47 to 49 • MCS: 50 to 52
Indications	Under development for the treatment of HP	An adjunct to calcium and vitamin D to control hypocalcemia in patients with HP

Notes:

* QoL = Quality of Life, SF-36 = 36-Item Short-Form Health Survey, PCS = Physical Component Summary, MCS = Mental Component Summary

Source: Literature review, FDA, EMA, Frost & Sullivan

Key Drivers of the HP Therapeutic Market in China

- *Emerging new therapies for HP.* The currently available therapies have various limitations as discussed above, including risk for complications, and limited ability to reduce incidences of hypercalcemia, hypocalcemia or hypercalciuria. As an emerging therapy for HP, palopegteriparatide, on the other hand, can address the fundamental cause of HP by restoring physiological and stable levels of PTH 24 hours throughout the day, and thereby maintain normal blood calcium levels, normalize urinary calcium excretion, reduce clinical hypercalcemia, reduce clinical hypocalcemia, normalize serum phosphate and normalize bone turnover. Emerging new therapies such as palopegteriparatide, once available in the market, are expected to boost the market growth by significant therapeutic desire increase from patients.
- *Increasing patient pool and disease awareness.* The improvement of early screening and diagnosis of thyroid cancer will contribute to an increasing patient pool for thyroid cancer and thyroidectomy cases, which will cause more HP consequently. Moreover, increasing education among doctors and patients is expected to improve their rate of awareness and treatment rate, which will further support the growth of the HP therapeutic market in China.

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- *Favorable policies.* The PRC government has been dedicated to increasing the accessibility and affordability of healthcare services by expanding medical insurance coverage. We expect to see more novel drugs be added to the NRDL, which is expected to drive the adoption rates of these new drugs and ultimately the HP therapeutic market in China. In September 2023, genetic HP has been included to the second China Rare Disease List issued by the National Health Commission, highlighting the favorable policies and the commission’s commitment to improving disease treatment and increasing medicine accessibility for HP.

Entry Barriers for the HP Therapeutic Market in China

Despite the market potential and opportunities in the HP therapeutic market, the barriers to entry remain high, primarily due to a combination of factors as highlighted below:

- *Technical and requisite R&D capability barriers to enter into the HP therapeutic market remain high.* Most patients with HP who are having conventional therapy will need to take calcium and vitamin D supplements for life, which lack efficacy and fail to restore normal parathyroid hormone physiology. PTH therapy, on the other hand, calls for strong R&D capability to overcome the inherent risks associated with conventional therapy, such as serum calcium fluctuation, high urine calcium and high serum phosphate. Further, the lack of patient data support for the pathogenesis, diagnosis and treatment methods of HP due to the limited number of cases and dispersed patients has created high scientific research barriers for drug research and development.
- *Marketing of HP drugs requires substantial efforts.* Providing sufficient physician and patient education is important for launching new drugs into the market, especially for drugs for the treatment of rare disease such as HP, due to the relatively limited number of patients and dispersed distribution. Therefore, substantial efforts are needed for commercializing the HP drugs.
- *HP drug development is capital intensive with substantial R&D costs.* Developing drugs for the treatment of rare diseases, such as HP, entails substantial R&D costs, including preclinical studies, clinical trials, regulatory submissions and post-marketing surveillance.

SOURCE OF INFORMATION

We commissioned Frost & Sullivan to conduct an analysis of and to prepare a report on global and China endocrine drug markets. We agreed to pay Frost & Sullivan a total fee of US\$165,462. Except as otherwise noted, all of the data and forecasts contained in this section are derived from the Frost & Sullivan Report. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking, and strategic and market planning for a variety of industries.

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The Frost & Sullivan Report was compiled based on the following assumptions: (i) the social, economic and political environments of the PRC will remain stable during the forecast period, which will ensure a sustainable and steady development of the PRC healthcare industry; (ii) the PRC healthcare market will grow as expected due to rising healthcare demand and supply; and (iii) the PRC government will continue to support healthcare reform.

In compiling and preparing the Frost & Sullivan Report, Frost & Sullivan used the following key methodologies to collect multiple sources, validate the data and information collected, and cross-check each respondent’s information and views against those of others: (i) secondary research, which involved reviewing published sources including national statistics, annual reports of listed companies, industry reports and data based on Frost & Sullivan’s own research database; and (ii) primary research, which involved in-depth interviews with the industry participants.

Frost & Sullivan’s projections are made based on various market determinants and their coefficients assigned to a market which indicate their relative importance. The market determinants represent both subjective assumptions and objective factors, therefore, the projected data may not be consistent with the real data.

REGULATORY ENVIRONMENT

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section sets out a summary of the major relevant laws, regulations, rules and policies which may have material impact on our business and operations.

REGULATIONS ON COMPANY ESTABLISHMENT AND FOREIGN INVESTMENT IN THE PRC

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 “PRC Company Law”), which was promulgated by the Standing Committee of the NPC in December 1993 and further amended in December 1999, August 2004, October 2005, December 2013, October 2018 and December 2023, respectively. According to the PRC Company Law, companies are generally classified into two categories: limited liability companies and companies limited by shares. The PRC Company Law also applies to foreign-invested limited liability companies and foreign-invested companies limited by shares. According to the PRC Company Law, where laws on foreign investment have other stipulations, such stipulations shall prevail.

Currently investment activities in the PRC by foreign investors are primarily governed by the Special Administrative Measures for the Access of Foreign Investment (Negative List) (Edition 2021) (《外商投資准入特別管理措施(負面清單)(2021年版)》) and Special Administrative Measures (Negative List) for the Access of Foreign Investment in Pilot Free Trade Zones (Edition 2021) (《自由貿易試驗區外商投資准入特別管理措施(負面清單)(2021年版)》) (collectively, the “Negative Lists”), which were promulgated by the MOFCOM and National Development and Reform Commission (the “NDRC”) in December 2021 and came into effect since January 1, 2022. The Negative Lists set out the special administrative measures in a unified manner in respect of the access of foreign investments, such as the industries that are prohibited for foreign investment, the limits on shareholding percentages of foreign investors and the requirements on the participation of foreign investors in the operation and management. The Negative Lists cover 11 industries, and any field not falling in the Negative Lists shall be administered under the principle of equal treatment for domestic and foreign investment. Our business as currently conducted does not fall within the confines of the Negative Lists and is not subject to foreign investment restrictions.

Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “Foreign Investment Law”) was promulgated by the NPC in March 2019 and came into effect in January 2020. After the Foreign Investment Law came into effect, the trio of Law on Wholly Foreign-owned Enterprises of the PRC (《中華人民共和國外資企業法》), the Law on Sino-foreign Equity Joint Ventures of the PRC (《中華人民共和國中外合資經營企業法》) and the Law on Sino-foreign Cooperative Joint Ventures of the PRC (《中華人民共和國中外合作經營企業法》) have been repealed simultaneously. The investment activities of foreign natural persons, enterprises or other organizations (hereinafter referred to as “foreign investors”) directly or indirectly within the territory of China shall comply with and be governed by the Foreign Investment Law, including: 1) foreign investors establishing foreign-invested enterprises in China alone or jointly with other investors; 2) foreign investors acquiring shares,

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equity, property shares, or other similar interests of Chinese domestic enterprises; 3) foreign investors investing in new projects in China alone or jointly with other investors; and 4) other forms of investment prescribed by laws, administrative regulations or the State Council.

In December 2019, the State Council promulgated the Regulations on Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) (the “Implementation Rules”), which came into effect in January 2020. The Implementation Rules further clarified that the state shall encourage and promote foreign investment, protect the lawful rights and interests in foreign investments, regulate foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

In December 2019, the MOFCOM and the SAMR promulgated the Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》) (the “Reporting Measures”), which came into effect in January 2020. After the Reporting Measures came into effect, the Interim Measures for the Administration of Filing for Establishment and Changes in Foreign Investment Enterprises (《外商投資企業設立及變更備案管理暫行辦法》) has been repealed simultaneously. Since January 1, 2020, foreign investors or foreign-invested enterprises carrying out investment activities directly or indirectly in China shall submit investment information to the relevant commerce administrative authorities according to the Reporting Measures.

REGULATIONS ON PHARMACEUTICAL PRODUCT DEVELOPMENT, APPROVAL AND REGISTRATION IN THE PRC

Drug Regulatory Regime

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “Drug Administration Law”) was promulgated by the Standing Committee of the NPC in September 1984. The latest amendment to the Drug Administration Law was promulgated in August 2019 and took effect in December 2019. The Regulations for the Implementation of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) (the “Regulations for the Implementation of the Drug Administration Law”) was promulgated by the State Council in August 2002, and was last amended and took effect in March 2019. The Drug Administration Law and the Regulations for the Implementation of the Drug Administration Law have laid down the current legal framework for drug development, production, distribution, use, supervision and management within the territory of China. The Drug Administration Law also regulates the packaging, pricing and advertisements of pharmaceutical products in the PRC. On May 9, 2022, the National Medical Products Administration issued the Implementation Regulations of the Drug Administration Law of the PRC (Revised Draft for Comments) (《中華人民共和國藥品管理法實施條例(修訂草案徵求意見稿)》), which made proposed changes in R&D, production, sales, supervision and management of drugs, and the proposed changes related to us mainly relates to our drug sales operation.

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The Law of the PRC on the Promotion of Basic Medical Care, Hygiene and Health (《中華人民共和國基本醫療衛生與健康促進法》) was promulgated by the Standing Committee of the NPC in December 2019 and took effect in June 2020. This law aims at developing medical care, hygiene and health undertakings, ensuring citizens’ access to basic medical and health services and raising the health level of citizens. Citizens shall have the right to obtain basic medical and health services from the State and the society pursuant to the law. The State shall establish basic medical and health care system and set up a sound medical and health service system to protect and realize citizens’ right to obtain basic medical and health services.

In June 2021, the National Healthcare Security Administration (the “NHSA”) promulgated the Healthcare Security Law (Draft for Comments) (《醫療保障法(徵求意見稿)》) for public comments. The law aims to regulate the networks of healthcare security, form a high-quality, multi-level healthcare security system, protect citizens’ lawful rights to healthcare security and promote the benign development of healthcare security.

Regulatory Authorities

In the PRC, pharmaceutical products, medical devices and equipment are monitored and supervised on a national scale by the NMPA. The local provincial medical products administrative authorities are responsible for supervision and administration of drugs within their respective administrative regions. The NMPA was newly formed under the SAMR. The NMPA’s predecessor, the State Drug Administration, the SDA, was replaced by the State Food and Drug Administration, the SFDA, which was later reorganized into the China Food and Drug Administration, the CFDA, as part of the institutional reforms implemented by the State Council. The CDE, which is subordinate to the NMPA, conducts the technical evaluation of each drug and biologic application to assess safety and efficacy.

In 2013, the Ministry of Health (the “MOH”) and the National Population and Family Planning Commission were integrated into the National Health and Family Planning Commission of the PRC (the “NHFPC”). In March 2018, the First Session of the Thirteenth NPC approved the State Council Institutional Reform Proposal (《國務院機構改革方案》), according to which, the responsibilities of NHFPC and certain other Governmental Authorities are consolidated into the National Health Commission (the “NHC”), and the NHFPC shall no longer be reserved. The responsibilities of the NHC include public hospital administration, prevention and control of chronic diseases and pandemics, promotion of maternal and children health and health of senior citizens as well as the drug use policies including organizing the formulation of national drug policies, the national essential drug system and the National Essential Drug List and drafting the administrative rules for the procurement, distribution and use of national essential drugs. According to the State Council Institutional Reform Proposal, the NHSA was finally established as a new organization directly under the State Council to integrate those functions and duties formerly assumed by the Ministry of Human Resources and Social Security of the PRC (the “MHRSS”) in terms of basic medical insurance systems and maternity insurance systems covering urban employees and urban residents, by the NHFPC in terms of the new rural cooperative healthcare system, by the NDRC in terms of drug and medical service price management, and by the Ministry of Civil Affairs in terms of medical aids.

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Regulations on the Clinical Trials and Registration of Drugs

Administrative Measures for Drug Registration

The Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the “Registration Measures”) were promulgated by the SAMR in January 2020 and took effect in July 2020, which replaced the previous Registration Measures promulgated by the SFDA in July 2007. Pursuant to the Registration Measures, drug marketing registration applications shall be subject to three categories, namely traditional Chinese drugs, chemical drugs and biological products. Among them, the registration applications of biological products shall be categorized by innovative biological products, new modified biological products, already-marketed biological products (including biological similar drugs), etc. If all the regulatory requirements are satisfied, a Drug Registration Certificate with a validity period of five years will be issued by the NMPA. After obtaining the Drug Registration Certificate, the applicant shall be the marketing authorization holder (the “MAH”). The MAH shall continually ensure the safety, efficacy and quality controllability of the drug marketed and shall apply for drug re-registration six months prior to the expiry date of the Drug Registration Certificate.

Accelerated Approval for Clinical Trial and Registration

The CFDA released the Circular concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) in November 2015, which clarified the measures and policies regarding, among others simplifying and accelerating the approval process of clinical trials, including but not limited to the adoption of a one-time umbrella approval procedure allowing the overall approval of all phases of a new drug’s clinical trials, replacing the phase-by-phase application and approval procedure.

The General Office of the State Council and the Central Committee of the Communist Party of China jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the “Innovation Opinions”) in October 2017. The Innovation Opinions established a framework for reforming the evaluation and approval system for drugs, medical devices and equipment. The Working Procedures for the Evaluation of Breakthrough Therapy Designation Drugs (for Trial Implementation) (《突破性治療藥物審評工作程序(試行)》), the Working Procedures for the Review and Approval of Conditioned Marketing of Drugs (for Trial Implementation) (《藥品附條件批准上市申請審評審批工作程序(試行)》) and the Working Procedures for the Prioritized Review and Approval of Drug Marketing Authorization (for Trial Implementation) (《藥品上市許可優先審評審批工作程序(試行)》), promulgated by the NMPA and came into effect on July 7, 2020 further clarified the availability and applicability of fast track registration procedures for innovative drugs.

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

Pursuant to the Administrative Measures for Communication of Drug R&D and Technical Review (《藥物研發與技術審評溝通交流管理辦法》) (the “Communication Measures”) issued by the CDE on December 10, 2020, which came effective on the same day, during the research and development, and application for registration stages of innovative drugs, the applicants may propose communication sessions with the CDE regarding key technical issues which are not addressed in drug development and evaluation guidelines. The forms of such communication sessions include face-to-face conference, video conference, telephone conference or written reply. In general, such communication sessions are classified into three types, namely, Class I, Class II and Class III, among which, Class I sessions are convened to discuss the key safety issues in the clinical trials of drugs and in the research and development of breakthrough therapeutic drugs, or other situations deemed applicable. Prior to applying for marketing approval for prophylactic or therapeutic biological products, in principle the applicant shall submit a request for communication sessions with the CDE. Further, the CDE issued the Guidelines of Application for and Management of Class I Session for Communication on Children’s Drugs (for Trial Implementation) (the “Guidelines of Class I Session for Children’s Drugs”) on April 18, 2023, which was promulgated for the purpose of refining the application and management process for communication and exchange of children’s medicines in accordance with the Communication Measures. According to the Guidelines of Class I Session for Children’s Drugs, application of registration or innovative drugs will be deemed as “other scenarios deemed applicable” for which a Class I session can be applied under the Communication Measures provided that such innovative drugs have been marketed abroad and have obtained pediatric use licenses, and have important value for meeting the clinical treatment needs of children in China. In particular, such scenario can be further classified into: the innovative drug has not been approved for marketing in China and the applicant is applying for marketing registration in China; the innovative drug has been marketed in China and has obtained an adult use license or a pediatric use license for some age groups, and the applicant is applying to increase the child use population; the innovative drug has been marketed in China and has obtained a pediatric use license or an adult use license for certain indications, and the applicant is applying to increase the indications for children. The Guidelines of Class I Session for Children’s Drugs also specify a clear pathway for applicant to submit the application of Class I sessions for children’s drugs to CDE, which include: (i) after receiving a request for a Class I session, the project manager of the CDE will review the “session purpose” prepared by the applicant; (ii) if the request for Class I Session meets the requirements specified thereunder, it will be forwarded to the relevant professional review team; and (iii) the clinical professional review team is responsible for reviewing the application material for Class I session and confirming whether to proceed with a Class I session. If the request for a Class I session meets the requirements but has significant deficiencies in the application materials (such as unclear pediatric clinical trial plans, obviously unreasonable trial design, or failure in submitting explanation for applying for Class I session), the application request will be rejected.

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According to the Announcement on the Issuance of the “Administrative Measures for Post-Marketing Changes of Drugs (Trial)” (2021 No. 8) (《國家藥監局關於發布〈藥品上市後變更管理辦法(試行)〉的公告》(2021年第8號)), the NMPA shall prioritize the evaluation and approval process for marketing registration applications of overseas-original chemical pharmaceuticals and biological products that have obtained marketing approval for shifting to domestic manufacture.

Acceptance of Foreign Clinical Trial Data

On July 6, 2018, the NMPA issued the Guiding Technical Principles on Accepting Foreign Drug Clinical Trial Data (《接受藥品境外臨床試驗數據的技術指導原則》) (the “Guiding Technical Principles”) as one of the implementing rules for the Innovation Opinions, which provides that overseas clinical data can be submitted for the drug registrations in China. According to the Guiding Technical Principles, applicants may use the data of overseas clinical trials to support drug registration in China, provided that applicants must ensure the authenticity, completeness, accuracy and traceability of overseas clinical trial data and such data must be obtained consistent with the relevant requirements under the Good Clinical Trial Practice (GCP) of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. Sponsors must also comply with other relevant sections of the Registration Measures when applying for drug registrations in China using overseas clinical trial data.

Approval Authority and Process for Clinical Trial Applications

According to the Registration Measures, upon the completion of the pharmaceutical, pharmacological and toxicological research, etc., which support the drug clinical trial, the applicant may submit relevant research materials for drug clinical trial application to CDE according to relevant requirements. The CDE shall organize pharmaceutical, medical and other technicians to review the accepted application and to decide whether to approve the drug clinical trial within 60 days of the date of acceptance of the application. The result will be notified to the applicant through the website of the CDE and if no notice of decision is issued within the aforementioned time limit, the application of clinical trial shall be deemed as approved and the applicant may carry out the drug clinical trial according to the submitted clinical trial plan. The Registration Measures further require that the sponsor, i.e., the applicant carrying out the drug clinical trial with approval, shall, prior to conducting the drug clinical trial, register the relevant information of the drug clinical trial plan on the Drug Clinical Trial Registration and Information Publicity Platform. During the drug clinical trials, the applicant shall update registration information continuously, and register information of the outcome of the drug clinical trial upon completion. The applicant shall be responsible for the authenticity of the drug clinical trial information registered on the platform. Pursuant to the Notice on the Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) promulgated by the SFDA in September 2013, the applicant shall complete the trial pre-registration within one month after obtaining the approval of the clinical trial application in order to obtain the trial’s unique registration number, and complete the registration of certain follow-up information before the first subject’s enrollment in the trial and submit for first-time publication. If the submission for first-time publication is not completed within one year after the approval, the applicant shall submit an explanation, and if the submission for first-time publication is not completed within three years after the approval, the approval of the clinical trial application shall automatically expire.

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Compliance with GCP and Drug Clinical Institutions

The conduct of clinical trials for the purpose of application for drug registration must adhere to the Good Clinical Trial Practice for Drugs (《藥物臨床試驗質量管理規範》) (the “GCP Rules”), which was promulgated by the SFDA in August 2003 and further amended by the NMPA and NHC in April 2020 and came into effect in July 2020. According to the GCP Rules, clinical trial means a systematic investigation of drugs conducted on humans (patients or healthy subjects) to reveal or validate, clinically, the medical, pharmacological and other pharmacodynamic effects, adverse reactions, or absorption, distribution, metabolism and excretion of a trial drug, so as to determine its efficacy and safety. In order to ensure the quality of clinical trials and the safety of human subjects, the GCP Rules provides comprehensive and substantive requirements on the design and conduct of clinical trials in China. In particular, the GCP Rules enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials.

The GCP Rules stipulated that the sponsor shall bear the cost of diagnosis, medical treatment and the corresponding compensation for any human subject who is harmed or dies due to reasons related to the clinical trial. The sponsor and investigator shall pay the human subject the compensation or indemnification in a timely manner. However, the GCP Rules promulgated in 2020 abolished the compulsory insurance that the sponsor shall provide to human subjects participating in a clinical trial as previously prescribed in the GCP Rules promulgated in 2003.

The GCP Rules also set out the qualifications and requirements for the investigators and drug clinical trial institutions, including: (i) possessing the qualification to practice in a drug clinical trial institution, possessing the professional knowledge, training experience and capability required for a clinical trial, and being able to provide the latest resume and relevant qualification documents as requested by the sponsor, ethics committee and competent medical products administration; (ii) being familiar with the trial protocol, investigator’s brochure and relevant information of the trial drug provided by the sponsor; (iii) being familiar and in compliance with the GCP Rules and relevant laws and regulations relating to clinical trials; (iv) keeping a copy of the authorization form on responsibility allocation signed by investigators; (v) investigators and drug clinical trial institutions shall accept supervision and inspection organized by the sponsor and inspection by the drug regulatory authorities; and (vi) in the case of investigators and drug clinical trial institutions authorizing other individual or institution to undertake certain responsibilities and functions relating to clinical trial, ensuring such individual or institution are qualified and establishing complete procedures to ensure the responsibilities and functions are fully performed and reliable data can be generated.

The GCP Rules also stipulate the responsibilities of ethics committee in clinical trial process. An ethics committee shall consist of experts working in the medical, pharmaceutical and other fields in accordance with the requirements of the competent health department. The clinical trial protocol may not be executed unless approved by the ethics committee. In November 2019, the NMPA and the NHC jointly promulgated the Notice on Issuing the

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Administration Rules of Drug Clinical Trial Institution (《關於發佈藥物臨床試驗機構管理規定的公告》) (the “Clinical Trial Institution Notice”), which stipulates that each drug clinical trial institution shall maintain an ethics committee responsible for the ethical review of drug clinical trial.

According to the Clinical Trial Institution Notice, drug clinical trial institutions refer to institutions eligible to undertake the drug clinical trials and shall have been duly recorded with the online platform designated by the NMPA. These rules have specified the requirements for drug clinical trial institutions and require that a clinical trial institution should evaluate or engage a third party to evaluate whether it has met such requirements before applying for recordal. A drug clinical trial applicant should only engage a duly recorded clinical trial institution to carry out a drug clinical trial and the clinical trial institution engaged must, during the conduct of clinical trials, comply with the GCP Rules and other technical guidelines for drug clinical trials.

Drug Marketing Registration

According to the Registration Measures, the applicant may submit an application for drug marketing registration to CDE upon completion of relevant research on pharmacy, pharmacology, toxicology and drug clinical trials which support the drug marketing registration, determination the quality standards of the drug, validation of commercial-scale production processes and preparation for acceptance of verification and inspection conducted by professional technical institution designated by competent NMPA. The application shall be accepted if the application materials are deemed acceptable upon examination in form. The CDE will organize pharmaceutical, medical and other technicians to conduct comprehensive review of the safety, efficacy and quality controllability, among others, of the drug based on the accepted application materials submitted by the applicant, the results of the verification and inspection conducted by professional technical institution, etc. If the comprehensive review conclusion is affirmative, the drug shall be approved for marketing and a Drug Registration Certificate will be issued containing the information of the drug approval number, the MAH, and the manufacturer.

According to the Registration Measures, overseas manufactured drugs (imported drugs) and locally manufactured drugs are subject to different registration pathways. Therefore, if a drug has been registered in the PRC as an overseas manufactured drug and then the manufacturing is to be moved to a PRC manufacturing site, the drug is required to apply for a new Drug Registration Certificate as a locally manufactured drug.

The MAH System

According to the Drug Administration Law, the state implements the MAH system. In accordance with the Drug Administration Law and the Registration Measures, the holder of a Drug Registration Certificate shall be an MAH. An MAH may manufacture and sell drugs or engage pharmaceutical manufacturing enterprise to manufacture drugs and/or pharmaceutical distribution enterprise to sell drugs.

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An MAH shall be responsible for non-clinical research, clinical trials, manufacturing and business operation, post-marketing research, adverse reaction monitoring and reporting and handling. An MAH may not engage a pharmaceutical manufacturing enterprise to produce blood products, narcotic drugs, psychotropic drugs, toxic drugs for medical use, and pharmaceutical precursor chemical, except as otherwise stipulated by the drug regulatory department under the State Council.

Where an MAH is an overseas enterprise, its designated domestic enterprise shall perform the obligations of an MAH and jointly assume the responsibilities of an MAH.

International multi-center clinical trials regulations

On January 30, 2015, the CFDA promulgated the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) (《國際多中心藥物臨床試驗指南(試行)》) (the “Multi Regional Clinical Trial Guidelines”), which took effect as of March 1, 2015, aiming to provide guidance for the regulation of application, implementation and administration of international multi-center clinical trials in China. Pursuant to the Multi-Center Clinical Trial Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Applicant may make use of the data derived from the international multi-center clinical trials for application to the NMPA for approval of a NDA/BLA after satisfying certain requirements under the Multi-Regional Clinical Trial Guidelines. International multi-center clinical trials shall follow internationally prevailing GCP principles and ethics requirements.

Data derived from international multi-center clinical trials can be used for the NDAs or BLAs with the NMPA. When using international multi-center clinical trial data to support NDAs or BLAs in China, applicants shall submit the completed global clinical trial report, statistical analysis report and database, along with relevant supporting data in accordance with ICH-CTD (International Conference on Harmonization-Common Technical Document) content and format requirements; subgroup research results summary and comparative analysis shall also be conducted concurrently.

Human Genetic Resources Approval

The Regulation on the Management of Human Genetic Resources (《人類遺傳資源管理條例》), promulgated by the State Council on May 28, 2019 and effective on July 1, 2019, replaces the Interim Administrative Measures on Human Genetic Resources (《人類遺傳資源管理暫行辦法》) promulgated by the Ministry of Science and Technology and the MOH in June 1998, and further regulates the collection, preservation, utilization and external provision of China’s human genetic resources. According to this regulation, “human genetic resource” includes human genetic resource materials and information. Human genetic resource materials refer to the genetic materials with respect to organs, tissues, cells and other genetic materials containing human genome, genes and other genetic substances. Human genetic resource information refers to information, such as data, generated from the use of human genetic resources materials. The Administrative Department of Science and Technology under the State Council is responsible for the management of human genetic resources at the national level, and the administrative departments of science and technology under the provincial governments are responsible for the management of human genetic resources at local level and

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are vertically directed by the central government of the PRC. Foreign organizations, individuals and institutions established or actually controlled by foreign organizations and individuals are not allowed to collect or preserve human genetic resources (including organs, tissues, cells and other genetic materials of human genome and gene) in China or provide human genetic resources abroad. Whoever utilizes China’s human genetic resources for international cooperation in scientific research shall meet the conditions stipulated in this regulation, and the two parties shall jointly submit an application to the Administrative Department of Science and Technology under the State Council for approval. Examination and approval shall become unnecessary for international cooperation in clinical tests on the basis of China’s human genetic resources in the clinical institution in order to obtain the marketing authorization in China with respect to relevant drugs and medical instruments, which will not involve the provision of materials of human genetic resources abroad. However, the two parties shall, prior to clinical tests, submit the categories, quantities and purposes of the human genetic resources to be utilized to the Administrative Department of Science and Technology under the State Council for filing. The Administrative Department of Science and Technology under the State Council and the Administrative Department of Science and Technology under the people’s governments of the provinces, autonomous regions and municipalities directly under the Central Government shall strengthen the supervision of filing. The two parties may utilize the information of human genetic resources generated from international cooperation in scientific research on the basis of China’s human genetic resources. On March 16, 2023, the State Council released the State Council Notice on Establishment of the Institutions (《國務院關於機構設置的通知》) (the “SC Notice”), which was promulgated based on the adopted Party and the State Council Institutional Reform Plan 2023 (《黨和國家機構改革方案(2023)》) (the “Reform Plan”) and become effective on the same date. According to the SC Notice and the Reform Plan, China National Center for Biotechnology Development (together with its subdivision the China Human Genetic Resources Administration Office), which is affiliated to the Ministry of Science and Technology, is expected to be an affiliated body of the NHC.

On March 21, 2022, the Ministry of Science and Technology issued the Implementing Rules of the Administrative Regulations on Human Genetic Resources (for Public Comments) (《人類遺傳資源管理條例實施細則(徵求意見稿)》) (the “Human Genetic Resources Implementing Rules”) for public comments, which provided specific provisions on the collection, preservation, utilization and external provision of human genetic resources of the PRC.

On May 26, 2023, the Ministry of Science and Technology promulgated the Implementation Rules for the Administrative Regulation on Human Genetic Resources (《人類遺傳資源管理條例實施細則》), or the Implementation Rules for HGR, which has come into effect on July 1, 2023. The Implementation Rules for HGR further provide detailed implementation regulations for the Administration of Human Genetic Resources of the PRC, such as:

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

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- Further clarifying the criteria to constitute a Foreign Entity, which shall include (i) any foreign organization or individual that holds directly or indirectly more than 50% of the shares, equity interests, voting rights, property shares or other interests in the institution, (ii) any foreign organization or individual that is able to dominate or have material effect on the decision-making or management of the institution through its voting right or other interests, although the shares, equity interests, voting rights, property share or other interests it directly or indirectly holds in the institution is less than 50%, (iii) any foreign organization or individual that is able to dominate or have material effect on the decision-making or management of the institution through investment relationship, contract or other arrangement; and (iv) other situations stipulated by laws, regulations and rules;
- Specifically listing the situations where security review may be required, which shall include: (i) human genetic resource information of important genetic families; (ii) human genetic resources information of specific regions, (iii) exome sequencing and genome sequencing information resources with a population greater than 500 cases; and (iv) other situation that may affect the public health, national security and social public interest of China; and
- Further improving the clarity and efficiency of the administration of human genetic resources, for example, clarifying the method for the calculation of illegal gains and providing detailed exemptions on certain matters that are subject to approval.

On October 17, 2020, the Standing Committee of the NPC adopted the Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the “Biosecurity Law”), which has become effective on April 15, 2021. The Biosecurity Law establishes an integrated system to regulate biosecurity related activities in China, including the security regulation of human genetic resources and biological resources. The Biosecurity Law for the first time expressly declares that China has sovereignty over its human genetic resources, and further endorsed the Regulation on the Management of Human Genetic Resources by recognizing the fundamental regulatory principles and systems established by it over the utilization of Chinese human genetic resources by foreign entities in China. Although the Biosecurity Law does not provide any specific new regulatory requirements for human genetic resources, because it is a law adopted by China’s highest legislative authority, it gives China’s major regulatory authority of human genetic resources, the NHC, significantly more power and discretion to regulate human genetic resources, and it is expected that the overall regulatory landscape of Chinese human genetic resources will evolve and become even more rigorous and sophisticated. Failure to comply with the requirement under the Biosecurity Law will result in penalties, including fines, suspension of related activities and confiscation of related human genetic resources and gains generated from conducting these activities.

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Regulations on Drug Manufacturing

According to the Drug Administration Law and the Regulations for the Implementation of the Drug Administration Law, a drug manufacturing enterprise is required to obtain a Drug Manufacturing Permit from the relevant provincial drug administration authority of the PRC. The grant of such permit is subject to an inspection of the manufacturing facilities, and an inspection to determine whether the sanitary condition, quality assurance systems, management structure and equipment meet the required standards. According to the Measures on the Supervision and Administration of the Manufacture of Drugs (《藥品生產監督管理辦法》) (the “Drug Manufacturing Measures”), last amended on January 22, 2020 and came into effect on July 1, 2020, the Drug Manufacturing Permit is valid for five years and shall be renewed at least six months prior to its expiration date upon a re-examination by the original issuing authority. In addition, the name, unified social credit code, registered address (business premises) and legal representative specified in the drug manufacturing permit shall be the same as that set forth in the business license as approved and issued by the local counterparts of the SAMR. According to the Drug Manufacturing Measures, if the MAH does not manufacture the drug but entrusts others to manufacture the drug, the MAH shall enter into an entrustment agreement and a quality agreement with a qualified drug producer and submit the relevant agreements and the application materials of the actual production site to the competent provincial counterpart of the NMPA where the MAH is located to apply for the Drug Manufacturing Permit.

The Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) (the “GMP Rules”) was last amended on January 17, 2011 and came into effect on March 1, 2011. The GMP Rules comprise a set of detailed standard guidelines governing the manufacture of drugs, including institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and management of customer complaints and AE reports. Under the Drug Manufacturing Measures, a GMP certification is no longer required for drug manufacturing enterprises, but drug manufacturing enterprises shall comply with the GMP Rules in their drug manufacturing activities.

Regulations on Drug Operation

According to the Drug Administration Law, the operation of drug business, including drug wholesale and drug retail, is prohibited without a Drug Operation Permit. A Drug Operation Permit shall state the validity period and the scope of business and be subject to review and reissuance upon expiry of the validity period.

According to the Measures for the Administration of Drug Operation License (《藥品經營許可證管理辦法》), promulgated on February 4, 2004 and amended on November 7, 2017, a Drug Operation Permit is valid for five years. Each holder of the Drug Operation Permit must apply for an extension of its permit six months prior to expiration.

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The Good Supply Practice for Pharmaceutical Products (《藥品經營質量管理規範》) (the “GSP Rules”) was last amended and came into effect on July 13, 2016. The GSP Rules set forth the basic standards in management of operation quality of drugs and apply to enterprises engaged in drug operations in the PRC, which require drug operators to implement strict controls on its operation of pharmaceutical products, including standards regarding staff qualifications, premises, warehouses, inspection equipment and facilities, management and quality control. Under the Drug Administration Law of the PRC, the GSP certification is no longer required for drug operators, but drug operators are still required to comply with the GSP Rules.

Regulation of Medical Devices

Pursuant to the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) amended by the State Council on February 9, 2021 and came into effect on June 1, 2021, in the PRC, medical devices have been classified into three categories based on the degree of risk. Class I medical devices refer to those devices with low risk and whose safety and effectiveness can be ensured through routine administration. Class II medical devices refer to those devices with medium risk and whose safety and effectiveness should be strictly controlled. Class III medical devices refer to those devices with high risk and whose safety and effectiveness must be strictly controlled with special measures.

REGULATIONS ON COVERAGE AND REIMBURSEMENT IN THE PRC

National Reimbursement Drug List

In 2015, the State Council announced the Outline for the Planning of the National Medical and Health Service System (2015-2020) (《全國醫療衛生服務體系規劃綱要(2015-2020年)》), which aims to establish a basic medical and healthcare system that covers both rural and urban citizens by 2020. Participants of the national medical insurance program and their employers, if any, are required to contribute to the medical insurance fund on a monthly basis. Program participants are eligible for full or partial reimbursement of the costs of medicines included in the National Drug Catalogue for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》) or the NRDL.

The NHSA has the power to determine which medicines are listed in the NRDL. Medicines listed in the NRDL are divided into two parts, List A and List B. List A drugs are widely used clinical treatments with good efficacy and lower prices compared to similar drugs. Patients purchasing medicines included in List A of the NRDL shall be reimbursed the purchase price through the medical insurance fund in full. While List B drugs are clinical treatments with good efficacy and slightly higher prices compared to List A drugs. Patients purchasing medicines included in List B of the NRDL are required to pay a certain percentage of the purchase price itself and obtain reimbursement for the remainder of the purchase price through the medical insurance fund. The NHSA promulgated the Announcement on the Release of the

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Work Plan for the Adjustment of the National Medical Insurance Drug Catalogue in 2019 (《關於公佈<2019年國家醫保藥品目錄調整工作方案>的公告》) on April 17, 2019, stipulating that the exclusive patent drugs with higher price or greater influence on the medical insurance fund shall be admitted into the NRDL through negotiation. According to the Notification on the Inclusion of Drugs under Negotiation in Part B of the Drugs Catalogue for the National Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance in 2019 (《關於將2019年談判藥品納入<國家基本醫療保險、工傷保險和生育保險藥品目錄>乙類範圍的通知》) promulgated by the NHSA and the MOHRSS on November 22, 2019, the negotiation drugs are an important part of the NRDL and the negotiated drugs shall be paid according to the relevant provisions of List B drugs during the drug negotiation agreement period. On June 29, 2023, the NHSA released the Work Plan for the Adjustment to 2023 Catalogue of Drugs for National Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《2023年國家基本醫療保險、工傷保險和生育保險藥品目錄調整工作方案》) and related documents, marking the official start of the latest round of adjustment to the NRDL.

Commercial Insurance

The State Council and the Central Committee of the Communist Party of China jointly issued the Plan for Healthy China 2030 (《“健康中國2030”規劃綱要》) (the “2030 Plan”) in October 2016, according to which, the country would establish a multi-level medical security system built around basic medical insurance, with other forms of insurance supplementing the basic medical insurance, including serious illness insurance for urban and rural residents, commercial health insurance and medical assistance. Furthermore, the 2030 Plan encourages enterprises and individuals to participate in commercial health insurance and various forms of supplementary insurance.

Volume-Based Procurement

Under the current PRC regime, in order to improve the affordability of drugs, ease the pressure of the medical insurance fund and provide space for the inclusion of innovative drugs, relevant Governmental Authorities gradually expanded the scope of Volume-Based Procurement.

In January 2019, the State Council promulgated the Pilot Program for the State-organized Volume-based Procurement and Usage of Drugs (《國家組織藥品集中採購和使用試點方案》), which was introduced into and implemented in eleven pilot cities including Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi’an (the “Eleven Cities”). In September 2019, nine national departments and agencies including the NHSA and the NMPA and other seven departments jointly issued the Implementation Opinions on Expanding the Regional Scope of the Pilot Program for the State-organized Volume-based Procurement and Usage of Drugs to Wider Areas (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》), pursuant to which the pilot program has expanded nationwide with the view of further reducing the medication burden of the masses and intensifying reform and innovation. In January 2021, the State Council further published the Opinions on Promoting the Normalization and Institutionalization of Volume-Based Procurement of Drugs (《國務院辦公

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廳關於推動藥品集中帶量採購工作常態化制度化開展的意見》), pursuant to which the drugs listed in the National Drug Catalogue for Basic Medical Insurance with large consumption and high procurement price in particular would be included in the procurement scope and various drugs on market which are clinically necessary and reliable will be covered gradually. Furthermore, the drugs that have passed (including those deemed to have passed) the consistency evaluation of the quality and efficacy of generic drugs shall be included in the scope of procurement with priority. In general, pursuant to the aforementioned state policies, the volume-based procurement system have been regularly and widely adopted in the PRC and the central and local government agencies are responsible for organizing and carrying out volume-based procurement every year on a regular basis. Under the current volume-based procurement system, the healthcare institutions shall procure the bid-winning drugs with priority and the doctors shall prescribe the bid-winning drugs, as applicable. According to the Executive Meeting of the State Council held on January 10, 2022, the meeting pointed out that it is necessary to promote the normalization and institutionalization of volume-based procurement, speed up its expansion, and continuously reduce the price of drugs to benefit patients. Focused on chronic diseases and common diseases, continue to promote the national volume-based procurement, and conduct provincial or inter-provincial alliance procurement of drugs outside the national volume-based procurement. Gradually expand the coverage of high-value medical consumables in volume-based procurement and carry out national and provincial volume-based procurement for drugs such as orthopedic consumables, drug balloons, dental implants of concern to the masses. As of July 2023, relevant Governmental Authorities have organized eight volume-based procurements, of which the first five procurements and the seventh procurement were relating to chemical drugs, the sixth procurement was relating to insulin particularly, and the eighth procurement included the Heparin.

According to the 14th Five-Year Plan on National Healthcare Security (《“十四五”全民醫療保障規劃》), the number of categories of the drugs that have been included in the scope of such system is expected to reach 500 by 2025.

All MAH holders for the drugs falling under the scope of the volume-based procurement and meet certain requirements in terms of quality standards, production capacity, supply stability and etc., may be eligible to participate in such procurement. For example, the local governmental department of Guangdong Province in charge of volume-based procurement recently announced that 294 drug products in total have been listed for volume-based procurement in Guangdong and other ten provincial regions, which only included the short acting dry powder hGH formulation products of four MAH holders. However, the long acting hGH formulation products have not been included in the scope of volume-based procurement scope yet, and no enterprise successfully won the bid for the short acting liquid hGH formulation products.

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REGULATIONS ON INTELLECTUAL PROPERTY RIGHTS IN THE PRC

Patents

Pursuant to the PRC Patent Law (《中華人民共和國專利法》), promulgated by the State Council on March 12, 1984, and last amended on October 17, 2020 and took effect on June 1, 2021, patents in China fall into three categories: invention patents, utility model patents and design patents. An invention patent is granted to a new technical solution proposed in respect of a product or method or an improvement of a product or method. A utility model is granted to a new technical solution that is practicable for application and proposed in respect of the shape, structure or a combination of both of a product. A design patent is granted to the new design of a certain product in shape, pattern or a combination of both and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to invention are effective for twenty years, utility models are effective for ten years, and designs are effective for fifteen years from the date of application. The PRC Patent Law adopts the principle of “first-to-file” system, which provides that where more than two persons files a patent application for the same invention, a patent will be granted to the person who files the application first.

Compared with the prior legislation, the main changes contained in the last amended PRC Patent Law are concentrated on the following aspects: (i) clarifying the incentive mechanism for inventor or designer relating to service inventions; (ii) extending the duration of design patent; (iii) establishing a new system of “open licensing” (開放許可); (iv) strengthening the joint liability of internet service providers for network patent infringement; (v) improving the distribution of burden of proof in patent infringement cases; (vi) increasing the compensation for patent infringement; and (vii) patent term adjustment for compensating unreasonable delays of relevant authorities in the examination of patent applications. In order to compensate for the time spent on drug marketing registration and approval procedures, for patents relating to new drugs approved for marketing in the PRC, the patent term may be extended upon request of the patent holder by up to five years as determined by the competent patent authorities, and the total valid period of a patent right shall not exceed 14 years after the relevant new drug marketing authorization is approved.

Patent enforcement

Unauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other patent infringement acts, will subject the infringers to infringement liability. Serious offences such as forgery of patents may be subject to criminal penalties.

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A patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority. A PRC court may issue a preliminary injunction upon the patent holder’s or an interested party’s request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as the loss suffered by the patent holder arising from the infringement or the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. Statutory damages may be awarded in the circumstances where the damages cannot be determined by the abovementioned calculation standards. The damage calculation methods shall be applied in the aforementioned order.

Medical patent compulsory license

According to the PRC Patent Law, for the purpose of public health, the State Intellectual Property Office (the “SIPO”) may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which the PRC has acceded.

Trade Secrets

According to the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), promulgated by the Standing Committee of the NPC in September 1993, and amended in November 2017 and April 2019 respectively, 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 PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others’ trade secrets by: (1) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; (3) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (4) instigating, inducing or assisting others to violate confidentiality obligation or to violate a rights holder’s requirements on keeping confidentiality of trade secrets, disclosing, using or permitting others to use the trade secrets of the rights holder. If a third party knows or should have known of the abovementioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others’ trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties. On November 22, 2022, the SAMR issued the PRC Anti-Unfair Competition Law (Draft for Comments) (《中華人民共和國反不正當競爭法(修訂草案徵求意見稿)》), which greatly adjusted the identification of unfair competition and the legal liability.

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Trademarks

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the Standing Committee of the NPC in August 1982, and amended in February 1993, October 2001, August 2013 and April 2019 respectively, the period of validity for a registered trademark is ten years, commencing from the date of registration. The registrant shall go through the formalities for renewal within twelve months prior to the expiry date of the trademark if continued use is intended. Where the registrant fails to do so, a grace period of six months may be granted. The validity period for each renewal of registration is ten 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 according to the law. In order to further improve the trademark system and solve prominent problems in the trademark field, the SIPO issued the Trademark Law of the PRC (Draft for Comments) (《中華人民共和國商標法修訂草案(徵求意見稿)》) on January 13, 2023.

Copyright

Pursuant to the Copyright Law of the PRC (《中華人民共和國著作權法》), effective in June 1, 1991 and latest amended on November 11, 2020 and became effective on June 1, 2021, copyrights include personal rights such as the right of publication and that of attribution as well as property rights such as the rights of reproduction and distribution. Reproducing, distributing, performing, projecting, broadcasting or compiling a work or communicating the same to the public via an information network without permission from the owner of the copyright therein, unless otherwise provided in the Copyright Law of the PRC, constitutes infringements of copyrights. The infringer must, according to the circumstances of the case, undertake to cease the infringement, take remedial action, and offer an apology or pay damages.

Pursuant to the Computer Software Copyright Protection Regulations (《計算機軟件保護條例》) promulgated on June 4, 1991 and latest amended on January 30, 2013, a software copyright owner may complete registration formalities with a software registration authority recognized by the State Council’s copyright administrative department. A software copyright owner may authorize others to exercise that copyright, and is entitled to receive remuneration.

Domain Names

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

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REGULATIONS ON ENVIRONMENTAL PROTECTION AND FIRE PREVENTION

Environment 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 NPC on December 26, 1989 and last amended on April 24, 2014, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Environmental Protection is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC.

Environmental Impact Assessment

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 an environmental impact report or the environmental impact statement to the relevant authority in charge of 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 Assessment Law of PRC (《中華人民共和國環境影響評價法》) (the "Environmental Impact Assessment Law"), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, construction entities shall implement the following procedures for their construction projects in accordance with the Category-based Administration Directory for the Environmental Impact Assessment of Construction Projects (《建設項目環境影響評價分類管理名錄》): (i) for projects with potentially serious environmental impacts, an environment impact report shall be prepared to provide a comprehensive assessment of their environmental impacts; (ii) for projects with potentially mild environmental impacts, an environmental impact statement shall be prepared to provide an analysis or specialized assessment of their environmental impacts; and (iii) for projects with very small environmental impacts so that an environmental impact assessment is not required, an environmental impact registration form shall be filled out. The construction project at issue may not proceed if its environmental impact assessment documents fail to pass the review of the competent authority in accordance with the laws and regulations or are disapproved after the review.

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According to the Category-based Administration Directory for the Environmental Impact Assessment of Construction Projects (Edition 2021) (《建設項目環境影響評價分類管理名錄(2021年版)》) promulgated by the Ministry of Ecology and Environment (the “MEE”), construction entities shall, in accordance with the provisions of this Directory, respectively prepare environmental impact reports or environmental impact statements on construction projects, or complete environmental impact registration forms on construction projects. The construction projects not covered by this Directory will not be included in the administration of environmental impact assessment of construction projects.

Pollutant Discharge Licensing

Pursuant to the Administrative Measures for Pollutant Discharge Licensing (for Trial Implementation) (《排污許可管理辦法(試行)》) promulgated on January 10, 2018 and partially revised on August 22, 2019 by MEE, enterprises and public institutions as well as other producers and operators included in the Catalogue of Classified Administration of Pollutant Discharge License for Stationary Pollution Sources shall apply for and obtain a pollutant discharge license within a prescribed time limit. Any enterprise that fails to obtain a pollutant discharge license as required shall not discharge pollutants.

According to the Catalogue of Classified Administration of Pollutant Discharge License for Stationary Pollution Sources (2019 Version) (《固定污染源排污許可分類管理名錄(2019年版)》) issued by the MEE on December 20, 2019 and effective on the same day, key management, simplified management and registration management of pollutant discharge permits are implemented according to factors such as the amount of pollutants generated, the amount of emissions, the degree of impact on the environment, etc., and only pollutant discharge entities that implement registration management do not need to apply for a pollutant discharge permit.

In addition, according to the Regulation on Pollutant Discharge Permit Administration (《排污許可管理條例》) issued by the State Council on January 24, 2021 and effective on March 1, 2021, the review, decision and information disclosure of pollutant discharge licenses shall be handled through the national pollutant discharge license management information platform. A pollutant discharge license is valid for 5 years and the pollutant-discharging entity should apply for renewal within the 60 days prior to the date of expiry.

Fire Prevention Design and Acceptance

The Fire Prevention Law of the PRC (《中華人民共和國消防法》) (the “Fire Prevention Law”) was adopted on April 29, 1998 and latest amended on April 29, 2021. According to the Fire Prevention Law, for special construction projects stipulated by the housing and urban-rural development authority of the State Council, the developer shall submit the fire safety design documents to the housing and urban-rural development authority for examination, while for construction projects other than those stipulated as special development projects, the developer shall, at the time of applying for the construction permit or approval for work commencement report, provide fire safety design drawings and technical materials which satisfy the construction needs.

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According to Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) issued by the Ministry of Housing and Urban-Rural Development of the PRC on April 1, 2020 and effective on June 1, 2020, an examination system for fire prevention design and acceptance only applies to special construction projects, and for other projects, a record-filing and spot check system would be applied.

OTHER SIGNIFICANT REGULATIONS OF THE PRC AFFECTING OUR BUSINESS

Product Liability

The Product Quality Law of the PRC (《中華人民共和國產品質量法》) (the “Product Quality Law”), promulgated by the Standing Committee of the NPC on February 22, 1993 and latest amended on December 29, 2018, is the principal governing law relating to the supervision and administration of product quality. According to the Product Quality Law, manufacturers shall be liable for the quality of products produced by them, and sellers shall take measures to ensure the quality of the products sold by them. A manufacturer shall be liable for compensating for any bodily injuries or property damages, other than the defective product itself, resulting from the defects in the product, unless the manufacturer is able to prove that (1) the product has never been distributed; (2) the defects causing injuries or damages did not exist at the time when the product was distributed; or (3) the science and technology at the time when the product was distributed was at a level incapable of detecting the defects. A seller shall be liable for compensating for any bodily injuries or property damages of others caused by the defects in the product if such defects are attributable to the seller. A seller shall pay compensation if it fails to indicate either the manufacturer or the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

On May 28, 2020, the Civil Code of the PRC (《中華人民共和國民法典》) was adopted by the third session of the 13th NPC, which came into effect on January 1, 2021. According to the Civil Code of the PRC, a patient may make a claim against the drug marketing authorization holder, a medical institution or producer for any damage arising from defects of drugs.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers’ rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Where the goods or services provided by a business operator do not satisfy quality requirements, the consumer may require the business operator to perform replacement or repair obligations.

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Regulation of Advertisement

Pursuant to the Advertisement Law of the PRC (《中華人民共和國廣告法》), which was promulgated by Standing Committee of the NPC on October 27, 1994 and effective from February 1, 1995 and latest amended and effective from April 29, 2021, advertisements shall not contain false statements or be deceitful or misleading to consumers. Advertisements relating to pharmaceuticals and medical devices, shall be reviewed by relevant authorities in accordance with applicable rules before being distributed by broadcasting, movies, television, newspapers, journals or otherwise. The Advertisement further stipulates that advertisements for medical treatment, pharmaceutical products or medical devices shall not contain: (i) any assertion or guarantee for efficacy and safety; (ii) any statement on cure rate or effectiveness rate; (iii) any comparison with the efficacy and safety of other pharmaceutical products or medical devices or with other healthcare institutions; (iv) recommendation or endorsement of an advertising endorser; or (v) other items as prohibited by laws and regulations.

Pursuant to the Interim Measures for the Administration of Internet Advertisement (《互聯網廣告管理暫行辦法》) which was promulgated by the State Administration of Industry and Commerce on July 4, 2016 and became effective as of September 1, 2016, the Internet advertisement must be visibly marked as “advertisement.” Advertisements for special commodities or services such as medical treatment, pharmaceuticals, foods for special medical purposes, medical instruments, agrochemicals, veterinary medicines and other health foods must be reviewed by competent authorities before online publication. On 24 March, 2023, the SAMR promulgated the Measures for Administration of Internet Advertising (《互聯網廣告管理辦法》) (the “Internet Advertising Measures”), which replaced the Interim Measures for the Administration of Internet Advertisement, and came into effect as of 1 May 2023. Pursuant to the Internet Advertising Measures, Internet advertisers are prohibited from publishing advertisements of prescription drugs on the Internet. Besides, Internet advertisers are prohibited from publishing advertisements for medical treatment, drugs, medical devices, health food and formula food for special medical purposes in disguised form by way of introducing knowledge on health or health maintenance. When introducing knowledge on health or health maintenance, the address, contact information, shopping links and other contents of sellers or service providers of relevant medical treatment, drugs, medical devices, health food, or formula food for special medical purposes shall not be presented on the same page or together with other contents.

Pursuant to the Measures for Administration of Medical Advertisement (《醫療廣告管理辦法》), which were jointly promulgated by the SAIC and the Ministry of Health on November 10, 2006 and effective on January 1, 2007, medical advertisements shall be reviewed by relevant health authorities and obtain a Medical Advertisement Examination Certificate before being released. Medical Advertisement Examination Certificate is valid for one year and may be renewed upon application.

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Pursuant to the Interim Measures for the Administration of Censorship of Advertisements on Drugs, Medical Devices, Dietary Supplements and Formula Foods for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) which were promulgated by the SAMR on December 24, 2019 and effective from March 1, 2020, for medical devices advertisement to be released and published, a manufacturer of medical devices shall obtain an approval from the NMPA at provincial level. In addition, the content of advertisements for medical devices is subject to certain guidelines as approved by the NMPA or its local counterparts at provincial level.

Pursuant to the Measures Regarding the Administration of Drug Information Service through the Internet (《互聯網藥品信息服務管理辦法》), which was promulgated by the CFDA and effective from July 8, 2004, and amended and effective from November 17, 2017, the Internet drug information services, referring to that of providing medical information (including medical devices information) services to Internet users through the Internet, are classified into two categories, namely, profit-making services and non-profit services. Any website intending to provide drug information services through Internet, shall be approved by NMPA at provincial level before applying for an operation permit or record-filing from the authority in charge of information industry under the State Council or the administration of telecommunication at the provincial level.

Information Security and Privacy Protection

On November 7, 2016, the SCNPC promulgated the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》), which became effect on June 1, 2017, any network operator shall comply with laws and regulations and fulfill their obligations to ensure the security of the network when conducting business and providing services. Those who provide services through networks shall take technical measures and other necessary measures in accordance with laws, regulations and compulsory national requirements to safeguard the safe and stable operation of the networks, respond to network security incidents effectively, prevent illegal and criminal activities committed on the network, and maintain the integrity, confidentiality, and availability of network data. Network operators shall keep the user information that they have collected in strict confidence. In addition, the network operators shall neither collect the personal information irrelevant to the services provided by them nor collect or use the personal information in violation of the provisions of any law or administrative regulation or the agreement between both parties. On September 12, 2022, the CAC issued the Decision on Amending the PRC Cybersecurity Law (Draft for Comments) 《關於修改〈中華人民共和國網絡安全法〉的決定(徵求意見稿)》, which further refines and enhances the legal liabilities for violating various existing provisions of the Cybersecurity Law of the PRC.

On June 10, 2021, the Standing Committee of the NPC 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 effect in September 2021. The Data Security Law provides for data security and privacy obligations on entities and individuals carrying out data activities and introduces a data classification and hierarchical protection system based on the importance of data in economic and social development, as well as the degree of harm it will cause to national security, public

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interests, or legitimate rights and interests of individuals or organizations when such data is tampered with, destroyed, leaked, or illegally acquired or used. The appropriate level of protection measures is required to be taken for each respective category of data. For example, a processor of important data shall designate the personnel and the management body responsible for data security, carry out risk assessments for its data processing activities and file the risk assessment reports with the competent authorities. In addition, the Data Security Law provides a national security review procedure for those data activities which affect or may affect national security and imposes export restrictions on certain data and information.

On December 28, 2021, the Cyberspace Administration of China (the “CAC”) and other twelve PRC regulatory authorities jointly revised and promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “Cyber Review Measures”), which came into effect on February 15, 2022. The Cyber Review Measures stipulate that, among others, (i) when the purchase of network products and services by a critical information infrastructures operator (the “CIIO”) or the data processing activities conducted by a network platform operator affect or may affect national security, a cybersecurity review shall be conducted pursuant to the Cyber Review Measures; (ii) an application for cybersecurity review shall be made by an issuer who is a network platform operator holding personal information of more than one million users before such issuer applies to list its securities abroad; and (iii) the relevant PRC Governmental Authorities may initiate cybersecurity review if such Governmental Authorities determine that the issuer’s network products or services, or data processing activities affect or may affect national security. As of the Latest Practicable Date, we had not received any notification from the relevant competent or regulatory authorities that we had been determined to be a critical information infrastructure operator or network platform operators engaging in data processing activities that affect or may affect national security.

On November 14, 2021, the CAC published 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”), which regulates the specific requirements in respect of the data processing activities conducted by data processors through internet in the view of personal data protection, important data safety, data cross-broader safety management and obligations of internet platform operators.

The Draft Cyber Data Regulations require that data processors conducting the following activities shall apply for cybersecurity review: (i) a merger, reorganization, or division to be conducted by an Internet platform operator who has amassed a large number of data resources that concern national security, economic development or the public interest, which will or may impact national security; (ii) the data processor processing the personal information of more than one million individuals is to go public overseas; (iii) the data processor is to go public in Hong Kong, which will or may impact national security; or (iv) other data processing activities that will or may have an impact national security. There have been no clarifications from the authorities as of the Latest Practicable Date as to the standards for determining such activities that “will or may impact national security.” As of the Latest Practicable Date, the Draft Cyber Data Regulations had not been formally adopted.

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On August 20, 2021, the Standing Committee of the NPC promulgated the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) (the “Personal Information Protection Law”), which took effect from November 1, 2021. Pursuant to the Personal Information Protection Law, personal information refers to the information related to an identified or identifiable individual recorded electronically or by other means, excluding the anonymized information, and processing of personal information includes among others, the collection, storage, use, handling, transmission, provision, disclosure, deletion of personal information. The Personal Information Protection Law explicitly sets forth the circumstances where it is allowed to process personal information, including (i) the consent of the individual has been obtained; (ii) it is necessary for the conclusion and performance of a contract under which an individual is a party, or it is necessary for human resource management in accordance with the labor related rules and regulations and the collective contracts formulated or concluded in accordance with laws; (iii) it is necessary to perform statutory duties or statutory obligations; (iv) it is necessary to respond to public health emergencies, or to protect the life, health and property safety of individuals in emergencies; (v) carrying out news reports, public opinion supervision and other acts for the public interest, and processing personal information within a reasonable scope; (vi) processing personal information disclosed by the individual or other legally disclosed personal information within a reasonable scope in accordance with this law; or (vii) other circumstances stipulated by laws and administrative regulations. In addition, the Personal Information Protection Law emphasizes that individuals have the right to withdraw their consent to process their personal information, and the processors must not refuse to provide products or services on the grounds that the individuals do not agree to the processing of their personal information or withdraw their consent, unless processing of personal information is necessary for the provision of products or services. Before processing the personal information, the processors should truthfully, accurately and completely inform individuals of the following matters in a conspicuous manner and in clear and easy-to-understand language: (i) the name and contact information of the personal information processor; (ii) the purpose of processing personal information, processing method, type of personal information processed, and the retention period; (iii) methods and procedures for individuals to exercise their rights under this law; (iv) other matters that should be notified according to laws and administrative regulations. Furthermore, the Personal Information Protection Law provides that personal information processors who use personal information to make automated decisions should ensure the transparency of decision-making and the fairness and impartiality of the results, and must not impose unreasonable differential treatment on individuals in terms of transaction prices or other transaction conditions.

In addition to the aforementioned general rules, the Personal Information Protection Law also introduces the rules for processing sensitive personal information, which refers to the personal information that, once leaked or illegally used, can easily lead to the infringement of the personal dignity of natural persons or harm personal and property safety, including biometrics, religious beliefs, specific identities, medical health, financial accounts, whereabouts and other information, as well as personal information of minors under the age of fourteen. Personal information processors can process sensitive personal information only if they have a specific purpose and sufficient necessity, and take strict protective measures. In addition, the law provides rules for cross-border provision of personal information. In

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particular, it is provided that the operators of critical information infrastructures and the personal information processors that process personal information up to the number prescribed by the national cyberspace administration shall store personal information collected and generated within the PRC. If it is really necessary to provide such personal information overseas, they shall pass the security assessment organized by the national cyberspace administration, except as otherwise stipulated by laws, administrative regulations and the national cyberspace administration. Any processor in violation of this law may be subject to administrative penalties including rectifications, warnings, fines, confiscation of illegal gains, suspension of the apps illegally processing personal information or suspension of the relevant business, revocation of the relevant business permit or the business license, civil liabilities or even criminal liabilities. The directly responsible personnel in charge and other directly responsible personnel may be imposed with fines and prohibited from serving as directors, supervisors, senior management personnel and personal information protection officers of related companies within a certain period of time.

On July 7, 2022, the CAC released the Measures on Security Assessment of Cross-border Data Transfer (數據出境安全評估辦法) (the "Data Export Measures"), which came into effect on September 1, 2022. The Data Export Measures require that any data processor provide abroad any important data collected and generated in their business operation within the territory of the PRC and any personal information for which security assessment is required shall apply for security assessment by the national cyberspace administration authorities before transferring any such important data or personal information abroad. The security assessment requirement also applies to any transfer of important data outside of China.

In addition, on February 24, 2023, the Measures of the Prescribed Agreement on Cross-border Data Transfer of Personal Information (《個人信息出境標準合同辦法》), or the Measures of Prescribed Agreement were promulgated by the CAC, which took effect on June 1, 2023. The Measures of Prescribed Agreement attach the prescribed template for cross-border data transfer agreement that could be used as an available option to satisfy the condition for cross-border transfer of personal information under Article 38 of the Personal Information Protection Law.

As of the Latest Practicable Date, we have formulated and updated from time to time internal management systems to comply with the applicable information security and privacy protection laws and regulations, and we will continue to maintain our business practices in a manner that complies with these laws and regulations.

Commercial Briberies in Pharmaceutical Industry

According to the Regulations on the Establishment of Adverse Records with Respect to Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》) promulgated in January 2007 and amended in December 2013, where a manufacturer of drugs, medical devices and medical disposables, an enterprise, an agency or an individual offers staff of a medical institution any items of value or other benefits, the enterprise should be listed in the adverse records with respect to commercial bribery in the

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event of the following circumstances: (1) where the act has constituted a crime of bribery as determined by the ruling of a people’s court, or where the circumstance of crime is not serious enough for the imposition of criminal punishment and criminal punishment is exempted as decided by the people’s court in accordance with the Criminal Law; (2) where the circumstance of the crime of bribery is minor and the relevant people’s procuratorate has decided not to lodge a prosecution; (3) where a discipline inspection and supervision authority has initiated a case of bribery and conducted investigation, and punishment has been imposed in accordance with the law; (4) where administrative penalties against the act of bribery have been imposed by, inter alia, the finance administration, the SAMR, the NMPA; (5) any other circumstances specified by laws, regulations and rules. If medical production and operation enterprises are listed into the Adverse Records of Commercial Briberies for the first time, their products shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies in local province for two years since publication of the record, and public medical institution, and medical and health institutions receiving financial subsidies in other province shall lower their rating in bidding or purchasing process. If medical production and operation enterprises are listed into the Adverse Records of Commercial Bribery for twice or more in five years, their products shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies nationwide for two years since publication of the record.

According to the Guiding Opinions on Establishment of the Trustworthiness Evaluation System for Drug Prices and Procurement by Bidding (《關於建立醫藥價格和招採信用評價制度的指導意見》) promulgated by the NHTA in August 2020 and took effect simultaneously, the NHTA would establish a catalogue of dishonest matters involving drug prices and procurement by bidding, and the kickbacks or other improper benefits in the purchase and sale of drugs, tax-related violations of laws, monopolistic practices, improper pricing practices, disruption of the order of centralized procurement, malicious breach of contracts and other malpractices, will be included in such catalogue. Provincial centralized procurement agencies shall assess and rate the dishonest conduct of pharmaceutical enterprises into four levels: general, medium, serious and particularly serious, based on the nature, circumstances, effectiveness and impact of such dishonest conduct. Further, the provincial centralized procurement agencies shall, according to the trustworthiness ratings of pharmaceutical enterprises, take punitive measures, such as warnings and admonishments, restriction on market entry, and release of dishonest information.

Anti-unfair Competition and Enterprise-related Crimes

Competition among business operators is generally governed by the Anti-unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) (the “Anti-unfair Competition Law”), which was promulgated by the Standing Committee of the NPC on 2 September 1993 and last amended on 23 April 2019. According to the Anti-unfair Competition Law, when trading on the market, operators must abide by the principles of voluntariness, equality, fairness and honesty and observe laws and business ethics. Acts of operators constitute unfair competition where they contravene the provisions of the Anti-unfair Competition Law and disturb market competition with a result of damaging the lawful rights

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and interests of other operators or consumers. Where the legitimate rights and interests of a operator are harmed by unfair competition, the operator may file a lawsuit with a People’s Court. The compensation for a operator who suffer damages due to unfair competition shall be determined in accordance with the actual losses suffered as a result of the infringement; where it is hard to ascertain the actual losses, the compensation shall be determined in accordance with the gains made by the infringing person from the infringement. For operators who infringe upon commercial secrets maliciously and if the case is serious, the compensation amount may be determined in accordance with one to five times the amount determined using the aforesaid method. The compensation amount shall also include reasonable expenses paid by the operator to stop the infringement. On November 22, 2022, the SAMR issued the PRC Anti-Unfair Competition Law (Draft for Comments) (《中華人民共和國反不正當競爭法(修訂草案徵求意見稿)》), which greatly adjusted the identification of unfair competition and the legal liability.

On June 3, 2021, the Supreme People’s Procuratorate and other seven PRC regulatory authorities or organizations jointly promulgated the Guiding Opinions on Establishment of a Third-party Supervision and Evaluation Mechanism for the Compliance of Enterprises Involved in Cases (for Trial Implementation) (《關於建立涉案企業合規第三方監督評估機制的指導意見(試行)》) (the “Guiding Opinions”). According to the Guiding Opinions, when the People’s Procuratorate handles an enterprise-related criminal case, a third-party supervision and evaluation mechanism for the compliance of the enterprise involved (the “third-party mechanism”) may be applied where the case meets the applicable conditions for the pilot program of corporate compliance reform, under which a third-party supervision and evaluation organization shall be organized to investigate, evaluate, supervise and inspect the compliance commitment of the enterprise involved. The third-party mechanism is applicable to the economic crimes and duty-related crimes committed during the production and operation activities of the market players such as companies and enterprises, and the People’s Procuratorate shall take the compliance materials such as the written compliance inspection report issued by the third party as important references when making prosecution decisions or issuing procuratorial opinions.

Regulations on Overseas Listing

CSRC Filing Requirements for Overseas Offering and Listing

On February 17, 2023, the China Securities Regulatory Commission (the “CSRC”) promulgated the Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》) and relevant five guidelines (together, the “Overseas Listing Trial Measures”), which became effective on March 31, 2023. The Overseas Listing Trial Measures comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities, and regulate both direct and indirect overseas offering and listing of PRC domestic companies’ securities by adopting a filing-based regulatory regime.

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Pursuant to the Overseas Listing Trial Measures, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfil the filing procedure with the CSRC and report relevant information. The Overseas Listing Trial Measures provide that an overseas offering and listing is explicitly prohibited, if any of the following exists: (i) such securities offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules; (ii) the intended overseas securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law; (iii) the domestic company intending to make the securities offering and listing, or its controlling shareholder(s) and the actual controller, have committed relevant crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (iv) the domestic company intending to make the securities offering and listing is currently under investigations for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has yet been made thereof; or (v) there are material ownership disputes over equity held by the domestic company’s controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller.

The Overseas Listing Trial Measures also provide that if the issuer meets both the following criteria, the overseas securities offering and listing conducted by such issuer will be deemed as indirect overseas offering by PRC domestic companies: (i) more than 50% of any of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies; and (ii) the main parts of the issuer’s business activities are conducted in mainland China, or its main place(s) of business are located in mainland China, or the majority of senior management staff in charge of its business operations and management are PRC citizens or have their usual place(s) of residence located in mainland China. The determination of the indirect overseas issuance and listing of domestic enterprises follows the principle of “substance over form.”

According to the Overseas Listing Trial Measures, where an issuer submits an application for initial public offering to competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted. Generally, once the filing documents are complete and in compliance with the stipulated requirements, the CSRC will, within 20 working days, conclude the review procedure and publish the filing results on the CSRC website. To the extent the filing documents are incomplete or do not conform to stipulated requirements, the CSRC will, within 5 working days upon receipt of filing documents, request supplementation and amendment to the filing. Then the issuer has 30 working days to prepare any requested supplemented/amended filing. In addition, following the listing on an overseas market, the issuer shall submit a report to the CSRC within 3 working days after the occurrence and public disclosure of the following events involving the issuer: (i) change of control; (ii) investigations or sanctions imposed by overseas regulators; (iii) change of listing status; and (iv) voluntary or involuntary delisting. Besides, if any material change in the principal business and operation of the issuer after its overseas offering and listing takes place and results in the issuer no longer within the scope of record-filing under Overseas Listing Trial Measures, the issuer shall submit a special report and a legal opinion issued by a PRC law firm to the CSRC within 3 working days after the occurrence of such change in order to provide an explanation of the relevant situation.

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Non-compliance with the Overseas Listing Trial Measures will result in regulatory action by the CSRC and fines for PRC issuers in an amount up to RMB10 million. If a domestic company fails to comply with the filing procedures or conceals material facts or falsifies major contents in the filing documents, it may be ordered to make corrections, warned, fined and other administrative penalties, and its controlling shareholder, de facto controller, directly responsible supervisors and other directly responsible persons may also be warned or fined.

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

On February 24, 2023, the CSRC, the Ministry of Finance, National Administration of State Secrets Protection and National Archives Administration of China jointly released the revised Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》), or the Archives Administration Provisions, which came into effect on March 31, 2023. The Archives Administration Provisions shall apply to both (i) the PRC domestic companies seeking direct listing on the overseas stock exchange and (ii) the PRC domestic operating entities of a foreign company seeking listing on the overseas stock exchange that qualifies as an “indirect listing” (above (i) and (ii) collectively, “Domestic Companies”).

According to the Archives Administration Provisions, the Domestic Companies shall establish and implement a solid confidentiality and archives administration system. If a Domestic Company decides to disclose any documents or materials containing state secrets, work secrets of governmental agencies or any Information that may be detrimental to national security or public interest once leaked, a domestic enterprise shall apply to the competent department with examination and approval authority for approval in accordance with the law, and file the same with the secrecy administration at the same level for the record. After obtaining the governmental clearance, the Domestic Company disclosing such information, as one party, and the securities companies and securities services providers receiving such information, as the other party, shall also enter into non-disclosure agreements, setting forth the confidentiality obligations of the securities companies and securities services providers. When providing above information to the securities companies and securities services providers retained by it, the Domestic Companies are also required to issue a written statement outlining its compliance with the relevant regulatory requirements and procedures.

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

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

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Foreign Exchange Control

The PRC Foreign Exchange Administration Regulations (《中華人民共和國外匯管理條例》) promulgated by the State Council on January 29, 1996, which was latest amended on August 5, 2008, are the principal regulations governing foreign currency exchange in China. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from the SAFE by complying with certain procedural requirements. In contrast, approval from or registration with appropriate Governmental Authorities or designated banks is required when RMB is to be converted into a foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency-denominated loans.

In 2019, the SAFE promulgated Notice by the State Administration of Foreign Exchange of Further Facilitating Cross-border Trade and Investment (《關於進一步促進跨境貿易投資便利化的通知》), which cancelled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. If a non-investing foreign-funded enterprise makes domestic equity investment with capital funds obtained from foreign exchange settlement, the investee shall undergo registration formalities for accepting domestic reinvestment and open the “capital account – account for settled foreign exchange to be paid” to receive the corresponding funds according to relevant provisions. On April 10, 2020, the SAFE promulgated the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (關於優化外匯管理 支持涉外業務發展的通知), or SAFE Circular 8, under which eligible enterprises are allowed to make domestic payments by using their capital funds, foreign loans and the income under capital accounts of overseas listing, without providing the evidentiary materials concerning authenticity of each expenditure in advance, provided that their capital use shall be authentic, and conform to the prevailing administrative regulations on the use of income under capital accounts.

Dividend Distribution

The SAFE promulgated the Notice on Improving the Check of Authenticity and Compliance to Further Promote the Reform of 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》) in January 2017, which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (1) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (2) domestic entities shall hold income to account for previous years’ losses before remitting the profits. Moreover, domestic entities shall make detailed explanations of 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.

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Foreign Exchange Registration of Offshore Investment by PRC Residents

In July 2014, the SAFE promulgated the Notice of the State Administration of Foreign Exchange on Issues concerning Foreign Exchange Administration of the Overseas Investment and Financing and the Round-tripping Investment Made by Domestic Residents through Special-Purpose Companies (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (the “SAFE Circular 37”). The SAFE Circular 37 requires PRC residents, including PRC individuals and PRC corporate entities, to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities.

Under the SAFE Circular 37, PRC residents who make, or have prior to the implementation of the SAFE Circular 37 made, direct or indirect investments in an offshore special purpose vehicle (the “SPV”) are required to register such investments with SAFE or its local branches. In addition, any PRC resident who is a direct or indirect shareholder of an SPV, is required to update its registration with the local branch of SAFE with respect to that SPV, to reflect any change of basic information or material events. If any PRC resident shareholder of such SPV fails to make the required registration or to update the registration, the subsidiary of such SPV in China may be prohibited from distributing its profits or the proceeds from any capital reduction, share transfer or liquidation to the SPV, and the SPV may also be prohibited from making additional capital contributions into its subsidiaries in China.

Employee Stock Incentive Plan

On February 15, 2012, the SAFE promulgated the Notice of the State Administration of Foreign Exchange on Issues concerning the Foreign Exchange Administration of Domestic Individuals’ Participation in Equity Incentive Plans of Overseas Listed Companies (《國家外匯管理局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 “Stock Option Rules”). In accordance with the Stock Option 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 the SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. In addition, the domestic agency is required to amend the SAFE registration with respect to the stock incentive plan if there is any material change to the stock incentive plan. Moreover, the SAFE Circular 37 provides that PRC residents who participate in a share incentive plan of an overseas unlisted special purpose company may register with local branches of SAFE before exercising rights.

Labor Law and Labor Contract Law

Pursuant to the PRC Labor Law (《中華人民共和國勞動法》) promulgated by the Standing Committee of the NPC on July 5, 1994 and latest amended on December 29, 2018 and the PRC Labor Contract Law (《中華人民共和國勞動合同法》) promulgated by the Standing Committee of the NPC on June 29, 2007 and latest amended on December 28, 2012, employers must execute written labor contracts with full-time employees. All employers must comply

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with local minimum wage standards. Employers must establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions. Violations of the PRC Labor Contract Law and the PRC Labor Law may result in the imposition of fines and other administrative and criminal liability in the case of serious violations.

Social Insurance and Housing Provident Funds

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was promulgated by the Standing Committee of the NPC in October 2010 and came into effect in July 2011, and further amended 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 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 amended in March 2002 and 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, maternity insurance and to housing provident funds. Any employer who fails to contribute may be fined and ordered to make good the deficit within a stipulated time limit.

Enterprise Income Tax

Pursuant to the PRC Enterprise Income Tax Law (《中華人民共和國企業所得稅法》) effective as of January 1, 2008 and latest amended on December 29, 2018, the income tax rate for both domestic and foreign-invested enterprises is 25% with certain exceptions. To clarify certain provisions in the PRC Enterprise Income Tax Law, the State Council promulgated the Implementation Rules of the Enterprise Income Tax Law (《中華人民共和國企業所得稅法實施條例》) on December 6, 2007, which was latest amended and became effective on April 23, 2019. Under the PRC Enterprise Income Tax Law and the Implementation Rules of the PRC Enterprise Income Tax Law, enterprises are classified as either “resident enterprises” or “non-resident enterprises.” Aside from enterprises established within the PRC, enterprises established outside of China whose “de facto management bodies” are located in China are considered “resident enterprises” and are subject to the uniform 25% enterprise income tax rate for their global income. In addition, the PRC Enterprise Income Tax Law provides that a non-resident enterprise refers to an entity established under foreign law whose “de facto management bodies” are not within the PRC, but has an establishment or place of business in the PRC, or does not have an establishment or place of business in the PRC but has income sourced within the PRC.

REGULATORY ENVIRONMENT

The Implementation Rules of the PRC Enterprise Income Tax Law provide that since January 1, 2008, an income tax rate of 10% shall normally be applicable to dividends declared to non-PRC resident enterprise investors that do not have an establishment or place of business in the PRC, or have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC. The income tax on the dividends may be reduced pursuant to a tax treaty between China and the jurisdictions in which the non-PRC shareholders reside.

According to the Notice of the State Administration of Taxation on Delivering the Table of Negotiated Dividends and Interest Rates to Lower Levels (《國家稅務總局關於下發協定股息稅率情況一覽表的通知》) issued on January 29, 2008, latest revised on February 29, 2008, and the Arrangement between Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) (the “Double Tax Avoidance Arrangement”), the withholding tax rate in respect of the payment of dividends by a PRC enterprise to a Hong Kong enterprise may be reduced to 5% from a standard rate of 10% if the Hong Kong enterprise directly holds at least 25% of the PRC enterprise and certain other conditions are met, including: (i) the Hong Kong enterprise must directly own the required percentage of equity interests and voting rights in the PRC resident enterprise; and (ii) the Hong Kong enterprise must have directly owned such required percentage in the PRC resident enterprise throughout the 12 months prior to receiving the dividends. However, based on the Circular on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties (《關於執行稅收協定股息條款有關問題的通知》) issued on February 20, 2009 by the State Taxation Administration, if the relevant PRC tax authorities determine, in their discretion, that a company benefits from such reduced income tax rate due to a structure or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment; and based on the Announcement on Certain Issues with Respect to the “Beneficial Owner” in Tax Treaties (《關於稅收協定中“受益所有人”有關問題的公告》) issued by the State Taxation Administration on February 3, 2018 and effective from April 1, 2018, if an applicant’s business activities do not constitute substantive business activities, it could result in the negative determination of the applicant’s status as a “beneficial owner”, and consequently, the applicant could be precluded from enjoying the above-mentioned reduced income tax rate of 5% under the Double Tax Avoidance Arrangement.

Other PRC National and Provincial-Level Laws and Regulations

We are subject to changing regulations under many other laws and regulations administered by Governmental Authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business.

We also comply with numerous additional national and provincial laws relating to matters such as safe working conditions, manufacturing practices, environmental protection and fire hazard control. We believe that we are currently in compliance with these laws and regulations; however, we may be required to incur significant costs to comply with these laws and regulations in the future. Unanticipated changes in existing regulatory requirements or adoption of new requirements could therefore have a material adverse effect on our business, results of operations and financial condition.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OVERVIEW

We are a late-stage, near-commercialization biopharmaceutical company focused on providing treatments in selected endocrinology diseases in China (including Hong Kong, Macau and Taiwan). Our Company was founded by our Founding Shareholders, namely, Ascendis Pharma A/S (through its wholly-owned subsidiaries), Vivo Capital and Sofinnova. Further information on our Founding Shareholders are set forth in “– [REDACTED] Investments – Information about our Shareholders” in this section below. For further details regarding Ascendis Pharma A/S and Vivo Capital, see also “Relationship with the Controlling Shareholders.”

Our Company was incorporated in the Cayman Islands on November 1, 2018. Our principal businesses are carried out by the Company and its subsidiaries including our wholly-owned major and operating subsidiary in Shanghai, the PRC, VISEN Shanghai.

OUR BUSINESS MILESTONES

The following table illustrates the key milestones of our business development since our inception:

November 2018	<p>Our Company was incorporated in the Cayman Islands</p> <p>The Series A financing was completed and a total of US\$40 million in cash was raised from Vivo Capital and Sofinnova</p> <p>Our Company entered into several Exclusive License Agreements with Ascendis Pharma Endocrinology Division, Ascendis Pharma Growth Disorders and Ascendis Pharma Bone Diseases, pursuant to which our Company was granted exclusive licenses to develop, manufacture and commercialize lonapegsomatropin, TransCon CNP (navepegritide) and palopegteriparatide, in China (including Hong Kong, Macau and Taiwan), and our Company issued to these three wholly-owned subsidiaries of Ascendis Pharma A/S an aggregate of 40,000,000 Series A Preferred Shares</p>
October 2019	<p>Our Company obtained the IND approval from the NMPA to commence the Phase 3 pivotal trial for lonapegsomatropin in China for the treatment of PGHD</p>
December 2020	<p>Our Company entered into a strategic cooperation agreement with CHARD on ACH registration study and diagnosis consensus</p>

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

January 2021	<p>Our Company completed the Series B financing and raised a total of approximately US\$150 million, and introduced investors including HongShan Growth, OrbiMed, Sherpa Healthcare Partners, Cormorant, HBM Healthcare Investments, Pivotal bioVenture Partners China, Logos Capital and CRF Investment</p> <p>Our Company obtained the IND approval from the NMPA to commence the China Phase 2 trial of TransCon CNP (navepegritide)</p>
March 2021	<p>The patient enrollment of children with GHD for the Phase 3 pivotal trial of lonapegsomatropin across 17 sites was completed</p> <p>The patient enrollment of the ACHieve Study was completed, with 83 subjects enrolled in six sites</p>
May 2021	<p>Our Company obtained the IND approval from the NMPA to commence the Phase 3 pivotal trial for palopegteriparatide in China for the treatment of adult HP</p> <p>ApproaCH Study, a national patient registry study for ACH, was initiated</p>
July 2021	<p>VISEN Shanghai entered into a strategic collaboration agreement with Peking University Health Science Center to initiate the PaTHway R study of palopegteriparatide, the first registry study for HP patients in China and one of the largest epidemiological surveys for this disease worldwide</p>
September 2021	<p>The China Phase 2 trial of TransCon CNP (navepegritide) was initiated</p>
April 2022	<p>The Phase 3 pivotal trial for lonapegsomatropin in patients with PGHD was completed</p>
June 2022	<p>The patient enrollment for the Phase 3 pivotal trial for palopegteriparatide was completed</p>
November 2022	<p>The results from the completed Phase 3 pivotal trial of lonapegsomatropin was announced, which continued to support lonapegsomatropin’s superior growth profile and comparable safety profile in comparison to daily hGH</p>

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

January 2023	Our Company completed the double-blind period for primary endpoint for our ongoing China Phase 3 pivotal trial of palopegteriparatide, PaTHway China Trial, which demonstrates consistency with the global Phase 3 pivotal trial in terms of primary endpoint and safety profile
June 2023	Our Company received confirmation from the CDE of the NMPA confirming the completion status of our Phase 3 pivotal trial and approving us to proceed with the BLA filing of lonapegsomatropin for the treatment of PGHD
July 2023	Our Company entered into a Technology Transfer Master Plan of the Core Product with Ascendis Pharma, which has marked the commencement of the Technology Transfer and Localization with respect to the manufacturing of the Core Product from Ascendis Pharma to us and sets forth the obligations of both parties under the Exclusive License Agreement with respect to such Technology Transfer and Localization
October 2023	Our Company entered into a commercial supply agreement with Ascendis Pharma for the purchase of Core Product from Ascendis Pharma by the Company, which will secure the imported drug supply of the Core Product after BLA filing approval. Under the commercial supply agreement, Ascendis Pharma will provide the Company with the agreed stock of packaged product for the initial launch of the Core Product
November 2023	The primary analysis of Phase 2 clinical trial in China of TransCon CNP (navepegritide) for the treatment of ACH has been completed, which completed the double-blind period with primary endpoint met according to the topline results
March 2024	The BLA filing of our Core Product for the treatment of PGHD was accepted by the NMPA

MAJOR CORPORATE DEVELOPMENT AND SHAREHOLDING CHANGES OF OUR GROUP

The following sets forth the major corporate history and shareholding changes of our Company and major subsidiary.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Our Company

Incorporation of our Company

Our Company was incorporated in the Cayman Islands under the Companies Act as an exempted company with limited liability on November 1, 2018, with an authorized capital of US\$50,000 divided into 500,000,000 shares with a par value of US\$0.0001 each. Immediately after the incorporation of our Company, one ordinary share was allotted and issued to its initial subscriber, International Corporation Services Ltd., and was then transferred to Vivo Plenilune IX Limited on November 2, 2018. Such ordinary share was repurchased and cancelled by the Company on November 7, 2018.

Series A Financing

On November 7, 2018, our Company entered into the Series A Share Purchase Agreement with our Founding Shareholders, namely Ascendis Pharma A/S, Vivo Capital and Sofinnova. The Founding Shareholders became acquainted with each other as each of Vivo Capital and Sofinnova is a minority shareholder of Ascendis Pharma A/S. They were enthusiastic about the potential of Ascendis’ endocrinology portfolio, the rapidly expanding pharmaceutical market in China, and the evolving regulatory landscape in the country. Motivated by these factors, they jointly established the Company to capture such market opportunity. Pursuant to the Series A Share Purchase Agreement, our Company issued 35,000,000 and 5,000,000 Series A Preferred Shares to Vivo Capital and Sofinnova, for a cash consideration of US\$35,000,000 and US\$5,000,000, respectively. In addition, our Company issued to three wholly-owned subsidiaries of Ascendis Pharma A/S an aggregate of 40,000,000 Series A Preferred Shares as consideration for them to enter into the Exclusive License Agreements and Clinical Supply Agreements in respect of lonapegsomatropin, TransCon CNP (navepegritide) and palopegteriparatide with our Company.

The Series A Preferred Shares were allotted and issued on November 7, 2018 as set forth in the table below:

<u>Name of Shareholders</u>	<u>Number of Series A Preferred Shares</u>	<u>Cash Consideration</u> <i>(US\$)</i>
Ascendis Pharma		
– Ascendis Pharma Endocrinology Division ⁽¹⁾	20,000,000	– ⁽²⁾
– Ascendis Pharma Growth Disorders ⁽¹⁾	7,500,000	– ⁽²⁾
– Ascendis Pharma Bone Diseases ⁽¹⁾	12,500,000	– ⁽²⁾
Vivo Capital	35,000,000	35,000,000
Sofinnova	5,000,000	5,000,000
Total	80,000,000	40,000,000

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Notes:

- (1) Ascendis Pharma Endocrinology Division, Ascendis Pharma Growth Disorders and Ascendis Pharma Bone Diseases are wholly-owned subsidiaries of Ascendis Pharma A/S.
- (2) 40,000,000 Series A Preferred Shares were allotted and issued to the three wholly-owned subsidiaries of Ascendis Pharma A/S as consideration for entering into the Exclusive License Agreements and Clinical Supply Agreements. For further details, please see the section headed “Business – Collaborations – Exclusive License Agreements with Ascendis Pharma” in this document.

Series B Financing

On January 8, 2021, our Company entered into the Series B Share Purchase Agreement with the following investors who subscribed from our Company an aggregate of 13,636,364 Series B Preferred Shares for a total consideration of approximately US\$150 million in accordance to the terms and subject to the conditions set forth therein.

The Series B Preferred Shares were allotted and issued on January 8, 2021 as set forth in the table below:

<u>Name of Shareholders</u>	<u>Number of Series B Preferred Shares</u>	<u>Consideration</u> <i>(US\$)</i>
HongShan Growth	4,090,909	44,999,999
OrbiMed		
– Worldwide Healthcare Trust PLC	1,454,546	16,000,006
– OrbiMed Genesis Master Fund, L.P.	181,818	1,999,998
– OrbiMed New Horizons Master Fund, L.P.	181,818	1,999,998
Sherpa Healthcare Partners		
– Sherpa Healthcare Fund I, L.P.	1,363,636	14,999,996
– Sherpa Healthcare Co-Investment Fund, L.P.	454,546	5,000,006
Cormorant		
– Cormorant Global Healthcare Master Fund, LP	248,400	2,732,400
– Cormorant Private Healthcare Fund III, LP	824,945	9,074,395
– CRMA SPV, L.P.	17,564	193,204
HBM Healthcare Investments	681,818	7,499,998
Pivotal bioVenture Partners China	590,909	6,499,999
Logos Capital	590,909	6,499,999
CRF Investment	454,545	4,999,995

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Name of Shareholders	Number of Series B Preferred Shares	Consideration (US\$)
Ascendis Pharma		
– Ascendis Pharma Endocrinology Division	568,182	6,250,002
– Ascendis Pharma Growth Disorders	213,068	2,343,748
– Ascendis Pharma Bone Diseases	355,114	3,906,254
Vivo Capital	1,136,364	12,500,004
Sofinnova	227,273	2,500,003
Total	13,636,364	150,000,004

Equity Incentive Plan

In order to motivate, attract and encourage certain employees, directors, consultants and other eligible persons, our Company adopted the Equity Incentive Plan which was approved by the Board on April 29, 2019, and amended and restated on January 8, 2021 and March 10, 2021 by the Board, respectively. The principal terms of the Equity Incentive Plan are set out in “Appendix IV – Statutory and General Information – D. Equity Incentive Plan.” The terms of the Equity Incentive Plan are not subject to the provisions of Chapter 17 of the Listing Rules. After [REDACTED], no further awards would be granted pursuant to this Equity Incentive Plan.

On March 30, 2021, the Company issued and allotted to VP EIP NUS LIMITED, VP EIP US LIMITED and Mr. Lu An-bang 11,000,000 Shares, 4,000,000 Shares and 5,000,000 Shares, respectively, for the operation of the Equity Incentive Plan.

The RSUs in respect of 5,000,000 Shares were granted to Mr. Lu An-bang on March 30, 2021. On the same date, Mr. Lu An-bang transferred the 5,000,000 Shares underlying Mr. Lu An-bang’s such RSUs to VPP LU LIMITED, a special purpose vehicle wholly owned by a family trust established by Mr. Lu An-bang (as the settlor) of which the trustee is Tricor Equity Trustee Limited for the benefit of, among others, Mr. Lu An-bang and his family members, by way of gift.

VP EIP NUS LIMITED is a special purpose vehicle wholly owned by a PRC employee trust (“PRC Employee Trust”) of which the trustee is Tricor Trust (Hong Kong) Limited (“Tricor HK”). The PRC Employee Trust is established as reserve for vesting of awards under the Equity Incentive Plan which may be granted to employees and consultants (each as defined thereunder) of PRC Nationality. VP EIP US LIMITED is a special purpose vehicle wholly owned by an U.S. employee escrow (“U.S. Employee Escrow”) of which the trustee is Tricor HK. The U.S. Employee Escrow is established as reserve for vesting of RSUs under the Equity Incentive Plan which may be granted to employees and consultants (each as defined

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

thereunder) of U.S. Nationality. Both the PRC Employee Trust and the U.S. Employee Escrow, managed by the trustee, an Independent Third Party, operate independently and all of the Shares held by the PRC Employee Trust and the U.S. Employee Escrow are non-voting Shares.

On March 30, 2021, the Company issued and allotted to VP EIP NUS LIMITED and VP EIP US LIMITED 11,000,000 Shares and 4,000,000 Shares, respectively, for the operation of the Equity Incentive Plan. On November 15, 2022, the Company entered into share surrender agreements with VP EIP NUS LIMITED and VP EIP US LIMITED, pursuant to which VP EIP NUS LIMITED surrendered for no consideration of 7,859,500 Shares, VP EIP US LIMITED surrendered for no consideration of 2,800,000 Shares. The surrendered shares were canceled accordingly on November 16, 2022. As a result, VP EIP NUS LIMITED and VP EIP US LIMITED holds 3,140,500 and 1,200,000 non-voting Shares in the Company, respectively. All the Shares issued and allotted by the Company to VP EIP NUS LIMITED and VP EIP US LIMITED are non-voting Shares.

As of the Latest Practicable Date, there were outstanding RSUs representing 6,475,000 Shares that had been granted to 26 grantees under the Equity Incentive Plan, among which RSUs representing 5,000,000 Shares were granted to Mr. Lu and held by VPP LU Limited, and RSUs representing 1,475,000 Shares have been granted to other grantees of the Company and held by VP EIP NUS LIMITED and VP EIP US LIMITED. The details of the grants are disclosed in the table below. It is expected that the Company may further grant 2,865,500 RSUs representing 2,865,500 Shares prior to [REDACTED] through the remaining non-voting Shares held by VP EIP NUS LIMITED and VP EIP US LIMITED and none of the future grantees under the Equity Incentive Plan would be the Directors or connected persons of the Company. As such, at the time of [REDACTED], save as Mr. Lu, no Director or connected person of the Company will be a grantee under the Equity Incentive Plan. After [REDACTED], no further awards would be granted pursuant to this Equity Incentive Plan.

[REDACTED] Share Award Scheme

Concurrently with the Share Surrender, the Company adopted the [REDACTED] Share Award Scheme which was approved by the Board on November 8, 2022 and the Shareholders on November 16, 2022, with effect from the [REDACTED]. The [REDACTED] Share Award Scheme is compliant with the provisions of Chapter 17 of the Listing Rules. The principal terms of the [REDACTED] Share Award Scheme are set out in “Appendix IV – Statutory and General Information – E. [REDACTED] Share Award Scheme.” Pursuant to the [REDACTED] Share Award Scheme, the maximum number of Shares in respect of which awards may be granted shall not exceed [REDACTED] Shares.

Our Major Subsidiary

VISEN Shanghai is our major subsidiary and operating entity. Incorporated in Shanghai, PRC on February 15, 2019, VISEN Shanghai is a wholly owned subsidiary of VISEN HK, with a registered and paid-in capital of US\$113,000,000 and US\$95,000,000, respectively. VISEN Shanghai primarily engages in the research and clinical development of our drug candidates.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

For details of shareholding changes of other subsidiaries within the two years immediately preceding the date of this document, see “Appendix IV – Statutory and General Information – A. Further Information about Our Group – 3. Changes in the share capital of our subsidiaries.”

ACQUISITION, MERGER AND DISPOSAL

Throughout the Track Record Period and as of the Latest Practicable Date, the Company did not conduct any acquisitions, mergers or disposals.

[REDACTED] INVESTMENTS

Overview

Our Company completed two rounds of [REDACTED] Investments, including Series A financing and Series B financing as described above. The consideration of the [REDACTED] Investments was determined based on arm’s length negotiations among our Founding Shareholders, and between our Company and the [REDACTED] Investors, respectively, after taking into account the timing of the investments and the status of our business and operating entity at the relevant time. In connection with the [REDACTED] Investments, our Founding Shareholders and the [REDACTED] Investors entered into the relevant share purchase agreements at the time of their respective investments.

Capitalization of our Company

The below table is a summary of the shareholding structure of our Company:

Name of Shareholders	As of the Latest Practicable Date ⁽¹⁾				As of the [REDACTED] ⁽²⁾		
	Series A Preferred Shares	Series B Preferred Shares	Shares	Aggregate number of Shares	Aggregate shareholding percentage	Aggregate number of Shares	Aggregate shareholding percentage
Ascendis Pharma							
– Ascendis Pharma Endocrinology Division	20,000,000	568,182	–	20,568,182	19.97%	[REDACTED]	[[REDACTED]%
– Ascendis Pharma Growth Disorders	7,500,000	213,068	–	7,713,068	7.49%	[REDACTED]	[[REDACTED]%
– Ascendis Pharma Bone Diseases	12,500,000	355,114	–	12,855,114	12.48%	[REDACTED]	[[REDACTED]%
Vivo Capital	35,000,000	1,136,364	–	36,136,364	35.09%	[REDACTED]	[[REDACTED]%
Sofinnova	5,000,000	227,273	–	5,227,273	5.08%	[REDACTED]	[[REDACTED]%
HongShan Growth	–	4,090,909	–	4,090,909	3.97%	[REDACTED]	[[REDACTED]%
OrbiMed							

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Name of Shareholders	As of the Latest Practicable Date ⁽¹⁾				As of the [REDACTED] ⁽²⁾		
	Series A Preferred Shares	Series B Preferred Shares	Shares	Aggregate number of Shares	Aggregate shareholding percentage	Aggregate number of Shares	Aggregate shareholding percentage
- Worldwide Healthcare Trust PLC	-	1,454,546	-	1,454,546	1.41%	[REDACTED]	[[REDACTED]%
- OrbiMed Genesis Master Fund, L.P.	-	181,818	-	181,818	0.18%	[REDACTED]	[[REDACTED]%
- OrbiMed New Horizons Master Fund, L.P.	-	181,818	-	181,818	0.18%	[REDACTED]	[[REDACTED]%
Sherpa Healthcare Partners							
- Sherpa Healthcare Fund I, L.P.	-	1,363,636	-	1,363,636	1.32%	[REDACTED]	[[REDACTED]%
- Sherpa Healthcare Co-Investment Fund, L.P.	-	454,546	-	454,546	0.44%	[REDACTED]	[[REDACTED]%
Cormorant							
- Cormorant Private Healthcare Fund III, LP	-	824,945	-	824,945	0.80%	[REDACTED]	[[REDACTED]%
- Cormorant Global Healthcare Master Fund, LP	-	248,400	-	248,400	0.24%	[REDACTED]	[[REDACTED]%
- CRMA SPV, L.P.	-	17,564	-	17,564	0.02%	[REDACTED]	[[REDACTED]%
HBM Healthcare Investments	-	681,818	-	681,818	0.66%	[REDACTED]	[[REDACTED]%
Pivotal bioVenture Partners China	-	590,909	-	590,909	0.57%	[REDACTED]	[[REDACTED]%
Logos Capital	-	590,909	-	590,909	0.57%	[REDACTED]	[[REDACTED]%
CRF Investment	-	454,545	-	454,545	0.44%	[REDACTED]	[[REDACTED]%
VP EIP NUS LIMITED	-	-	3,140,500 ⁽³⁾	3,140,500	3.05%	[REDACTED]	[[REDACTED]%
VP EIP US LIMITED	-	-	1,200,000 ⁽³⁾	1,200,000	1.17%	[REDACTED]	[[REDACTED]%
VPP LU LIMITED	-	-	5,000,000 ⁽³⁾	5,000,000	4.86%	[REDACTED]	[[REDACTED]%
Total	80,000,000	13,636,364	9,340,500	102,976,864	100.00%	[REDACTED]	[[REDACTED]%

Notes:

- (1) Based on the assumption that the conversion of the Preferred Shares into Shares on a one-to-one basis has been completed prior to the [REDACTED].
- (2) Calculated after taking into account the Shares to be issued pursuant to the [REDACTED], assuming that the [REDACTED] is not exercised and no Shares are issued under the [REDACTED] Share Award Scheme.
- (3) The Shares held by each of VP EIP NUS LIMITED, VP EIP US LIMITED and VPP LU LIMITED do not carry voting rights pursuant to the existing Memorandum and Articles of Association of our Company.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Principal terms of the [REDACTED] Investments and rights of our Founding Shareholders and [REDACTED] Investors

The below table summarizes the principal terms of the [REDACTED] Investments:

	<u>Series A Financing</u>	<u>Series B Financing</u>
Cost per Preferred Share (approximation)	US\$1.00	US\$11.00
Corresponding valuation of our Company (approximation) ⁽¹⁾	US\$80 million	US\$1,030 million
Date of the agreement(s)	November 7, 2018	January 8, 2021
Funds raised by our Group (approximation)	US\$40 million ⁽²⁾	US\$150 million
Date on which investment was fully settled	November 7, 2018	January 9, 2021
Discount/(Premium) to the [REDACTED] ⁽³⁾	[REDACTED]%	[REDACTED]% ⁽⁴⁾
Lock-up Period		

According to the Shareholders’ Agreement and subject to certain conditions as contained therein, each of our Series A Preferred Shareholders and Series B Preferred Shareholders has agreed that, upon request by the Company or the [REDACTED], it will not sell or otherwise transfer or dispose of any securities of the Company held immediately before the date of this document without prior written consent of the Company or the [REDACTED], for a period of time specified by the [REDACTED] not to exceed 180 days from the date of this document or the [REDACTED] of the [REDACTED] as may be requested by the [REDACTED].

Use of Proceeds from the [REDACTED] Investments

We utilized the proceeds for the principal business of our Group as approved by the Board, including, but not limited to, R&D activities, the growth and expansion of our Group’s business and general working capital purposes in accordance with the budget approved by the Board. As at the Latest Practicable Date, approximately 79.7% of the net proceeds from the [REDACTED] Investments have been utilized. We intended to use the rest net proceeds from the [REDACTED] investment for further research and development activities, working capital, and other general corporate purposes.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

	<u>Series A Financing</u>	<u>Series B Financing</u>
Strategic benefits of the [REDACTED] Investments		At the time of the [REDACTED] Investments, our Directors were of the view that our Company could benefit from the capital that would be provided by the investors' investments in our Company and the investors' knowledge and experience.

Notes:

- (1) The corresponding valuation of our Company is calculated based on the capitalization of our Company of the relevant time taking into account the funds raised without taking into account the Shares issued pursuant to the Equity Incentive Plan after the Series B Financing. The valuation of the Company increased significantly during the period between our Series A Financing and Series B Financing, primarily due to (i) the continuous and successful building of our management and operation team; (ii) the R&D and regulatory milestones achieved by us on our Core Product, lonapegsomatropin, including IND approval to initiate the Phase 3 pivotal study of the Core Product in PGHD and initiation of this study; and (iii) the R&D and regulatory milestones achieved by us on another key drug candidate, TransCon CNP (navepegritide), including IND approval to initiate the China Phase 2 trial.
- (2) 40,000,000 Series A Preferred Shares were allotted and issued to Ascendis Pharma as consideration for entering into the Exclusive License Agreements and Clinical Supply Agreements.
- (3) The discount/(premium) to the [REDACTED] is calculated based on the assumption that the [REDACTED] is HK\$[REDACTED] per Share, being the mid-point of the [REDACTED] of HK\$[REDACTED] to HK\$[REDACTED], assuming the conversion of the Preferred Shares into Shares on a one-to-one basis has completed prior to [REDACTED].
- (4) Calculated on the basis of the [REDACTED] of HK\$[REDACTED], the mid-point of the proposed range of HK\$[REDACTED] to HK\$[REDACTED], the valuation of the Company upon [REDACTED] will be decrease from that of Series B Financing, which is mainly due to market fluctuations which reflects market variability and broader economic conditions which influenced investor sentiment and valuation metrics. The biotech industry is particularly sensitive to short-term market dynamics due to the lengthy and costly nature of drug development, as well as shifts in regulatory landscapes and healthcare policies. However, these factors do not affect the Company's long-term potential and market prospects. Between the Series B financing and the Latest Practicable Date, the Company has achieved various milestones, including (i) the acceptance of the BLA filing of our Core Product for the treatment of PGHD by the NMPA, (ii) the completion of the primary analysis of the Phase 2 clinical trial in China of TransCon CNP (navepegritide) for the treatment of ACH with the primary endpoint met according to the topline results, and (iii) the completion of the double-blind period for primary endpoint for our ongoing China Phase 3 pivotal trial of palopegteriparatide, PaTHway China Trial, which demonstrates consistency with the global Phase 3 pivotal trial in terms of primary endpoint and safety profile.

Special Rights of the Founding Shareholders and [REDACTED] Investors

Pursuant to the Shareholders' Agreement and the existing Memorandum and Articles of Association of our Company, certain of our Founding Shareholders and the [REDACTED] Investors have, among other rights, (i) information and inspection rights; (ii) the right to elect Directors and the right of participation in the meetings of the Board; (iii) the right to appoint observers to attend the meetings of the Board; (iv) pre-emptive rights; (v) rights of first refusal and co-sale; (vi) conversion rights; (vii) liquidation preference; and (viii) protective provisions.

Pursuant to the Shareholders' Agreement, all Preferred Shares shall be converted into Shares of our Company immediately before the completion of the [REDACTED] on a one-to-one ratio, and all the above shareholders' special rights granted to the [REDACTED] Investors will be automatically terminated upon or before the [REDACTED].

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Information about our Shareholders

The background information of our Founding Shareholders and [REDACTED] Investors is set out below:

Founding Shareholders

Ascendis Pharma

Ascendis Pharma Endocrinology Division, Ascendis Pharma Growth Disorders and Ascendis Pharma Bone Diseases are wholly-owned subsidiaries of Ascendis Pharma A/S, a Danish-based biopharmaceutical company listed on the Nasdaq (Ticker Symbol: ASND). None of the shareholders of Ascendis Pharma A/S holds over 30% equity interest in it. For further details of Ascendis Pharma A/S, please see the section headed “Relationship with the Controlling Shareholders” in this document.

Vivo Capital

Vivo Plenilune IX Limited (“Vivo Capital”) is a company established under the Laws of Cayman Islands. Vivo Capital is a wholly-owned subsidiary of Vivo Capital Fund IX (Cayman), L.P., which is in turn controlled by its general partner, Vivo Capital IX (Cayman), LLC. (collectively, “Vivo Funds”). As of the Latest Practicable Date, Vivo Capital Fund IX (Cayman), L.P. has over 40 limited partners, among which the largest limited partner held less than 20% of its partnership interest. Vivo Capital IX (Cayman), LLC. is beneficially owned by Frank Kung, Ed Engleman, Fu Shan, Mahendra Shah, Michael J. CHANG and Jack Nielsen, other than Fu Shan and Michael J. CHANG, who are the Directors of our Company, each of the voting members of Vivo Capital IX (Cayman), LLC. is an Independent Third Party.

Vivo Funds are under the management of Vivo Capital LLC. Founded in 1996, Vivo Capital LLC provides a multi-fund investment platform, covering private equity including buyout, venture capital, and public equity. Funds managed by Vivo Capital LLC invest broadly in healthcare across all fund strategies, including biotechnology, pharmaceuticals, medical devices, and healthcare services, with a focus on the largest healthcare markets.

Vivo Capital is a Sophisticated Investor by virtue of the investment experience and size of assets under management of Vivo Capital LLC. As of December 31, 2023, Vivo Capital is a leading healthcare investment firm with approximately US\$5.8 billion in assets under management. Portfolio companies of Vivo Capital include, but are not limited to, TOT BIOPHARM International Company Limited (東曜藥業股份有限公司) (HKEx: 1875), InnoCare Pharma Limited (諾誠健華醫藥有限公司) (HKEx: 9969), Lepu Biopharma Co., Ltd. (樂普生物科技股份有限公司) (HKEx: 2157) and LEPU ScienTech Medical Technology (Shanghai) Co., Ltd. (樂普心泰醫療科技(上海)股份有限公司) (HKEx: 2291). For further details of Vivo Capital, please see the section headed “Relationship with the Controlling Shareholders” in this document.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Sofinnova

Sofinnova Venture Partners IX, L.P. (“Sofinnova”), is a limited partnership established under the laws of the State of Delaware, with Sofinnova Management IX, L.L.C. (“Sofinnova GP”) as its general partner. Sofinnova GP is controlled by its sole managing member, James I. Healy, MD, PhD. Dr. Healy is currently on the board of directors of Bolt Therapeutics, Inc. (Nasdaq: BOLT), ArriVent BioPharma, Inc. (Nasdaq: AVBP), Y-mAbs Therapeutics, Inc. (Nasdaq: YMAB) and Natera, Inc. (Nasdaq: NTRA), and on the board of directors of several private companies. He holds an M.D. and a Ph.D. in Immunology from Stanford University School of Medicine and holds a B.A. in Molecular Biology and a B.A. in Scandinavian Studies from the University of California, Berkeley. As of December 31, 2023, Sofinnova is a fund with \$510 million in capital commitments and managed and advised by Sofinnova Investments, Inc., a registered investment adviser regulated by the U.S. Securities and Exchange Commission under the Investment Advisers Act of 1940. As of December 31, 2023, Sofinnova had 51 limited partners consisting mainly of endowment and foundations, family offices, insurance and institutions, pension funds and private funds. Among these limited partners, the largest limited partner held less than 10% of the aggregate partnership interests. Sofinnova is a clinical-stage focused biopharmaceutical investment fund and invests in both private and public equity of therapeutics-focused companies. Its portfolio companies include Ascendis Pharma A/S (Nasdaq: ASND), Natera, Inc. (Nasdaq: NTRA), NextCure Inc (Nasdaq: NXTC) and PDS Biotechnology Corporation (Nasdaq: PDSB). Sofinnova is a Sophisticated Investor. To the best knowledge of our Directors, save as disclosed in this document, each of the abovementioned entities is an Independent Third Party.

[REDACTED] Investors

HongShan Growth

HSG Growth VI Holdco F LTD. (“HongShan Growth”) is a company incorporated in the Cayman Islands and is a wholly-owned subsidiary of HongShan Capital Growth Fund VI, L.P. (“HongShan GVI Fund”). HongShan GVI Fund is an investment fund whose primary purpose is to make equity investments in private companies. The general partner of HongShan GVI Fund is HSG Growth VI Management, L.P., whose general partner is HSG Holding Limited, a wholly-owned subsidiary of SNP China Enterprises Limited. Neil Nanpeng Shen is the sole shareholder of SNP China Enterprises Limited. None of the limited partners of HongShan GVI Fund has more than 30% of the limited partnership interests of HongShan GVI Fund. To the best knowledge of our Directors, save as disclosed in this document, each of HongShan Growth, the abovementioned entities and Neil Nanpeng Shen is an Independent Third Party.

HongShan Growth is a Sophisticated Investor by virtue of the investment experience of HongShan GVI Fund. As of March 31, 2024, HongShan Growth managed US\$420 million of assets. HongShan is a leading venture capital and private equity firm investing across technology, healthcare and consumer sectors. Since 2005, HongShan has been fostering entrepreneurship and innovation, backing more than 1,500 companies around the globe. Investment funds affiliated with HongShan have invested in other technology, biotechnology

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

or healthcare companies such as CStone Pharmaceuticals (基石藥業) (HKEx: 2616), Innovent Biologics, Inc. (信達生物製藥) (HKEx: 1801), Venus Medtech (Hangzhou) Inc. (杭州啟明醫療器械股份有限公司) (HKEx: 2500), Bii Biosciences Limited (騰盛博藥生物科技股份有限公司) (HKEx: 2137), Jiangsu Recbio Technology Co., Ltd. (江蘇瑞科生物技術股份有限公司) (HKEx: 2179), Beijing Fourth Paradigm Technology Co., Ltd. (北京第四範式智能技術股份有限公司) (HKEx: 6682).

OrbiMed

Worldwide Healthcare Trust PLC (“WWH”) is a publicly-listed investment trust organized under the laws of England. WWH is listed on the London Stock Exchange (LON: WWH).

OrbiMed Genesis Master Fund, L.P. (“GEN”) is an exempted limited partnership organized under the laws of the Cayman Islands. It is a pooled-investment fund with OrbiMed Advisors LLC acting as its investment manager and OrbiMed Genesis GP LLC as its general partner. OrbiMed Advisors LLC is the managing member of OrbiMed Genesis GP LLC. As of December 31, 2023, GEN has 87 limited partners with the largest single investor holding approximately 11.8% interest in GEN.

OrbiMed New Horizons Master Fund, L.P. (“ONH”) is an exempted limited partnership organized under the laws of the Cayman Islands. It is a pooled-investment fund with OrbiMed Advisors LLC acting as its investment manager and OrbiMed New Horizons GP LLC as its general partner. OrbiMed Advisors LLC is the managing member of OrbiMed New Horizons GP LLC. As of December 31, 2023, ONH has 83 limited partners with the largest single investor holding approximately 18.5% interest in ONH.

WWH, GEN, and ONH are investment vehicles of OrbiMed. OrbiMed Capital LLC is the portfolio manager of WWH. OrbiMed Advisors LLC is the investment manager of GEN and ONH. OrbiMed Capital LLC and OrbiMed Advisors LLC exercise voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild.

OrbiMed is a Sophisticated Investor. As of March 2024, OrbiMed is a leading healthcare investment firm with approximately US\$17 billion in assets under management. OrbiMed invests globally in the healthcare sector with investments ranging from early stage private companies to large multinational corporations. Portfolio companies of OrbiMed include, but are not limited to, Arrail Group Limited (瑞爾集團有限公司) (HKEx: 6639), Suzhou Basecare Medical Corporation Limited (蘇州貝康醫療股份有限公司) (HKEx: 2170), and others.

To the best knowledge of our Directors, save as disclosed in this document, each of the abovementioned entities is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Sherpa Healthcare Partners

Sherpa Healthcare Fund I, L.P. is a limited partnership established under the laws of the Cayman Islands, with Sherpa Healthcare Fund I, GP, Ltd. acting as its general partner. Sherpa Healthcare Co-Investment Fund, L.P. is a limited partnership established under the laws of the Cayman Islands, with Sherpa Healthcare Co-Investment GP Ltd. acting as its general partner. Each of the Sherpa Healthcare Partners is ultimately controlled by Mr. Cai Daqing (蔡大慶). As of the Latest Practicable Date, Sherpa Healthcare Partners have over 20 limited partners mainly including family offices, foundations, asset managements, public listed Companies, fund of funds, and pension funds. To the best knowledge of our Directors, save as disclosed in this document, each of the abovementioned entities and Mr. Cai Daqing is an Independent Third Party.

Together with its affiliates, Sherpa Healthcare Partners are specializing in investments in the healthcare sector, including biotech, pharmaceuticals, medical devices, equipment and diagnostics, healthcare services and healthcare-related information technology and mobile technology companies, all having a nexus to greater China. The portfolio companies of Sherpa Healthcare Partners include New Horizon Health Limited (諾輝健康) (HKEx: 6606), Shanghai HeartCare Medical Technology Corporation Limited (上海心瑋醫療科技股份有限公司) (HKEx: 6609), Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (四川科倫博泰生物醫藥股份有限公司) (HKEx: 6990), CYTEK BIOSCIENCES, INC. (Nasdaq: CTKB). Considering its extensive investment experience in the healthcare industry and its significant commitment to the healthcare section, Sherpa Healthcare Partners is a Sophisticated Investor.

Cormorant

Cormorant Global Healthcare Master Fund, LP and CRMA SPV, L.P. are exempt limited partnerships incorporated under the laws of Cayman Islands as pooled investment vehicles organized as a hedge fund and a special purpose vehicle, respectively. Cormorant Private Healthcare Fund III, LP, a limited partnership incorporated under the laws of Delaware, is a pooled investment vehicle organized as a private equity fund. All three entities are managed by Cormorant Asset Management, LP, an investment advisor registered with the U.S. Securities and Exchange Commission, which is controlled by Ms. Chen Bihua. Founded in 2013 by Ms. Chen Bihua, Cormorant manages approximately US\$3 billion of assets across private and public companies, focusing on innovative biotech, medtech and life science companies. Cormorant has invested in a number of biotechnology or healthcare companies including but not limited to New Horizon Health Limited (6606.HK), Innovent Biologics, Inc. (1801.HK), Kangji Medical Holdings Limited (9997.HK) and Hansoh Pharmaceutical Group Company Limited (3692.HK). To the best knowledge of our Directors, save as disclosed in this document, each of the abovementioned entities and Ms. Chen Bihua is an Independent Third Party. Cormorant provides investment advisory services on discretionary basis.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

HBM Healthcare Investments

HBM Healthcare Investments (Cayman) Ltd. or HBM Healthcare Investments, is a company established under the laws of Cayman Islands and is a wholly-owned subsidiary of HBM Healthcare Investments Ltd. HBM Healthcare Investments holds and manages an international portfolio of promising companies in the human medicine, biotechnology, medical technology and diagnostics sectors and related areas. HBM Healthcare Investments Ltd is listed on SIX Swiss Exchange (ticker: HBMN), with USD 2.1 billion net assets, and has an international shareholder base. To the best knowledge of our Directors, save as disclosed in this document, each of the abovementioned entities is an Independent Third Party. HBM Healthcare Investments is operating on a “discretionary basis.” The board of directors of HBM Healthcare Investments (Cayman) Ltd. has sole voting and investment power with respect to the Shares held by HBM Healthcare Investments (Cayman) Ltd. The board of directors of HBM Healthcare Investments (Cayman) Ltd. is comprised of Jean-Marc Lesieur, Richard Coles, Sophia Harris, Dr. Andreas Wicki, Paul Woodhouse and Mark Kronenfeld, none of whom has individual voting or investment power with respect to such Shares, and each disclaims beneficial ownership of such Shares except to the extent of any pecuniary interest therein.

Pivotal bioVenture Partners China

Cosmic Clover Limited is an investment holding company incorporated in the BVI and is a subsidiary of Pivotal bioVenture Partners China USD Fund I, L.P. (“Pivotal bioVenture Partners China”, an exempted limited partnership registered in the Cayman Islands). The Ultimate General Partner of Pivotal bioVenture Partners China is Pivotal bioVenture Partners China USD Fund I U.G.P. Limited which is an indirect subsidiary of Nan Fung International Holdings Limited (“Nan Fung”). As of the Latest Practicable Date, Pivotal bioVenture Partners China had three limited partners with Pivotal China Partners Limited, which is its largest limited partner, holding approximately 97% of its partnership interest. Pivotal China Partners Limited is an indirect subsidiary of Nan Fung Life Sciences Holdings Limited (“NFLS”). Portfolio companies of NFLS include, but are not limited to, InnoCare Pharma Limited (諾誠健華醫藥有限公司) (HKEx: 9969), Wuxi Apptec Co., Ltd. (無錫藥明康德新藥開發股份有限公司) (HKEx: 2359), Arcutis Biotherapeutics Inc (NASDAQ: ARQT), Vaxcyte (NASDAQ: PCVX), and Exscientia PLC (NASDAQ: EXAI).

The principal activities of Nan Fung and its subsidiaries (collectively, “Nan Fung Group”) include property investment and development, life sciences investment, financial investments, property management and construction. Nan Fung Group has been developing properties in Hong Kong since 1965 and since then, Nan Fung Group has invested in commercial and residential projects in other jurisdictions including the PRC, Macau, Singapore, Japan, Malaysia, the United Kingdom and the United States. Nan Fung Group has set up NFLS as a global life sciences investment platform, investing across the entire value chain of the life sciences industry. NFLS aspires to be the ideal partner for scientists, entrepreneurs, corporations and investors in the life sciences spectrum. Supported by the Group’s solid financial strength and investing expertise, NFLS has built teams and established significant presences in Hong Kong, Mainland China and the US. which holds diverse portfolios of the life

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

sciences industry including therapeutics, medical devices, diagnostics, tools, and healthcare services. As of the Latest Practicable Date, it managed the committed capital of approximately US\$2 billion. The ultimate holding company of Nan Fung Group is Chen’s Group International Limited, which is wholly owned by the estate of the late Dr. Chen Din Hwa, a Hong Kong industrial tycoon. To the best knowledge of our Directors, save as disclosed in this document, each of the abovementioned entities and Dr. Chen Din Hwa is an Independent Third Party.

Logos Capital

Logos Opportunities Fund II LP is a limited partnership established under the Laws of the State of Delaware, with Logos Opportunities GP LLC acting as its general partner, whose ultimate beneficiary owners are Independent Third Parties. Logos Global Management LP (“Logos Capital”) is the Investment Adviser to Logos Opportunities Fund II LP (collectively, “Logos”). As of the Latest Practicable Date, Logos Opportunities Fund II LP has over 50 limited partners, mainly including family offices, foundations and fund of funds with the largest single investor holding lower than 15% of the shares. Logos is a biotechnology-focused investment firm which combines scientific and financial expertise with in-house clinical trial analytics to identify transformative therapies in healthcare. To the best knowledge of our Directors, save as disclosed in this document, each of the abovementioned entities is an Independent Third Party.

CRF Investment

CRF is a limited liability company incorporated under the laws of the Cayman Islands. CRF is wholly-owned by China Reform Conson Soochow Overseas Fund I L.P., which is a China-related overseas investment firm specializing in high-end manufacturing and healthcare sectors with totaled US\$450 million Fund size.

China Reform Conson Soochow Overseas Fund I L.P. is solely advised by CDG Capital Company Limited (“CDG Capital”, 晨嶺資本), and mainly sponsored by China Reform Holdings Corporation Ltd (“CRHC”) (through China Reform Investment Fund I L.P.), Qingdao Conson Development (Group) Co., Ltd. (through its wholly-owned subsidiary) and Soochow Securities Co., Ltd. (through its wholly-owned subsidiary). The General Partner of China Reform Conson Soochow Overseas Fund I L.P. is China Reform Puissance Overseas GP LP, an exempted limited partnership incorporated under the laws of the Cayman Islands. CRF provides investment advisory services on discretionary basis.

To the best knowledge of our Directors, save as disclosed in this document, CRF Investment Holdings Company Limited is an Independent Third Party.

Save as disclosed above and to the best knowledge of our Directors, our [REDACTED] Investors and their ultimate beneficial owners are Independent Third Parties.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

[REDACTED] Float

Upon completion of the [REDACTED] (assuming the [REDACTED] is not exercised and no Shares are issued under the [REDACTED] Share Award Scheme), Ascendis Pharma A/S and Vivo Capital, will hold (directly or indirectly) approximately [[REDACTED]%] and [[REDACTED]%] of the total issued Shares, respectively, and each is therefore our core connected person under the Listing Rules. As a result, such Shares will not count towards the [REDACTED] float. In addition, the Shares held by VPP LU LIMITED (a special purpose vehicle wholly owned by a family trust established by Mr. Lu An-bang (as the settlor)), representing approximately [[REDACTED]%] of the total issued Shares, will not be counted towards the [REDACTED] float.

Except as disclosed above, Shares held by Sofinnova, other [REDACTED] Investors, VP EIP NUS LIMITED, VP EIP US LIMITED, the special purpose vehicles wholly owned by PRC Employee Trust and U.S. Employee Escrow for the purpose of reserving for vesting of awards under the Equity Incentive Plan and the [REDACTED] in the [REDACTED] will be counted towards the [REDACTED] float for the purpose of Rule 8.08 of the Listing Rules after the [REDACTED]. Hence, [[REDACTED]%] of our Company’s total issued Shares will be held by the [REDACTED] upon completion of the [REDACTED] as required under Rule 8.08(1)(a) of the Listing Rules that requires more than 25% of the Company’s total issued shares must be held by the [REDACTED] upon the completion of the [REDACTED]. In addition, the market capitalization of the portion of the total number of the Company’s issued Shares held by the [REDACTED] pursuant to the requirements under Rule 18A.07 of the Listing Rules (based on the [REDACTED] of HK\$[REDACTED], being the mid-point of the [REDACTED]) would be over HK\$375 million at the time of the [REDACTED].

Compliance with the Guide for New Listing Applicants

The Joint Sponsors confirm that the investments by our Founding Shareholders and the [REDACTED] Investors are in compliance with Chapter 4.2 of the Guide for New Listing Applicants issued by the Stock Exchange.

PRC REGULATORY REQUIREMENTS

Our PRC Legal Adviser confirms that as of the Latest Practicable Date, VISEN Shanghai and VISEN Suzhou had been duly established as wholly foreign owned enterprises and all regulatory approvals and permits in respect of the incorporation of VISEN Shanghai and VISEN Suzhou had been obtained in accordance with PRC laws.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Under the Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》) (“M&A Rules”), a foreign investor is required to obtain necessary approvals from MOFCOM or the department of commerce at the provincial level when:

- a foreign investor acquires equity in a domestic enterprise (thereby converting it into a foreign-invested enterprise), or subscribes for new registered capital in a domestic enterprise via an increase of registered capital (thereby converting it into a foreign-invested enterprise); or
- a foreign investor establishes a foreign-invested enterprise that purchases and operates assets of a domestic enterprise, or that purchases assets of a domestic enterprise and injects those assets to establish a foreign-invested enterprise.

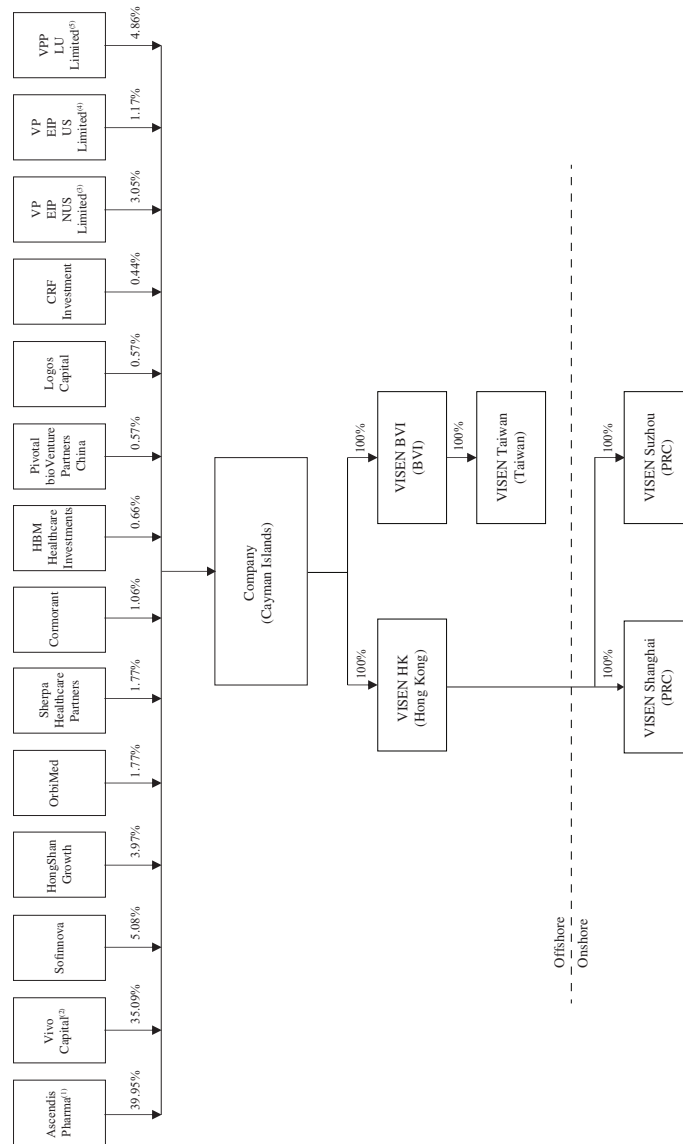
Furthermore, according to Article 11 of the M&A Rules, where a domestic company or enterprise, or a domestic natural person, through an overseas company established or controlled by it/them, acquires a domestic company that is related to or connected with it/them, an approval on such connected transaction from MOFCOM is required.

As advised by our PRC Legal Adviser, the MOFCOM approvals under the M&A Rules are not required because VISEN Shanghai and VISEN Suzhou was incorporated as a foreign-invested enterprise without involving acquisition of the equity or assets of a “PRC domestic company”, as such term is defined under the M&A Rules. However, there is uncertainty as to how the M&A Rules will be interpreted or implemented and whether the MOFCOM and other related Governmental Authorities would promulgate future PRC laws, regulations or rules contrary to the M&A Rules.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OUR CORPORATE STRUCTURE IMMEDIATELY PRIOR TO THE [REDACTED]

The following chart depicts our corporate and shareholding structure as at the Latest Practicable Date, assuming that all of the Preferred Shares have been converted to ordinary Shares on a one-to-one basis, the [REDACTED] is not exercised, and no Shares are issued under the [REDACTED] Share Award Scheme:



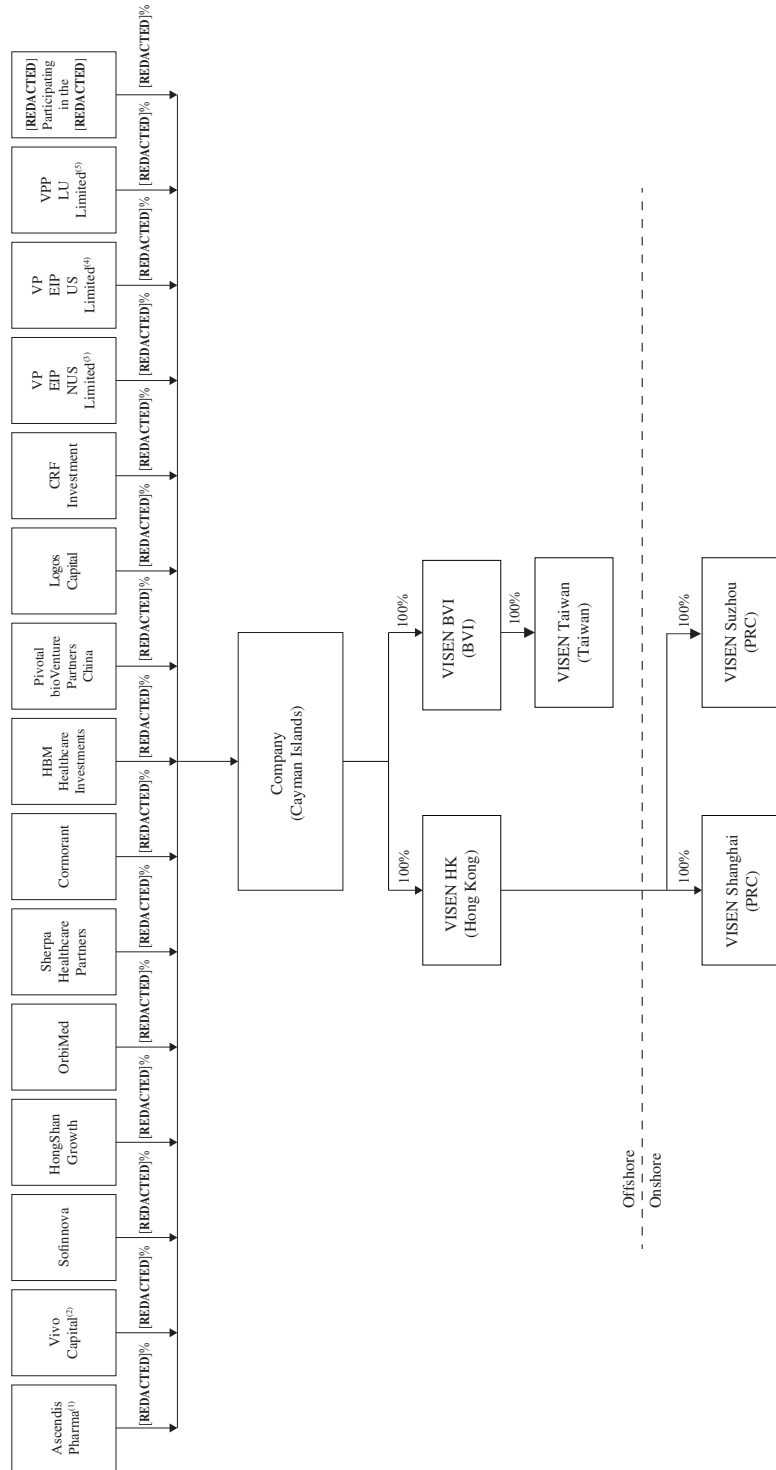
Notes:

- (1) Ascendis Pharma A/S, through its wholly-owned subsidiaries, Ascendis Pharma Endocrinology Division, Ascendis Pharma Bone Diseases and Ascendis Pharma Growth Disorders, collectively, hold an aggregate of 40,000,000 Series A Preferred Shares and 1,136,364 Series B Preferred Shares of the Company prior to the [REDACTED].
- (2) Vivo Capital holds an aggregate of 35,000,000 Series A Preferred Shares and 1,136,364 Series B Preferred Shares of the Company prior to the [REDACTED].
- (3) VP EIP NUS LIMITED is a special purpose vehicle wholly owned by the PRC Employee Trust of which the trustee is Tricor HK. The PRC Employee Trust is established as reserve for grant or vesting of awards under the Equity Incentive Plan which have been or may be granted to employees and consultants of PRC Nationality. Tricor HK is an Independent Third Party.
- (4) VP EIP US LIMITED is a special purpose vehicle wholly owned by the U.S. Employee Escrow of which the trustee is Tricor HK. The U.S. Employee Escrow is established as reserve for grant or vesting of RSUs under the Equity Incentive Plan which have been or may be granted to employees and consultants of U.S. Nationality.
- (5) VPP LU LIMITED is a special purpose vehicle wholly owned by a family trust established by Mr. LU An-bang (as the settlor) of which the trustee is Tricor Equity Trustee Limited for the benefit of, among others, Mr. LU An-bang and his family members. Tricor Equity Trustee Limited is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OUR CORPORATE STRUCTURE IMMEDIATELY FOLLOWING THE [REDACTED]

The following chart depicts our corporate and shareholding structure immediately following the completion of the [REDACTED], assuming that all of the Preferred Shares have been converted to Shares on a one-to-one basis, the [REDACTED] is not exercised, and no Shares are issued under the [REDACTED] Share Award Scheme:



Notes (1)-(5): see the preceding page for the notes

BUSINESS

The information presented in this section is derived from various government publications and other publicly available sources. We believe that the sources of such information are appropriate and we have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading in any material respect. The information included herein has not been independently verified by our Company, the Joint Sponsors, [REDACTED], the [REDACTED], and [REDACTED], the [REDACTED], any of our or their respective directors, officers or representatives or any other person or party involved in the [REDACTED], and no representation is given as to its accuracy, completeness or fairness of such information. The information and statistics may not be consistent with other information and statistics compiled within or outside of China. Statistical data in these publications and sources also include estimates and future projections based on a number of assumptions. If any one or more of the assumptions underlying the market data are later found to be inaccurate, actual results may differ from the projections based on these assumptions. Accordingly, such information should not be unduly relied upon.

OVERVIEW

We are a late-stage, near-commercialization biopharmaceutical company focused on providing treatments in selected endocrinology diseases in China (including Hong Kong, Macau and Taiwan).

Our Core Product. Our Core Product, lonapegsomatropin, is a drug candidate studied by us to treat children aged 3 to 17 years old with GHD in a completed Phase 3 pivotal trial in China, where each subject received treatment for 52 weeks. Lonapegsomatropin is the only LAGH that has demonstrated superior efficacy and comparable safety in active-controlled and parallel-group trial comparisons with daily hGH, as validated in the completed Phase 3 pivotal trial in China. In this trial, lonapegsomatropin was associated with an AHV of 10.66 cm/year at 52 weeks compared to 9.75 cm/year for daily hGH, with a p-value of 0.0010. Height SDS at 52 weeks increased over baseline by 1.01 for lonapegsomatropin and by 0.83 for daily hGH, with a p-value of 0.0015, and statistical significance of change in height SDS from baseline (Δ height SDS) was demonstrated in the lonapegsomatropin group from and including 13 weeks onwards. The published results of the trial has demonstrated consistency with the completed global Phase 3 pivotal trial, which supported the marketing approvals from the FDA and the EMA in PGHD and demonstrated lonapegsomatropin’s superior growth profile and comparable safety profile in comparison with daily hGH. On March 7, 2024, the BLA filing of our Core Product for the treatment of PGHD was accepted by the NMPA.

Lonapegsomatropin provides a convenient once-weekly dosing regimen in injection frequency as compared to once-daily hGH, which may foster increased dosing compliance for pediatric patients in daily lives. As a result, it has the potential to further improve treatment outcomes and duration over daily hGH in real-world settings. Leveraging its novel molecular design, our Core Product is the only LAGH that releases unmodified hGH *in vivo* in between weekly doses in a stable manner, offering our Core Product the first-mover advantage in unmodified LAGH treatments. Such unmodified hGH is identical in the molecular composition to the endogenous growth hormone secreted by pituitary gland and preserves its original mode of action.

BUSINESS

Overview of endocrinology. Endocrinology is a large therapeutic area spanning over 170 diseases, among which 79, or nearly half, still lack disease-specific drugs, indicating significant unmet medical needs. Endocrine diseases may occur at all ages, affecting newborn to elderly patients, and are often associated with significant disease and socioeconomic burden and require life-long treatment.

Pediatric and adult endocrinology. By age of onset, endocrine diseases can be categorized into pediatric endocrine diseases and adult endocrine diseases, with each group having its unique characteristics. Pediatric patients, as growing individuals, have special needs related to growth and development, and hence they often face a limited treatment window and an urgent need for timely treatment. Discomfort and pain in treatment may affect children’s compliance, calling for significant demand to develop convenient treatment options with simplified drug regimens and improved treatment experience. Adult endocrine disorders often require life-long treatment, creating significant needs for treatment options with reduced compliance burden and favorable long-term safety profile.

Market potential. The endocrine drugs market in China excluding diabetes is estimated to grow to RMB74.2 billion by 2030, at a CAGR of 19.9% from 2023, according to Frost & Sullivan. Notably, the growth rate of this market in China has been and is expected to continue to be significantly higher than the growth rates of such market globally during the same periods, driven by a combination of factors, including innovation in endocrine drugs, increasing patient pool, improving health awareness and favorable healthcare policies.

Favorable healthcare policies. Endocrine diseases are designated, by the PRC State Council, as a category of chronic diseases that is of high national priority. Furthermore, the “Healthy China Action (2019-2030)” (《健康中國行動(2019-2030年)》) announced a national goal to reduce the rate of stunting in children aged under five from 8.1% in 2013 to below 7% by 2022 and below 5% by 2030, highlighting China’s focus on promoting children’s health and encouraging the development of pediatric drugs. See “Industry Overview – Overview of Non-Diabetic Endocrine Drug Market – Favorable Healthcare Policies” for more details.

Late-stage assets in China. Leveraging our clinical development capabilities, we provide patients in China (including Hong Kong, Macau and Taiwan) with access to the following endocrine solutions: (i) our Core Product, lonapegsomatropin, has completed the Phase 3 pivotal trial on human subjects in China for the treatment of PGHD; the BLA filing was made on January 18, 2024 and was subsequently accepted by the NMPA on March 7, 2024; (ii) TransCon CNP (navepegritide) has completed the double-blind period of Phase 2 clinical trial in China for the treatment of ACH and the last patient last visit of open-label extension (“OLE”) period of this trial was completed in April 2024; and (iii) palopegteriparatide is currently undergoing development in a Phase 3 pivotal trial in China for the treatment of adult patients with HP; it has completed the double-blind period in January 2023, and the expected NDA filing to the NMPA will be in the first half of 2025. See below and “– Our Drug Pipeline” for further details.

BUSINESS

Pipeline. Below is a pipeline diagram setting forth our drug candidates:

	Drug Candidate*	Indication	Clinical Development and Regulatory Status					Upcoming Milestones of Trials Conducted by VISEN
			IND	Phase 1	Phase 2	Phase 3	BLA / NDA	
Pediatric Endocrinology	★ Lonapegsomatropin	Pediatric Growth Hormone Deficiency	Completed China Phase 3 pivotal trial in April 2022 (BLA accepted by the NMPA in March 2024) ¹⁾					Expected BLA approval date in mid 2025
	➡ TransCon CNP (navepegritide)	Achondroplasia	Ongoing China Phase 2 trial, double-blind period completed in November 2023 ²⁾					Expected NDA submission to the NMPA
Adult Endocrinology	➡ Palopegteriparatide	Hypoparathyroidism	Ongoing China Phase 3 pivotal trial, double-blind period completed in January 2023 ³⁾					Expected NDA submission to the NMPA in first half of 2025

★ Core Product ➡ Key drug candidates

* VISEN has gained exclusive licensed rights to develop, manufacture and commercialize all drug candidates in endocrinology in China (including Hong Kong, Macau and Taiwan).

Notes:

- (1) VISEN completed the Phase 3 pivotal trial of lonapegsomatropin in China for the treatment of PGHD in April 2022 which met its primary endpoint according to our published results. We made the BLA filing with the NMPA on January 18, 2024 for our Core Product for the treatment of PGHD, which was subsequently accepted by the NMPA on March 7, 2024.
- (2) The primary analysis of the double-blind period of the Phase 2 clinical trials of TransCon CNP (navepegritide) in China for the treatment of ACH was completed in November 2023, with primary endpoint met according to the topline results. We became the sole sponsor for the OLE period of this trial in January 2023 and the last patient last visit of the OLE period was completed in April 2024.
- (3) VISEN completed the primary analysis of the Phase 3 pivotal trial of palopegteriparatide in China for the treatment of adult HP in January 2023 which met its primary efficacy and key secondary endpoints according to its topline data.

- ***Lonapegsomatropin***, our Core Product, is a drug candidate studied by us to treat children aged 3 to 17 years old with GHD in a completed Phase 3 pivotal trial in China, where each subject received treatment for 52 weeks. We in-licensed lonapegsomatropin from Ascendis Pharma in November 2018. Prior to our in-licensing, lonapegsomatropin had been studied by Ascendis Pharma in over 300 children with GHD across three Phase 3 programs. Lonapegsomatropin is the only LAGH that has demonstrated superior efficacy and comparable safety in active-controlled and parallel-group trial comparisons with daily hGH, as validated in the completed Phase 3 pivotal trial in China. In this trial, lonapegsomatropin was associated with an AHV of 10.66 cm/year compared to 9.75 cm/year for daily hGH at 52 weeks, with a p-value of 0.0010. Height SDS at 52 weeks increased over baseline by 1.01 for lonapegsomatropin and by 0.83 for daily hGH, with a p-value of 0.0015, and statistical significance of change in height SDS from baseline (Δ height SDS) was demonstrated in the lonapegsomatropin group from and including 13 weeks onwards. The published results of the trial has demonstrated consistency with the completed global Phase 3 pivotal trial, which supported the marketing approvals from the FDA and the EMA in PGHD and demonstrated lonapegsomatropin’s superior growth profile and comparable safety profile in comparison with daily hGH.

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Leveraging its novel molecular design, lonapegsomatropin is the only LAGH that releases unmodified hGH *in vivo* consistently in between weekly doses, offering our Core Product the first-mover advantage in unmodified LAGH treatments. Such unmodified hGH is identical in the molecular composition to the endogenous growth hormone secreted by pituitary gland and preserves its original mode of action. This is in distinction to other LAGH therapies under development and/or in commercial use in China, where the active components are modified proteins or peptides that may potentially alter the potency of hGH, its PK or PD profiles, tissue penetration and receptor binding, and potentially negatively impact drug efficacy and safety.

Our Core Product provides a convenient once-weekly dosing regimen in injection frequency as compared to once-daily hGH, which may foster increased dosing compliance for pediatric patients in daily lives. As a result, it has the potential to further improve treatment outcomes and duration over daily hGH in real-world settings. A convenient auto-injector was included in the FDA and EMA approvals of lonapegsomatropin for PGHD.

China accounted for the largest share of the global hGH market in 2023, surpassing the United States and representing 34% of the global market. The hGH market in China was RMB11.6 billion in 2023 and is expected to grow to RMB28.6 billion by 2030, at a CAGR of 13.7% from 2023 to 2030, according to Frost & Sullivan.

In May 2023, we submitted a formal communication application package to the CDE of the NMPA, in accordance with the Administrative Measures for Communication of Drug R&D and Technical Review (《藥物研發與技術審評溝通交流管理辦法》), which requires in principle an application prior to a BLA submission for therapeutic biological drug candidates. In June 2023, we received official response in writing from the CDE of the NMPA, confirming that (i) the Core Product’s Phase 3 pivotal trial was completed; (ii) primary endpoint of the trial demonstrate: (a) superiority efficacy over daily hGH in terms of 52-week AHV which is consistent with results from the global clinical trials; and (b) similar safety profile comparing to daily growth hormone products; and (iii) based on the data provided, the CDE of the NMPA agrees for us to proceed with our BLA filing of the Core Product for the treatment of PGHD. We made the BLA filing with the NMPA on January 18, 2024 for our Core Product for the treatment of PGHD, after which we submitted supplemental administrative materials per request from the CDE of the NMPA, and the BLA filing was subsequently accepted by the NMPA on March 7, 2024.

- ***TransCon CNP (navepegritide)*** is a disease-modifying therapy studied by us to treat children aged 2 to 10 years old with ACH in China, where there is currently no effective disease-modifying therapy approved. We in-licensed the TransCon CNP (navepegritide) from Ascendis Pharma in November 2018. Prior to our in-licensing, TransCon CNP (navepegritide) had been studied by Ascendis Pharma in 45 healthy adult male subjects in a Phase 1 global trial. TransCon CNP (navepegritide) is designed to optimize efficacy with a safe and convenient once-weekly dose, and is the first ACH therapy in clinical development in China to date, according to Frost & Sullivan.

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TransCon CNP (navepegritide) has completed the double-blind period of Phase 2 clinical trial in China for the treatment of ACH. We became the sole sponsor for the OLE period of this trial in January 2023 and the last patient last visit of the OLE period was completed in April 2024. In this Phase 2 trial, subjects received their assigned dose (or placebo) for 52 weeks, after which they will continue participation in the OLE period for approximately 52 weeks where all subjects will receive TransCon CNP (navepegritide). The primary analysis of double-blind period for our ongoing China Phase 2 trial was completed in November 2023. The topline results of the primary endpoint, AGV at 52 weeks, demonstrated a greater AGV of 5.939 cm/year for the cohort dosed at 100 µg/kg/week compared to 4.760 cm/year for placebo. The topline results also suggest that TransCon CNP (navepegritide) was generally well tolerated, without drug-related serious adverse events, and adverse events leading to discontinuation of the drug in the subjects. The topline results from China Phase 2 trial demonstrate consistency with the global Phase 2 trial in terms of primary endpoint and safety profile.

- ***Palopegteriparatide*** is a treatment studied by us to treat adults with HP. We in-licensed palopegteriparatide from Ascendis Pharma in November 2018. Prior to our in-licensing, palopegteriparatide had been studied by Ascendis Pharma in healthy adult volunteers in a Phase 1 trial. The current treatments for HP are inadequate due to their limited therapeutic benefits and the need for chronic administration of calcium in high doses and increased risks of associated complications. Palopegteriparatide is designed to restore physiologic levels and activity of PTH throughout 24 hours per day, thereby addressing full aspects of the disease, including normalizing serum and urinary calcium and serum phosphate levels.

We are studying palopegteriparatide in a Phase 3 pivotal trial in China, and have completed its double-blind period in January 2023. Subjects received palopegteriparatide or placebo in the double-blind period for 26 weeks, after which they will continue in the trial as part of a long-term OLE study of up to 156 weeks. The primary endpoint, defined as the proportion of subjects with albumin-adjusted serum calcium within the normal range, independence from calcitriol or alfacalcidol active vitamin D, and independence from therapeutic doses of calcium (i.e., taking calcium supplements ≤600 mg/day) at 26 weeks of treatment, and no increase in prescribed study drug within 4 weeks prior to Week 26 visit, was achieved by 77.6% (45 of 58) of palopegteriparatide-treated patients, compared to 0.0% (0 of 22) of patients in control group (p-value <0.0001). The topline data also suggest palopegteriparatide was generally well tolerated, without drug-related serious adverse events, and adverse events leading to discontinuation of the drug in the subjects. The topline data from China Phase 3 pivotal trial demonstrate consistency with the global Phase 3 pivotal trial, in terms of primary endpoint and safety profile.

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Transient conjugation technology. Our drug pipeline is developed based on transient conjugation technology (TransCon) that enables a prodrug, in which the parent drug is protected in an inactive form, to release unmodified parent drug in a predictable manner after distribution into the body and resume physiologic activity. The effectiveness and vast potential of this transient conjugation technology (TransCon) have been supported by the FDA and EMA approvals of lonapegsomatropin for PGHD – the first marketing approvals obtained by a drug generated from this technology.

R&D execution capabilities. Since our inception, our management and internal R&D teams have carried out extensive R&D activities. In carrying out clinical development operations, our R&D team reviewed all relevant clinical data generated from the global clinical trials of the three drug candidates conducted by our collaboration partner, Ascendis Pharma, and prepared for clinical trial initiations in China. Leveraging strong domain knowledge in the specific disease epidemiology, disease characteristics, local clinical practice as well as the current status of the market for the indications targeted by these drug candidates, our R&D team designed and implemented the study protocol for the clinical trials in China, and has substantially advanced the clinical development of our three drug candidates. See “– Our Drug Pipeline” and “– Research and Development” for more details.

Commercialization planning. In anticipation of the upcoming commercial launch of our drug candidates, we started building up a focused and specialized commercialization team with strong expertise in endocrinology. With respect to specific characteristic of each pipeline drug and their respective market conditions, we have designed tailor-made programs for commercialization, patient awareness, and market access. For lonapegsomatropin, we plan to deploy a pediatric endocrine medical representative team to cover public hospitals, establish collaborations with an extensive network of private clinics, and offer a comprehensive service program to cover majority of the potential markets for lonapegsomatropin. For TransCon CNP (navepegritide), the disease-modifying drug for ACH, we plan to leverage lonapegsomatropin team for commercial coverage, build up the awareness of ACH and establish TransCon CNP (navepegritide) as the standard of care for ACH, and participate in the negotiation of NRDL to maximize patient access. For palopegteriparatide, the PTH replacement therapy for HP, we plan to deploy a separate adult endocrinology medical representative team, establish HP treatment centers to cover broad geographic areas and a large patient pool via a “hub-and-spoke” model, engage in various activities to improve disease awareness, advance diagnosis and treatment for HP, and participate in the negotiation of NRDL to maximize patient access. Further, we have entered into a strategic collaboration agreement with Shanghai Pharmaceutical aiming to establish the necessary management framework in line with the GSP.

Commercial supply and local manufacturing capability. We plan to implement a three-step plan to source commercial supply for the commercialization of lonapegsomatropin as early as possible and address the vast domestic market potentials in China (including Hong Kong, Macau and Taiwan) effectively and secure sustainable drug supply for local patients. In the short term, we plan to first source the commercial drug supply from our collaboration partner, Ascendis Pharma. We have successfully reached a commercial supply agreement for the commercial supply of Core Product by Ascendis Pharma in October 2023. In the medium term, we will collaborate with WuXi Biologics to manufacture lonapegsomatropin for commercial supply in China (including Hong Kong, Macau and Taiwan). In the long term, we plan to establish our in-house manufacturing capabilities.

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CMC R&D and Local BLA for local manufacturing. According to the Exclusive License Agreement, we have the contractual right to obtain full knowledge of the Core Product drug substance manufacturing technology knowhow from Ascendis Pharma. As a step towards local manufacturing of our Core Product, in July 2023, we entered into a bilateral Technology Transfer Master Plan of the Core Product with Ascendis Pharma, which has marked the commencement of the technology transfer (“Technology Transfer”) with respect to the manufacturing of the Core Product from Ascendis Pharma to us and sets forth the obligations of both parties under the Exclusive License Agreements with respect to the Technology Transfer. After completion of the Technology Transfer, we will have the full knowledge of the Core Product drug substance manufacturing technology knowhow to independently collaborate with WuXi Biologics or any other chosen CDMO in China. Further, in December 2023, we entered into a bilateral collaboration agreement with WuXi Biologics, pursuant to which WuXi Biologics will serve as the local CDMO of the Technology Transfer to conduct the process development and validation achieving the localization of the manufacturing technology (together with the Technology Transfer, the “Technology Transfer and Localization”). Completion of the Technology Transfer and Localization, which is expected to be in 2026, will confer to us the technical capabilities to manufacture the Core Product drug substance in collaboration with WuXi Biologics. We are also developing the DCD technology in the form of prefilled syringe as a drug delivery system for the Core Product drug substance. Once this development is finished, WuXi Biologics will have the capability to produce the Core Product. The commercialization of the Core Product produced by WuXi Biologics will start once we obtain the approval of Local BLA, which is expected to occur in 2028. See “– Research and Development – CMC Development Programs” for more details. We expect to procure the Core Product from Ascendis Pharma for the commercial supply until 2028 following our anticipated commercialization in 2025.

License agreements. Pursuant to the terms of each Exclusive License Agreement we entered into with Ascendis Pharma, we were granted an exclusive license to develop, manufacture and commercialize the applicable drug candidates in endocrinology in China (including Hong Kong, Macau and Taiwan). Under the Exclusive License Agreements, we are not obligated to make cash payments, in the name of initial upfront payment, royalty payment or milestone payment associated with development milestones. In addition, during the term of the Exclusive License Agreements, we are entitled to a first right of negotiation to obtain rights to develop and commercialize endocrine drugs in China (including Hong Kong, Macau and Taiwan) developed by Ascendis Pharma based on the validated technology. See “– Collaborations” for more details.

Shareholder base. Our Founding Shareholders include Ascendis Pharma (through its subsidiaries), Vivo Capital and Sofinnova. Since our inception, we have raised approximately US\$40 million from our Founding Shareholders and an additional US\$150 million subsequently from a group of strategic and life sciences focused institutional investors who support our mission, including our Founding Shareholders, HongShan Growth, OrbiMed, Sherpa Healthcare Partners, Cormorant, HBM Healthcare Investments, Pivotal bioVenture Partners China, Logos Capital and CRF Investment.

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OUR STRENGTHS

We believe the following strengths have contributed to our success and differentiated us from our competitors.

Late-stage pipeline based on validated technology, fast approaching revenue generation with high degree of certainty

With a therapeutic pipeline built on validated technology and in late clinical development stages, we are fast approaching revenue generation with high degree of certainty.

Our drug pipeline is generated based on transient conjugation technology (TransCon). Transient conjugation molecules have three components: an existing parent drug, an inert carrier that protects it, and a linker that temporarily binds the two. When bound, the carrier inactivates and shields the parent drug from clearance. After distribution into the body, transient conjugation enables unmodified parent drug to be released in a predictable manner and maintain physiologic activity. Overall, transient conjugation technology (TransCon) is designed to combine known biology with the benefits of prodrug and sustained-release technologies to potentially optimize therapeutic effect, which could mean enhancing efficacy, improving tolerability and convenience, or reducing caregiver burden.

We believe other long-acting drug release technologies have limitations, which signifies the high entry barrier of this technical field. For example, permanent modification technologies, such as PEGylation and fusion protein, are often used to develop long-acting drugs, but exhibit risks of altering the potency of drugs and negatively impacting drug efficacy and safety. With respect to the application of long-acting technologies in hGH products, out of the nearly 20 global LAGH drug candidates that were once in the clinical-stage, or even approved, most did not reach commercial stage primarily due to clinical trial data issue, including high rate of lipoatrophy at injection site, unsatisfactory IGF-1 profile peak, duration and presumed unfavorable benefit risk profile ratio. While a few were able to reach commercial stage, they were subsequently removed from the market primarily due to factors such as market development strategies, cost considerations, competitive advantages and disadvantages of the product, and other relevant factors. Among all already commercialized LAGH drugs or clinical-stage LAGH drug candidates, very few have been able to demonstrate non-inferior or superior efficacy in active-controlled and parallel-group trial comparisons with daily hGH.

Leveraging our clinical development capabilities, all three of our pipeline drug candidates have either completed or are undergoing pivotal/clinical trials in China, and are fast approaching commercial launch stage.

- *Lonapegsomatropin*. We obtained IND approval from the NMPA in October 2019 to initiate the Phase 3 pivotal trial for our Core Product, lonapegsomatropin, in China for the treatment of PGHD. Shortly after IND approval, we completed the first site initiation in December 2019 in an efficient manner. We randomized the first patient in China in January 2020 and completed patient enrollment for this trial in March 2021 according to our initial targeted timeline without any early termination or

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suspension of our clinical trials despite the disruption of COVID-19 pandemic and clinical site lock-down. In this trial on human subjects, we assessed the efficacy, popPK profile, safety and tolerability of this drug candidate and enrolled 154 and treated 153* treatment-naïve, pre-pubertal children with GHD across multiple centers in China. Each participant received either once-weekly lonapegsomatropin or once-daily hGH for 52 weeks. We completed this trial in April 2022. According to our published results, lonapegsomatropin was shown to be non-inferior and, additionally, superior to the daily hGH on the primary endpoint of AHV at 52 weeks; it was well tolerated and demonstrated comparable safety as compared to daily hGH, consistent with the global data reported in the global trial of this drug candidate. On March 7, 2024, the BLA filing of our Core Product for the treatment of PGHD was accepted by the NMPA.

- *TransCon CNP (navepegritide)*. TransCon CNP (navepegritide) has completed the double-blind period of Phase 2 clinical trial in China for the treatment of ACH. We became the sole sponsor for the OLE period of this trial in January 2023 and the last patient last visit of the OLE period was completed in April 2024. The primary analysis of double-blind period for our ongoing China Phase 2 trial was completed in November 2023. The topline results of the primary endpoint, AGV at 52 weeks, demonstrated a greater AGV of 5.939 cm/year for the cohort dosed at 100 µg/kg/week compared to 4.760 cm/year for placebo. The topline results also suggest that TransCon CNP (navepegritide) was generally well tolerated, without drug-related serious adverse events, and adverse events leading to discontinuation of the drug in the subjects. The topline results from China Phase 2 trial demonstrate consistency with the global Phase 2 trial in terms of primary endpoint and safety profile.
- *Palopegteriparatide*. We obtained IND approval from the NMPA in May 2021 to initiate the Phase 3 pivotal trial for palopegteriparatide in China for the treatment of adult HP. This trial is designed to assess the efficacy, safety and tolerability of palopegteriparatide in 76 adults with HP, across multiple centers in China. Each participant will receive palopegteriparatide or placebo for 26 weeks, after which they will continue participation in the trial as part of a long-term OLE study of up to 156 weeks where all participants will receive palopegteriparatide, with the dose adjusted to their individual needs. We screened the first patient in November 2021 and completed patient enrollment in June 2022. In January 2023, we completed the double-blind period of this trial. The primary endpoint was achieved by 77.6% (45 of 58) of palopegteriparatide-treated patients, compared to 0.0% (0 of 22) for patients in control group (p-value < 0.0001). The topline data also suggest palopegteriparatide was generally well tolerated. The topline data from China Phase 3 pivotal trial demonstrate consistency with the global Phase 3 pivotal trial, in terms of primary endpoint and safety profile. The expected NDA filing to the NMPA is planned for the first half of 2025.

* One child dropped out prior to receiving treatment due to reasons unrelated to the clinical trial.

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We have started preparation work for commercialization capabilities of our Core Product, lonapegsomatropin, backed by patient support and market access. We expect NDA approvals for our two key drug candidates, palopegteriparatide and TransCon CNP (navepegritide), to follow in the coming years, by when all of our pipeline candidates will reach commercialization stage. See “– Our Strategies” and “– Commercialization Plan, Patient Support and Market Access” for more details.

Lonapegsomatropin as the long-acting hGH replacement therapy for PGHD in China, the largest and fast-growing hGH market in the world

Lonapegsomatropin, our Core Product, is a once-weekly growth hormone replacement therapy for PGHD that received marketing approvals from the FDA and the EMA, and the only LAGH with superior efficacy and comparable safety in comparison to daily hGH – the current treatment for PGHD. We in-licensed lonapegsomatropin from Ascendis Pharma in November 2018. Prior to our in-licensing, lonapegsomatropin had been studied by Ascendis Pharma in over 300 children with GHD across three Phase 3 programs.

PGHD is a medical condition of noticeable short height in children due to insufficient growth hormone. The current treatment for PGHD is daily subcutaneous injections of hGH. Daily therapy with hGH has been shown to increase growth and improve metabolic function in children. However, the burden of daily administration often resulted in poor patient compliance, as supported by a 2021 study. According to Frost & Sullivan, up to 82% of the patients missed at least one daily dose per week. Poor compliance could potentially lead to suboptimal treatment outcomes. In a separate study of 110 children, two out of three patients missed more than one injection per week on average, and suboptimal growth outcomes were observed in patients who missed over one dose per week compared to patients missed no more than one dose on average.

The hGH market in China grew rapidly from RMB4.0 billion in 2018 to RMB11.6 billion in 2023, at a CAGR of 23.9%. hGH therapy can be applied to treat PGHD and other short statures. The prevalence of PGHD in China was 3.4 million in 2023, while the prevalence of short statures under the age of 18 was 8.1 million in the same year. From 2018 to 2023, the hGH market in China achieved a higher CAGR than the hGH market in the United States, according to Frost & Sullivan. China accounted for the largest share of the global hGH market in 2023, surpassing the United States and representing 34% of the global market. The hGH market in China is expected to reach RMB28.6 billion in 2030. Due to the burden of daily hGH injections and its associated poor treatment compliance and suboptimal treatment outcomes, this market is undergoing a paradigm shift from daily hGH treatment to LAGH treatment, with the market share of LAGH projected to be 73.8% of the whole hGH market in China in 2030, compared to an estimated market share of 25.0% in 2023, according to Frost & Sullivan. In addition to drug innovations, favorable government initiatives are expected to further drive the growth of hGH market in China. “Healthy China Action (2019-2030)” (《健康中國行動(2019-2030年)》) issued by National Health Commission in September 2019, for example, announced a national goal to reduce the stunting rate of children under the age of five from 8.1% in 2013 to below 7% by 2022 and below 5% by 2030.

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Lonapegsomatropin is a drug candidate in China indicated for PGHD. Leveraging transient conjugation technology (TransCon), lonapegsomatropin is designed to enable a weekly dosing scheme and the release of unmodified hGH *in vivo* which is identical in the molecular composition to the endogenous growth hormone secreted by pituitary gland and preserves its original mode of action. Due to these unique features, lonapegsomatropin overcomes the drawbacks of daily hGH treatments, particularly the daily administration requirement and the associated poor compliance and suboptimal treatment outcomes. It also demonstrates potential advantages over modified LAGHs, some of which have shown severe injection site reactions or even lipoatrophy due to high dose and long exposure of active molecule at the injection site, according to Frost & Sullivan.

The published results of the completed Phase 3 pivotal trial in China consistently supported lonapegsomatropin’s superior growth profile and comparable safety profile in comparison to daily hGH. In this trial, lonapegsomatropin was associated with an AHV of 10.66 cm/year compared to 9.75 cm/year for daily hGH at 52 weeks, with a p-value of 0.0010, making it the first weekly LAGH with data that demonstrated superior efficacy compared to a daily somatotropin and the only LAGH achieved such superiority in a pivotal trial to date. Height SDS at 52 weeks increased over baseline by 1.01 for lonapegsomatropin and by 0.83 for daily hGH, with a p-value of 0.0015, and statistical significance of change in height SDS from baseline (Δ height SDS) was demonstrated in the lonapegsomatropin group from and including 13 weeks onwards.

A convenient auto-injector was introduced to the global clinical development of lonapegsomatropin for PGHD, which could further differentiate lonapegsomatropin from other hGH therapies. To facilitate ease of use, the auto-injector is designed to offer easy injection, hidden needle, small injection volume, and six-month room temperature storage. This auto-injector was included in the FDA and EMA approvals of lonapegsomatropin and is the first FDA-approved and the first EMA-approved auto-injector to deliver once-weekly growth hormone to pediatric patients, according to Frost & Sullivan.

See “– Our Strengths – Late-stage pipeline based on validated technology, fast approaching revenue generation with high degree of certainty” for more details regarding the clinical development of lonapegsomatropin in China.

TransCon CNP (navepegritide) as the disease-modifying therapy in China (including Hong Kong, Macau and Taiwan) for ACH

TransCon CNP (navepegritide) is a long-acting prodrug of CNP and disease-modifying therapy in development for ACH in children in China (including Hong Kong, Macau and Taiwan). We in-licensed the TransCon CNP (navepegritide) from Ascendis Pharma in November 2018. Prior to our in-licensing, TransCon CNP (navepegritide) had been studied by Ascendis Pharma in 45 healthy adult male subjects in a Phase 1 global trial.

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ACH is the most common form of dwarfism that results in severe skeletal complications and comorbidities. Patients often face multiple surgeries to alleviate the various complications associated with ACH. The prevalence of ACH in China was 51.2 thousand in 2023. Currently, there is no approved therapy available in China to treat the genetic basis of ACH, with medical and surgical interventions limited to addressing some of the symptoms, including spinal stenosis, hydrocephalus and obstructive sleep apnoea. To date, TransCon CNP (navepegritide) is the first ACH therapy in clinical development in China, designed to optimize efficacy with a safe and convenient once-weekly dose. It is able to provide effective shielding of CNP from neutral endopeptidase degradation in the subcutaneous tissue and the blood compartment, minimize binding of CNP to the NPR-C receptor to decrease clearance, reduce binding of CNP to the NPR-B receptor in the cardiovascular system to avoid hypotension, and release unmodified CNP, which is small enough in size to allow effective penetration into growth plates.

TransCon CNP (navepegritide) has completed the double-blind period of Phase 2 clinical trial in China for the treatment of ACH. We became the sole sponsor for the OLE period of this trial in January 2023 and the last patient last visit of the OLE period was completed in April 2024. The primary analysis of double-blind period for our ongoing China Phase 2 trial was completed in November 2023. The topline results of the primary endpoint, AGV at 52 weeks, demonstrated a greater AGV of 5.939 cm/year for the cohort dosed at 100 µg/kg/week compared to 4.760 cm/year for placebo. The topline results also suggest that TransCon CNP (navepegritide) was generally well tolerated, without drug-related serious adverse events, and adverse events leading to discontinuation of the drug in the subjects. The topline results from China Phase 2 trial demonstrate consistency with the global Phase 2 trial in terms of primary endpoint and safety profile.

See “– Our Strengths – Late-stage pipeline based on validated technology, fast approaching revenue generation with high degree of certainty” for more details regarding the clinical development of TransCon CNP (navepegritide) in China.

Palopegteriparatide as the PTH replacement therapy in China (including Hong Kong, Macau and Taiwan) addressing the underlying cause of HP

Palopegteriparatide is an investigational long-acting prodrug of PTH in development for the treatment of adult patients with HP. We in-licensed palopegteriparatide from Ascendis Pharma in November 2018. Prior to our in-licensing, palopegteriparatide had been studied by Ascendis Pharma in healthy adult volunteers in a Phase 1 trial.

HP is a syndrome of abnormal calcium and phosphorus metabolism caused by decreased secretion or defective function of PTH. The prevalence of HP in China was 410.1 thousand in 2023. The conventional therapy consisting of calcium in combination with active vitamin D and sometimes other supplements, while can increase serum calcium level, is hard to restore the serum calcium level to the normal range. Additionally, the use of very high doses of calcium and active vitamin D which is often required by conventional therapy, causes serum calcium fluctuation, high urine calcium and high serum phosphate, potentially putting HP

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patients at risk for many complications such as impaired renal function and extraskeletal calcifications. Some individuals remain symptomatic or fail to meet treatment goals even after conventional therapy, with some requiring multiple hospitalizations for hypocalcemia or HP complications. PTH therapy, as a feasible alternative to conventional therapy, has been shown to maintain normocalcemia without the need (or with reduced need) for concurrent treatment with the therapeutic dosage of calcium and active vitamin D analogs. However, the only currently available PTH therapy (i) is unable to achieve the physiological level and activities of PTH due to its short half-life; and (ii) has not demonstrated the ability to reduce hypercalcemia (elevated serum calcium levels), hypocalcemia (low serum calcium) or hypercalciuria (elevated urinary calcium) relative to conventional therapy in treated patients.

Palopegteriparatide is designed as a once-daily PTH replacement therapy with a long half-life to address the fundamental cause of HP by restoring physiological and stable levels of PTH 24 hours throughout the day, thereby addressing all aspects of the disease including normalizing serum and urinary calcium and serum phosphate levels. By doing so, palopegteriparatide serves as a PTH replacement therapy and has the potential to address both the short-term symptoms and long-term complications of HP, including kidney stones, renal disease and brain calcification, and as a result, improve quality of life.

We are studying palopegteriparatide in a China Phase 3 pivotal trial, and have completed its double-blind period in January 2023. Based on the topline data from China Phase 3 pivotal trial, the primary endpoint, defined as the proportion of subjects with albumin-adjusted serum calcium within the normal range, independence from calcitriol or alfacalcidol active vitamin D, and independence from therapeutic doses of calcium (i.e., taking calcium supplements ≤ 600 mg/day) at 26 weeks of treatment, and no increase in prescribed study drug within 4 weeks prior to Week 26 visit, was achieved by 77.6% (45 of 58) of palopegteriparatide-treated patients, compared to 0.0% (0 of 22) of patients in control group (p-value < 0.0001). The topline data also suggest palopegteriparatide was generally well tolerated, without drug-related serious adverse events and adverse events leading to discontinuation of the drug in the subjects. The topline data from China Phase 3 pivotal trial demonstrate consistency with the global Phase 3 pivotal trial, in terms of primary endpoint and safety profile.

See “– Our Strengths – Late-stage pipeline based on validated technology, fast approaching revenue generation with high degree of certainty” for more details regarding the clinical development of palopegteriparatide in China.

Strong clinical and regulatory capabilities with proved track-records in developing our drug candidate pipeline products

We leverage our understanding of the regulatory landscape in China to expedite the approval and commercial launch of each of our drug candidates. With insights and expertise in the endocrinology field, we are able to navigate the development, regulatory and commercialization landscape in China and seek opportunities to quickly bring our drug candidates to patients while maximizing the full value of each of our drug candidates.

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Operationally, our R&D team manages all of the key aspects of our trials, including clinical trial design, implementation, the collection and analysis of trial data, and regulatory submission and communications. Our R&D team is composed of departments of clinical development, regulatory affairs, medical affairs and CMC, and is headed by Dr. WANG Yan, Mr. David YU, Mr. GU Qing and Dr. ZHU Jing, respectively. See “– Research and Development – R&D Team and Capabilities” for more details. As of the Latest Practicable Date, the Company’s R&D team consisted of 36 full-time employees, with approximately 41% holding a Ph.D. or an M.D. degree. We expect to grow our R&D team as we continue our development activities. Almost all of our R&D team members have in-depth industry knowledge and clinical development experience in multinational companies. Our R&D team has an average of over 14 years of experience in the clinical development of drugs and/or endocrine therapies and some of them have extensive expertise in endocrinology and related areas and worked on the clinical development of other endocrine drugs. Our R&D capabilities are also supported by a scientific advisory board comprising three reputable KOLs in endocrinology and pediatrics, a steering committee for our Phase 3 pivotal trial in PGHD in China, comprising KOLs, overseas clinical professional experts and biostatisticians, as well as a data monitoring committee for the Phase 2 clinical trial of TransCon CNP (navepegritide) in children with ACH in China, comprising experienced KOLs and members from reputable medical institutions around the world.

To date, our team has demonstrated a strong ability to optimize study design and development strategy in China, which has enabled us to advance our drug candidates directly into pivotal studies in China utilizing validated endpoints, such as popPK. We carry out clinical execution in an efficient manner. With respect to the clinical development of lonapegsomatropin for PGHD in China, we obtained IND approval 11 months after in-licensing of this drug candidate, and dosed our first patient within three months after IND approval. We also have completed full patient enrollment according to our initial targeted timeline without any early termination or suspension of our clinical trials despite the disruption of the COVID-19 pandemic and the investigational site lockdown.

As one of the pioneering biopharmaceutical companies in China focusing on endocrinology, we proactively seek opportunities to get involved in the development of the Chinese healthcare ecosystem, including the scientific communication of disease awareness and diagnosis, HCP education and drug regulation. We supported the founding of Achondroplasia Advisory Board under the governance of the Advisory Board of CHARD in June 2019 and subsequently entered a five-year strategic cooperation with CHARD, on a national patient registry and diagnosis consensus of ACH in China. We also initiated the PaTHway R study in collaboration with Peking University Health Science Center in January 2022, which is the first registry study for HP patients in China and one of the largest epidemiological surveys for this disease worldwide. We plan to continue to proactively get involved in driving drug policies and treatment guidelines for endocrine drugs.

BUSINESS

World-class management team with deep commercialization expertise and strong support from Shareholders and investors

Our management team consists of experienced industry leaders who have deep knowledge of the clinical development, commercialization and regulatory landscape in China (including Hong Kong, Macau and Taiwan). We recognize that our ability to secure the best assets and efficiently execute the clinical development of drug candidates in China (including Hong Kong, Macau and Taiwan) requires a trusted team with an established track record, and we have consistently focused on identifying and cultivating top-tier talent. Our management team has capabilities spanning drug development, manufacturing, commercialization and business development, as well as experience from multinational corporations and working on drugs targeting endocrine indications, with an average of 17 years of experience in the industry. Our management team is led by:

- Mr. LU An-Bang, our Chief Executive Officer and Executive Director, is responsible for the overall development strategy and business direction of our Group. Mr. Lu has over 31 years of experience in global biopharmaceutical development with a proven track record of commercialization and operational success in China. Prior to joining us, Mr. Lu served as the general manager, president and the head of greater China at Takeda Pharmaceutical Company Limited, a global biopharmaceutical company, from 2010 to 2017. During Mr. Lu’s tenure, Mr. Lu oversaw Takeda’s critical growth and Takeda has achieved over ten times increase in sales revenue in China. Prior to Takeda, Mr. Lu served as the general manager at Servier (Tianjin), responsible for the overall development of Mainland China business.
- Dr. CHEN Jun, Ph.D., our Chief Commercial Officer, is responsible for the overall management of the drug commercialization of our Group. Dr. Chen has over 25 years of global pharmaceutical industry experience in China and the United States. Dr. Chen served as vice president of the diabetes portfolio business unit at Eli Lilly China from July 2018 to March 2021. From May 2016 to July 2018, he was vice president of the diabetes business group in China (including Hong Kong, Macau and Taiwan) at Medtronic China. Dr. Chen served various management roles at Novo Nordisk USA and China from January 2002 to April 2016, where he most recently served as vice president of marketing at Novo Nordisk China. He was an associate at McKinsey & Company from 2000 to 2002. Prior to that, Dr. Chen was a pharmaceutical scientist at Merck & Co. and its affiliate company Merial Ltd. from 1997 to 2000. Over his tenure, Dr. Chen commercialized multiple blockbuster endocrinology products and managed a large commercial organization with more than 1,000 staff.

Our management team also includes other senior members who oversee functions including clinical science, regulatory affairs, commercialization, clinical operations, quality assurance, biostatistics, CMC, and project management, with extensive expertise in their respective areas.

BUSINESS

We are supported by a network of Shareholders and investors who share our values and missions, including our Founding Shareholders, namely, Ascendis Pharma, Vivo Capital and Sofinnova, as well as a group of strategic and life sciences focused institutional investors, namely, HongShan Growth, OrbiMed, Sherpa Healthcare Partners, Cormorant, HBM Healthcare Investments, Pivotal bioVenture Partners China, Logos Capital and CRF Investment. We believe our relationships with these investors will further drive our success in developing value-creating partnerships.

OUR STRATEGIES

Rapidly advance the regulatory approval of our Core Product and the clinical development and regulatory approval of other pipeline candidates

Having completed the Phase 3 pivotal trial of our Core Product, lonapegsomatropin, for the treatment of PGHD in China, we are focusing on rapidly advancing the regulatory approval of this drug candidate. On March 7, 2024, the BLA filing of our Core Product for the treatment of PGHD was accepted by the NMPA.

We also intend to leverage our own clinical development capabilities and joint global studies with Ascendis Pharma to rapidly advance the clinical development and regulatory approval of our key drug candidates, TransCon CNP (navepegritide) and palopegteriparatide. Specifically, TransCon CNP (navepegritide) has completed the double-blind period of Phase 2 clinical trial in China for the treatment of ACH. We became the sole sponsor for the OLE period of this trial in January 2023 and the last patient last visit of the OLE period was completed in April 2024.

We are developing palopegteriparatide in an ongoing Phase 3 pivotal trial, and completed its double-blind period in January 2023. We expect to align the timing for NDA filing for palopegteriparatide in China with the global regulatory status of this drug candidate, aiming to leverage the global data and regulatory status of palopegteriparatide to facilitate the review process by the NMPA. In terms of the global regulatory status of palopegteriparatide, Ascendis Pharma obtained EMA approval in November 2023 and FDA approval in August 2024. We expect to make the NDA filing to the NMPA in the first half of 2025.

Build commercialization capabilities backed by patient support and market access in anticipation of the commercial launch of our Core Product and lay the foundation for commercialization of future drug candidates

In anticipation of the upcoming commercial launch of our drug candidates, we have added Dr. CHEN Jun as Chief Commercial Officer and started building up a focused and specialized commercialization team with strong expertise in endocrinology. We expect to implement the following strategies for the commercialization of each drug candidate.

BUSINESS

Lonapegsomatropin

The commercial goal for lonapegsomatropin is two-fold: (i) to accelerate market transition from short-acting daily growth hormone to long-acting weekly growth hormone; and (ii) to establish lonapegsomatropin as the leading LAGH.

Lonapegsomatropin will be positioned to reflect its value propositions to patients. We plan to deploy a pediatric medical representative team covering majority of the market potential for lonapegsomatropin. We plan to build extensive collaborations with private hospitals/clinics where patients can have easy access for prescription refill and continued services. Additionally, we plan to offer multiple patient support programs including a comprehensive patient starter kit, assistance from a professional service team, as well as a digital patient service platform to provide added value to patients. By conveying the distinct product advantages and value propositions over other marketed growth hormone products, we expect to establish a leading market position in the large and fast-growing hGH market in China.

TransCon CNP (navepegritide)

Once TransCon CNP (navepegritide) is commercially available, our main commercial goals are to build up the awareness of ACH among key stakeholders, establish TransCon CNP (navepegritide) as the standard of care for ACH, and establish patient access. A successful execution of this commercial strategy will enable a rapid revenue uptake of TransCon CNP (navepegritide).

We have already initiated a number of activities to develop the ACH market, including supporting ApproaCH Registry Study which will generate China-specific ACH epidemiology data, supporting the development of the first ACH Expert Consensus in China on Diagnosis and Treatment, and facilitating the inclusion of ACH in China Rare Disease List. Upon product launch, we plan to participate in the negotiation of NRDL to maximize patient access. The synergy between lonapegsomatropin and TransCon CNP (navepegritide) allows us to share one medical representative team. We expect TransCon CNP (navepegritide) will achieve a rapid revenues uptake.

Palopegteriparatide

The commercial goal for palopegteriparatide includes market development, patient education, patient access, and establishing HP treatment centers.

We plan to engage in various activities to improve disease awareness and advance diagnosis and treatment, such as facilitating the update of HP diagnosis and treatment guideline, and initiating PaTHway R study – the first HP patient registry study in China. Additionally, we plan to initiate extensive patient education activities through patient advocacy and social media. Upon product launch, we plan to participate in the negotiation of NRDL to maximize patient access. We plan to deploy a separate adult endocrinology medical representative team and a “hub-and-spoke” model to cost effectively cover HP market potential.

BUSINESS

Establish localized manufacturing capabilities to secure the supply of our Core Product and future potential drug candidates in China (including Hong Kong, Macau and Taiwan)

We plan to establish localized manufacturing capabilities for lonapegsomatropin in China to address the vast domestic market potentials in China (including Hong Kong, Macau and Taiwan) effectively and secure sustainable drug supply for local patients. We plan to implement a three-step drug procurement and manufacturing plan to realize the commercialization of lonapegsomatropin as early as possible and address the vast domestic market potentials in China (including Hong Kong, Macau and Taiwan) effectively and secure sustainable drug supply for local patients. In the short term, we plan to first source the commercial drug supply from our collaboration partner, Ascendis Pharma. We have successfully reached a commercial supply agreement for the commercial supply of the Core Product by Ascendis Pharma in October 2023. Please refer to “Connected Transactions” for more details. In the medium term, we will collaborate with WuXi Biologics to manufacture lonapegsomatropin for commercial supply. As a step towards such goal, in July 2023, we entered into a Technology Transfer Master Plan of the Core Product with Ascendis Pharma, which has marked the commencement of the Technology Transfer with respect to the manufacturing of the Core Product from Ascendis Pharma to us and sets forth the obligations of both parties under the Exclusive License Agreement with respect to the Technology Transfer. After completion of the Technology Transfer, we will have the full knowledge of Core Product drug substance manufacturing technology knowhow to independently collaborate with WuXi Biologics or any other chosen CDMO in China. Further, in December 2023, we entered into a collaboration agreement with WuXi Biologics, pursuant to which WuXi Biologics will serve as the local CDMO of the Technology Transfer to conduct the process development and validation achieving the localization of the manufacturing technology. Completion of the Technology Transfer and Localization, which is expected to be in 2026, will confer to us the technical capabilities to manufacture the lonapegsomatropin drug substance in collaboration with WuXi Biologics. We are also developing the DCD technology in the form of prefilled syringe as a drug delivery system for the Core Product drug substance. Once this development is finished, WuXi Biologics will have the capability to produce the Core Product. For more information regarding the DCD, please refer to “– Research and Development – CMC Development Programs – Dual Chamber Device Technology Development.” The commercialization of the Core Product produced by WuXi Biologics will start once we obtain the approval of Local BLA, which is expected to occur in 2028. In the long term, we plan to establish our in-house manufacturing capabilities.

Expand the endocrine disease indications covered by our Core Product, two key drug candidates, and new potential drugs based on transient conjugation technology (TransCon)

In addition to rapidly advancing in clinical development of our three drug candidates, we will further develop our Core Product, lonapegsomatropin, to cover more indications that may be eligible for hGH treatment, including other pediatric pathological short stature diseases such as idiopathic short stature (“ISS”).

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In addition, under the Exclusive License Agreements with Ascendis Pharma, we hold a right of first negotiation on certain future Ascendis Pharma products within the endocrine disease area for China (including Hong Kong, Macau and Taiwan). This will enable us to source, develop and commercialize additional drug candidates that are based on the unique transient conjugation technology (TransCon) and have the potential to be highly differentiated endocrine therapies. We plan to collaborate with Ascendis Pharma to evaluate future potential drug candidates and exercise our right for those products which address unmet medical needs and possess strong commercial potential in China (including Hong Kong, Macau and Taiwan). See “– Collaborations – Exclusive License Agreements with Ascendis Pharma” for more details.

Further expand our pipeline portfolio through strategic in-licensing, collaborations and partnerships for endocrine therapies looking to enter China (including Hong Kong, Macau and Taiwan)

We will continue to select, develop, and market paradigm-shifting therapeutic drugs that have the potential to fulfill current unmet medical needs. We aim to bridge global innovation to bring endocrine therapies to achieve better treatment processes and outcomes for Chinese patients, and plan to become the partner of choice in endocrinology for China (including Hong Kong, Macau and Taiwan). We plan to fully exploit our extensive knowledge in endocrinology and our deep understanding of the medical need and technology, and through identifying and executing attractive licensing and collaboration opportunities or through mergers and acquisitions, we seek to pursue business development opportunities to further expand our portfolio with other potential biopharmaceutical partners with endocrine drugs, drug candidates or technologies that may be synergistic or complementary to our portfolio.

Our scaled operation and platform, integrated with a commercial team that targets the same group of doctors and call points in the endocrinology specialty, is highly synergistic with strong operating leverage to maximize the value of additional endocrine products looking to enter China (including Hong Kong, Macau and Taiwan):

- *Synergistic clinical stage products with potential.* We prioritize bringing in drugs or drug candidates based on their clinical profile, degree of novelty and validation, technology differentiation, the unmet medical needs of the target disease and respective commercial potential in China (including Hong Kong, Macau and Taiwan).
- *Marketed endocrine products with only light commercialization effort required and attractive cashflow or margin.* We are strategically seeking to in-license or acquire rights to drugs that are either already launched or in late-stage development in regulated markets such as the United States and the European Union that may be synergistic or complementary to our portfolio.

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As a complementary measure, we will opportunistically look to establish an internally developed pipeline of promising therapies, with local CDMO support or through mergers and acquisitions of research-driven biotech companies, when the products' target or MoA fit with our overall product offering suite and target large market opportunities.

Establish a recognized and leading franchise in endocrinology in China (including Hong Kong, Macau and Taiwan)

We focus on the market of China (including Hong Kong, Macau and Taiwan), where we see tremendous market potential, a large untapped patient population and unmet medical needs across a wide range of endocrine diseases. Furthermore, recent NMPA regulatory reforms are expected to continue to accelerate drug development and approval, particularly for drug candidates validated overseas, as well as driving growth and demand for new therapies in China. We believe these favorable drug policies and potential market opportunities will continue to drive innovation and market growth in China (including Hong Kong, Macau and Taiwan).

Since our inception we have established an in-house operational team with core functions spanning medical science, regulatory affairs, clinical operations, quality assurance, pharmacovigilance and data management, statistics and medical affairs, and rapidly advanced the clinical development of our pipeline drugs. And we will leverage our regulatory capabilities in China to expedite the approval and commercial launch of each of our drug candidates. As we transition into a commercial-ready company with drug candidates preparing for product launch, we are expanding our overall capabilities in drug registration, patient support, market access, and plan to build a strong commercial team comprising direct sales and distribution partners to maximize the value of our assets. In the long term, we plan to further strengthen our platform with supply-chain capabilities, including the establishment of our own GMP manufacturing facility for in-house commercial supply.

The hallmark of our portfolio strategy is to develop therapies from overseas, bridging innovations and their clinical development for Chinese patients, and we will continue to further expand our therapeutic offerings, as means to improve both clinical outcome and the standard of treatments accessible to patients suffering from endocrine diseases. By developing end-to-end capabilities integrating research and discovery, clinical development, commercialization, manufacturing and business development of endocrine therapies, we seek to become a recognized leader in China (including Hong Kong, Macau and Taiwan) and maximize our value as a dedicated franchise in endocrinology.

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OUR DRUG PIPELINE

Our drug pipeline currently consists of long-acting therapies targeting endocrine indications with the potential to address large markets in China. We focus on pediatric endocrine diseases and adult endocrine diseases, with each group having its unique characteristics. Children are not just small adults when it comes to endocrine disorders and treatment. As growing individuals, pediatric patients have special needs related to growth and development, and hence they often face a limited treatment window and an urgent need for timely treatment. Hormone problems affecting growth or development can have significant effects on a child’s lifelong physical and emotional well-being. In addition, treatment compliance for children often requires parent supervision and discomfort and pain in treatment may affect children’s compliance, calling for more convenient treatment options with simplified drug regimens and improved treatment experience. Adult endocrine disorders often require life-long treatment, creating significant needs for treatment options with reduced compliance burden and favorable long-term safety profile. Below is a pipeline diagram setting forth our drug candidates:

	Drug Candidate*	Indication	Clinical Development and Regulatory Status					Upcoming Milestones of Trials Conducted by VISEN
			IND	Phase 1	Phase 2	Phase 3	BLA / NDA	
Pediatric Endocrinology	★ Lonapegsomatropin	Pediatric Growth Hormone Deficiency	Completed China Phase 3 pivotal trial in April 2022 (BLA accepted by the NMPA in March 2024) ⁽¹⁾					Expected BLA approval date in mid 2025
	➡ TransCon CNP (navepegritide)	Achondroplasia	Ongoing China Phase 2 trial, double-blind period completed in November 2023 ⁽²⁾					Expected NDA submission to the NMPA
Adult Endocrinology	➡ Palopegteriparatide	Hypoparathyroidism	Ongoing China Phase 3 pivotal trial, double-blind period completed in January 2023 ⁽³⁾					Expected NDA submission to the NMPA in first half of 2025

★ Core Product ➡ Key drug candidates

* VISEN has gained exclusive licensed rights to develop, manufacture and commercialize all drug candidates in endocrinology in China (including Hong Kong, Macau and Taiwan).

Notes:

- (1) VISEN completed the Phase 3 pivotal trial of lonapegsomatropin in China for the treatment of PGHD in April 2022 which met its primary endpoint according to the published results. We made the BLA filing with the NMPA on January 18, 2024 for our Core Product for the treatment of PGHD, which was subsequently accepted by the NMPA on March 7, 2024.
- (2) The primary analysis of the double-blind period of the Phase 2 clinical trials of TransCon CNP (navepegritide) in China for the treatment of ACH was completed in November 2023, with primary endpoint met according to the topline data. We became the sole sponsor for the OLE period of this trial in January 2023 and the last patient last visit of the OLE period was completed in April 2024.
- (3) VISEN completed the primary analysis of the Phase 3 pivotal trial of palopegteriparatide in China for the treatment of adult HP in January 2023 which met its primary efficacy and key secondary endpoints according to its topline data.

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We acquired three drug candidates from Ascendis Pharma in November 2018 on a royalty-free basis and hold exclusive rights to develop, manufacture and commercialize all of our drug candidates in China (including Hong Kong, Macau and Taiwan). See “– Transient Conjugation Technology (TransCon)” for more details regarding the transient conjugation technology (TransCon) that our drug candidates are based on.

Lonapegsomatropin – A Long-Acting hGH Replacement Therapy for PGHD

Overview

Lonapegsomatropin, our Core Product, is a once-weekly LAGH replacement therapy approved in the United States and the European Union for PGHD. It is a new molecular entity and possesses a new composition of matter for which intellectual property rights have been granted in the United States, the European Union and China. In accordance with relevant procedures of World Health Organization, our Core Product was assigned to the recommended INN of “lonapegsomatropin.” This once-weekly treatment could reduce treatment burden and potentially replace the daily hGH therapies, which have been the prevalent treatment for over 30 years.

Building on the global clinical success of lonapegsomatropin and leveraging our independent R&D strength and regulatory capabilities, we are developing lonapegsomatropin for the treatment of PGHD in China, and have completed the Phase 3 pivotal trial in April 2022, according to the study protocol. The completed China Phase 3 pivotal trial continued to support lonapegsomatropin’s superior growth profile and comparable safety profile in comparison to daily hGH, where lonapegsomatropin was associated with an AHV of 10.66 cm/year at 52 weeks compared to 9.75 cm/year for daily hGH, with a p-value of 0.0010. These trials proved that weekly lonapegsomatropin is the first LAGH with data demonstrating superior efficacy compared to a daily somatotropin. In China, lonapegsomatropin is the only LAGH that releases unmodified hGH *in vivo*, which is identical in the molecular composition to the endogenous growth hormone secreted by pituitary gland and preserves its original mode of action, offering our Core Product the first-mover advantage in unmodified LAGH treatments.

In May 2023, we submitted a formal communication application package to the CDE of the NMPA, in accordance with the Administrative Measures for Communication of Drug R&D and Technical Review (《藥物研發與技術審評溝通交流管理辦法》), which requires in principle an application prior to a BLA submission for therapeutic biological drug candidates. In June 2023, we received official response in writing from the CDE of the NMPA, confirming that (i) the Core Product’s Phase 3 pivotal trial was completed; (ii) primary endpoint of the trial demonstrate: (a) superiority efficacy over daily hGH in terms of 52-week AHV which is consistent with results from the global clinical trials; and (b) similar safety profile comparing to daily growth hormone products; and (iii) based on the data provided, the CDE of the NMPA agrees for us to proceed with our BLA filing of the Core Product for the treatment of PGHD.

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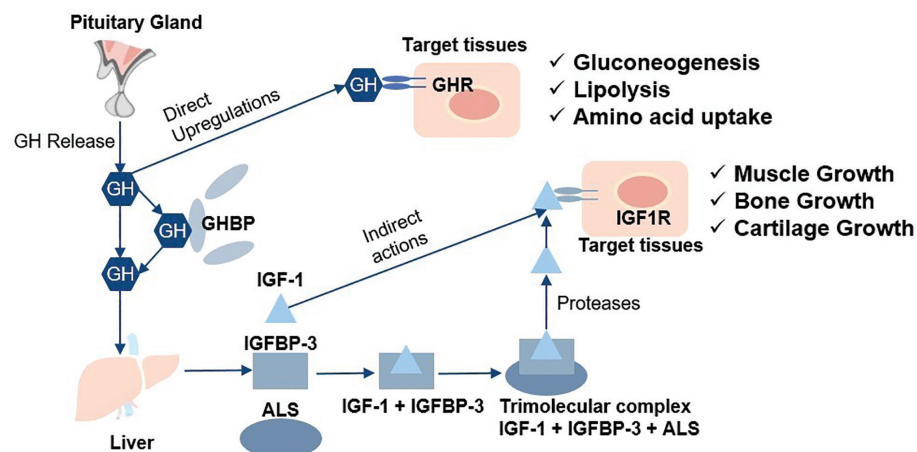
On March 7, 2024, the BLA filing of our Core Product for the treatment of PGHD was accepted by the NMPA and we expect to obtain the BLA approval in the mid of 2025. In Hong Kong, we have signed a regulatory affairs service agreement with an external service provider in August 2023, and expect to submit the BLA filing in 2025 and obtain the BLA approval by 2026.

Etiology of GHD and MoA of Lonapegsomatropin

PGHD is a medical condition of noticeable short height in children due to insufficient growth hormones. PGHD can be (i) congenital, resulting from genetic mutations or from structural defects in the brain; (ii) acquired later in life as a result of trauma, infection, radiation therapy, or tumor growth within the brain; or (iii) idiopathic with no known or diagnosable cause. The burden of PGHD is considerable and not limited to short stature. The severity of PGHD impact on children appears to be variable and individualized, but early identification and growth hormone treatment may lead to fewer long-term complications.

As depicted in the figure below, growth hormone produces its effects both directly in peripheral tissues, such as epiphyseal chondrocytes and adipocytes, and indirectly via stimulation of local and hepatic IGF-1 production. Growth hormone and IGF-1 work in concert, with IGF-1 augmenting the anabolic actions of growth hormone while opposing the hyperglycemic and lipolytic effects of growth hormone.

Function of Growth Hormone

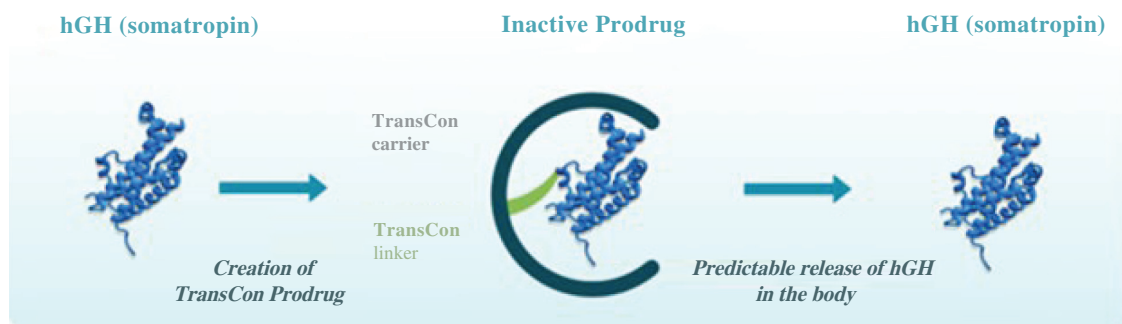


Source: Literature Review, Frost & Sullivan Analysis

Insufficient secretion of growth hormones in the human body will reduce these metabolic effects and limit the growth of muscles and bones. Due to its interaction with growth hormones, IGF-1 is a well-established PD surrogate endpoint of growth hormone activity and a primary biomarker of growth hormone efficacy. Lonapegsomatropin is designed as a LAGH therapy to preserve the MoA of daily hGH, including both direct effects on peripheral tissues and indirect effects on tissues via stimulation of IGF-1 production, and maintain characteristics of daily hGH, such as safety, efficacy and tolerability, including lack of immunogenicity.

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MoA of lonapegsomatropin



Source: Ascendis Pharma[©]

As depicted in the figure above, unmodified 22 kDa growth hormone – the active parent drug, is bound via a low molecular weight transient conjugation linker to an inert carrier molecule, methoxypolyethylene glycol (“mPEG”), to create the active product, lonapegsomatropin. The carrier shields growth hormone from receptor binding and renal excretion, thus extending its circulation time. With autohydrolysis of the transient conjugation linker, lonapegsomatropin gradually releases unmodified growth hormone over a one-week period, designed to maintain similar growth hormone exposure levels and volume of distribution to those obtained with daily hGH administration. As a result, lonapegsomatropin offers a convenient once-weekly dosing regimen and thereby significantly reducing the burden of drug administration. After being released, the unmodified growth hormone binds to a dimeric hGH receptor in the cell membrane of target cells resulting in intracellular signal transduction and a host of pharmacodynamic effects. The unmodified growth hormone has direct tissue and metabolic effects, and indirect effects mediated by IGF-1, including stimulation of chondrocyte differentiation and proliferation, stimulation of hepatic glucose output, protein synthesis and lipolysis. It also stimulates skeletal growth in pediatric patients with GHD as a result of effects on the growth plates (epiphyses) of bones. See “– Transient Conjugation Technology (TransCon)” for more details regarding the transient conjugation technology (TransCon). In the global clinical trials conducted by Ascendis Pharma, lonapegsomatropin had consistently demonstrated IGF-1 levels that are comparable to daily hGH when administered at an equivalent dose.

Market Opportunity and Competitive Landscape

PGHD is a serious disease that affects children and is characterized by short stature, metabolic abnormalities and poor quality of life. PGHD can be congenital, acquired, or idiopathic.

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The prevalence of PGHD in China was 3.4 million in 2023 representing a large market, especially due to the lack of convenient and effective hGH therapies. The currently available treatments for PGHD are either daily hGH or LAGH, with the estimated average annual treatment cost of the currently available LAGH in China being RMB121,333. According to Frost & Sullivan, the hGH market in China almost tripled from 2018 to 2023 and is estimated to continue to grow to RMB28.6 billion by 2030, at a CAGR of 13.7% from 2023. From 2018 to 2023, the hGH market in China achieved a higher CAGR than the hGH market in the United States, according to Frost & Sullivan. China accounted for the largest share of the global hGH market in 2023, surpassing the United States and representing 34% of the global market.

The increasing market acceptance of premium-valued LAGH will drive a treatment paradigm shift towards LAGH and the organic growth of the hGH drug market in China. In addition, as the average duration of treatment and the patient penetration increase, the hGH market in China is well-positioned to enjoy a strong potential for growth. Favorable government initiatives are also expected to further drive the growth of the hGH market in China. “Healthy China Action (2019-2030)” issued by the National Health Commission in September 2019, for example, announces a national goal to reduce the rate of stunting in children under the age of five from 8.1% in 2013 to below 7% by 2022 and below 5% by 2030.

Most marketed hGH therapies for PGHD in China are daily hGH treatments, with daily subcutaneous injections of hGH being the current treatment. However, due to the treatment burden of daily hGH and associated poor treatment compliance and suboptimal treatment outcomes, the market has increasingly accepted the paradigm shift from daily hGH treatment to the LAGH treatment. According to Frost & Sullivan, the LAGH market is projected to continue to grow significantly and will overtake the daily hGH market.

Currently in China, only one LAGH therapy has received marketing approval and several are currently under clinical development, as outlined in the tables below. Among the only marketed LAGH and all LAGH candidates in clinical development in China, lonapegsomatropin is the only LAGH that has demonstrated superior efficacy and comparable safety in active-controlled and parallel-group trial comparisons with daily hGH. In addition, lonapegsomatropin is the only LAGH that releases unmodified hGH *in vivo*, which is identical in the molecular form to the endogenous growth hormone secreted by pituitary gland and preserves its original mode of action. This is in distinction to other LAGH therapies under development and/or in commercial use in China, where the active components are modified proteins or peptides that may potentially alter the potency of hGH, its PK or PD profiles, tissue penetration and receptor binding, and potentially negatively impact drug efficacy and safety.

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Marketed LAGH Therapies in China, as of the Latest Practicable Date*

Brand Name	Company	Formulation	Development Approach	NMPA Approval Time	Indication(s)
Jintrolong ⁽¹⁾	GeneScience Pharmaceuticals	PEGylated hGH	Modified hGH	2014	PGHD

Clinical Stage Pipeline LAGH Therapies in China, as of the Latest Practicable Date*

Investigational Drug	Drug Form	Development Approach	Company	Global Status	China Status	Date**	Indication(s)
Lonapegsomatropin	Transiently conjugated hGH	Unmodified hGH	VISEN ⁽²⁾	FDA & EMA approved ⁽³⁾	BLA	March 7, 2024	PGHD
Y-shaped pegylated somatropin	PEGylated hGH	Modified hGH	Xiamen Amoytop	Not yet initiated	BLA	January 11, 2024	PGHD
Somapacitan-beco	Mutated hGH attached to an albumin affinity tag	Modified hGH	Novo Nordisk	FDA & EMA approved	BLA	September 5, 2024	PGHD
PEG-recombinant hGH	PEGylated hGH	Modified hGH	Anhui Anke	Not yet initiated	Phase 3	November 23, 2017	PGHD
Eftansomatropin GX-H9/TJ101	Hy-Fc (Fc fusion protein)	Modified hGH	Genexine/I-Mab Biopharma	Phase 2 completed	Phase 3	December 8, 2020	PGHD
HSA-recombinant hGH	HSA/recombinant hGH	Modified hGH	Uniongen	Not yet initiated	Phase 3	May 22, 2024	PGHD
QHRD211/ZHB111	PEGylated hGH	Modified hGH	Qianhong Biopharma	Not yet initiated	Phase 2/3	August 13, 2024	PGHD
AK2017	Fc fusion protein	Modified hGH	Anhui Anke	Not yet initiated	Phase 2	December 27, 2023	PGHD
F-899 (Fc fusion protein)	Fc fusion protein	Modified hGH	Yifan	Not yet initiated	Phase 1	May 28, 2021	N/A
GB08	Fc fusion protein	Modified hGH	Kexing	Not yet initiated	Phase 1	June 7, 2024	PGHD

* All marketed and clinical-stage pipeline LAGH therapies were and/or are being studied in active-controlled and parallel-group trial comparisons with daily hGH. Pricing information for the marketed LAGH in China varies across different geographic areas and depends on body weight of the patients. Pricing information is not available for LAGH therapies in clinical development in China.

** Refers to date when the clinical trial information was first publicly posted.

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Notes:

- (1) In 2023, the median unit price of Jintrolong in China is RMB3,500/(1ml:54IU). As of the Latest Practicable Date, Jintrolong has not been included in the NRDL.
- (2) VISEN has gained exclusive licensed rights to develop, manufacture and commercialize in China (including Hong Kong, Macau and Taiwan); Ascendis Pharma has rights to develop, manufacture and commercialize outside of China (including Hong Kong, Macau and Taiwan).
- (3) Lonapegsomatropin is the first once-weekly LAGH approved by both the FDA and EMA for PGHD.

Source: CDE, Frost & Sullivan Analysis

See “Industry Overview – Human Growth Hormone – China hGH Market Landscape” for more details regarding the market of LAGH in China.

Limitations of Current Treatments and Potential Advantages of Lonapegsomatropin

The current treatment for PGHD is daily subcutaneous injections of hGH. Daily hGH therapies have been shown to increase growth and improve metabolic effects in children, including reducing adiposity and improving cardiovascular health. However, daily hGH requires patients, approximately 93% of which are children, to receive thousands of injections over the course of many years. The burden of daily administration often results in poor patient compliance, as supported by a 2021 study. According to Frost & Sullivan, up to 82% of the patients with PGHD missed at least one daily dose per week. Poor compliance could potentially lead to suboptimal treatment outcomes. In a separate study of 110 children, two out of three patients missed more than one injection per week on average, and suboptimal growth outcomes were observed in patients who missed over one dose per week compared to patients missed no more than one dose on average.

To overcome the limitations associated with the current treatment, LAGH has been introduced, aiming to reduce injection frequency and thereby improve compliance and treatment outcomes. Due to the potential significant advantages of LAGH over daily hGH in terms of increased acceptance, tolerability, and therapeutic flexibility to patients, LAGH is expected to gradually replace daily hGH as the standard treatment of care for PGHD. Despite the potential significant advantage, there are also significant technical entry barriers to developing LAGH. Out of the nearly 20 LAGHs that were once in the clinical-stage, or even approved, most did not reach commercial stage primarily due to clinical trial data issue, including high rate of lipoatrophy at injection site, unsatisfactory IGF-1 profile peak, duration and presumed unfavorable benefit risk profile ratio, such as PHA-794428 (developed by Pfizer) and NNC126-0083 (developed by Novo Nordisk) both utilizing PEGylated hGH formulation and TV-1106 utilizing growth hormone fusion protein (developed by Teva), some reached commercial stage but were subsequently removed from the market primarily due to factors including market development strategies, cost considerations and competitive advantages and disadvantages of the product, such as Nutropin Depot utilizing Depot formulation (developed by Genentech), and globally only few have demonstrated non-inferior or superior efficacy in active-controlled and parallel-group trial comparisons with daily hGH. Due to technological limitations, there remains needs for safe and effective LAGH therapies and long-acting technologies.

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Enabled by the flexible, versatile and reliable transient conjugation technology (TransCon), lonapegsomatropin is the first once-weekly LAGH replacement therapy for PGHD that received marketing approvals from the FDA and the EMA on August 25, 2021 and January 12, 2022, respectively. Lonapegsomatropin is designed based on the transient conjugation technology (TransCon), which enables extended half-life and therefore a weekly dosing scheme and the release of unmodified hGH in the bloodstream which is identical to the endogenous growth hormone. The only marketed LAGH and all LAGH candidates in clinical development in China, except for lonapegsomatropin, are developed using modified hGH. Due to its unique features, lonapegsomatropin retains the same mode of action and the same physiological volume of distribution as the endogenous growth hormone. Endogenous growth hormone has dual modes of action, with direct action by circulating growth hormone on target tissues and indirect action by locally produced IGF-1 in the liver (via GHR), while modified hGH often substantially alters its molecular size, which changes its receptor binding affinity and its ability to reach the target tissue, and ultimately impacts its efficacy. The active component of lonapegsomatropin is the released endogenous growth hormone, the safety profile of which has been clinically proven for almost four decades. In contrast, the modified LAGH is a new active drug molecule, with no prior clinical safety experience outside of its clinical trials. Before the endogenous growth hormone is released in the bloodstream, lonapegsomatropin exists as an inactive prodrug, it therefore presents no biological activities and is well tolerated at the injection site – subcutaneous tissue. In contrast, some modified LAGH has shown severe injection site reactions or even lipoatrophy due to high dose and long exposure of active molecule at the injection site. Due to the design advantages of lonapegsomatropin, it has proven, in the global and China Phase 3 active-controlled and parallel-group trial comparisons, superior efficacy to daily hGH, and it has also demonstrated similar safety to daily hGH. In addition, lonapegsomatropin is coupled with an auto-injector device that offers easy injection, hidden needle, small injection volume, and six-month room temperature storage features, all of which can dramatically improve patient injection experience and compliance, allowing us to develop competitive advantages. The differentiating design features of lonapegsomatropin can work together to enable a long-acting and once-weekly hGH replacement therapy in China, that addresses medical needs in growth hormone therapy by reducing the number of injections patients require, while leveraging the safety and efficacy database that has been established with unmodified daily hGH products. See “Industry Overview – Human Growth Hormone – The hGH Market in China” and “Industry Overview – Human Growth Hormone – China hGH Market Landscape” for more details regarding the development of hGH.

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Summary of Clinical Results

The following table sets forth an overview of the key clinical studies of the Core Product:

Trial	Sponsor/Subject/ Trial Status	Primary Endpoint	Secondary Endpoints	Trial Key Summary
Phase 3 China Pivotal Trial* (January 2020 – April 2022) (NCT04326374) (52 weeks of treatment period)	<ul style="list-style-type: none"> The Company Children with GHD Completed 	AHV at 52 weeks, with a non-inferiority analysis comparing the difference between the two treatment groups, followed by a test of superiority if non-inferiority was established	<p>AHV over 52 weeks, height SDS and change from baseline over 52 weeks, IGF-1/IGF-1 SDS and change from baseline, and normalization of IGF-1 SDS</p> <p>Safety endpoints: AEs, local tolerability, parameters of glucose metabolism and lipid parameters, hormone levels, other hematology and biochemistry blood parameters, Electrocardiograms (ECGs), vital sign, Bone age (BA) Pop PK/PD</p>	154 treatment-naïve, pre-pubertal children with GHD were enrolled. Results from the completed Phase 3 pivotal trial supported that once-weekly lonapegsomatropin was non-inferior and, additionally, superior to once-daily IGH on the primary endpoint of AHV at 52 weeks. ANCOVA-adjusted least squares mean AHV at 52 weeks was 10.66 cm/year for lonapegsomatropin, compared to 9.75 cm/year for daily IGH, with a p-value of 0.0010. The estimated treatment difference was 0.91 cm/year with a 95% confidence interval of 0.37 to 1.45 cm/year.
Phase 3 heiGHT Trial (pivotal trial) (December 2016 – January 2019) (NCT02781727) (52 weeks of treatment period)	<ul style="list-style-type: none"> Ascendis Pharma Children with GHD Completed 	AHV at 52 weeks, with a non-inferiority analysis comparing the difference between the two treatment groups, followed by a test of superiority if the non-inferiority was established	<p>AHV at further visits, change in height SDS, serum IGF-1 and IGFBP-3, IGF-1 SDS and normalization of IGF-1 SDS, IGFBP-3 SDS</p> <p>Safety endpoints: AEs, Clinical laboratory investigations, vital sign, electrocardiograms (ECGs), Bone age (BA) PK/PD endpoints</p>	161 treatment-naïve pediatric subjects with GHD were enrolled from 73 sites across 15 countries. Trial met its primary objective of noninferiority in AHV and further showed superiority of lonapegsomatropin compared to daily somatropin, with similar safety, in treatment-naïve children with GHD. (Paul S. Thornton, et al. <i>J Clin Endocrinol Metab.</i> 2021;106(11): 3184–3195)
Phase 3 flIGHt Trial (switch trial) (November 2017 – March 2019) (NCT03305016) (26 weeks of treatment period)	<ul style="list-style-type: none"> Ascendis Pharma Children with GHD Completed 	Safety endpoints: AEs, local tolerability, antibodies, IGF-1 SDS >2.0, >3.0 with confirmation, HbA1c and lipid, hormone levels, other hematology and chemistry parameters, vital sign	<p>Efficacy endpoints as measured at 26 weeks of weekly lonapegsomatropin treatment included the following: AHV, ΔHSDS, IGF-1 SDS, IGFBP-3 SDS</p> <p>PK/PD endpoints</p> <p>Others</p>	146 children with GHD (143 of which were treatment-experienced with daily somatropin) were enrolled from 28 sites across 4 countries. Lonapegsomatropin treatment outcomes were as expected across a range of ages and treatment experiences. Switching to lonapegsomatropin resulted in a similar AE profile to daily somatropin therapy. (Aristides K Maniatis, et al. <i>Horm Res Paediatr</i> 2022;95:233-243)
Phase 3 eniGHten Trial (long-term extension trial) (December 2017 – February 2023) (NCT03344458) (Up to 4 years of treatment period)	<ul style="list-style-type: none"> Ascendis Pharma Children with GHD Completed 	long-term safety: AEs, antibodies, IGF-1 SDS >2.0, >3.0 with confirmation, HbA1c and lipids, hormone levels, other hematology and chemistry parameters, Vital sign	<p>Long-term efficacy endpoints:</p> <ul style="list-style-type: none"> AHV ΔHSDS Proportion of subjects with IGF-1 SDS of 0 to +2.0 IGF-1 SDS IGFBP-3 SDS <p>Patient-Reported Outcomes</p> <p>PD endpoints</p>	Nearly all subjects who completed the heiGHT Trial or the flIGHt Trial had rolled over to the eniGHten Trial for long-term extension studies. Subjects in the US switched to the lonapegsomatropin Auto-Injector when available. Long-term data showed that lonapegsomatropin continued to be safe and well-tolerated, and continued improvement of height SDS through the second year of therapy without excess advancement of bone age. (Aristides K Maniatis, et al. <i>J Clin Endocrinol Metab.</i> 2022;107(7): e2680-e2689)

Note: * We in-licensed lonapegsomatropin from Ascendis Pharma in November 2018. Prior to our in-licensing, lonapegsomatropin had been studied by Ascendis Pharma in over 300 children with GHD across three Phase 3 programs. Phase 1 trial of performing initial safety or tolerability evaluation in healthy adults and Phase 2 trial of proof-of-concept studies in China have been waived by the NMPA.

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VISEN Pharmaceuticals’ Completed Phase 3 Pivotal Trial in Children (Aged 3-17 Years Old) with GHD, January 2020 - April 2022

We studied lonapegsomatropin in China for PGHD in a Phase 3 pivotal trial. The aim of this trial is to assess the efficacy, popPK profile, safety and tolerability of lonapegsomatropin in treatment-naïve, pre-pubertal pediatric subjects with GHD compared to daily hGH as current treatment in order to support a BLA filing to the NMPA for lonapegsomatropin for PGHD. We randomized the first patient in China in January 2020, completed target patient enrollment in March 2021, and completed this trial in April 2022.

Study Design. The Phase 3 pivotal trial was a multi-center, randomized, open-label, active-controlled trial that enrolled 154 and treated 153* treatment-naïve, pre-pubertal children with GHD. The main inclusion criteria included (i) pre-pubertal children with GHD (either isolated or as part of a multiple pituitary hormone deficiency) in Tanner stage 1, aged three to 17 years old; (ii) impaired height defined as at least 2.0 standard deviation below the mean height for chronological age and sex according to the Chinese 2005 standard, (iii) body mass index within ± 2.0 standard deviation of the mean body mass index for bone age and sex; (iv) bone age at least six months less than the chronological age; and (v) baseline IGF-1 level of at least 1.0 standard deviation below the mean IGF-1 level standardized for age and sex according to the central laboratory reference values. The main exclusion criteria included (i) children with a body weight below 12 kg; (ii) prior exposure to recombinant hGH or IGF-1 therapy; and (iii) children with past or present intracranial tumor growth as confirmed by a sella magnetic resonance imaging scan at screening. Out of these 153 randomized and dosed subjects, one withdrew from the study due to an AE which was not related to lonapegsomatropin according to the investigator, and one withdrew voluntarily, resulting in a total of 151 subjects completed the trial.

Summary of Study Disposition

	Lonapegsomatropin (N=101) n (%)	Daily recombinant human growth hormone (“rhGH”) (N=53) n (%)	Total (N=154) n (%)
Number of Subjects Randomized and Dosed	100 (99.0)	53 (100)	153 (99.4)
Study Completion Status			
Completed	98 (97.0)	53 (100)	151 (98.1)
Discontinued	3 (3.0)	0	3 (1.9)
Adverse Event	1 (1.0)	0	1 (0.6)

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	Lonapegsomatropin (N=101) n (%)	Daily recombinant human growth hormone (“rhGH”) (N=53) n (%)	Total (N=154) n (%)
Lost to Follow-up	0	0	0
Physician Decision	0	0	0
Trial Site Terminated by Sponsor	0	0	0
Study Terminated by Sponsor	0	0	0
Study Subject Withdrawal by			
Parent or Guardian*	1 (1.0)	0	1 (0.6)
Withdrawal by Subject	0	0	0
Lack of Efficacy	0	0	0
Voluntary withdrawal	1 (1.0)	0	1 (0.6)

* One child dropped out prior to receiving treatment due to reasons unrelated to the clinical trial.

Subjects were randomized in a 2:1 ratio into one of the two treatment groups – once-weekly injections of lonapegsomatropin at 0.24 mg/kg/week or daily injections of recombinant hGH (Norditropin®) at 34 µg/kg/day, which is equivalent to 0.24 mg/kg/week. The primary endpoint for this trial was to demonstrate non-inferiority, and if achieved, superiority of lonapegsomatropin in comparison to daily hGH on AHV at 52 weeks. The secondary endpoints for this trial were to evaluate the safety, tolerability, popPK and PD profiles of lonapegsomatropin in pediatric subjects with GHD. Based on the low immunogenicity of lonapegsomatropin as supported by its MoA and demonstrated in the global trial, immunogenicity was not evaluated in the China Phase 3 pivotal trial.

Waiver of Individual PK Studies. A unique aspect of the study design of this Phase 3 pivotal trial is the waiver of individual PK studies from the trial protocol and the introduction of popPK as a secondary endpoint to study hGH concentrations within the study group that receives once-weekly injections of lonapegsomatropin. PopPK has become a popular method especially in children, due to the potential for sparse sampling, flexible sampling times, computing of heterogeneous data, and identification of variability sources. This design allows us to utilize PK data collected from different pediatric subjects to simulate the PK profile with mathematical models.

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Efficacy Results. Results from the completed Phase 3 pivotal trial supported that once-weekly lonapegsomatropin was non-inferior and, additionally, superior to once-daily hGH on the primary endpoint of AHV at 52 weeks. ANCOVA-adjusted least squares mean AHV at 52 weeks was 10.66 cm/year for lonapegsomatropin, compared to 9.75 cm/year for daily hGH, with a p-value of 0.0010. The estimated treatment difference was 0.91 cm/year with a 95% confidence interval of 0.37 to 1.45 cm/year. The treatment difference reached statistical significance of change in height SDS from baseline (Δ height SDS) from and including 13 weeks onwards. Multiple pre-specified sensitivity analyses were completed and reinforced the robustness of these results.

Primary Efficacy Endpoint at 52 Weeks

	Lonapegsomatropin (N=100)	Daily rhGH (N=53)
AHV (cm/year)		
Least square mean (standard error)	10.66 (0.22)	9.75 (0.26)
Least square mean difference (standard error)	0.91 (0.28)	
Difference (95% confidence interval)	(0.37, 1.45)	
P-value	0.0010	

Height SDS at 52 weeks increased over baseline by 1.01 for lonapegsomatropin and by 0.83 for daily hGH, with a p-value of 0.0015, and statistical significance of change in height SDS from baseline (Δ height SDS) was demonstrated in the lonapegsomatropin group from and including 13 weeks onwards. The results were consistent with the efficacy results from the global Phase 3 program of lonapegsomatropin conducted by Ascendis Pharma that supported the FDA and EMA approvals.

Height SDS Improvement at 52 Weeks

	Lonapegsomatropin (N=100)	Daily rhGH (N=53)
Height SDS Change from Baseline		
Least square mean (standard error)	1.01 (0.04)	0.83 (0.05)
P-value	0.0015	

According to the results, average IGF-1 SDS for both lonapegsomatropin and daily hGH generally increased within normal range over 52 weeks and was relatively higher for lonapegsomatropin than daily hGH (0.76~1.45 vs -0.3~0.3 over 52 weeks), which appeared to parallel the superior growth outcomes observed for lonapegsomatropin relative to daily hGH.

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Average IGF-1 SDS Over 52 Weeks for the Subjects

	Lonapegsomatropin (N=100)	Daily rhGH (N=53)
Least Square Mean (Standard Error)		
Average IGF-1 SDS		
Week 5	0.76 (0.12)	-0.27 (0.15)
Week 13	1.52 (0.10)	-0.03 (0.12)
Week 26	1.31 (0.12)	0.09 (0.14)
Week 39	-0.11 (0.10)	0.30 (0.13)
Week 52	1.45 (0.14)	0.17 (0.16)

Safety and Tolerability Results. The results indicated that lonapegsomatropin was generally safe and well-tolerated, with AEs consistent with the type and frequency observed with daily hGH therapy and comparable between arms of the trial. The incidence of AEs was similar between lonapegsomatropin and daily rhGH groups (98.0% vs. 94.3%). Most TEAEs were mild (88.2% in total) to moderate (7.2% in total), and only two severe AEs occurred in the lonapegsomatropin group (bronchitis and bacterial tonsillitis). Both were not related to lonapegsomatropin, according to the investigator. The most common AEs in patients administered lonapegsomatropin or daily hGH were upper respiratory tract infection. Reported SAEs and SAEs related to lonapegsomatropin and daily hGH were infrequent and similar between arms of the trial. Two patients experienced AEs that led to the discontinuation of lonapegsomatropin, but only one (subcutaneous abscess) was possibly related to lonapegsomatropin, according to the investigator. No deaths were reported in either arm. As such, we believe the occurrence of SAEs has no material adverse impact on the clinical development and future commercialization of the Core Product. Throughout the trial, blood glucose were generally stable and remained within the normal range for both arms. Other laboratory parameters were also similar between arms of the trial. The safety and tolerability results from this China Phase 3 pivotal trial are consistent with the safety and tolerability results from the global Phase 3 program of lonapegsomatropin that supported its FDA and EMA approvals.

Overall TEAE Summary

	Lonapegsomatropin (N=100) n (%)	Daily rhGH (N=53) n (%)	Total (N=153) n (%)
TEAE	98 (98.0)	50 (94.3)	148 (96.7)
Mild	89 (89.0)	46 (86.8)	135 (88.2)
Moderate	7 (7.0)	4 (7.5)	11 (7.2)
Severe	2 (2.0)	0	2 (1.3)

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Future Clinical Development Plan

Under the relevant Exclusive License Agreement, we are able to select the indication(s) for development of lonapegsomatropin in China (including Hong Kong, Macau and Taiwan). Therefore, in addition to rapidly advancing in clinical development of our three drug candidates, we will further develop our Core Product, lonapegsomatropin, to cover more indications that may be eligible for hGH treatment, including other pediatric pathological short stature diseases such as ISS. As discussed in more details below, we intend to conduct a multi-center, randomized, open-label, active-controlled, parallel-group Phase 2b/3 trial to investigate the efficacy and safety of Core Product in children with ISS, with ongoing updates to the trial protocol. A multi-national clinical trial will be considered for both oversea and China registration.

ISS is defined as a condition characterized by a height more than 2 SD below corresponding average height for a given age, sex and population without evidence of underlying disease. Children with ISS, constituting approximately 38.8% of individuals with short stature, represent the majority in need of non-traditional use of human growth hormone. Given such circumstance, we plan to study our Core Product, lonapegsomatropin, in mainland China for ISS in a Phase 2b/3 trial. The aim of the trial would be to evaluate the effect of the Core Product on promoting growth in children with ISS and its safety profile, to support the application of ISS indication. The Phase 2b/3 trial plans to be designed as a multi-center, randomized, open-label, active-controlled, parallel-group trial that seamlessly integrates dose-finding and efficacy confirmatory phases, aiming to efficiently determine the optimal dosage for subsequent phase 3 efficacy evaluation. The Phase 2b/3 trial is estimated to follow the following timeline: we plan to finalize the study design, develop the study protocol, and conduct pre-IND communication with NMPA shortly following the completion of the [REDACTED]. If we proceed as planned, we expect to make IND filing in 2025.

Licenses, Rights and Obligations

We hold exclusive rights to develop, manufacture and commercialize lonapegsomatropin in China (including Hong Kong, Macau and Taiwan) on a royalty-free basis. See “– Collaborations – Exclusive License Agreements with Ascendis Pharma” for more details regarding our exclusive license arrangements with Ascendis Pharma.

Our R&D Work

We have been the sole sponsor of China clinical study and remain in charge of the clinical development process in China since in-licensing of lonapegsomatropin. As further disclosed below, we are fully responsible for the following aspects of the R&D activities for the development of lonapegsomatropin in China: (i) IND preparation, (ii) pre-IND communication and IND approval, (iii) trial preparation of site selection, (iv) clinical trial personnel training, (v) medical monitoring and data management, (vi) statistical management, (vii) patient enrollment, and (viii) BLA preparation, and have exclusive control over the supervision of clinical sites as well as the coordination of external vendors. We have the research expertise or access to the research expertise required for the development of lonapegsomatropin, including medical science, regulatory, clinical operation, quality assurance, pharmacovigilance and data management, statistics and medical affairs.

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We incurred R&D expenses of RMB106.2 million, RMB28.7 million and RMB12.7 million on the development of lonapegsomatropin for the treatment of PGHD in 2022, 2023 and the four months ended April 30, 2024, respectively, accounting for 59.1%, 49.8% and 49.2% of our total research and development costs, respectively, for the same periods. See “Financial Information” for more details. We anticipate incurring additional costs and expenses in connection with our future R&D work as discussed below.

During the Track Record Period, we procured R&D consulting services from Ascendis Pharma mainly for the pharmacovigilance and biometry for data analysis including statistical programming and statistical analysis, and the regulatory strategy advice and documentation support to prepare for our Import BLA submission package with the NMPA, which, as advised by Frost & Sullivan, is consistent with the industry practice. The amount of R&D consulting services rendered by Ascendis Pharma relating to lonapegsomatropin was RMB7.0 million, RMB6.3 million and RMB2.9 million in 2022, 2023 and the four months ended April 30, 2024, respectively.

IND Preparation

Upon receiving the relevant clinical data from Ascendis Pharma, we reviewed all the data generated from the global trials of lonapegsomatropin, and quickly began to prepare for clinical initiations in China. We developed a study protocol taking into consideration of the specific disease epidemiology, disease characteristics, domestic clinical practice as well as the current status of hGH market in China.

To ensure smooth initiation and operation of scientifically-sound studies, we set up a steering committee comprising KOLs, overseas clinical professional experts and biostatisticians. Three investigators sit in the steering committee, including Professor Xiaoping Luo, who holds various positions in Tongji Hospital, Tongji Medical College of Huazhong University of Science and Technology, Professor Junfen Fu from Children’s Hospital of Zhejiang University School of Medicine and Professor Chunxiu Gong from Beijing Children’s Hospital. Professor Ruihua Sun from China-Japan Friendship Hospital and Professor Martin O. Savage from London, United Kingdom are the Biostatistical Expert and Consultant of the steering committee, respectively. From January to March 2019, our R&D team organized a number of meetings with the KOLs to optimize the study designs for lonapegsomatropin. The design of studies has taken into consideration of both (i) the scientific rationale, such as MoA, pre-clinical data, available global clinical data, and development opportunity, and (ii) market opportunities in China, such as addressable patient population, product positioning and competitive landscape of lonapegsomatropin.

Pre-IND Communication and IND Approval

On April 1, 2019, we initiated pre-IND communication with the CDE, seeking their opinions on our study designs, including with respect to the size of the patient enrollment, option to conduct popPK studies, waiver of individual PK study and immunogenic assay, and option to advance lonapegsomatropin directly into Phase 3 pivotal trial in children with GHD

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in China in light of the clinical data generated by Ascendis Pharma from the global clinical trials of lonapegsomatropin, without performing initial safety or tolerability evaluation in healthy adults in a Phase 1 trial or proof-of-concept studies in a Phase 2 trial. To support our proposal to waive individual PK study, we have identified the Asian population from a bioequivalence Phase 1 clinical trial conducted by Ascendis Pharma and demonstrated in the pre-IND communication that no difference in PK profile was observed between the Asian group and the non-Asian group. During pre-IND communication, waiver of immunogenic assay was also accepted by CDE. Following several rounds of communication with the CDE, we considered all suggestions from the CDE and submitted an IND application in July 2019, which was accepted by the NMPA on August 9, 2019. On October 25, 2019, we obtained the IND approval from the NMPA with no negative feedback for the proposed clinical development plan and the trial design of Phase 3 pivotal trial of lonapegsomatropin.

Trial Preparation of Site Selection

We conducted a number of activities in connection with trial preparation and site selection, including:

- Developing and approving trial-related documentation, including, without limitation, the finalized protocol, informed consent form, case report form;
- Assessing potential challenges and risk for study conduct and other medical considerations;
- Establishing operational strategies including enrollment strategy;
- Evaluating site feasibility and preparing related submission to Human Genetics Resources Administration of China ("HGRAC"); and
- Ensuring all study preparation including investigational drug and clinical supplies was ready before the first patient was randomized.

Leveraging our insights and expertise in the endocrinology field, we managed to obtain the HGRAC approval and complete site initiation in an efficient manner and at a record speed: On November 26, 2019, 31 days after obtaining the IND approval, we obtained an approval from the HGRAC to commence the Phase 3 pivotal trial. Subsequently on December 23, 2019, we completed the first site initiation. Overall, we engaged a total of 17 GCP certified investigational sites specialized in pediatric endocrinology for the Phase 3 pivotal trial.

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Clinical Trial Personnel Training

In order to complete a smooth and high-quality Phase 3 pivotal trial, we designed a systematic training program with respect to the equipment to be used for the Phase 3 pivotal trial, including:

- Anthropometer measurement of the height of patients for the assessment of the primary endpoint for this trial (AHV at 52 weeks);
- Electronic data capture ("EDC") system that collects the clinical data in electronic format;
- Interactive response technology ("IRT") that automates patient randomization, kit assignment, drug supply, and inventory management;
- Central lab system that collects blood samples; and
- Central image system that measures bone age.

We also conducted training for investigators and sub-investigators at site initiation visit of each clinical site.

Medical Monitoring and Data Management

We developed a comprehensive medical monitoring and data management plan encompassing the following:

- *Monthly monitoring of medical data.* Our medical and clinical development department reviews the medical data with CRO once a month, analyzing screening situation, inclusion and exclusion criteria, follow-up information and safety information of the subjects in combination with the study protocol. The Phase 3 pivotal trial used Medidata's Rave EDC system to collect the clinical trial data at the sites. Data were entered into the electronic case report form ("eCRF") from the source documents by designated investigational site staff using single data entry with electronic verification. In general, queries were sent to the investigational site using an electronic data query system which provided an automatic audit trail of the corrections made by designated investigational site staff. Laboratory data will be uploaded in the central lab's own system and data will transfer regularly. After the data had been entered and saved, various edit checks were performed for the purpose of ensuring the accuracy, integrity, and validity of the collected data. Under our standard, 100% quality control ("QC") check and 0% error rate are required for key safety and efficacy (critical) variables. During the trial, we continuously monitor the quality of data entry services provided by CROs, including the progress report, data entry rate, source data verification ("SDV") rate, open query rate, missing page numbers, medical coding correctness, external data transfer, safety data reconciliation with pharmacovigilance database.

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- *Data surveillance and data dry run.* To ensure the data entry quality and early detection of any signal in safety and trial conduction, we have completed two rounds of data surveillance, upon 20% and 50% patient enrollment, respectively, and conducted four rounds of data dry run every three months, upon 80%, 100%, 100% and 100% patient enrollment, respectively, and before database lock on March 8, 2021, June 4, 2021, September 6, 2021 and December 6, 2021, respectively. No major issues with respect to data quality or entry were observed during the data surveillance and data dry runs.
- *Real-time communication of AEs.* Our clinical operation team communicated with the CRO timely for AEs in clinical trials. Our clinical operation team and medical team discussed the types of AEs, completed reports according to the operating procedures timely and analyzed the severity of AEs and their correlation to lonapegsomatropin. For reported SAEs, CRO pharmacovigilance staff and medical staff and our clinical operation team sent the inquiry to the investigators. The investigators then completed the follow-up report form with the follow-up information of the subjects.
- *Real-time communication of protocol deviation cases.* Our medical and clinical development led the adoption and modification of clinical trial plans of lonapegsomatropin, managed the overall operation and reporting of CRO and provided guidance for daily work and development of CRO. Our medical and clinical development department communicated with the CRO timely to discuss protocol deviation cases, analyzed the causes and solutions for each case, and provided feedback to clinical supervisors and main researchers to avoid the recurrence of such events.

Statistical Management

We established a dedicated team responsible for the statistical analysis of the study, with support from Ascendis Pharma. The efficacy analyses, including the primary efficacy analysis for the primary endpoint were based on the intention to treat population. The sensitivity analysis for the primary endpoint was performed based on the Per Protocol (“PP”) population, and the PP population was analyzed based on the actual treatment given. AHV at 52 weeks of lonapegsomatropin was compared to that of daily hGH by a non-inferiority comparison with a margin of 2.0 cm/year. Once non-inferiority in AHV was established, subsequent hypothesis testing for superiority were conducted. For the primary efficacy analysis, a two-sided 95% internal was calculated for the difference in least square means between the two treatment groups (i.e., AHV at 52 weeks in the lonapegsomatropin treatment group minus that in the daily hGH treatment group). Results from the completed Phase 3 pivotal trial supported that once-weekly lonapegsomatropin was non-inferior and, additionally, superior to once-daily hGH on the primary endpoint of AHV at 52 weeks.

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Patient Enrollment

In January 2020, we randomized the first patient in China for the Phase 3 pivotal trial. Patient enrollment was then put on temporary hold for at least four months due to the close of pediatric outpatient departments in response to the outbreak of COVID-19 in China in early 2020. After the hospitals re-opened in April 2020, we leveraged our strong site engagement and clinical development capabilities to complete site initiations for the remaining nine sites selected by us at that time within 36 days, demonstrating strong execution efficiency. Since October 2020, we have implemented strategies to achieve our patient enrollment goals, including adding new sites, enhancing site selection processes, efficiently obtaining HGRAC approval, and completing site initiation activities. On March 31, 2021, we completed patient enrollment for the Phase 3 pivotal trial for lonapegsomatropin according to our initial targeted timeline without any early termination or suspension of our clinical trials despite the disruption of COVID-19 pandemic and clinical site lock-down, highlighting the strong execution capabilities of our management and clinical R&D team.

Trial Completion

We conducted a number of R&D activities relating to clinical trial execution, including, without limitation, clinical trial personnel training; investigational site initiation, management and monitoring; medical and safety monitoring; data management; pharmacovigilance; quality assurance; and clinical data collection and vendor management. We independently completed the Phase 3 pivotal trial of the Core Product in April 2022.

Data analysis and Clinical Study Report (Main CSR and PopPK/PD Report)

We conducted several R&D activities relating to clinical trial data analysis, data reporting and clinical study report (“CSR”) developing after the completion of Phase 3 pivotal trial, including, without limitation, clinical data cleaning, clinical data reconciliation, clinical database lock, statistical analysis, data interpretation and CSR development. Following the achievement of clinical data lock on April 29, 2022, within one month after the completion of Phase 3 pivotal trial (the top performance in local market), the statistical analysis and data interpretation was conducted and CSR was drafted in compliance with the ICH E3 Structure and Content of Clinical Study Reports – Scientific Guideline (“ICH E3 Guideline”) published by International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (“ICH”) and local regulations. According to the Phase 3 China study design approved by the CDE and the ethics committee, two CSRs are developed to include main clinical study results (“Main CSR”) and PopPK and PD analysis results (“PopPK/PD report”) of PGHD population in China. PopPK/PD report is to characterize the PK and PD profile based on legacy global population PK model. After testing the collected blood samples during the last patient last visit in April 2022, PK sample analysis for the Phase 3 pivotal trial was concluded by the end of April 2022. Subsequently, all PK data were transferred to a third-party organization for PK and PD modelling and analysis. Main CSR is an integrated full report that combines clinical and statistical descriptions, presentations, and analyses into a single document, following ICH E3 guidelines, with tables, figures, and appendices incorporated within or at the end of the text. The PopPK/PD report and Main CSR were completed on November 17, 2022 and March 29, 2023, respectively.

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Given the above circumstance, NMPA agreed to waive the requirements of individual phase 1 PK study and phase 2 study (proof-of-concept) in China and confirmed the sufficiency of a confirmatory Phase 3 study including PopPK and PD in the registration process of China. The R&D process for the Core Product is faster than normal practice within the industry. The drug development process normally progresses from one stage to another with the support of pre-clinical and clinical data. Even for overseas imported drugs, regulatory authorities in China typically require independent Phase 1 PK study and Phase 3 study for registration purposes. However, considering the entire R&D efforts for the Core Product, we have managed to expedite such process.

BLA Dossier Preparation

As required by ICH and NMPA to continuously consolidate BLA submission package, we compiled a substantial number of documents based on data of global and local studies in four categories, including clinical documents, non-clinical documents, CMC documents and administrative documents. BLA application is designed for imported drugs that have already approved and commercially available overseas. According to the ICH M4E Common technical document for the registration of pharmaceuticals for human use – efficacy (“ICH M4E(R2) Guideline”), an internationally recognized guideline that plays a pivotal role in the field, if the drug has already been marketed, post-marketing data, including safety reports, should be summarized when available. The Guiding Principles for New Drug Clinical Safety Evaluation Techniques (《新藥臨床安全性評價技術指導原則》) also mentions the necessity to refer to the ICH M4E(R2) Guideline for other clinical safety principles.

In light of such guidelines, we decided to incorporate global safety data in line with those in the most recent global safety report submitted to the FDA as of August 25, 2023 into BLA dossier for the following reasons: (i) the BLA filing submission package in China would have contained the most up-to-date data and accurate data; and (ii) it would be a responsible and ethical approach for the Company to benefit the PGHD population in China. This required additional time for data collection, analysis, and comparison to ensure the inclusion of accurate and comprehensive data after August 25, 2023, the data collection cut-off date for the latest periodic safety report. We have updated the BLA submission package according to the global safety data since November 2023 and completed such update in January 2024.

Material Communications and BLA Submission with the NMPA

Material Communications Before Completion of the Phase 3 Pivotal Trial

On April 1, 2019, we initiated pre-IND communications with the NMPA, seeking the NMPA’s opinions on our study design. See “– Our Drug Pipeline – Lonapegsomatropin – A Long-Acting hGH Replacement Therapy for PGHD – Our R&D Work – Pre-IND Communication and IND Approval” for more details regarding the pre-IND communications. We did not receive any negative feedback from the NMPA on our proposed trial design.

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On August 9, 2019, our IND application was accepted by the NMPA. Subsequently on October 25, 2019, we obtained the IND approval from the NMPA to directly advance lonapegsomatropin to a Phase 3 pivotal trial in pediatric patients with GHD.

Material Communications After Completion of the Phase 3 Pivotal Trial

On March 31, 2023, we informed the NMPA of the completion status of our Phase 3 pivotal trial with results summary through the Drug Clinical Trial Registration and Information Publicity Platform which, as advised by our PRC Legal Adviser, is an official trial registration and publicity platform operated by the CDE which is a subdivision of NMPA whose function includes acceptance and technical evaluation of drug clinical trials and drug marketing authorization applications. The trial status on such platform was subsequently shown as “completed” on April 4, 2023 which, as advised by our PRC Legal Adviser, demonstrated that CDE has reviewed the materials submitted by us and agreed to reflect our Phase 3 pivotal trial status as “completed” for public review.

Following the completion of the Phase 3 pivotal trial, we engaged in the following formal communication with the NMPA in accordance with the Administrative Measures for Communication of Drug R&D and Technical Review (《藥物研發與技術審評溝通交流管理辦法》).

Pursuant to such measures, a company that intends to make a BLA filing (a “BLA applicant”) for a therapeutic biological product is required in principal to submit communication application to the CDE of the NMPA to discuss with the regulator whether the research data available satisfies the technical requirement to make a BLA filing. Upon receiving the application, the CDE of the NMPA is required to carry out a two-tier review: first to preliminarily verify whether information in the application is satisfactory and then to perform a complete review of the documents received. The CDE of the NMPA will schedule a communication meeting with the applicant unless it has provided written response or the matters raised by the applicant are resolved. Since lonapegsomatropin is a therapeutic biological product within the meaning of the aforementioned measures, we have completed the required communication process as set forth in more details below.

On May 31, 2023, we submitted a formal communication application package to the CDE of the NMPA, seeking their opinions on matters concerning, among other things, the completion of the Core Product’s Phase 3 pivotal trial, and the permission of BLA filing of the Core Product in China for PGHD.

On June 19, 2023, we received official response in writing from the CDE of the NMPA, confirming that (i) the Core Product’s Phase 3 pivotal trial was completed; (ii) primary endpoint of the trial demonstrate: (a) superiority efficacy over daily hGH in terms of 52-week AHV which is consistent with results from the global clinical trials; and (b) similar safety profile comparing to daily growth hormone products; and (iii) based on the data provided, the CDE of the NMPA agrees for us to proceed with our BLA filing of the Core Product for the treatment of PGHD.

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BLA Submission with the NMPA

We made the BLA filing with the NMPA on January 18, 2024 for our Core Product for the treatment of PGHD, after which we submitted supplemental administrative materials per request from the CDE of the NMPA, and the BLA filing was subsequently accepted by the NMPA on March 7, 2024. After the completion of our Core Product China Phase 3 pivotal trial in April 2022, we hold our submission of BLA filing with the NMPA until January 2024, primarily due to the following: (i) we have observed the necessity to incorporate the global safety data from the latest periodic safety report of Ascendis Pharma with a data collection cut-off date of August 25, 2023 into our BLA submission package with the NMPA, which we believe will bring us in line with international practices and domestic guidelines and may facilitate the BLA review process. See “– Our Drug Pipeline – Lonapegsomatropin – A Long-Acting hGH Replacement Therapy for PGHD – Our R&D Work – BLA Dossier Preparation” for more details; (ii) to ensure compliance with our Core Product Phase 3 China study design approved by the CDE and the ethics committee, the population pharmacokinetic (popPK) and pharmacodynamics (PD) analysis was conducted and concluded in November 2022; and (iii) we initiated a restructuring and reduced our staff counts in the first quarter of 2023 in light of the challenging market conditions, which had temporarily delayed our BLA submission workstream.

We are not aware of any legal claims or proceedings that may have an adverse effect on our development for lonapegsomatropin for the treatment of PGHD in China. As of the Latest Practicable Date, we have not received objections to our clinical development plans with respect to the regulatory review or approval process of lonapegsomatropin in China.

BLA Approval Analysis

We expect to receive the BLA approval for the Core Product for the treatment of PGHD in mid-2025 and we reasonably believe that it is unlikely that substantial additional clinical trials or R&D work will be required by the NMPA before the obtaining of the BLA approval for the Core Product in China, given the following considerations:

- *The expected mid-2025 BLA approval for the Core Product aligns with the current industry practice.* As advised by Frost & Sullivan, according to historical data from the NMPA, the average time between receiving the market application acceptance notice from the NMPA and receiving the new drug approval from the NMPA for Class 3.1 biopharmaceutical new drugs (approved for overseas marketing but not yet approved in China) since 2020 is approximately 376 days. The BLA filing for the Core Product for the treatment of PGHD, a Class 3.1 biopharmaceutical new drug application, was accepted by the NMPA on March 7, 2024, and we believe that the timeline for receiving NMPA approval in mid-2025 aligns with the current industry practice with respect to the NMPA’s review process.

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- *The approval rate for hGH products, especially LAGH, after BLA filing is high. As advised by Frost & Sullivan, the approval rate by the NMPA for hGH products that have submitted new drug applications, including those withdrawn from marketing, is over 90%. Among all hGH products, only one LAGH drug has submitted new drug application and received the marketing approval, resulting in a 100% success rate for marketing approval of LAGH products. As further advised by Frost & Sullivan, for these approved hGH products, NMPA did not request further clinical trials to be conducted during the review process and NMPA approved such drugs on their first new drug application.*
- *The approval rate of Class 3.1 new drug application by the NMPA is high. As advised by Frost & Sullivan, the approval rate by the NMPA since 2020 for the new drug application of Class 3.1 biopharmaceutical drugs that have already been approved overseas and conducted corresponding clinical trials in China, is 100%, and such Class 3.1 biopharmaceutical drugs were approved on their first new drug application, indicating that the possibility of the NMPA requiring substantial and additional clinical trial is remote.*
- *We reasonably believe that it is unlikely that additional new clinical trials will be required during the review process for the Core Product BLA application, given that: (i) the Phase 3 pivotal trial study protocol in China for the Core Product, including study endpoint, has been approved by the NMPA; (ii) the Phase 3 pivotal trial conducted by us in China adhered to the study protocol approved by both the NMPA and the ethics committee; (iii) the Phase 3 pivotal trial design in China complies with and meets the requirements outlined in the Clinical Trial Technical Guidance Principles for Growth Hormone Formulations in Growth Hormone Deficiency (生長激素製劑用於生長激素缺乏症臨床試驗技術指導原則) issued by the CDE of the NMPA in February 2024; (iv) the results of the Phase 3 pivotal trial in China have achieved the primary endpoint and secondary endpoints, indicating that the Core Product was generally safe and well-tolerated, and are consistent with the efficacy, safety and tolerability results from the global Phase 3 program that supported its approvals from the FDA and the EMA; and (v) on June 19, 2023, we received official response in writing from the CDE of the NMPA, confirming that (a) the Core Product's Phase 3 pivotal trial was completed; (b) primary endpoint of the trial demonstrate: (1) superiority efficacy over daily hGH in terms of 52-week AHV which is consistent with results from the global clinical trials; and (2) similar safety profile comparing to daily growth hormone products; and (c) based on the data provided, the CDE of the NMPA agrees for us to proceed with the BLA filing of the Core Product for the treatment of PGHD.*

Having considered (i) the view of Frost & Sullivan, regarding the success rate of marketing approval of hGH products and LAGH drug and that NMPA did not request further clinical trials to be conducted during the review process and NMPA approved such drugs on their first new drug application as stated above; and (ii) each of the basis for our expectation to receive the BLA approval for the Core Product for the treatment of PGHD as stated above,

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our Directors are of the view that it is unlikely that additional new clinical trials will be required during the review process for the Core Product BLA application and we expect to receive the BLA approval for the Core Product for the treatment of PGHD in mid-2025. The Joint Sponsors, on the basis of above and independent due diligence conducted, are of the view that it is unlikely that additional new clinical trials will be required during the review process for the Core Product BLA application.

Our Future R&D Work

We expect to engage in additional R&D work in connection with the regulatory filings in China, which includes product registration testing associated with the verification of lonapegsomatropin to support our BLA approval for the treatment of PGHD. Under the Exclusive License Agreement, we have the sole responsibility for obtaining and maintaining regulatory approvals for lonapegsomatropin in China (including Hong Kong, Macau and Taiwan). In connection with the preparation of such regulatory filings, we expect to receive consulting services from Ascendis Pharma mainly for (i) the technology transfer of lonapegsomatropin drug substance from Ascendis Pharma to us, and (ii) consulting the technology localization process that involves the lonapegsomatropin drug substance manufacturing scale-up.

Subsequent to the BLA approval from the NMPA, if obtained, we expect to submit a separate BLA, the Local BLA, to the NMPA to enable the local manufacturing of lonapegsomatropin in China in the future. The Local BLA is separate from the Import BLA approval that only allows a company to import and commercialize drug products that are manufactured overseas. As advised by the PRC Legal Adviser, the Import BLA only allows us to import and commercialize lonapegsomatropin in China, whereas the Local BLA will allow us to locally manufacture and commercialize lonapegsomatropin in China. It is also customary practice to obtain an Import BLA prior to the Local BLA in order to realize near-term revenue benefits while establishing local manufacturing capabilities, as advised by Frost & Sullivan. As part of the Local BLA filing, we are required to furnish, among other materials, a drug manufacturing certificate, which certifies the local manufacturing capabilities of the manufacturing facility. Under the Drug Administration Law, we will also attain marketing authorization holder status as we hold the drug approval license. For more details regarding the Import BLA and Local BLA, refer to “Risk Factors – Key Risks Related to Our Business, Business Operations, Intellectual Property, Regulatory Approval of Our Drug Candidates, Commercialization and Financial Prospects – Under China’s regulatory framework, in addition to obtaining marketing approval for commercializing imported drug products, a separate marketing approval from the NMPA is required to commercialize locally manufactured drug products. If we are unable to obtain marketing approval to commercialize locally manufactured drug products, our business prospects will be adversely affected, which will ultimately affect our long-term profitability” and “Regulatory Environment – Regulations on Pharmaceutical Product Development, Approval and Registration in the PRC – Regulations on the Clinical Trials and Registration of Drugs - Drug Marketing Registration.”

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To prepare for the Local BLA submission, we expect to engage in further R&D work relating to the following:

- process development, optimization studies, analytical methods and verification studies to verify the transferred process and methods in the year of 2024. These processes establish the blueprints for the development of drug substance and drug product from laboratory scale to manufacturing scale;
- engineering runs in 2025 and early 2026, including (i) drug substance engineering runs; and (ii) drug product engineering runs. These runs will ensure the scale-up process works for drug substance and drug product production; and
- process performance qualification (“PPQ”) runs in 2026, including (i) drug substance PPQ runs; and (ii) drug product PPQ runs. These runs will ensure that the commercial manufacturing process for drug substance and drug product can be operated consistently and within the pre-defined parameters and therefore to produce the consistent commercial lonapegsomatropin drug substance and drug product.

For more details, refer to “– Research and Development – CMC Development Programs” and “Future Plans and Use of [REDACTED] – Use of [REDACTED].”

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET LONAPEGOMATROPIN IN CHINA (INCLUDING HONG KONG, MACAU AND TAIWAN) SUCCESSFULLY.

TransCon CNP (navepegritide) – A Disease-Modifying Therapy for ACH

Overview

TransCon CNP (navepegritide) is a disease-modifying long-acting prodrug of CNP in development for the treatment of ACH in children in China (including Hong Kong, Macau and Taiwan), for which there is currently no effective disease-modifying therapy approved. TransCon CNP (navepegritide) is designed to optimize efficacy with a safe and convenient once-weekly dose. It is designed to provide effective shielding of CNP from neutral endopeptidase degradation in subcutaneous tissue and the blood compartment, minimize binding of CNP to the NPR-C receptor to decrease clearance, reduce binding of CNP to the NPR-B receptor in the cardiovascular system to avoid hypotension, and release unmodified CNP, which is small enough in size to allow effective penetration into growth plates.

TransCon CNP (navepegritide) has completed the double-blind period of Phase 2 clinical trial in China for the treatment of ACH with primary endpoint met according to the topline results during the double-blind period. We became the sole sponsor for the OLE period of this trial in January 2023 and the last patient last visit of the OLE period was completed in April 2024. The primary analysis of double-blind period for our ongoing China Phase 2 trial was

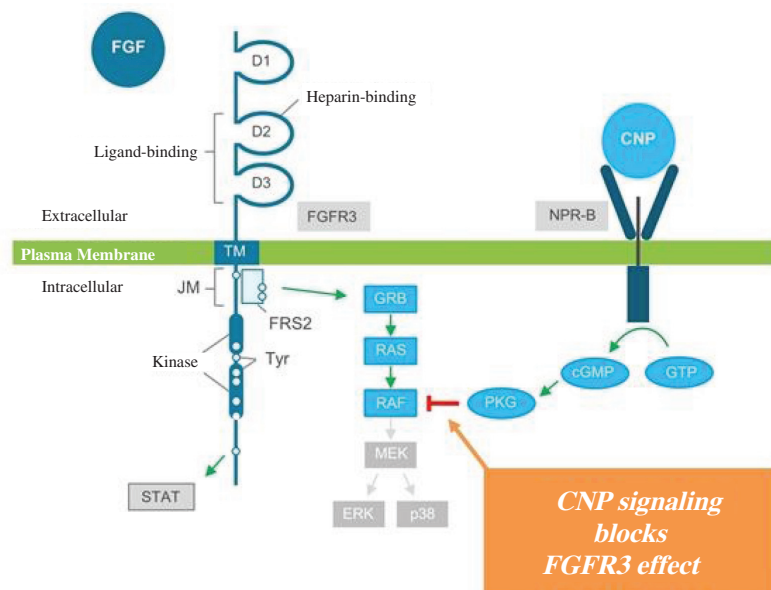
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completed in November 2023. The topline results of the primary endpoint, AGV at 52 weeks, demonstrated a greater AGV of 5.939 cm/year for the cohort dosed at 100 µg/kg/week compared to 4.760 cm/year for placebo. The topline results also suggest that TransCon CNP (navepegritide) was generally well tolerated, without drug-related serious adverse events, and adverse events leading to discontinuation of the drug in the subjects. The topline results from China Phase 2 trial demonstrate consistency with the global Phase 2 trial in terms of primary endpoint and safety profile.

Etiology of ACH and MoA of TransCon CNP (navepegritide)

ACH is caused by an autosomal dominant activating mutation in FGFR3 that leads to an imbalance in the effects of the FGFR3 and CNP signaling pathways. The role of a defect in the FGFR3 signaling pathway in the development of ACH is well understood. As depicted in the figure below, FGFR3 negatively regulates chondrocyte proliferation and differentiation and hence bone growth. ACH results from a mutation in FGFR3 which leaves the receptor constitutively activated. CNP inhibits the FGFR3 pathway and thereby promotes proliferation and differentiation of chondrocytes to restore bone growth.

FGFR Signaling Pathway



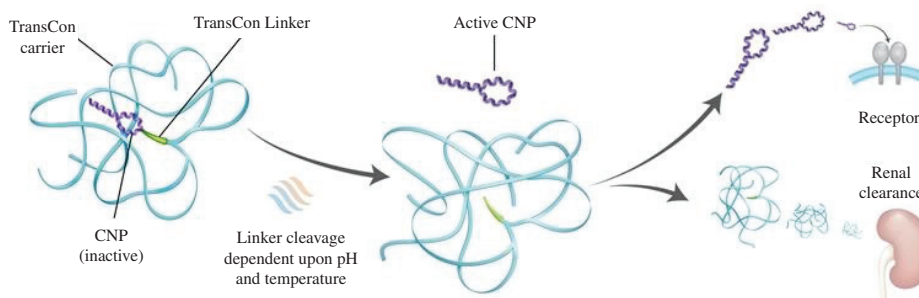
Source: Ascendis Pharma[®]

Pre-clinical and clinical data show that the CNP pathway stimulates growth and increased CNP helps to counteract the effects of the FGFR3 mutation downstream. Additionally, CNP does not alter the function of fibroblast growth factor (“FGF”) receptors or change endogenous levels of FGF ligands, reducing the risk of interfering with normal FGF biology. As ACH is caused by an FGFR3 mutation that chronically inhibits growth, it is expected that a more constant CNP exposure at lower C_{max} correlates with better therapeutic outcomes, with lower cardiovascular risk.

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TransCon CNP (navepegritide) is designed to provide continuous CNP exposure at therapeutic levels with a well-tolerated and convenient once-weekly dose, in order to continuously inhibit abnormal FGFR3 signaling, restoring proliferation and differentiation of chondrocytes to rebalance bone growth.

MoA of TransCon CNP (navepegritide)



Source: Ascendis Pharma[®]

As depicted in the figure above, TransCon CNP (navepegritide) is an essentially inactive prodrug consisting of CNP-38 transiently bound to a carrier molecule, 2 branched 20 kDa methoxy polyethylene glycol (mPEG), via a transient conjugation linker linked to the epsilon amino of lysine in position 26 of the CNP molecule. CNP-38 is identical to the unmodified carboxy terminal amino acid residues 89 through 126 of human CNP. The carrier molecule, mPEG, acts as a chemically inert carrier, extending CNP-38 circulation time in the body through minimizing renal clearance of the TransCon CNP (navepegritide) prodrug, shielding of the CNP molecule from proteolytic degradation and from binding to its primary activating and clearance receptors, NPR-B receptor and NPR-C receptor, and largely inactivating CNP-38 until its release. TransCon CNP (navepegritide) releases active CNP-38 via auto-cleavage of the transient conjugation linker in a controlled manner following first-order kinetics dependent on pH and temperature. Following the cleavage of the transient conjugation linker under physiologic pH and temperature, active CNP-38 peptide is slowly and continuously released and, due to the small size of the peptide, assumed to be subjected to the same distribution and pharmacodynamics mechanisms as endogenous CNP. As such, the transient conjugation technology (TransCon) is designed to provide sustained exposure of active CNP-38, allowing an optimal PK profile for use in children and adolescents with ACH, demonstrated by observed apparent mean elimination half-life of 120h in adults (Phase 1 trial TCC-101) supporting once-weekly dose administration. This is in contrast to the short systemic half-life of endogenous CNP in humans of only 2 to 3 minutes (Hunt 1994), and the half-life of vosoritide of approximately 45 minutes (BioMarin 2012). See “– Transient Conjugation Technology (TransCon)” for more details regarding the transient conjugation technology (TransCon).

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Market Opportunity and Competitive Landscape

ACH is the most common form of dwarfism that results in severe skeletal complications and comorbidities, including foramen magnum and spiral stenosis, sleep apnea and chronic ear infections. Patients often face multiple surgeries to alleviate the various complications associated with ACH.

The prevalence of ACH in China was 51.2 thousand in 2023. ACH represents an untapped market with immediate medical needs, given there is currently no effective disease-modifying therapy for ACH approved in China. The chart below sets forth ACH therapy in clinical development in China.

ACH Therapies with Clinical Activities in China, as of the Latest Practicable Date

<u>Product</u>	<u>Drug Structure</u>	<u>Company</u>	<u>Development Status</u>
TransCon CNP (navepegritide)	Prodrug of CNP	VISEN ⁽¹⁾	Phase 2
SAR442501	FGFR3 antibody	Sanofi	Phase 2

Note:

- (1) VISEN has gained exclusive licensed rights to develop, manufacture and commercialize in China (including Hong Kong, Macau and Taiwan); Ascendis Pharma retains the rights to develop, manufacture and commercialize outside of China (including Hong Kong, Macau and Taiwan).

Source: CDE, Frost & Sullivan Analysis

See “Industry Overview – Achondroplasia – Competitive Landscape of the ACH Market in China” for more details regarding the market of ACH.

Limitations of Current Treatment and Potential Advantages of TransCon CNP (navepegritide)

Currently, there is no approved therapy available in China to treat the genetic basis of ACH, with medical and surgical interventions limited to addressing some of the symptoms, including spinal stenosis, hydrocephalus and obstructive sleep apnoea. Administration of CNP to patients with ACH and in animal models of ACH has been found to stimulate growth. Vosoritide (Vosoritide), as a CNP analogue, has been developed to provide better stability of CNP and is approved by the FDA for the treatment of ACH in the United States. However, Voxzogo (Vosoritide) is a short-acting CNP-39 analogue with a half-life of 20 to 45 minutes and daily injection is required. In addition to limited efficacy, short-acting CNP and CNP analogues that result in high C_{max} levels may cause adverse cardiovascular events. As ACH is caused by an FGFR3 mutation that chronically inhibits growth, we expect a more constant CNP exposure at lower C_{max} to correlate with better therapeutic outcomes, with lower cardiovascular risk. TransCon CNP (navepegritide) is an investigational long-acting prodrug of CNP designed to provide continuous CNP exposure at therapeutic levels with a well-tolerated and convenient once-weekly dose.

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Summary of Clinical Results

The following table sets forth an overview of the key clinical studies of TransCon CNP (navepegritide):

Trial	Sponsor/Subject/ Trial Status	Primary Endpoint	Secondary Endpoints	Trial Key Summary
Phase 2 ACcomplishH China Trial* (September 2021 – present) (NCT05246033)	<ul style="list-style-type: none"> • Double-blind period by Ascendis Pharma; OLE period by the Company • Children with ACH • Ongoing 	<p>Safety: AEs, Clinical laboratory investigations, vital sign, ECG, radiographic findings, anti-drug antibodies (ADA)</p> <p>Efficacy: AGV at week 52</p>	<p>Efficacy: Change in body proportionality (upper to lower body segment ratio)</p> <p>PK endpoints</p>	<p>A total of 24 male and female pre-pubertal children with ACH were included into two dose-escalation cohorts, Cohort 1C (50 µg CNP/kg/week) and Cohort 1D (100 µg CNP/kg/week), each consisting of up to 12 children. The topline results of the primary endpoint, AGV, at 52 weeks, demonstrated a greater AGV of 5.939 cm/year for the cohort dosed at 100 µg/kg/week compared to 4.760 cm/year for placebo. The topline results also suggest that TransCon CNP (navepegritide) was generally well tolerated, without drug-related serious adverse events, and adverse events leading to discontinuation of the drug in the subjects.</p>
Phase 3 Pivotal Trial (March 2023 – present) (NCT05598320)	<ul style="list-style-type: none"> • Ascendis Pharma • Children with ACH • Ongoing 	<p>AHV at week 52</p>	<p>Height Z-score at week 52</p>	<p>The aim of the global Phase 3 pivotal trial is to evaluate efficacy and safety of TransCon CNP (navepegritide) administered once weekly subcutaneous doses of 100 µg/kg compared to placebo on AHV after a 52-week randomized treatment period in children aged 2 to 11 years with genetically confirmed ACH. A total of 84 prepubertal children with ACH were enrolled and randomized 2:1 to once-weekly subcutaneous injection of TransCon CNP (navepegritide) or placebo for 52 weeks. The trial met its primary endpoint, demonstrating TransCon CNP (navepegritide) at 100 µg/kg/week was superior to placebo on the primary efficacy endpoint of AGV with LS mean treatment difference of 1.49 cm/year at week 52 (AGV of 5.89 cm/year compared to 4.41 cm/year, p<0.0001) and was generally well-tolerated.</p>
Phase 2 ACcomplishH Trial (June 2020 – present) (NCT04085523)	<ul style="list-style-type: none"> • Ascendis Pharma • Children with ACH • Ongoing (Primary Completion in September 2022) 	<p>To determine the safety of once weekly subcutaneous (SC) doses of TransCon CNP</p> <p>To evaluate the effect of once weekly SC doses of TransCon CNP on AHV</p>	<p>Body proportionality (upper to lower body segment ratio) in prepubertal children with ACH at 52 weeks</p> <p>Pharmacokinetic (PK)</p> <p>Immunogenic response</p>	<p>42 eligible participants with genetically confirmed achondroplasia were enrolled and randomized 3:1 to once-weekly subcutaneous injections of TransCon CNP (navepegritide) (6, 20, 50, or 100 µg CNP/kg/week) or placebo for 52 weeks. The trial met its primary endpoint, demonstrating that TransCon CNP (navepegritide) at 100 µg/kg/week was superior to placebo on the primary efficacy endpoint of AHV at 52 weeks and was generally tolerable, supporting continued development of TransCon CNP (navepegritide) at the selected dose of 100 µg CNP/kg/week in the ongoing pivotal trial. (Ravi Savarirayan, et al. <i>Lancet</i> 2023; 65:102258)</p>
(52 weeks of double-blind period followed by 104 weeks of OLE period)				

Note: * We in-licensed the TransCon CNP (navepegritide) from Ascendis Pharma in November 2018. Prior to our in-licensing, TransCon CNP (navepegritide) had been studied by Ascendis Pharma in 45 healthy adult male subjects in a Phase 1 global trial. Phase 1 trial of performing initial safety or tolerability evaluation in healthy adults has been waived by the NMPA.

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ACHieve Study in China, a Nature History Capture Trial Conducted by VISEN Pharmaceuticals and Sponsored by Ascendis Pharma

The ACHieve study, a longitudinal and observational global study sponsored by Ascendis Pharma, initiated patient enrollment in November 2020 and concluded enrollment in March 2021, with 83 subjects enrolled across six sites. In November 2023, Ascendis Pharma informed us that they have decided to begin the process for terminating this study by the end of 2023, indicating that there have been fewer participants ongoing in the study as some of the patients from this study have rolled over into studies of TransCon CNP (navepegritide) and others have discontinued for other reasons. As part of this global study, we conducted the ACHieve study in China to collect baseline data of the patients with ACH, serving as a source of valuable information for the natural history of ACH. Additionally, we have rolled over 24 patients from the ACHieve Study in China to the China Phase 2 trial facilitating a fast start for the trial.

Ongoing China Phase 2 trial, ACcomplisH China Trial, in Children (Aged 2–10 Years Old) with ACH in China (including Hong Kong, Macau and Taiwan) Conducted by VISEN Pharmaceuticals and Sponsored by Ascendis Pharma for Double-blind Period and Sponsored by VISEN Pharmaceuticals for OLE Period

The ACcomplisH China Trial (TCC-204) is a multicenter Phase 2 clinical trial of weekly TransCon CNP (navepegritide) administered subcutaneously in children with ACH. See “– Our Drug Pipeline – TransCon CNP (navepegritide) – A Disease-Modifying Therapy for ACH – Summary of Clinical Results” above. We had been the exclusive authorized agent for the China Phase 2 trial, which was sponsored by Ascendis Pharma for the double-blind period, and we became the sole sponsor for the OLE period of this trial as it commenced in January 2023 and the last patient last visit of the OLE period was completed in April 2024. The primary objectives of the China Phase 2 trial are to determine the safety of once weekly subcutaneous doses of TransCon CNP (navepegritide) in children with ACH, and to evaluate the effect of once weekly subcutaneous doses of TransCon CNP (navepegritide) on 12-month AGV in children with ACH. We obtained IND approval from the NMPA on January 6, 2021 to initiate the China Phase 2 trial in September 2021 and have finished patient enrollment.

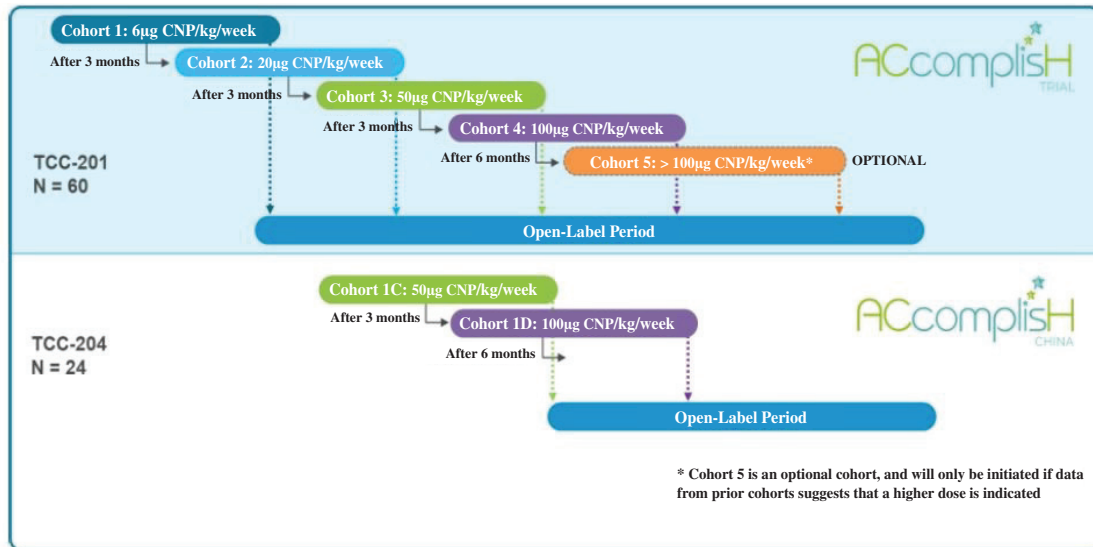
Study Design. The China Phase 2 trial is designed to enroll participants aged two to ten years old, the same age range as the global Phase 2 trial, and administer the same dose level as in the global Phase 2 trial. A total of 24 male and female pre-pubertal children with ACH will be included in the screening visit. The China Phase 2 trial comprises two dose-escalation cohorts, Cohort 1C (50 µg CNP/kg/week) and Cohort 1D (100 µg CNP/kg/week), each consisting of up to 12 children.

The China Phase 2 trial is double-blind and placebo-controlled. Patients in each cohort will be randomized to receive either TransCon CNP (navepegritide) or placebo in a 3:1 ratio and will follow the dose escalation plan outlined in the global Phase 2 trial. Each participant will receive their assigned dose (or placebo) for 52 weeks, after which they will continue participation in the OLE period for approximately 52 weeks where all participants will receive TransCon CNP (navepegritide). In the OLE period, participants may receive the highest dose level of TransCon CNP (navepegritide) that has been reviewed and recommended by the data monitoring committee (“DMC”) of both the global Phase 2 trial and the China Phase 2 trial.

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When the China Phase 2 trial was initiated to enroll participants, Cohort 1 and Cohort 2 of the global Phase 2 trial had enough data for the DMC to review and make a recommendation to initiate the next higher dose level at Cohort 3. These blinded data from the global Phase 2 trial informed the dose selection of 50 and 100 µg/kg/week for Cohort 1C and Cohort 1D of the China Phase 2 trial. A summary of the study design of the China Phase 2 trial and its relationship with the global Phase 2 trial is outlined in the figures below.

Study Design of China Phase 2 trial



* Cohort 5 is an optional cohort, and will only be initiated if data from prior cohorts suggests that a higher dose is indicated. Based on the data review from the global Phase 2 trial, there were no plans to pursue a dose higher than 100 µg CNP/kg/week, as of the Latest Practicable Date.

Source: Ascendis Pharma®; Company Information

The primary analysis of double-blind period for our ongoing China Phase 2 trial was completed in November 2023. The topline results of the primary endpoint, AGV, at 52 weeks, demonstrated a greater AGV of 5.939 cm/year for the cohort dosed at 100 µg/kg/week compared to 4.760 cm/year for placebo. The topline results also suggest that TransCon CNP (navepegitide) was generally well tolerated, without drug-related serious adverse events, and adverse events leading to discontinuation of the drug in the subjects. The topline results from China Phase 2 trial demonstrate consistency with the global Phase 2 trial, in terms of primary endpoint and safety profile.

ApproaCH Registry Study, for ACH and Collaboration with CHARD

In addition to the China Phase 2 trial, we supported the founding of Achondroplasia Advisory Board by providing funding under the governance of CHARD’s Advisory Board, in June 2019 and subsequently entered a five-year strategic cooperation with CHARD on a national patient registry and diagnosis consensus of ACH in China in December 2020 to initiate the ApproaCH project, to which we were responsible for funding. As part of the ApproaCH project, the first ACH Expert Consensus in China on Diagnosis and Treatment was published

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on Chinese Journal of Pediatrics in July 2021; a national patient registry study, ApproaCH Registry Study, was initiated in September 2020 and achieved the first wave screening and enrollment in October 2021 in 17 hospitals across China, to further understand the natural history and current standard of care and economic burden in patients; additional education programs will be done to improve the disease awareness and care in both healthcare professionals and patients. As of December 2023, the ApproaCH Registry Study has reached its targeted enrollment number of 380 patients and completed an initial 154 follow-ups. Upon its expected completion in 2025, the study will provide valuable scientific data on the demographic and clinical characteristics of patients with ACH in China.

Future Clinical Development Plan

In March 2023, all 24 patients have completed the double-blind treatment period and continued to the OLE period. In April 2024, the last patient last visit of the OLE period was completed. In accordance with the study protocol, we intend to use the data from the double-blind period and the OLE period to support an NDA submission to the NMPA for TransCon CNP (navepegritide) in children with ACH.

Licenses, Rights and Obligations

We hold exclusive rights to develop, manufacture and commercialize TransCon CNP (navepegritide) in China (including Hong Kong, Macau and Taiwan) on a royalty-free basis. See “– Collaborations – Exclusive License Agreements with Ascendis Pharma” for more details regarding our exclusive license arrangements with Ascendis Pharma.

Our R&D Work

Our role changed from an exclusive agent to the sole sponsor since January 2023: for the OLE period of the China Phase 2 trial beginning from January 2023, we became in charge of the clinical development process in China. As the sole sponsor and under the applicable research and technical development plans, we are now fully responsible for the following aspects of the R&D activities for the development of TransCon CNP (navepegritide) in China: (i) IND preparation, (ii) pre-IND communication and IND approval, (iii) trial preparation of site selection, (iv) clinical trial personnel training, (v) medical monitoring and data management, (vi) statistical management, and (vii) patient enrollment, and have exclusive control over the supervision of clinical sites as well as the coordination of external vendors. We have the research expertise or access to the research expertise required for the development of TransCon CNP (navepegritide), including medical science, regulatory, clinical operation, quality assurance, pharmacovigilance and data management, statistics and medical affairs.

We incurred R&D expenses of RMB17.8 million, RMB9.4 million and RMB6.2 million on the development of TransCon CNP (navepegritide) in 2022, 2023 and the four months ended April 30, 2024, respectively. We anticipate that we will incur significantly more costs and expenses in connection with our future R&D work as discussed below.

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During the Track Record Period, we procured R&D consulting services from Ascendis Pharma with respect to pharmacovigilance and biometry for data analysis which, as advised by Frost & Sullivan, is consistent with the industry practice. The amount of R&D consulting services rendered by Ascendis Pharma relating to TransCon CNP (navepegritide) was RMB0.1 million, RMB3.0 million and RMB2.1 million in 2022, 2023 and the four months ended April 30, 2024, respectively.

IND Preparation

Since the in-licensing of TransCon CNP (navepegritide), our senior management has led an internal R&D team and worked in close collaboration with Ascendis Pharma and our scientific advisory board and industry-leading CROs to carry out R&D activities. Upon receiving the relevant clinical data from Ascendis Pharma, our R&D team reviewed all the data generated from the global Phase 2 trial of TransCon CNP (navepegritide) and prepared for clinical trial initiations in China. Additionally, in October 2019, our R&D team organized a scientific advisory board meeting with the KOLs to optimize the study designs for TransCon CNP (navepegritide). The study designs have taken into consideration both (i) the scientific rationale, such as the MoA, pre-clinical data, available global clinical data, and development opportunity; and (ii) market opportunities in China, such as addressable patient population, product positioning and competitive landscape of TransCon CNP (navepegritide). A data monitoring committee was also established by Ascendis Pharma and supported by us to provide recommendations on the action to be taken (i.e., continue the trial(s) (including planned dose escalation) without modification; continue the trial(s) with modifications; or discontinue the trial(s)) based on review of the unblinded data, including Erin Nissen Castelloe, MD, Bradley S. Miller, MD, PhD, Eric T. Rush, MD, FAAP, FACMG and Huijuan Zhu, MD, who are experienced KOLs and members from reputable medical institutions around the world.

Pre-IND Communication and IND Approval

We obtained IND approval from the NMPA on January 6, 2021 to initiate the China Phase 2 trial in September 2021, which demonstrates our advanced R&D capabilities.

Trial Preparation of Site Selection

We conducted a number of activities in connection with trial preparation and site selection, including:

- Developing and approving trial-related documentation, including, without limitation, the finalized protocol, informed consent form, case report form;
- Assessing potential challenges and risk for study conduct and other medical considerations;
- Establishing operational strategies including recruitment strategy;

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- Evaluating site feasibility and preparing related submissions to the HGRAC; and
- Ensuring all study preparation including investigational drug and clinical supplies was ready before the first patient was randomized.

Leveraging our insights and expertise in the pediatric endocrinology field, we managed to obtain the HGRAC approval and complete site initiation in an efficient manner. On November 17, 2020 and September 10, 2021, we completed the first site initiation for the ACHieve Study in China and the China Phase 2 trial, respectively. Overall, we engaged a total of six GCP certified investigational sites specialized in pediatric endocrinology for the ACHieve Study and the China Phase 2 trial.

Clinical Trial Personnel Training

In order to complete a smooth and high-quality China Phase 2 trial, we designed a systematic training program with respect to the equipment to be used for the trial, including:

- Equipment that measures the anthropometric parameters of patients for the assessment of the primary and secondary endpoints for this trial;
- Electronic data capture ("EDC") system that collects the clinical data in electronic format;
- Interactive response technology ("IRT") that automates patient randomization, kit assignment, drug supply and inventory management;
- Central lab system that collects blood samples; and
- Central image system that measures bone age.

We also conducted training for anthropometrists to be certificated as well as for investigators and sub-investigators at site initiation visit of each clinical site.

Medical Monitoring and Data Management

We developed a comprehensive medical monitoring and data management plan encompassing the following:

- *Monthly monitoring of medical data.* Our medical and clinical development department reviews the medical data with Ascendis Pharma once a month, analyzing screening situation, inclusion and exclusion criteria, follow-up information and safety information of the subjects in combination with the study protocol. The China Phase 2 trial uses OmniComm system to collect the clinical trial data at the sites. Data are entered into the eCRF from the source documents by designated investigational site staff using single data entry with electronic verification. In

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general, queries are sent to the investigational site using an electronic data query system which provided an automatic audit trail of the corrections made by designated investigational site staff. Laboratory data will be uploaded in the central lab's own system and data will transfer regularly. After the data have been entered and saved, various edit checks will be performed for the purpose of ensuring the accuracy, integrity, and validity of the collected data. Under our standard, 100% quality control ("QC") check and 0% error rate are required for key safety and efficacy (critical) variables. During the trial, we continuously monitor the quality of data entry, including the progress report, data entry rate, source data verification ("SDV") rate, open query rate, missing page numbers, medical coding correctness, external data transfer, safety data reconciliation with pharmacovigilance database.

- *Real-time communication of AEs.* Our clinical operation team communicates with the CRO timely for AEs in clinical trials. Our clinical operation team and medical team discuss the types of AEs and complete reports according to the operating procedures timely and analyze the severity of AEs and their correlation to TransCon CNP (navepegritide). For reported SAEs, CRO pharmacovigilance staff and medical staff and our clinical operation team send the inquiry to the investigators. The investigators then complete the follow-up report form with the follow-up information of the subjects.
- *Real-time communication of protocol deviation cases.* Our medical and clinical development department leads the adoption and modification of clinical trial plans of TransCon CNP (navepegritide), manages the overall operation and reporting and provides guidance for daily work and development. Our medical and clinical development department also communicates with Ascendis Pharma timely to discuss protocol deviation cases, analyzes the causes and solutions for each case, and provides feedback to clinical supervisors and main researchers to avoid the recurrence of such events.

Future R&D Work

We expect to engage in additional R&D work in connection with the ongoing China Phase 2 trial of TransCon CNP (navepegritide) for the treatment of ACH. In connection with such additional R&D work, we expect to receive consulting services from Ascendis Pharma to support our clinical data and statistics management.

Material Communications with the NMPA

On October 19, 2020, we filed an IND application to the NMPA to initiate the China Phase 2 trial for TransCon CNP (navepegritide) for the treatment of pre-pubertal children with ACH. On January 6, 2021, we obtained IND approval from the NMPA to initiate the China Phase 2 trial for the treatment of ACH.

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As of the Latest Practicable Date, we have not received objections to our clinical development plans with respect to the regulatory review or approval process of TransCon CNP (navepegritide) in China.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TRANSCON CNP (NAVEPEGTRITIDE) IN CHINA (INCLUDING HONG KONG, MACAU AND TAIWAN) SUCCESSFULLY.

Palopegteriparatide – A PTH Replacement Therapy Addressing the Underlying Cause of HP

Overview

Palopegteriparatide is an investigational long-acting prodrug of PTH in development as a novel once-daily PTH replacement therapy for HP. The current treatments for HP are inadequate due to their limited therapeutic benefits and the need for chronic administration of calcium in high doses and increased risks of associated complications. Palopegteriparatide is designed to be the standard of care that can potentially address both the short-term symptoms and long-term complications of HP by providing sustained release of serum PTH to restore the physiological levels and activity of PTH throughout 24 hours per day. In accordance with relevant procedures of World Health Organization, this drug candidate was assigned to the recommended INN of “palopegteriparatide.”

In China, we are developing palopegteriparatide for the treatment of adult HP, following our receipt of the IND approval from the NMPA in May 2021. We have completed the double-blind period for the China Phase 3 pivotal trial in January 2023. Based on the topline data from China Phase 3 pivotal trial, the primary endpoint, defined as the proportion of subjects with albumin-adjusted serum calcium within the normal range, independence from calcitriol or alfacalcidol active vitamin D, and independence from therapeutic doses of calcium (i.e., taking calcium supplements ≤ 600 mg/day) at 26 weeks of treatment, and no increase in prescribed study drug within 4 weeks prior to Week 26 visit, was achieved by 77.6% (45 of 58) of palopegteriparatide-treated patients, compared to 0.0% (0 of 22) of patients in control group (p-value < 0.0001). The topline data also suggest palopegteriparatide was generally well tolerated, without drug-related serious adverse events and adverse events leading to discontinuation of the drug in the subjects. The topline data from China Phase 3 pivotal trial demonstrate consistency with the global Phase 3 pivotal trial, in terms of primary endpoint and safety profile.

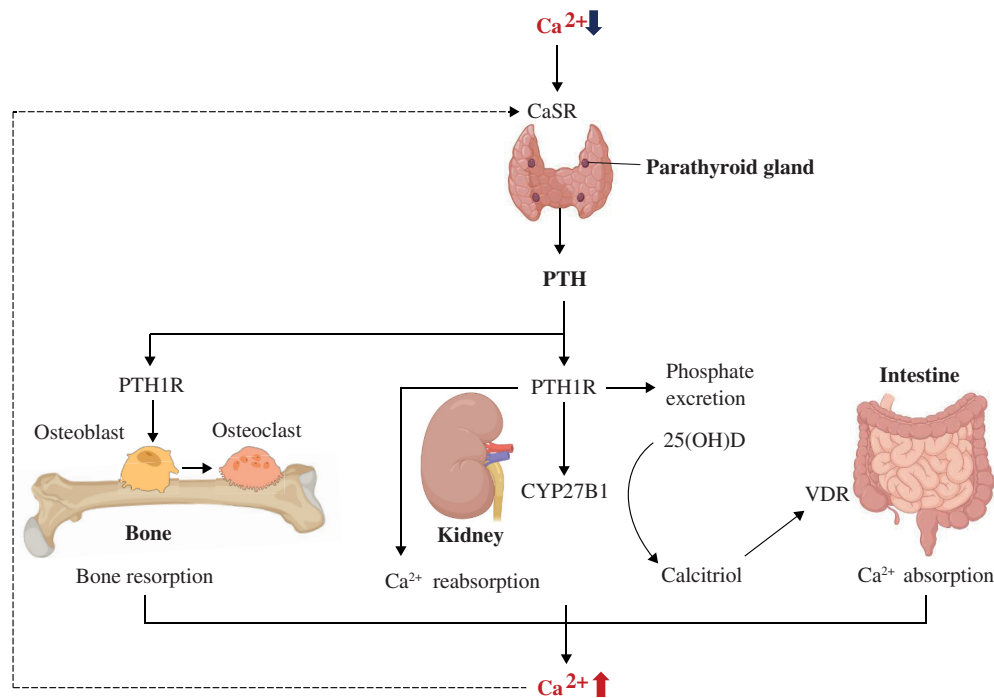
Etiology of HP and MoA of Palopegteriparatide

HP is a syndrome of abnormal calcium and phosphorus metabolism caused by decreased secretion or defective function of PTH. It is characterized by hypocalcemia, hyperphosphatemia and inappropriately low serum levels of PTH. HP may be due to congenital or acquired disorders. The most common cause of HP is neck surgery, accounting for 75% of the cases. Postsurgical HP occurs after thyroidectomy and parathyroidectomy due to injury of

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parathyroid glands and/or their blood supply. The causes of non-surgical HP, which comprise the remaining 25% of the cases, include autoimmune diseases or genetic abnormalities, invasive parathyroid disease, and external beam therapy and radioactive iodine treatment of thyroid disease. Properly functioning parathyroid glands maintain proper levels of both calcium and phosphorus by turning the secretion of PTH off or on. As depicted in the figure below, PTH has direct and indirect effects on the bones (i.e., stimulates the release of calcium), kidneys (i.e., increases serum calcium levels) and the small intestine (i.e., stimulates the production of an enzyme that catalyzes the synthesis of active vitamin D which plays a role in calcium absorption). When calcium levels in the blood fall too low, parathyroid glands secrete enough PTH to restore the balance by releasing calcium from bones and increasing the amount of calcium absorbed from the small intestine. There is a negative feedback loop when blood calcium levels increase to attenuate secretion of PTH.

Regulation of Extracellular Calcium Homeostasis by Properly Functioning Parathyroid Glands



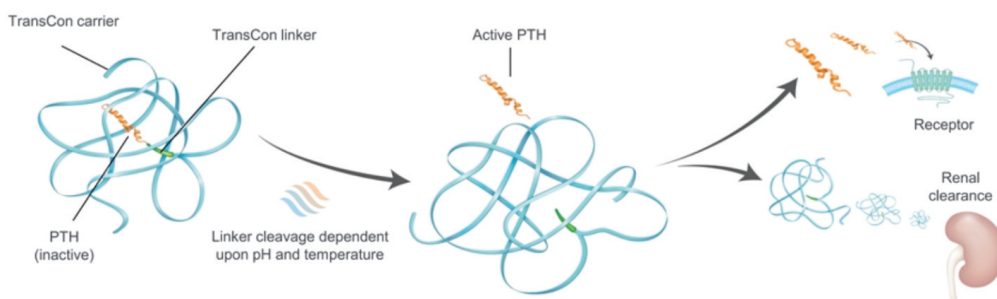
Source: Literature Review, Frost & Sullivan Analysis

Damaged or removed parathyroid glands, for example from thyroid or parathyroid surgery, cannot produce adequate PTH or at all, which will lead to hypocalcemia by impairing osteoclast activity, which diminishes the efflux of calcium from bone, by enhancing urinary calcium excretion and by inhibiting the renal synthesis of calcitriol, which impairs the intestinal absorption of dietary calcium. PTH deficiency also causes hyperphosphatemia, owing to an increase in the renal tubular reabsorption of phosphate.

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Palopegteriparatide is designed to achieve and maintain a steady concentration of PTH in the blood at levels similar to those observed in healthy individuals. Leveraging the ability of the transient conjugation technology (TransCon) to generate long-acting prodrugs of unmodified parent drugs, palopegteriparatide is designed to restore physiologic levels and activity of PTH throughout 24 hours per day, thereby fundamentally addressing the underlying cause of the symptoms.

MoA of Palopegteriparatide



Source: Ascendis Pharma®

As depicted in the figure above, palopegteriparatide consists of a parent drug, PTH (1-34), transiently bound to an inert carrier (40 kDa mPEG) via a proprietary linker. The carrier inactivates the parent drug and shields it from receptor uptake, renal clearance, and enzymatic degradation. Following a single subcutaneous injection and upon exposure to physiologic pH and temperature, autocleavage of the linker occurs, thus releasing active PTH in a controlled manner and leading to PTH exposure over several days. See “– Transient Conjugation Technology (TransCon)” for more details regarding the transient conjugation technology (TransCon).

Market Opportunity and Competitive Landscape

The prevalence of HP in China was 410.1 thousand in 2023, representing a significant market. No PTH replacement therapy has been approved for HP treatment in China and palopegteriparatide is the only PTH replacement therapy that has initiated clinical development in China. The following charts set forth the PTH replacement therapy that is in clinical development in China.

PTH Replacement Therapy with Clinical Activities in China, as of the Latest Practicable Date

<u>Investigational Drug</u>	<u>Drug Structure</u>	<u>Company</u>	<u>Clinical Status</u>
Palopegteriparatide	Prodrug of PTH	VISEN ⁽¹⁾	Phase 3

Note:

(1) VISEN has gained exclusive licensed rights to develop, manufacture and commercialize in China (including Hong Kong, Macau and Taiwan); Ascendis Pharma retains the rights to develop, manufacture and commercialize outside of China (including Hong Kong, Macau and Taiwan).

Source: CDE, Frost & Sullivan Analysis

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See “Industry Overview – Hypoparathyroidism – Competitive Landscape of the HP Market in China” for more details regarding the market of HP.

Limitations of Currently Available Treatment Options and Potential Advantages of Palopegteriparatide

Treatment of HP is aimed at correcting hypocalcemia and hyperphosphatemia, reducing symptoms, and preventing chronic complications resulting from the disease or its treatment. Due to the limitations of currently available treatment options, the generally accepted target serum calcium concentration for HP patients is in the lower end of the normal range, a state in which symptoms of hypocalcemia are generally uncommon. Current treatments globally generally fall into two categories: conventional therapy and PTH therapy.

- ***Conventional therapy.*** Conventional therapy consists of calcium in combination with active vitamin D and sometimes other supplements. While conventional therapy can increase serum calcium level, it is hard to restore the serum calcium level to a narrow range within the lower end of the normal range. Additionally, conventional therapy often requires the use of very high doses of calcium and active vitamin D, which cause serum calcium fluctuation, high urine calcium and high serum phosphate, potentially putting HP patients at risk for many complications such as impaired renal function and extraskeletal calcifications. Some individuals remain symptomatic or fail to meet treatment goals even after conventional therapy, with some requiring multiple hospitalizations for hypocalcemia or HP complications.
- ***PTH therapy.*** PTH therapy, as a feasible alternative to conventional treatment, has been shown to maintain normocalcemia without the need (or with reduced need) for concurrent treatment with the therapeutic dosage of calcium and active vitamin D analogs. To date, once-daily Natpara (PTH (1-84)) is the only PTH therapy that has been approved in the United States and the European Union, although merely indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with HP. Natpara (PTH (1-84)) received the marketing approval from the FDA in 2015 and a conditional marketing authorization from the EMA in 2017, respectively, but was later recalled from the United States market. Because Natpara (PTH (1-84)) was approved as an adjunct to calcium and vitamin D, it does not eliminate the inherent risks associated with conventional therapy. In addition, PTH (1-84) has not been able to show meaningful benefits on clinical episodes of hypocalcemia or hypercalcemia or effect on 24-hour urine calcium excretion.

According to Frost & Sullivan, Natpara (PTH (1-84)) is the only available PTH therapy, but is unable to achieve the physiological level and activities of PTH due to its short half-life, and therefore does not have an ideal PK. Natpara (PTH (1-84)) has not demonstrated the ability to reduce incidences of hypercalcemia (elevated serum calcium levels), hypocalcemia (low serum calcium) or hypercalciuria (elevated urinary calcium) relative to conventional therapy in treated patients. Unlike PTH (1-84), palopegteriparatide is designed as a once-daily PTH

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therapy with a long half-life to address the fundamental cause of HP by restoring physiological and stable levels of PTH 24 hours throughout the day. PK data from MAD cohorts in Ascendis Pharma's Phase 1 clinical trial of palopegteriparatide in healthy subjects demonstrated a half-life of approximately 60 hours, supporting an infusion-like profile of free PTH. This substantial half-life extension of PTH would reflect more closely the physiological levels of PTH observed in healthy individuals, maintain normal blood calcium levels, normalize urinary calcium excretion, reduce clinical hypercalcemia, reduce clinical hypocalcemia, normalize serum phosphate and normalize bone turnover. This infusion-like PK profile of palopegteriparatide translates into a predictable serum calcium response, suggesting the ability to titrate patients with HP into the normal calcemic range. By providing steady levels of PTH in the physiological range, palopegteriparatide has the potential to address the fundamental limitations of short-acting PTH molecules, such as PTH (1-84) and PTH (1-34) and become a highly differentiated therapy for HP.

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Summary of Clinical Results

The following table sets forth an overview of the key clinical studies of palopegteriparatide:

Trial	Sponsor/Subject/ Trial Status	Primary Endpoint	Secondary Endpoints	Trial Key Summary
Phase 3 PaTHway China Trial* (June 2022 – present) (NCT05387070)	<ul style="list-style-type: none"> The Company Adults with HP Ongoing (Primary Completion in January 2023) 	<p>Multi-component endpoint was defined as the proportion of participants who met the following criteria at Week 26 of blinded treatment:</p> <ul style="list-style-type: none"> Albumin-adjusted serum calcium measured within 4 weeks prior to and at the Week 26 visit within the normal range and alfacalcidol within 4 weeks prior to the Week 26 visit and Independence from therapeutic doses of calcium within 4 weeks prior to the Week 26 visit and No increase in prescribed study drug within 4 weeks prior to the Week 26 visit 	<p>Safety and tolerability, HPES, PD markers (serum calcium) and active vitamin D and effect during Extension Period, BMD, bone turnover markers (serum PINP and CTx), patient-reported health-related QoL and a clinician-reported outcome (ClinRO) assessment</p>	<p>81 subjects enrolled and 80 subjects dosed in the trial. The primary endpoint, defined as the proportion of subjects with albumin-adjusted serum calcium within the normal range, independence from calcitriol or alfacalcidol active vitamin D, and independence from therapeutic doses of calcium at 26 weeks of treatment, and no increase in prescribed study drug within 4 weeks prior to Week 26 visit, was achieved by 77.6% (45 of 58) of palopegteriparatide-treated patients, compared to 0.0% (0 of 22) of patients in control group (p-value <0.0001). The topline data also suggest palopegteriparatide was generally well tolerated, without drug-related serious adverse events, and adverse events leading to discontinuation of the drug in the subjects. The topline data from China Phase 3 pivotal trial demonstrate consistency with the global Phase 3 pivotal trial, in terms of primary endpoint and safety profile.</p>
Phase 3 PaTHway Trial (February 2021 – present) (NCT04701203)	<ul style="list-style-type: none"> Ascendis Pharma Adults with HP Ongoing (Primary Completion in January 2022) 	<p>Multi-component endpoint was defined as the proportion of participants who met the following criteria at Week 26 of blinded treatment:</p> <ul style="list-style-type: none"> Albumin-adjusted serum calcium measured within 4 weeks prior to and at the Week 26 visit within the normal range and alfacalcidol within 4 weeks prior to the Week 26 visit and Independence from therapeutic doses of calcium within 4 weeks prior to the Week 26 visit and No increase in prescribed study drug within 4 weeks prior to the Week 26 visit 	<p>Safety and tolerability, HPES, PD markers (serum calcium) and active vitamin D and antibodies (ADA), treatment effect during Extension Period, BMD, bone turnover markers (serum PINP and CTx), patient-reported health-related QoL and a clinician-reported outcome (ClinRO) assessment</p>	<p>82 adults with chronic HP were enrolled and dosed in the trial. The trial met primary and all key secondary endpoints: 78.7% of patients treated with palopegteriparatide achieved the primary endpoint, defined as serum calcium levels in the normal range (8.3-10.6 mg/dL) and independence from conventional therapy (active vitamin D and >600 mg/day of calcium supplements) with no increase in prescribed study drug within the 4 weeks prior to the 26 weeks visit, compared to 4.8% of patients in the control group (p-value <0.0001), and statistically significant improvements were observed on all key prespecified secondary endpoints (i.e., HPES and SF-36) compared to the control group. In addition, topline results at 52 weeks (OLE period) of the global Phase 3 pivotal trial showed that treatment with palopegteriparatide resulted in sustained improvements through week 52, as well as safety and tolerability similar to that of the initial 26-week double-blind period of the trial. (Aliya A Khan, et al. <i>J Bone Miner Res.</i>2023;38 (1): 14–25)</p>
Phase 2 PaTH Forward Trial (August 2019– present) (NCT04009291)	<ul style="list-style-type: none"> Ascendis Pharma Adults with HP Ongoing (Primary Completion in March 2020) 	<p>To assess the effectiveness of daily TransCon PTH on serum and urine calcium levels (FECa) and active vitamin D and calcium doses at 4 weeks of treatment</p>	<p>Safety and tolerability, HPES, serum and urine calcium levels (FECa), daily pill burden (vitamin D and calcium), serum phosphate, serum magnesium, and calcium x phosphate product (sCa x sP product)</p>	<p>59 individuals with hypoparathyroidism were enrolled and treated with TransCon PTH 15, 18, or 21 µg PTH(1-34)/day or placebo for 4 weeks, followed by a 22-week extension during which TransCon PTH dose was titrated (6-60 µg PTH(1-34)/day). Preliminary data at 26, 58, 84 and 110 weeks from the OLE period of the PaTH Forward Trial supported palopegteriparatide as a potential hormone replacement therapy for adults with HP. (Aliya A Khan, et al. <i>J Clin Endocrinol Metab.</i> 2022; 107(1): e372–e385)</p>

Note: * We in-licensed the palopegteriparatide from Ascendis Pharma in November 2018. Prior to our in-licensing, palopegteriparatide had been studied by Ascendis Pharma in healthy adult volunteers in a Phase 1 trial. Phase 1 trial of performing initial safety or tolerability evaluation in healthy adults and Phase 2 trial of proof-of-concept studies in China have been waived by the NMPA.

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VISEN Pharmaceuticals’ Ongoing China Phase 3 pivotal trial, PaTHway China Trial, in HP

We are developing palopegteriparatide in China in adult HP in a China Phase 3 pivotal trial. The aim of this trial is to assess the efficacy, safety and tolerability of palopegteriparatide in adults with HP to support an NDA filing to the NMPA for palopegteriparatide in adult HP. We screened the first patient in China in November 2021 and completed patient enrollment in June 2022. We completed the double-blind period in January 2023 while the long-term OLE portion of this trial is ongoing as of the Latest Practicable Date.

Study Design. The China Phase 3 pivotal trial, is a multi-center, randomized, double-blind, placebo-controlled trial that was designed to enroll 76 adults with HP. The main inclusion criteria include: (i) males and females aged 18 years old or above; (ii) subjects with postsurgical chronic HP, or auto-immune, genetic, or idiopathic HP for at least 26 weeks; and (iii) doses of conventional therapy (e.g., calcitriol, alfacalcidol, calcium supplements) be at or above a minimum threshold (calcitriol ≥ 0.5 $\mu\text{g/day}$, or alfacalcidol ≥ 1.0 $\mu\text{g/day}$ and (elemental) calcium ≥ 800 mg/day for at least 12 weeks prior to screening.). The main exclusion criteria include: (i) impaired responsiveness to PTH, which is characterized as PTH-resistance, with elevated PTH levels in the setting of hypocalcemia; (ii) any disease that might affect calcium metabolism or calcium-phosphate homeostasis or PTH levels other than HP, such as active hyperthyroidism; and (iii) high risk thyroid cancer within two years.

During the first 26 weeks of the trial, subjects will be randomized in a 3:1 ratio into one of the two treatment groups – once-daily injections of palopegteriparatide at 18 $\mu\text{g/day}$ or placebo for palopegteriparatide (excipient solution), co-administered with conventional therapy. Randomization will be stratified by etiology of HP (postsurgical vs. other). All subjects will start with the study drug (18 $\mu\text{g/day}$) and will be individually and progressively titrated to an optimal dose in dose increments of 3 $\mu\text{g/day}$. Palopegteriparatide or placebo will be administered as a subcutaneous injection using a pre-filled injection pen. Neither trial participants nor their doctors will know who has been assigned to each group. After the 26 weeks, participants will continue in the trial as part of a long-term OLE study of up to 156 weeks. During the 3-year extension, all participants will receive palopegteriparatide, with the dose adjusted to their individual needs in order to enhance local long-term data for future scientific communication.

The primary endpoint for this trial are the proportion of subjects with albumin-adjusted serum calcium within the normal range, independence from calcitriol or alfacalcidol active vitamin D, and independence from therapeutic doses of calcium (i.e., taking calcium supplements ≤ 600 mg/day) at 26 weeks of treatment. The key secondary endpoints for this trial are change from baseline in HP patient experience scale (“HPES”) and change from baseline in 36-Item Short Form Survey (“SF-36”) at 26 weeks of treatment. HPES is a well-developed, disease-specific, PRO measure to assess the symptoms and impacts associated with HP in adults.⁴ The HPES-symptom assesses the key HP-related physical and cognitive symptoms

4 <https://jpro.springeropen.com/articles/10.1186/s41687-021-00320-2>

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from the patient perspective. The HPES-impact assesses the key impacts of these symptoms on patient functioning and well-being, including physical functioning, daily life, psychological well-being and social life and relationships. SF-36 is a multipurpose short-form health survey with 36 questions that yields an eight-scale profile of functional health and general well-being, as well as two psychometrically-based physical and mental health summary measures and a preference-based health utility index. It is viewed as a practical, reliable and valid measure of physical and mental health. The primary and key secondary efficacy endpoints will be measured at predefined timepoints during the period of the long-term OLE study.

Convenient Prefilled Pen. A single-patient-used prefilled pen will be included in this ongoing trial for administration of palopegteriparatide and placebo according to the study protocol. With this convenient prefilled pen, subjects can inject study drug on their own after receiving brief training. According to the study protocol for this Phase 3 pivotal trial, the China Phase 3 pivotal trial, palopegteriparatide is supplied as a solution with a concentration of 0.3 mg PTH (1-34)/mL in a single-patient-use prefilled pen intended for subcutaneous injection. Excipients include metacresol, mannitol, succinic acid, and NaOH/(HCl). The prefilled pens are stored in the refrigerator until first use; the palopegteriparatide drug product is stable at room temperature below 86°F (30°C) for the 14 days in-use period when dosing with the pre-filled pen. Three presentations of the prefilled pen containing palopegteriparatide drug product are available, which are 6, 9, and 12 µg/day; 15, 18, and 21 µg/day; and 24, 27 and 30 µg/day, respectively. The placebo for palopegteriparatide drug product (excipient solution in the pens) are in three pen presentations to mimic dose ranges of 6, 9, and 12 µg/day; 15, 18, and 21 µg/day; and 24, 27 and 30 µg/day, respectively, within the Blind Treatment Period. We intend to include this pen device as part of our NDA filing to the NMPA, making the convenient prefilled pen available to patients using our marketed drug.

Based on the topline data from China Phase 3 pivotal trial, the primary endpoint, defined as the proportion of subjects with albumin-adjusted serum calcium within the normal range, independence from calcitriol or alfacalcidol active vitamin D, and independence from therapeutic doses of calcium (i.e., taking calcium supplements ≤ 600 mg/day) at 26 weeks of treatment, and no increase in prescribed study drug within 4 weeks prior to Week 26 visit, was achieved by 77.6% (45 of 58) of palopegteriparatide-treated patients, compared to 0.0% (0 of 22) of patients in control group (p-value < 0.0001). 89.7% of palopegteriparatide-treated patients achieved independence from conventional therapy, and palopegteriparatide treatment demonstrated a statistically significant improvement compared to control group at Week 26 in HPES Symptoms Physical Domain scores (P=0.022). The mean observed 24-hour urine calcium values had normalized in the palopegteriparatide-treated patients (164.9 mg/day) but not in the control group (253.2 mg/day). Additionally, with palopegteriparatide treatment, bone turnover markers increased above baseline suppressed levels. As expected in HP, bone density was at the upper end of normal at baseline and trended down toward mid-normal with palopegteriparatide therapy. The topline data also suggest palopegteriparatide was generally well tolerated, without drug-related serious adverse events and adverse events leading to discontinuation of the drug in the subjects. The topline data from China Phase 3 pivotal trial demonstrate consistency with the global Phase 3 pivotal trial, in terms of primary endpoint and safety profile.

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PaTHway R Study for HP

In addition to the China Phase 3 pivotal trial, we entered into a strategic cooperation agreement with Peking University Health Science Center to initiate the PaTHway R study in July 2021, in order to enhance the understanding of the real-world clinical practice of disease management in China for HP. PaTHway R is the first registry study for HP in China and one of the largest epidemiological surveys for this disease worldwide and was kicked off in January 2022. This study is expected to recruit at least 500 patients in eight top hospitals as investigational sites with a goal to provide evidence of diagnosis, treatment, economic burden, and quality of life of the patients with HP. As of December 23, 2022, this study had completed the patient enrollment of a total of 526 subjects. We expect that the data from this study could help the scientific society yield a whitepaper and update the Treatment Guideline for HP, as well as to generate data to support the reimbursement negotiation of palopegteriparatide into NRDL.

Future Clinical Development Plan

We successfully obtained IND approval from the NMPA in May 2021 and initiated a China Phase 3 pivotal trial, in China for the treatment of adult HP by screening the first patient in November 2021. In accordance with the study protocol, we intend to use the data from the double-blind period to support an NDA submission to the NMPA for palopegteriparatide in adult HP, while we continue to conduct the OLE portion of this trial.

Licenses, Rights and Obligations

We hold exclusive rights to develop, manufacture and commercialize palopegteriparatide in China (including Hong Kong, Macau and Taiwan) on a royalty-free basis. See “– Collaborations – Exclusive License Agreements with Ascendis Pharma” for more details regarding our exclusive license arrangements with Ascendis Pharma.

Our R&D Work

We have been the sole sponsor of China clinical study and remain in charge of the clinical development process in China since in-licensing of palopegteriparatide. As further disclosed below, we are fully responsible for the following aspects of the R&D activities for the development of palopegteriparatide in China: (i) IND preparation, (ii) pre-IND communication and IND approval, (iii) trial preparation of site selection, (iv) clinical trial personnel training, (v) medical monitoring and data management, (vi) statistical management, and (vii) patient enrollment, and have exclusive control over the supervision of clinical sites as well as the coordination of external vendors. We have the research expertise or access to the research expertise required for the development of palopegteriparatide, including medical science, regulatory, clinical operation, quality assurance, pharmacovigilance and data management, statistics and medical affairs.

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We incurred R&D expenses of RMB55.5 million, RMB19.6 million and RMB6.9 million on the development of palopegteriparatide in 2022, 2023 and the four months ended April 30, 2024, respectively. We anticipate that we will incur significantly more costs and expenses in connection with our future R&D work as discussed below.

During the Track Record Period, we procured R&D consulting services from Ascendis Pharma with respect to pharmacovigilance and biometry for data analysis, for example, statistical programming and statistical analysis which, as advised by Frost & Sullivan, is consistent with the industry practice. The amount of R&D consulting services rendered by Ascendis Pharma relating to palopegteriparatide was RMB0.9 million, RMB0.7 million and RMB0.1 million in 2022, 2023 and the four months ended April 30, 2024, respectively.

IND Preparation

Since the in-licensing of palopegteriparatide, our senior management has led an internal R&D team and worked in close collaboration with our scientific advisory board and industry-leading CROs to carry out R&D activities. Upon receiving the relevant clinical data from Ascendis Pharma, our R&D team reviewed all the data generated from the global trials of palopegteriparatide and prepared for clinical trial initiations in China. Taking into consideration the specific disease epidemiology, disease characteristics, local clinical practice as well as the status of the PTH market in China, we prepared the clinical study protocol of palopegteriparatide in China to verify the efficacy and safety of palopegteriparatide in Chinese population in order to support the future clinical development and regulatory filings for palopegteriparatide in China.

Additionally, in December 2020 our R&D team organized a meeting with the KOLs on the scientific advisory board to optimize the study designs for palopegteriparatide's China alone trial. The study designs have taken into consideration both (i) the scientific rationale, such as MoA, well established pre-clinical data and the most updated global clinical data, the global study protocol, as well as local clinical practice; and (ii) market opportunities in China, such as addressable patient population, product positioning and competitive landscape of palopegteriparatide.

Pre-IND Communication and IND Approval

During pre-IND communication, waiver of Phase 1 and 2 trial and immunogenic assay have been accepted by CDE. In the current China Phase 3 pivotal trial, quality of life questionnaires has been used for patient life quality evaluation. In China, we received the IND approval from the NMPA in May 2021 to develop palopegteriparatide for the treatment of adult HP.

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Trial Preparation of Site Selection

We conducted a number of activities in connection with trial preparation and site selection, including:

- Developing and approving trial-related documentation, including, without limitation, the finalized protocol, informed consent form, case report form;
- Assessing potential challenges and risks for study conduct and other medical considerations;
- Establishing operational strategies including recruitment strategy;
- Evaluating site feasibility and preparing related submission to the HGRAC; and
- Ensuring all study preparation including investigational drug and clinical supplies was ready before the first patient was randomized.

Leveraging our insights and expertise in the endocrinology field, we managed to obtain the HGRAC approval and complete site initiation in an efficient manner. We completed the first site initiation on October 15, 2021. The last site has been completed on March 24, 2022. Overall, we engaged a total of 14 GCP certified investigational sites specialized in endocrinology across China for this Phase 3 pivotal trial.

Clinical Trial Personnel Training

In order to complete a smooth and high-quality Phase 3 pivotal trial, we designed a systematic training program with respect to the equipment to be used for the trial, including:

- Central image system dual X-ray absorptiometry (“DXA”) that measures the bone mineral density (“BMD”) and trabecular bone score (“TBS”) for the assessment of the secondary efficacy endpoints for this trial;
- Electronic data capture (“EDC”) system that collects the clinical data in electronic format;
- Interactive response technology (“IRT”) that automates patient randomization, kit assignment, drug supply; and
- Central lab system that collects blood samples.

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Medical Monitoring and Data Management

We developed a comprehensive medical monitoring and data management plan encompassing the following:

- *Monthly monitoring of medical data.* During the trial, we continuously monitor the quality of data entry, including the progress report, data entry rate, source data verification ("SDV") rate, open query rate, missing page numbers, medical coding correctness, external data transfer and safety data reconciliation with pharmacovigilance database.
- *Real-time communication of AEs.* For reported SAEs, pharmacovigilance staff and medical staff and our clinical operation team send the inquiry to the investigators. The investigators then complete the follow-up report form with the follow-up information of the subjects.
- *Real-time communication of protocol deviation cases.* Our medical and clinical operation team discusses protocol deviation cases, analyzes the causes and solutions for each case, and provides feedback to clinical supervisors and main researchers to avoid the recurrence of such events.

Future R&D Work

We expect to engage in additional R&D work in connection with the ongoing China Phase 3 pivotal trial and the preparation of regulatory filings of palopegteriparatide in China. In connection with our expected NDA with the NMPA for palopegteriparatide, we expect to receive consulting services from Ascendis Pharma to support our biostatistical activities including data programming and statistical analysis, which is consistent with the industry practice.

Material Communications with the NMPA

On March 22, 2021, the NMPA accepted our IND application to the NMPA to initiate the China Phase 3 pivotal trial of palopegteriparatide, in China for the treatment of HP.

On May 31, 2021, we obtained IND approval to initiate this Phase 3 pivotal trial.

As of the Latest Practicable Date, we have not received objections to our clinical development plans with respect to the regulatory review or approval process of palopegteriparatide in China.

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WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET PALOPEGTERIPARATIDE IN CHINA (INCLUDING HONG KONG, MACAU AND TAIWAN) SUCCESSFULLY.

TRANSIENT CONJUGATION TECHNOLOGY (TRANSCON)

Our drug pipeline is generated based on transient conjugation technology (TransCon) developed by Ascendis Pharma. Transient conjugation molecules have three components: an existing parent drug, an inert carrier that protects it, and a linker that temporarily binds the two. When bound, the carrier inactivates and shields the parent drug from clearance. After distribution into the body, transient conjugation enables unmodified parent drug to be released in a predictable manner and maintain physiologic activity. Overall, transient conjugation technology (TransCon) is designed to combine known biology with the benefits of prodrug and sustained-release technologies to potentially optimize therapeutic effect, which could mean enhancing efficacy, improving tolerability and convenience, or reducing caregiver burden.

Transient conjugation linkers. Transient conjugation linkers are reversible linkers that enable the transient conjugation of a broad range of therapies, including proteins, peptides and small molecules, to transient conjugation carriers. Transient conjugation linkers can be applied to various types of parent drugs and be tailored to achieve half-life extension enabling daily, weekly, monthly and half-yearly dosing, and customize the PK profile for each individual drug candidate to potentially optimize the therapeutic effect. Transient conjugation linkers are self-cleaving through an intra-molecular assisted cleavage process causing the linker to release the unmodified parent drug at predetermined rates governed by physiological pH and temperature conditions, which are tightly regulated in the body. Consequently, transient conjugation platform-enabled prodrugs can be designed to release the unmodified parent drug at predictable rates.

Transient conjugation carriers. Transient conjugation carriers are self-eliminating hydrogels that inactivate and protect the drug through a shielding effect, which prevents rapid excretion and degradation of the parent drug and may enable benefits that include improved injection site tolerability, reduced systemic adverse effects and low immunogenicity. Our drug candidates, lonapegsomatropin, TransCon CNP (navepegritide) and palopegteriparatide, are built on systemic carriers and are readily absorbed into the bloodstream after administration, thus minimizing exposure of the subcutaneous tissue to active drug, which has the potential to improve injection site tolerability.

Parent drug. The transient conjugation technology (TransCon) is applicable across a broad range of therapeutic classes and are currently used to create long-acting product candidates based on proteins, peptides and small molecules. Because the parent drug is unmodified, its original mode of action is expected to be maintained, which could lead to a potentially higher development and regulatory success rate for our drug candidates as compared to the development of drug compounds without established biology.

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The transient conjugation technology (TransCon) is designed to combine known biology with the benefits of conventional prodrug and sustained release technologies to solve the fundamental limitations seen in other approaches to extending duration of a drug’s action in the body. The FDA and EMA approvals of lonapegsomatropin for PGHD represents the first marketing approvals obtained by a drug generated from the transient conjugation technology (TransCon) and an important milestone that demonstrates the effectiveness and vast potential of the transient conjugation technology (TransCon).

RESEARCH AND DEVELOPMENT

We are dedicated to building a pipeline of endocrine therapies in China (including Hong Kong, Macau and Taiwan). We believe successful clinical development execution is critical to our future growth and our ability to remain competitive in the biopharmaceutical market in China.

R&D Team and Capabilities

We have a strong China-based in-house clinical R&D team led by a seasoned management team with strong therapeutic area expertise and experience in global biopharmaceutical development, medical practice and strategic planning. We have assembled senior R&D personnel with extensive expertise in clinical development, regulatory affairs, medical affairs, and CMC, headed by Dr. WANG Yan, Mr. David YU, Mr. GU Qing and Dr. ZHU Jing, respectively. Our R&D team is led by the foregoing four department heads collectively. Our R&D capabilities are also supported by our scientific advisory board comprising reputable KOLs in endocrinology and pediatrics.

Below sets forth information about our R&D team heads that play key roles in leading the development of our each drug candidate and local manufacture project as of the Latest Practicable Date:

- *Head of Clinical Development, Dr. WANG Yan.* Dr. Wang has over 19 years of drug development experience in global pharmaceutical industry (Ipsen, Pfizer, Servier) and local innovative biotech company (Huahui Health, Beijing HAFO Biomedical Research & Development Co., Ltd.), covering therapeutic areas including endocrinology and metabolism, pediatric, rare disease, oncology, cardiovascular disease, psychology, neurology and hepatology. Dr. Wang has three years of medical practitioner experience in pneumology and gastroenterology and six years of research experience in hepatology and hepatitis during post-graduate period. Dr. Wang obtained her bachelor’s degree in clinical medicine from Beijing Medical University (北京醫科大學) (currently known as Peking University Health Science Center (北京大學醫學部)) in the PRC in July 1995. Dr. Wang further obtained her master’s in internal medicine and doctoral degree in infectious disease from Peking University (北京大學) in the PRC in June 2001 and June 2004, respectively.

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- *Head of Regulatory Affairs, Mr. David YU.* Mr. Yu has over 20 years of experience in handling investigational new drug application, biologics license application and new drug application for both local and imported products, covering biologic products and chemicals. He has served as the regulatory affair head of innovative drug registration at Shanghai Pharma Group before joining the Company. During his career in regulatory affairs, Mr. Yu has also held registration leadership positions at BMS and Parexel CRO in China. Mr. Yu obtained his bachelor's degree in pharmaceuticals from Peking University Health Science Center (北京大學醫學部) in the PRC in July 1999 and his master's in economics from Beijing International Studies University (北京第二外國語學院) in the PRC in June 2011.
- *Head of Medical Affairs, Mr. GU Qing.* Mr. Gu has over 22 years of experience in global pharmaceutical industry (Xian Janssen Pharmaceutical, GlaxoSmithKline, Novo Nordisk, AstraZeneca and Lilly China) as product manager, marketing manager and director, brand director, and has four years of experience as medical practitioner. Mr. Gu obtained his bachelor's degree in prevention medicine from Nanjing Railway Medical College (南京鐵道醫學院) (later merged into Southeast University (東南大學)) in the PRC in July 1995.
- *Head of CMC, Dr. ZHU Jing.* Dr. Zhu has about 14 years of research and working experience in biologics CMC process development and manufacturing, with focus on CMC technical management and biologics drug product development and manufacturing. Dr. Zhu worked at I-Mab Biopharma and WuXi Biologics prior to joining us. Dr. Zhu obtained her master's in pharmaceutics from Tianjin University in July 2009 and her doctoral degree in pharmacy from University of Nottingham in March 2015.

Below is a breakdown of our R&D personnel working on the three drug candidates as of the Latest Practicable Date.

<u>Department</u>	<u>Number of Employees*</u>	<u>R&D Roles and Responsibilities</u>
Clinical Development Head	1	Oversee and coordinate clinical operation, clinical science, quality GCP, data manager, pharmacovigilance and statistician
Clinical science	2	Protocol development, medical monitoring, CSR
Data manager	1	Data management
Statistician	1	Statistical plan, statistical analysis
Clinical operations	9	Clinical study conduct, drug supply
Pharmacovigilance	1	Drug safety, pharmacovigilance

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Department	Number of Employees*	R&D Roles and Responsibilities
Quality GCP	2	Quality assurance (following GxP guidance)
Regulatory affairs	5	Regulatory activities in relation to China authority, such as IND/BLA/quality control testing
Medical affairs	7	Epi data of disease collection, communication and engage KOLs for product and disease
CMC	7	CMC-related activities including process, analytical and formulation development, and pre-clinical, clinical and commercial supply manufacturing support
Total	36	

Note:

* During the Track Record Period and up to the Latest Practicable Date, none of our R&D staff has been previously employed by Ascendis Pharma, and Ascendis Pharma has no R&D staff whose sole job responsibility is to interact with us.

Our R&D team has extensive expertise in medical science, regulatory, clinical operation, quality assurance, pharmacovigilance and data management, statistics, and medical affairs, enabling us to lead and guide the external CROs and collaboration partners in a more efficient and effective manner. As of the Latest Practicable Date, our R&D team consists of 36 full-time employees, with approximately 41% holding a Ph.D. or an M.D. degree. We expect to grow our R&D team as we continue our development activities. Almost all of our R&D team members have in-depth industry knowledge and clinical development experience in multinational companies. Our R&D team has an average of over 14 years of experience in the clinical development of drugs and/or endocrine therapies and some of them have extensive expertise in endocrinology and related areas and worked on the clinical development of other endocrine drugs. Despite experiencing employee turnover within a reasonable range, primarily due to retirements or resignations for personal reasons, which did not have any material impact on our R&D capabilities or business operations going forward, we maintain a robust and relatively comprehensive R&D organization structure, as demonstrated by a series of R&D milestones that we have achieved during the Track Record Period.

To date, our R&D team has demonstrated a strong capability to optimize study design and development strategy in China, which has enabled us to advance our drug candidates directly into pivotal studies, work seamlessly with our collaboration partners, and conduct clinical execution in an efficient manner. Specifically, in April 2022, we completed the China Phase 3 pivotal trial of the Core Product; in January 2023, we completed the double-blind period for

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the ongoing China Phase 3 pivotal trial of palopegteriparatide; and in March 2023, TransCon CNP (navepegritide) has completed the double-blind period of Phase 2 clinical trial in China for the treatment of ACH. In anticipation of the indication expansion of ISS for the Core Product, we plan to expand our R&D team in respect of clinical operation starting from early 2025. We also plan to build up our R&D team in CMC field, such as drug product development scientist and quality assurance manager, based on the respective expected timeline for Technology Transfer and Localization and collaboration with WuXi Biologics. As demonstrated by a series of R&D milestones achieved by us during the Track Record Period and up to the Latest Practicable Date, we believe our in-house R&D team with talent pool expanding with our future R&D timeline will be sufficient for the purpose of executing our R&D activities independently without assistance from Ascendis Pharma. Further, between 2024 and 2026, we expect to continue to conduct R&D activities in relation to the lonapegsomatropin drug substance technology transfer and localization, which involves transferring the know-how of and localizing the manufacturing technology of the Core Product drug substance from Ascendis Pharma to us at the designated local CDMO, WuXi Biologics. During the same period, we will develop dual chamber device (DCD) technology for the drug product and conduct comparability studies to prove that the locally produced drug product is comparable to the imported drug product. Upon the completion of relevant R&D activities and obtaining the Local BLA registration, we will be able to manufacture the Core Product independently without assistance from Ascendis Pharma. With our insights and expertise in the endocrinology field, we believe we are able to navigate the research, development, regulatory and commercialization landscape in China and seek opportunities to maximize the full value of each of our pipeline assets and future endocrine drug candidates. For further details regarding the R&D activities conducted by us to date, see “– Our Drug Pipeline – Lonapegsomatropin – A Long-Acting hGH Replacement Therapy for PGHD – Our R&D Work,” “Palopegteriparatide – A PTH Replacement Therapy Addressing the Underlying Cause of HP – Our R&D Work” and “TransCon CNP (navepegritide) – A Disease-Modifying Therapy for ACH – Our R&D Work.” For further details regarding the lonapegsomatropin drug substance technology transfer and localization and DCD technology development, see “– Research and Development – CMC Development Programs.”

Clinical Development Programs

Since the in-licensing of our drug candidates from Ascendis Pharma, our senior management has led an internal clinical R&D team and worked in close collaboration with our scientific advisory board and industry-leading CROs to carry out R&D activities. Our R&D team reviewed all relevant clinical data generated from the global clinical trials of the three drug candidates conducted by Ascendis Pharma and prepared for clinical trial initiations in China. Leveraging strong domain knowledge in the specific disease epidemiology, disease characteristics, local clinical practice as well as the current status of the market for the indications targeted by these drug candidates, our R&D team designed and implemented the study protocol for the clinical trials in China, and has successfully completed the pivotal Phase 3 trial of lonapegsomatropin for PGHD, the double-blind period of pivotal Phase 3 trial of palopegteriparatide for adult HP and the double-blind period of Phase 2 trial of TransCon CNP (navepegritide) for ACH.

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The study designs have taken into consideration both (i) the scientific rationale, such as MoA, well established pre-clinical data, the most updated global clinical data, the global study protocol, and local clinical practice; as well as (ii) market opportunities in China, such as addressable patient population, product positioning and competitive landscape of each of our drug candidates. Our clinical R&D team organized a number of meetings with the KOLs on our scientific board to optimize the study designs for our drug candidates. In addition, our R&D team engaged in pre-IND communications with the NMPA, have made multiple IND submissions to the NMPA and have obtained the IND approval for all of our drug candidates.

Our R&D team manages all key aspects of our trials, oversees clinical development work and performs the following functions: (i) clinical development strategy; (ii) market assessment and demand analysis; (iii) trial proposal and protocol design, including study objectives and primary/secondary endpoints; (iv) clinical site selections, initiations, management and monitoring; (v) biostatistics, including data management and programming; (vi) pharmacovigilance; (vii) quality assurance; (viii) investigator and site contracts; (ix) medical and safety monitoring; (x) clinical data collection and statistical analysis; and (xi) regulatory submission and communication. In addition, we leverage our external CROs to perform clinical trials. We implemented a variety of measures to guide our CROs, including comprehensive planning ahead of trial execution, regular communication and quality check of working progress, milestone program based on quality assurance check, and a vendor management system.

For further details regarding the R&D activities conducted by us to date, refer to “– Our Drug Pipeline – Lonapegsomatropin – A Long-Acting hGH Replacement Therapy for PGHD – Our R&D Work,” “– Our Drug Pipeline – Palopegteriparatide – A PTH Replacement Therapy Addressing the Underlying Cause of HP – Our R&D Work” and “– Our Drug Pipeline – TransCon CNP (navepegritide) – A Disease-Modifying Therapy for ACH – Our R&D Work.” For further details regarding the R&D activities to be conducted by and responsible by us under the applicable Exclusive License Agreements, refer to “– Collaborations – Exclusive License Agreements with Ascendis Pharma.”

CMC Development Programs

Lonapegsomatropin Drug Substance Technology Transfer and Localization

According to the Exclusive License Agreement, we have the contractual right to obtain full knowledge of the Core Product drug substance manufacturing technology knowhow from Ascendis Pharma. To realize the medium-term commercial supply of lonapegsomatropin, in July 2023, we entered into a bilateral Technology Transfer Master Plan of the Core Product with Ascendis Pharma, which has marked the commencement of the Technology Transfer with respect to the manufacturing of the Core Product from Ascendis Pharma to us and sets forth the obligations of both parties under the Exclusive License Agreement with respect to the Technology Transfer. After completion of the Technology Transfer, we will have the full knowledge of the Core Product drug substance manufacturing technology knowhow to independently collaborate with WuXi Biologics or any other chosen CDMO in China. Further,

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in December 2023, we entered into a bilateral collaboration agreement with WuXi Biologics, pursuant to which WuXi Biologics will serve as the local CDMO of the Technology Transfer to conduct the process development and validation achieving the localization of the manufacturing technology. Completion of the Technology Transfer and Localization, which is expected to be in 2026, will confer to us the technical capabilities to manufacture the Core Product drug substance in collaboration with WuXi Biologics.

To implement the technology transfer, WuXi Biologics will, as requested by us, prepare a Technology Transfer Protocol to outline the scope of work, the process flow, and the expected timeline of the technology transfer. The Technology Transfer Protocol will be acknowledged by Ascendis Pharma and us to standardize the technology transfer procedures between the transferring units and the recipient. We do not expect to enter into a tripartite contractual arrangement with Ascendis Pharma and WuXi Biologics with respect to the Technology Transfer and Localization process of the Core Product.

The following table sets forth the details of the Technology Transfer Master Plan we entered into with Ascendis Pharma and the collaboration agreement we entered into with WuXi Biologics.

	Technology Transfer Master Plan (Our Company, Ascendis Pharma)	Collaboration Agreement (Our Company, WuXi Biologics)
Signing Date	July 2023	December 2023
Scope of Work	Ascendis Pharma shall transfer (i) know-how and documentations, (ii) manufacturing process, including hGH intermediate, lonapegsomatropin drug substance and UBP2 enzymatic cleavage reagent, and (iii) analytical methods for hGH intermediate, lonapegsomatropin drug substance and UBP2 enzymatic cleavage reagent to our Company and selected local CDMO.	WuXi Biologics shall serve as the local CDMO for the purpose of the Technology Transfer and Localization, and conduct process development, process validation, and BLA support of both the lonapegsomatropin drug substance and dual chamber device development of the Core Product. We will entrust WuXi Biologics with the local commercial supply of the Core Product.
Payment	No payment is required.	We are required to make payments to Wuxi Biologics according to the payment schedule agreed by the parties.

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	<u>Technology Transfer Master Plan (Our Company, Ascendis Pharma)</u>	<u>Collaboration Agreement (Our Company, WuXi Biologics)</u>
Confidentiality	To ensure the confidentiality of the technical information, a three-way confidentiality agreement has been signed among our Company, Ascendis Pharma and the selected CDMO, WuXi Biologics.	We and Wuxi Biologics agree to keep confidential any information in relation to the performance of the agreement that is reasonably deemed as confidential.

Dual Chamber Device Technology Development

In addition to the Technology Transfer and Localization, we are developing in-house DCD technology in the form of prefilled syringe as a drug delivery system for freeze-dried powder formed from lonapegsomatropin drug substance, as part of the intellectual property of the drug delivery system currently used for lonapegsomatropin overseas is owned by an overseas drug product contract manufacturing organization who is not able to transfer such technology to us and at the same time does not own relevant allowed patent in China (including Hong Kong, Macau and Taiwan), which allows us to develop in-house DCD technology free of potential patent infringement with the contract manufacturing organization, as advised by our legal adviser as to intellectual property law.

The DCD system addresses the limitations encountered by traditional drug delivery system, including time-consuming preparation and susceptibility to contamination dosing. The DCD system integrates two separate medication components in a single device, keeping the chambers separate until administration to ensure the drug's stability and integrity until it is ready for use. The core technology of DCD involves the design and development of a container closure system with two separate chambers that can be connected prior to use, enabling storage and reconstitution of a drug and a diluent in a single device, alongside advanced filling and freeze-drying manufacturing that surpass traditional drug delivery system.

Our senior R&D personnel led by the head of our CMC team, Dr. ZHU Jing, are equipped with the expertise in biologics drug product development and are committed to the development of the DCD technology in-house. As of the date of this document, we have successfully achieved the lab-scale production of the DCD product. We expect to transfer the DCD product manufacturing process which has been developed at lab-scale by our Company to WuXi Biologics. Process characterization studies will be conducted to analyze critical process parameters in order to establish a well-controlled list of critical quality attributes. See “– Commercial Supply and Manufacturing – Step 2: Collaborative Local Manufacturing with Local CDMO” for more details.

Local BLA

The Technology Transfer and Localization arrangement and the DCD development pave our path to obtaining the Local BLA approval and achieving the collaborative local manufacturing of the Core Product at the commercial scale, in details as follows.

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Timeframe	Lonapegsomatropin Drug Substance Technology Transfer and Localization (Our Company, Ascendis Pharma and WuXi Biologics)	Dual Chamber Device (DCD) Development (Our Company and WuXi Biologics)
2023-2026E	<ul style="list-style-type: none"> • <i>Technology Transfer and Localization and lab-scale lonapegsomatropin drug substance production.</i> Technical documents and know-how are being transferred from Ascendis Pharma to us and selected CDMO to implement the laboratory-scale studies, for example, transferring raw materials, methods reference standards and technical information to WuXi Biologics that will conduct the laboratory studies, gap analysis, process facility fitness studies, methods transfer and verification at the laboratory, and local process lock. • <i>Manufacturing scale-up from lab-scale to the Good Manufacturing Practice (GMP) production.</i> <ul style="list-style-type: none"> ○ GMP manufacturing preparation: equipment, facility and materials. ○ Engineering run production for the purpose of demonstrating that the local process can be scaled-up successfully and get ready for the Process Performance Qualification (PPQ) runs. ○ Process Performance Qualification (PPQ) run production to demonstrate the capability of reproducible commercial manufacturing. 	<ul style="list-style-type: none"> • <i>In-house lab-scale development.</i> As of the Latest Practicable Date, by utilizing the Pre-PPQ DS, we have developed in-house the DCD technology in the form of prefilled syringe as a drug delivery system for the lonapegsomatropin drug substance at lab-scale, including the development of the DCD container closure system, verifying the drug product process, evaluating compatibility with the container closure system, and assessing equipment and infrastructure requirements. • <i>Anticipated DCD know-how transfer from our Company to Wuxi Biologics and process characterization.</i> We expect to transfer the DCD product manufacturing process which has been developed at lab-scale by our Company to WuXi Biologics. Process characterization studies will be conducted to analyze critical process parameters in order to establish a well-controlled list of critical quality attributes. • <i>Manufacturing scale-up.</i> We plan to conduct engineering runs to scale up the manufacturing process from lab-scale to at-scale production, ensuring the quality consistency of the DCD products. • <i>Process Validation.</i> Validation studies will subsequently be conducted to ensure that the manufacturing process consistently yields DCD products that adhere to predefined quality standards.

As the Core Product is a biological product combined with the TransCon technology, its manufacturing process involves plenty of steps and strict quality control. As advised by Frost & Sullivan, completion of both lonapegsomatropin drug substance technology transfer and the DCD technology development in approximately three years is in line with the industry normal practice, upon which time we would possess the technology and capability to produce the Core Product independently in China and there is no additional technology required for us. The cost of the foregoing projects mainly consists of FTE costs, material costs for various batches from lab-scale to commercial scale, and CDMO charges. We have allocated approximately HK\$[REDACTED] million (representing [REDACTED]% of [REDACTED] of the [REDACTED]) for the foregoing projects. See “Future Plans and Use of [REDACTED]” for more details.

BUSINESS



Timeframe

Local BLA Preparation and Submission

2026E-
2028E

With the completion of both lonapegsomatropin drug substance technology transfer and the DCD technology development, we plan to target the following in relation to the BLA preparation and submission:

- Conduct stability study of the PPQ batch samples
- Conduct comparability studies of the locally produced product against the imported product to provide analytical confirmation that the similar quality attributes between locally produced product and the imported product, including CMC lab comparison and animal study comparison
- Compile BLA dossier
- Submit the Local BLA with the NMPA
- Prepare for the pre-approval inspection from the NMPA



2028E

Expected Local BLA Approval and Commencement of Collaborative Local Manufacturing

Under the Exclusive License Agreement, we have established the preliminary framework for a purchase agreement with Ascendis Pharma concerning materials intended for the Technology Transfer and Localization upon the successful completion of the [REDACTED]. Currently, only initial arrangements have been made under this framework, with no additional actions taken at this stage. We believe that it is unlikely to fail in reaching such agreement with Ascendis Pharma, given that (i) such agreement will be on normal commercial terms and is for both parties' mutual benefits, and (ii) the raw materials purchase is a necessary part of the Technology Transfer and Localization which Ascendis Pharma shall cooperate in good faith to facilitate pursuant to the Exclusive License Agreement entered with us.

Scientific Advisory Board

Our R&D team is backed by a scientific advisory board comprising reputable KOLs in endocrinology and pediatrics in China. Our scientific advisory board provides expertise and advice to our product portfolio strategy including providing inputs to our development plan, and execution and lifecycle management of our pipeline drug candidates, and also assists with the overall supervision of the product portfolio development and enrichment.

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Members of our scientific advisory board are not employees of our Group and we compensate them for providing the above services based on hourly rates at fair market value for a term of one year subject to a service fee cap, and arrange for travel and accommodation for their attendance of the consultation meeting in accordance with the consulting service agreements they entered into with the Company.

Two previous members of our scientific advisory board serve as principal investigators (the “Overlapping Members”) for our clinical programs – one member served as the principal investigator for our completed Phase 3 pivotal trial for lonapegsomatropin in PGHD in China, and the other member served as the principal investigator for the China Phase 3 pivotal trial for palopegteriparatide in adult HP in China. A principal investigator is a physician who leads the conduct of a clinical trial at a study site. According to GCP, the principal investigator is responsible for ensuring the study is conducted in accordance with regulatory requirements and GCP. Compliance with GCP provides for assurance that the rights, safety and well-being of trial participants are protected, and that the results of the clinical trials are credible and accurate. Pursuant to their respective consulting service agreements, each of the Overlapping Members was entitled to a maximum of RMB120,000 based on an hourly rate of RMB3,000 for up to 40 hours during a term of one year, which was determined on an arm’s length basis at prevailing market rate. For the year ended December 31, 2021, the Overlapping Members received RMB3,000 and RMB32,000, respectively, for their services rendered pursuant to their respective consulting service agreements, which were within the service fee cap under the relevant consulting service agreements.

Our principal investigators were employees of the trial sites who are contracted and compensated by the trial sites for supervising our clinical trials. They are not employees of our Group and we do not enter into contracts with them for acting as the principal investigators in connection with our clinical trials. We selected qualified clinical trial sites based on their qualifications and experience, contracted with the sites for conducting our clinical trials and reimbursed the sites for the expenses incurred by them in carrying out the trials including employee costs. The principal investigators were contracted and compensated by the trial sites as their employees for supervising our clinical trials. In addition, one of the Overlapping Members had been serving as a member of the steering committee for our study of lonapegsomatropin since October 2019. He received certain compensation for the two years ended December 31, 2020 and 2021, respectively for the consulting services provided in connection with the study designs of lonapegsomatropin under the relevant consulting service agreement he entered into with the Company, which were determined on an arm’s length basis and based on an hourly rate at prevailing market rate.

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Our PRC Legal Adviser confirmed that our consulting service arrangements with the Overlapping Members, are in compliance with the PRC law and there is no requirement from the NMPA or other competent PRC authorities regarding: (i) the compensation paid by us to members of our scientific advisory board who are also our principal investigators, and (ii) the disclosure of the above compensation paid by us.

We believe that we have implemented sufficient measures to ensure the integrity of our clinical studies and the independence of the opinions of our clinical trial principal investigators on the basis that (i) our Phase 3 pivotal trial of our Core Product for the treatment of PGHD was specifically designed in accordance with the applicable protocol and legal, regulatory and scientific standards, to ensure that no individual could impact the outcome of the study once the protocols were established and the trial commenced. We are not aware of any incidents or conflict of interests that resulted in any breach of applicable standards or laws by our principal investigators when providing services in connection with our clinical trials; (ii) under the consulting service agreements, the Overlapping Members must declare sponsorship from the Company if their services provided under their respective consulting service agreements involve direct contact with the patients, and undertake that they will remain independent of all decisions relating to drug choice they make; (iii) our principal investigators are required to comply with GCP, GVP, and other regulatory regulations and guidelines enforced by the NMPA and comparable regulatory authorities for all of our drug candidates in clinical development as well as their employers' internal policies, which provide for procedures to ensure that trials are properly conducted and generation of reliable data; and (iv) we maintain a qualified and experienced quality assurance team responsible for ensuring that we and our investigators and CROs maintain compliance with all applicable regulations, standards, protocols and internal policies.

Steering Committee for Phase 3 Pivotal Trial in PGHD in China

To ensure smooth initiation and operation of scientifically-sound studies, we set up a steering committee comprising KOLs, overseas clinical professional experts and biostatisticians. Three investigators sit in the steering committee, including Professor Xiaoping Luo, who holds various positions in Tongji Hospital, Tongji Medical College of Huazhong University of Science and Technology, Professor Junfen Fu from Children's Hospital of Zhejiang University School of Medicine and Professor Chunxiu Gong from Beijing Children's Hospital. Professor Ruihua Sun from China-Japan Friendship Hospital and Professor Martin O. Savage from London, United Kingdom are the Biostatistical Expert and Consultant of the steering committee, respectively. The steering committee provides expertise and advice in order to supervise the progress of the trial, reviews at regular intervals all relevant information that may affect the study conduct as well as endorse and support patient enrollment goals in compliance with relevant guidelines.

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Data Monitoring Committee for Phase 2 Clinical Trials of TransCon CNP (navepegritide) in Children with ACH

A data monitoring committee (“DMC”) was established for the global Phase 2 trial and the China Phase 2 trial, both of which are clinical trials for TransCon CNP (navepegritide) in children with ACH. The DMC convenes to provide recommendations on the action to be taken (i.e., continue the trial(s) (including planned dose escalation) without modification; continue the trial(s) with modifications; or discontinue the trial(s)) based on review of the unblinded data. In the global Phase 2 trial, once all participants in a cohort have received at least 12 weeks of treatment, the DMC will review all available data and make a recommendation regarding the initiation of the next higher dose cohort. In the China Phase 2 trial, the DMC will determine the dose level for the open label period, based on the dose escalation data in both the global Phase 2 trial and the China Phase 2 trial. The Chairperson of the DMC is Erin Nissen Castelloe, MD, a pharmaceutical medicine consultant based in California, United States. The DMC also consists of three other members who are reputable in the areas of endocrinology and pediatrics. Bradley S. Miller, MD, PhD is Professor of Pediatrics, Pediatric Endocrinology from University of Minnesota Masonic Children’s Hospital. Eric T. Rush, MD, FAAP, FACMG holds various positions including the Clinical Geneticist in the Division of Clinical Genetics and the Medical Director of the Office of Faculty Affairs and Development in Children’s Mercy Kansas City, the Associate Professor of Pediatrics in University of Missouri-Kansas City, and the Clinical Associate Professor (Volunteer) of Internal Medicine of University of Kansas Medical Center. Huijuan Zhu, MD is the Chief Physician of the Department of Endocrinology, Peking Union Medical College Hospital in Beijing, China.

Relationships with CROs and SMOs

We collaborate with reputable CROs and SMOs for the support of our clinical trials in line with industry practice. We select our CROs and SMOs through an objective bidding process, considering multiple factors such as professional experience, qualifications, quality assessment and service fees, among others. Our CROs offer a comprehensive range of services required for complex clinical trials in accordance with the agreed trial design and under our supervision, while our SMOs provide an extensive array of services to assist us in executing and overseeing clinical trials, including trial preparation, clinical safety management, data management, and report preparation. We choose to engage CROs and SMOs based on the complexity, flexibility, and workload of specific trial requirements, allowing us to leverage the experience and expertise of our in-house team on critical elements like clinical science, new site selection, and early setup, while delegating other tasks to the CROs and SMOs. We closely monitor our CROs and SMOs to help ensure their performance will comply with all applicable laws and regulations as well as follow our protocols, which in turn protects the integrity and authenticity of the data from our clinical trials and studies. We have demonstrated our ability to conduct clinical trials in a reliable and efficient manner through collaboration with CROs and SMOs through the multiple milestones we have achieved so far.

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We have worked with CROs and SMOs for our clinical trials, including the clinical trial for lonapegsomatropin. For example, under our respective agreements with the CRO and the SMO in relation to the clinical trial for lonapegsomatropin, we are responsible for protocol development and medical monitoring, while the CRO and the SMO take responsibility for clinical monitoring, project management, data management and clinical study report. In return for their services, we make scheduled payments as agreed in the agreements. We and the CROs and SMOs are allowed to contract for multiple projects through the issuance of multiple work orders without having to re-negotiate the basic terms contained in the agreement, for which extra fees will be incurred. Under the agreements, we own all intellectual property and trial results and the CRO and the SMO must maintain strict confidentiality with respect to the information they acquired from us during clinical trials.

During the Track Record Period, we engaged 4 CROs and 3 SMOs, respectively. The following table sets forth the details of our major CRO and SMOs we engaged during the Track Record Period.

Major CRO and SMOs	Background	Involvement and Contribution	Annual Transaction Amount as of December 31,			Transaction Amount For the Four Months Ended April 30,
			2022	2023	2024	
			RMB'000	RMB'000	RMB'000	
Supplier C	A CRO based in Hangzhou, providing full value chain for clinical development	<ul style="list-style-type: none"> Core Product: safety evaluation, clinical trial execution, and central image, CSR preparation Palopegteriparatide: assist us with data management, safety information collection and biostatic analysis TransCon CNP (navepegritide): pharmacovigilance service for safety evaluation 	5,355	1,413	679	

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Major CRO and SMOs	Background	Involvement and Contribution	Transaction Amount For the		
			Annual Transaction Amount as of December 31,		Four Months Ended April 30,
			2022	2023	2024
			RMB'000	RMB'000	RMB'000
SMO A	A SMO based in Shanghai, providing all in all medical research service	Implementation and management of clinical trials for the core production palopegteriparotide in the PRC, including trial preparation, clinical safety management, data management and report preparation	1,860	935	160
SMO B	A SMO based in Hangzhou, providing all in all medical research service	Implementation and management of clinical trials for the core production of our three drug candidates in the PRC, including trial preparation, clinical safety management, data management and report preparation	1,062	595	61
SMO C	A SMO based in Beijing, providing all in all medical research service	Implementation and management of clinical trials for the core production of TransCon CNP (navepegtrotide) in the PRC, including trial preparation, clinical safety management, data management and report preparation	267	33	30
		Total	8,544	2,976	930

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R&D Expenses

For each year ended December 31, 2022, 2023 and the four months ended April 30, 2024, our total R&D expenses amounted to RMB179.5 million, RMB57.7 million and RMB25.8 million, respectively. See “Financial Information” for more details. We expect that our R&D expenses to increase generally in line with the advancement of our clinical and development programs in the future.

During the Track Record Period, we procured R&D consulting services from Ascendis Pharma mainly for the following activities: (i) for lonapegsomatropin, (a) the pharmacovigilance and biometry for data analysis including statistical programming and statistical analysis, and (b) the regulatory strategy advice and documentation support to prepare for our Import BLA submission package with the NMPA; (ii) for TransCon CNP (navepegritide) and palopegteriparatide, the pharmacovigilance and biometry for data analysis including statistical programming and statistical analysis. The amount of R&D consulting services rendered by Ascendis Pharma relating to our three drug candidates was RMB8.0 million, RMB10.0 million and RMB5.1 million in 2022, 2023 and the four months ended April 30, 2024, respectively. In connection with our expected R&D and regulatory activities of three drug candidates, we expect to procure R&D consulting services from Ascendis Pharma mainly for the following activities: (i) for lonapegsomatropin, (a) the technology transfer of lonapegsomatropin drug substance from Ascendis Pharma to us, and (b) consulting the technology localization process that involves the lonapegsomatropin drug substance manufacturing scale-up; (ii) for TransCon CNP (navepegritide) and palopegteriparatide, the support of data programming and statistical analysis, and the regulatory strategy advice and documentation support in connection with our expected NDA with the NMPA. See “Connected Transactions – Non-Exempt and Partially-Exempt Continuing Connected Transactions – Exclusive License Agreements” for more details.

COMMERCIALIZATION PLAN, PATIENT SUPPORT AND MARKET ACCESS

We are solely responsible for and take full control over the commercialization of our Core Product and two drug candidates in China (including Hong Kong, Macau and Taiwan). We build up our in-house commercialization team in line with the overall R&D and commercialization timeline of our drug candidate pipeline. In the past few years, we have built up a specialized commercialization team with strong expertise in endocrinology, to drive medical activities in the market of China (including Hong Kong, Macau and Taiwan) in accordance with local rules and regulations. In April 2021, we added Dr. CHEN Jun, Ph.D., as Chief Commercial Officer to our management team, to enhance our commercialization capabilities. Dr. Chen has over 25 years of experience in the healthcare industry and over 20 years of experience in the commercialization of endocrine products, including growth hormone. The addition of Dr. Chen enabled us to initiate the development of our product launch team (including aspects of medical affairs and commercial strategy development) of ten employees as of the Latest Practicable Date. In addition to Dr. Chen, our product launch team also includes key leadership members such as medical affairs and marketing head Mr. GU Qing, who has 18 years of marketing experience in the healthcare industry, and commercial strategy development head Mr. PAN Haifeng, who has 22 years of experience in the

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commercialization of endocrine products. We believe our key commercialization leadership members, who have substantial experience and strong track records relevant to our pipeline drug candidates, can leverage their expertise launching endocrine drugs in China (including Hong Kong, Macau and Taiwan).

In anticipation of the potential BLA approval of our Core Product in mid-2025 and subsequent commercial launch later that year, we plan to expand our commercial team equipped with field sales, regional marketing, medical affairs and customer service functions starting from early 2025. We also plan to build up our commercial infrastructure for palopegteriparatide and TransCon CNP (navepegritide) based on the respective expected commercial launch timeline. We believe our internal commercialization team with expanded talent pool will be sufficient for the purpose of executing our commercialization plan. Further, we have entered into a strategic collaboration agreement with Shanghai Pharmaceutical aiming to establish the necessary management framework in line with the GSP. We have also entered into the strategic collaboration with the United Family Healthcare to jointly develop capabilities in diagnosis, treatment and services for children with medical needs in growth and development.

The following sets forth the commercialization plans and strategies devised by our product launch team for the three drug candidates in the market of China (including Hong Kong, Macau and Taiwan).

Lonapegsomatropin

Lonapegsomatropin has the potential to capture a significant share in the highly attractive hGH market in China. China accounted for the largest share of the global hGH market in 2023, reaching RMB11.6 billion in 2023 at a CAGR of 23.9% from 2018 to 2023. The hGH market in China is expected to continue its fast growth to reach RMB28.6 billion in 2030, powered by increasing patient penetration, extending average duration of treatment, and growing acceptance of LAGH treatment. The LAGH market is expected to increase from approximately 25.0% in 2023 to approximately 73.8% in 2030 of the total hGH market in China. The hGH market in China is characterized with patient payment primarily out-of-pocket and sales primarily from private hospitals and clinics, resulting in hGH product prices being less vulnerable to various price-cutting measures such as price negotiation in NRDL and price cut in volume-based procurement. The future competitive landscape of LAGH is expected to be moderate, as there is currently one LAGH product available and only a handful of products under development. Lonapegsomatropin, with its profiles in efficacy, safety and convenience, is a promising drug candidate among the potential competitors. Our commercialization strategies will be in line with the expected growth of hGH and LAGH market size by focusing on the following areas: (i) recognizing the importance of understanding the market and patient needs and conducting necessary market research and feasibility studies to ensure our product meets the market need; (ii) ensuring clear communication of our product's benefits to the target market; and (iii) establishing effective sales channels and distribution network and ensuring supply capacity to meet the market demand.

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Our initial focus of commercialization is patients suffering from short stature and diagnosed with PGHD. The commercial goal for lonapegsomatropin is two-fold: (i) to accelerate market upgrade from short-acting daily growth hormone to long-acting weekly growth hormone; and (ii) to establish lonapegsomatropin as the leading LAGH.

To realize our commercial goals, we have devised a competitive and productive promotional program. The hGH market in China is highly concentrated, with the majority of PGHD diagnoses being made by pediatric endocrinologists in around 200 top-tier hospitals in China. To maximize the coverage of our target customer segment, we have identified around 1,000 public hospitals as our target market, including all major children's hospitals as well as major Tier 3 hospitals and some Tier 2 hospitals with sizable pediatric departments. We plan to establish a relatively small but elite commercial team in the first few years after our first commercial launch to cover the top-tier hospitals and to establish the brand position, followed by expanding the team to cover most of target market. For hospitals beyond our target market, we plan to establish external partnerships with distributors and/or CSOs to broaden patient accessibility through incremental coverage across China. In addition to focusing on the target public hospitals that handle the majority of PGHD diagnoses, we also plan to establish extensive coverage of private hospitals/clinics, which are responsible for approximately 67% of hGH sales, where drug listing is relatively simple and patients can have easy access to treatment initiation, prescription refills and quality customer services.

We also plan to deploy a series of programs towards patients undergoing lonapegsomatropin therapy. These programs include providing a comprehensive patient starter kit, offering assistance from a professional service team, and developing a digital patient service platform to enhance patient experience and convenience. The digital patient service platform includes social media and app that offer features such as injection guidance, FAQs, refill-services, and virtual classrooms. This platform creates an ecosystem connecting patients, caregivers and physicians, aiming to improve the treatment experience and optimize compliance and treatment outcomes. As PGHD patients have higher annual treatment costs and longer treatment durations compared to many common chronic diseases, we expect such programs will be productive.

We expect the pricing of our Core Product to be determined by various factors such as (i) the competitive landscape of the addressable market at the time of our commercial launch, (ii) the value propositions of our Core Product including the drug efficacy and safety as well as the drug administration convenience, (iii) the supply and production costs, and (iv) our pricing strategies. As the Core Product is currently under the BLA review by the NMPA, we have not formulated concrete pricing strategy at this stage but we expect that the Core Product will be priced at a fair premium compared to its competitors in China (including Hong Kong, Macau and Taiwan), reflecting its value propositions. As the hGH market in China is characterized with patient payment primarily out-of-pocket and sales primarily from private hospitals and clinics, we plan to primarily focus on the self-pay market for the commercialization of our Core Product. We plan to promote our Core Product primarily through our in-house sales and marketing team through various marketing activities focusing on promoting the clinical benefits and accessibility of our Core Product. We may also engage contract sales organizations

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to promote our Core Product in peripheral cities or regions that are otherwise not covered by our in-house sales and marketing team. We will collaborate with distributors to establish an effective distribution network of our Core Product. For this purpose, we have entered into a strategic collaboration agreement with Shanghai Pharmaceutical aiming to establish the necessary management framework in line with the GSP.

We plan to provide the treatments in selected endocrinology diseases by highlighting four key product advantages: (i) lonapegsomatropin preserves the natural dual mode MoA of endogenous growth hormone by releasing unmodified hGH, which includes both a direct effect at the bone plate and the indirect effect mediated by IGF-1 at the liver. With this advantage, lonapegsomatropin is the only LAGH that has demonstrated superior efficacy and comparable safety in active-controlled and parallel-group trial comparisons with daily hGH, as validated in the completed Phase 3 pivotal trial in China, potentially enabling children with PGHD to achieve treatment goals more effectively within a limited treatment time window; (ii) lonapegsomatropin demonstrates key pharmacological profiles, including a molecular structure of the active drug substance, receptor binding affinity, plasma concentration, tissue distribution, and a safety profile comparable to daily hGH, which has been utilized by clinicians for over 30 years with a high level of confidence in its safety. In contrast, the other LAGHs permanently alter the molecular structure of hGH, resulting in new active drug molecules that have significantly different pharmacological profiles from the daily hGH and limited clinical experience; (iii) lonapegsomatropin offers more than 300 injection-free days per year compared to daily hGH, thus could greatly improve treatment compliance and treatment outcomes; and (iv) lonapegsomatropin can be stored for 54 months at 2-8°C or up to six months at room temperatures of $\leq 30^{\circ}\text{C}$, a more patient-friendly storage requirement than other growth hormone products that typically require constant storage at 2-8°C and for no more than 24 months. This advantage offers great flexibility for children with PGHD and their caregivers, enabling convenient transportation and usage of the medication. By effectively communicating the value propositions of lonapegsomatropin to HCPs, we anticipate successfully persuading prescribing doctors about the product’s benefits and establishing a promising position in the market.

Since the commercial launch of lonapegsomatropin by Ascendis Pharma in the fourth quarter of 2021, Ascendis Pharma has recorded sales revenue of lonapegsomatropin of EUR0.9 million, EUR35.7 million and EUR178.7 million in 2021, 2022 and 2023, respectively, according to its annual reports.

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TransCon CNP (navepegritide)

ACH is a widely recognized condition that can be readily diagnosed by experienced pediatricians, resulting in a high awareness and diagnosis rate. Patients with ACH have normal mental development and a pressing need for treatment prior to reaching puberty. There is no available disease-modifying drug to treat ACH in China. TransCon CNP (navepegritide) is the only disease-modifying drug under clinical development in China with positive efficacy results in clinical trials. Once approved, TransCon CNP (navepegritide) is expected to be utilized by patients over several years during the growth period from two to 15 years. In addition, TransCon CNP (navepegritide) has a long half-life of 120 hours porting once-weekly dose administration.

Once TransCon CNP (navepegritide) is commercially available, our main commercial goals are to build up the awareness of ACH among key stakeholders, establish TransCon CNP (navepegritide) as the standard of care for ACH, and establish patient access. The successful execution of this commercial strategy holds the potential to achieve a rapid revenue uptake from TransCon CNP (navepegritide).

To build up the disease awareness among key stakeholders, we have already formed a strategic alliance with CHARD in 2020 and supported its ApproaCH Registry Study, which was kicked off in April 2021 and aims to generate China specific epidemiology data on ACH, including disease prevalence, disease burden, and current diagnosis and treatment status. The study will help key stakeholders understand the patient burden and potentially facilitate the future inclusion of TransCon CNP (navepegritide) into NRDL, eventually benefitting most patients with ACH in China. We have actively supported the establishment of October 3 as ACH day in China and have been involved in organizing various patient activities in relation to this important day over the past years.

To standardize ACH diagnosis and treatment, we have supported the development of the first ACH Expert Consensus in China on Diagnosis and Treatment which was published in Chinese Journal of Pediatrics in July 2021. Once TransCon CNP (navepegritide) is approved, we plan to work with academy association, CHARD and clinical experts to update ACH treatment guideline in China and establish TransCon CNP (navepegritide) as the standard of care for ACH.

To establish market access of TransCon CNP (navepegritide) after its approval, we have advocated for the inclusion of ACH in the second China Rare Disease List issued by the National Health Commission in September 2023, highlighting the commission's commitment to improving disease treatment and increasing medicine accessibility for ACH. TransCon CNP (navepegritide), as a potential treatment for ACH, can benefit from multiple favorite policies for rare diseases in clinical development, drug registration, pricing and market access. Once the product is approved, we will leverage the rare disease designation of ACH and the result of ApproaCH Registry Study to include TransCon CNP (navepegritide) into the NRDL and establish broad patient access.

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We expect TransCon CNP (navepegritide) to be included in the NRDL soon after its approval by undergoing the pricing negotiation process with relevant governmental authorities. To optimize resources and maximize the effectiveness of our commercial efforts for TransCon CNP (navepegritide), we have devised a comprehensive and productive program. Given that the group of HCPs specialized in endocrinology or genetic diseases who treat ACH largely overlaps with the target HCPs for lonapegsomatropin, we plan to leverage the promotional synergy between TransCon CNP (navepegritide) and lonapegsomatropin. This includes utilizing the shared field medical representative team, patient service infrastructure, channel and distribution network, thereby minimizing the required promotion resources for TransCon CNP (navepegritide).

Palopegteriparatide

HP is a chronic disease characterized by the deficiency of PTH, which plays a crucial role in calcium and phosphate metabolism. HP affects a significant patient population, with approximately 410 thousand individuals affected in 2023. Patients with HP experience daily challenges related to both physical and mental well-being and often require lifelong treatment. The optimal approach for managing HP involves PTH replacement therapy to compensate for the insufficient physiological levels of PTH in the body. Currently, there is no available PTH replacement therapy for HP due to the extremely short half-life of native PTH, which lasts only a few minutes. Palopegteriparatide, by leveraging the ability of the transient conjugation technology (TransCon) to generate long-acting prodrugs of unmodified parent drugs, successfully extends the half-life of PTH to 60 hours, and is potentially the first PTH replacement therapy for HP treatment over multi-year or even lifetime. Palopegteriparatide possesses many advantages over conventional therapy as demonstrated in the Phase 3 clinical trials, and is the most advanced PTH replacement drug under clinical development in China with few competing products.

The commercial goal for palopegteriparatide includes market development, patient access and establishing HP treatment centers. Once commercially launched, we expect a rapid revenue uptake of palopegteriparatide.

To develop the HP market, we have supported the PaTHway R study, the first China HP registry study which kicked off in January 2022. This study aims to generate epidemiology data of HP in China, including disease prevalence, disease burden, and current diagnosis and treatment status. The study will help key stakeholders understand the patient burden and broaden disease awareness. We have also planned for extensive patient education activities through patient advocacy and social media to raise the awareness of HP and its disease burden, and ultimately increase diagnosis and treatment rates. We have already started operating a HP disease education platform in WeChat which has attracted around 5,000 subscribers, a potential patient pool after palopegteriparatide launch. We have actively supported the establishment of June 1 as the HP Day in China and have been involved in organizing various patient activities in relation to this important day over the past years. We also plan to work with academic associations and clinical experts to update the HP diagnosis and treatment guideline to include Palopegteriparatide as the PTH replacement therapy for HP.

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To establish market access of palopegteriparatide after its approval, we have advocated for the inclusion of genetic HP in the second China Rare Disease List issued by the National Health Commission in September 2023, highlighting the commission’s commitment to improving disease treatment and increasing medicine accessibility for genetic HP. Palopegteriparatide, as a potential treatment for HP (including genetic HP), can benefit from multiple favorable policies for rare diseases in clinical development, drug registration, pricing and market access. Once the product is approved, we will leverage the rare disease designation of genetic HP, the result of PaTHway Registry Study and clinical value to include Palopegteriparatide into NRDL and establish broad patient access. A sample program is also planned to provide patients with easier access to the therapy.

We expect palopegteriparatide to be included in the NRDL soon after its approval by undergoing the pricing negotiation process with relevant governmental authorities. We plan to deploy an effective and productive commercial program for palopegteriparatide. We plan to deploy our commercial resources in a “hub-and-spoke” model. We plan to support dozens of major hospitals with HP treatment expertise to establish HP Center of Excellence across China as “hubs.” HP patients can receive high-quality diagnosis and key therapy decisions at these “hubs.” In addition, we plan to cover a few hundred regional hospitals as “spokes.” The “spoke” hospitals can identify potential HP patients, channel them to “hubs” for key therapy decisions, while providing easy access for patients’ prescription refills and ongoing HP management. As most HP patients are treated by adult endocrinologists, we plan to deploy a separate adult endocrinology medical representative team and MSL team to cover these hospitals. The “hub-and-spoke” model may allow us to leverage a small but elite medical representative team and productive promotion program to cover broad geographic areas and a large patient pool.

COMMERCIAL SUPPLY AND MANUFACTURING

We plan to implement a three-step plan to source commercial supply for the commercialization of lonapegsomatropin as early as possible and address the vast domestic market potentials in China (including Hong Kong, Macau and Taiwan) effectively and secure sustainable drug supply for local patients.

Step 1: Commercial Drug Procurement from Importation

In the short term, we plan to source the commercial drug supply of Core Product from our collaboration partner, Ascendis Pharma. We have signed a Commercial Supply Agreement in October 2023 with Ascendis Pharma in anticipation of the potential BLA approval and subsequent commercial launch of the Core Product. We agreed to purchase and Ascendis Pharma agreed to sell, lonapegsomatropin drug packages, auto-injectors and demo products. The amount to be paid to Ascendis Pharma shall be determined by the manufacturing costs that may be incurred by Ascendis Pharma plus an additional 20% markup. The Commercial Supply Agreement will secure the imported drug supply after the expected BLA approval for the initial commercial launch of the Core Product in China. We expect the quantity of relevant products

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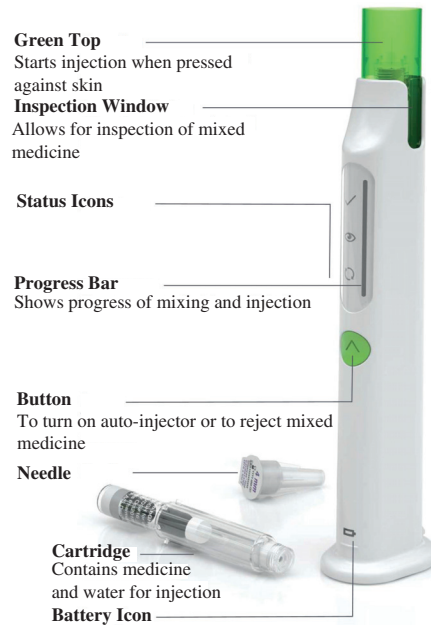
to be sufficient for the initial commercial launch according to our commercialization plan. We may utilize the [REDACTED] of the [REDACTED] to fund payment for the commercial supply of additional Core Product from Ascendis Pharma based on the market demand, before our expected collaborative local manufacturing capability is established in 2028.

After the expected initial commercial launch of the Core Product in China, patients for drug administration of the imported Core Product will need to purchase (i) lonapegsomatropin drug package, comprising (a) Core Product in the form of dual chamber cartridge injection, and (b) disposable injection needle; and (ii) a separate auto-injector, which is reusable in nature and can improve patient injection experience and compliance. The Core Product is used exclusively with the auto-injector. In the short term, we will procure the lonapegsomatropin drug packages and auto-injectors from Ascendis Pharma pursuant to the Commercial Supply Agreement.

The approvals from the FDA and EMA of lonapegsomatropin include an auto-injector and cartridges which, after first removed from a refrigerator, allow families to store the medicine at room temperature for up to six months. This is the first FDA-approved once-weekly pediatric growth hormone delivered with an auto-injector. This state-of-the-art auto-injector was first introduced in the enliGHten Trial and was designed to be user-friendly and improve treatment compliance for pediatric with GHD. The auto-injector provides a fully automated reconstitution of the lyophilized drug product which is followed by a manual mixing step controlled by the device. With simple operation, the device has a single, low-volume injection for the majority of patients of less than 0.6 mL and requires a small, 31-gauge needle that is only 4 millimeters in length, which is comparable to needles used to administer daily hGH. When the injection needle is inserted into the skin, the device automatically delivers the drug product. The built-in electronics and software assist the user during the entire preparation and injection sequence and provide confirmation that the full dose has been delivered.

According to relevant laws and regulations in China, the auto-injector is classified a medical device exempted from clinical trial requirements in accordance with the Catalogue of Medical Devices Exempted from Clinical Evaluation (《免於臨床評價醫療器械目錄》) promulgated by the NMPA, and requires the registration dossier with the NMPA separate from the BLA submission for the Core Product for PGHD. The import medical device registration application for the auto-injector was submitted by a third-party marketing authorization holder to the NMPA in June 2023 and has been approved in April 2024, ahead of the expected BLA approval date of the Core Product for PGHD in the mid of 2025. Since the Core Product is used exclusively with the auto-injector produced by such marketing authorization holder, we expect to rely on its auto-injector supply before we establish our collaborative local manufacturing capability with local CDMO. See “– Commercial Supply and Manufacturing – Step 2: Collaborative Local Manufacturing with Local CDMO.”

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Source: Ascendis Pharma[®]

In relation to the Commercial Supply Agreement, we entered into a quality agreement with Ascendis Pharma in June 2024, which elaborated details of the Commercial Supply Agreement to ensure compliance with GMP and other relevant laws and regulatory guidelines for the Core Product production. Further, we may utilize the [REDACTED] of the [REDACTED] to fund the payment for additional commercial supply of lonapegsomatropin from Ascendis Pharma based on the market demand. See “Future Plans and Use of [REDACTED]” for more details. Even if in the unlikely event that the execution of the foregoing additional commercial supply agreement fails, we will still be able to commercialize our drug candidates in China (including Hong Kong, Macau and Taiwan) under existing contractual arrangement with Ascendis Pharma. Therefore, we believe any failure to execute the foregoing additional commercial supply agreement will not directly hamper our business, financial condition or results of operations.

For our other drug candidates in the pipeline, we may determine to source the commercial drug supply of TransCon CNP and palopegteriparatide from Ascendis Pharma in the future subject to the pace of the regulatory review and our commercialization plan.

Step 2: Collaborative Local Manufacturing with Local CDMO

In the medium term, we will collaborate with WuXi Biologics for the commercial production of lonapegsomatropin. Upon the completion of CMC R&D work and the approval of the Local BLA, which is expected in 2028, we will commence the product supply and commercial sales of the Core Product produced at the local CDMO, WuXi Biologics.

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As advised by Frost & Sullivan, in the context of rapidly growing new drug development costs, increasingly complex development processes, and even more intense competition, multinational pharmaceutical and biotechnology companies have continued to increase outsourcing to CDMOs, and the reliance on CDMO services is in line with the industry norm. Going forward, we will regularly assess CDMO performance based on metrics such as on-time delivery, product quality and cost-effectiveness. We will ensure to establish trust and commitment with CDMO through transparent communication and collaboration, which we believe will allow for better risk-sharing and problem solving. In the long term, we will build internal capabilities for manufacturing our products in-house to reduce our reliance on CDMO. See “– Commercial Supply and Manufacturing – Step 3: In-house Manufacturing.”

Step 3: In-house Manufacturing

In the long term, we plan to establish our in-house manufacturing capabilities.

We strive to establish a recognized and leading franchise in endocrinology that integrates research and discovery, clinical development, commercialization, manufacturing and business development and become a partner of choice for endocrine treatment looking to enter China (including Hong Kong, Macau and Taiwan), which we believe will enable us to more deeply explore the hGH market in China, which has already exceeded RMB11.6 billion by 2023, increasing at a CAGR of more than 23.9% over five years.

Strategic Change Regarding Commercial Drug Procurement Arrangement

In relation to the Core Product supply, we entered into three agreements with Ascendis Pharma in details as follows. See “Connected Transactions” for more details.

	<u>Cost Sharing and Volume Commitment Agreement</u>	<u>Commitment and Pre-payment Agreement⁽¹⁾</u>	<u>Commercial Supply Agreement</u>
Signing Date	December 2021	August 2022	October 2023
Term	December 2021 – December 2026	August 2022 – upon fulfilment of obligations thereunder	N/A

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	<u>Cost Sharing and Volume Commitment Agreement</u>	<u>Commitment and Pre-payment Agreement⁽¹⁾</u>	<u>Commercial Supply Agreement</u>
Description	The Cost Sharing and Volume Commitment Agreement dictates that we have the right to reserve from Ascendis Pharma the volume of lonapegsomatropin drug substance produced at Overseas CDMO B (as defined below in note (1)) until 2026 for future production of the Core Product to be supplied by Ascendis Pharma.	The Commitment and Pre-payment Agreement was entered pursuant to the Cost Sharing and Volume Commitment Agreement, and we confirmed with Ascendis Pharma that two batches of lonapegsomatropin drug substance to be produced at Overseas CDMO B (“Reserved Drug Substance”) will be reserved for future production of the Core Product to be supplied by Ascendis Pharma.	The Commercial Supply Agreement was entered in anticipation of the potential BLA approval and subsequent commercial launch of the Core Product. We agreed to purchase, and Ascendis Pharma agreed to sell, lonapegsomatropin Drug Package (as defined below), auto-injector and Demo Product (as defined below).
Product	Lonapegsomatropin drug substance	Lonapegsomatropin drug substance	<ul style="list-style-type: none"> • Drug package, comprising (i) dual chamber cartridges containing lonapegsomatropin drug substance, and (ii) injection needle (“Drug Package”). • Auto-injector • Demo product items intended for marketing display (“Demo Product”).

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	<u>Cost Sharing and Volume Commitment Agreement</u>	<u>Commitment and Pre-payment Agreement⁽¹⁾</u>	<u>Commercial Supply Agreement</u>
Product Quantity	Not exceeding 25% of the reserved capacity of lonapegsomatropin drug substance by Ascendis Pharma at Overseas CDMO B.	N/A ⁽¹⁾	<ul style="list-style-type: none"> • Drug Package: four batches upon our notification to Ascendis Pharma to initiate manufacturing, specifying the amount to be allocated to each batch. • Auto-injector: four batches to be delivered to us following our binding purchase orders specifying the requested amount. • Demo Product: specified amount.
Consideration	Amount to be paid to Ascendis Pharma shall be determined by 25% of the actual costs incurred by Ascendis Pharma for the establishment of production capacity of lonapegsomatropin at Overseas CDMO B, with our total payment not exceeding 25% of the total estimated cost in the Cost Sharing and Volume Commitment Agreement without our prior written consent.	N/A ⁽¹⁾	Amount to be paid to Ascendis Pharma shall be determined by manufacturing costs that may be incurred by Ascendis Pharma plus an additional 20% mark up.

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	<u>Cost Sharing and Volume Commitment Agreement</u>	<u>Commitment and Pre-payment Agreement⁽¹⁾</u>	<u>Commercial Supply Agreement</u>
Status	<p>In 2022, 2023 and the four months ended April 30, 2024, the amount paid by us to Ascendis Pharma under the cost sharing arrangement was approximately RMB21.6 million, RMB8.5 million and nil, respectively. In exchange, we obtained ownership of certain amount of Pre-PPQ lonapegsomatropin drug substance⁽²⁾ from Ascendis Pharma. Due to the completion of this project, we expect to incur no further costs under such cost sharing arrangement.</p>	<p>Due to the Strategic Change⁽¹⁾, we exercised the right to cancel our commitment to purchase the Reserved Drug Substance (as defined below) in February 2023.</p>	<ul style="list-style-type: none">• Drug package: a payment of RMB39.2 million (EUR5.0 million) was made by us for the Drug Package in November 2023. The remaining purchase price of the Drug Package will be paid in two installments in later stage in line with our commercialization plan.• Auto-injector: no payment has been made during the Track Record Period.• Demo Product: no payment has been made during the Track Record Period.

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	<u>Cost Sharing and Volume Commitment Agreement</u>	<u>Commitment and Pre-payment Agreement⁽¹⁾</u>	<u>Commercial Supply Agreement</u>
Impact on the commercialization plan	<p>The Cost Sharing and Volume Commitment Agreement has not yielded commercial supply to us. However, it has secured a backup supplier of lonapegsomatropin drug substance at Overseas CDMO B in case it is needed, and enables us to obtain certain amount of Pre-PPQ lonapegsomatropin drug substance⁽²⁾ which the Company that can be used for ongoing and future R&D activities.</p>	<p>N/A⁽¹⁾</p>	<p>The Commercial Supply Agreement will secure the imported drug supply after the expected BLA approval for the initial commercial launch of the Core Product in China. We expect the quantity of relevant products under the Commercial Supply Agreement to be sufficient for the initial commercial launch according to our commercialization plan. We may utilize the [REDACTED] of the [REDACTED] to fund the payment for the commercial supply of lonapegsomatropin from Ascendis Pharma based on the market demand. See “Future Plans and Use of [REDACTED]” for more details.</p>

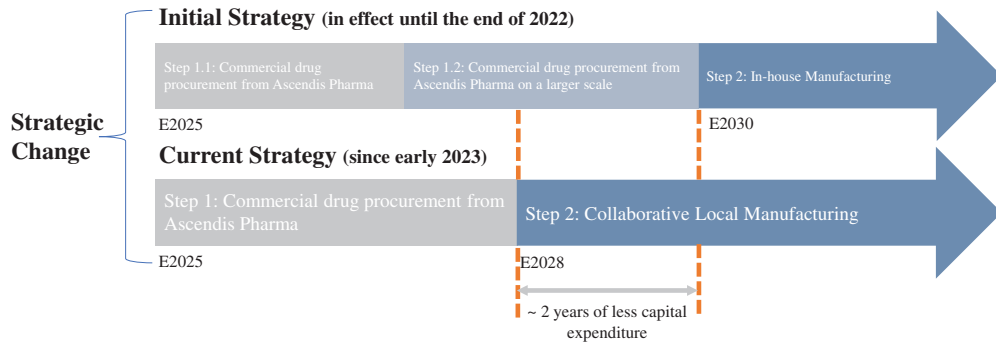
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Notes:

- (1) Strategic change relating to the lonapegsomatropin drug procurement and local manufacturing plan

In light of our focus on capital efficiency and sustainability as well as uncertainties surrounding the capital market and the related impacts, we have made strategic change (the “Strategic Change”) relating to the lonapegsomatropin drug procurement and local manufacturing plan. Initially, we planned to (i) sell imported drugs supplied by Ascendis Pharma with drug substance produced by an overseas CDMO A (“CDMO A”), and in line with the projected market demand, transit to (ii) sell imported drugs supplied by Ascendis Pharma with drug substance produced by an overseas CDMO B (“CDMO B”) who is capable of producing drug substances in larger scale compared to that of CDMO A, and (iii) ultimately sell drugs produced locally by building our own manufacturing facility (collectively, the “Initial Strategy”). Under the current strategy, (i) in the short term, we will sell imported drugs supplied by Ascendis Pharma with drug substance produced by the CDMO A, and (ii) in medium term, we will partner with WuXi Biologics, the chosen local CDMO, to achieve local manufacturing of Core Product, instead of building our own manufacturing facility (collectively, the “Current Strategy”).

The chart below illustrates our transition from the Initial Strategy to the Current Strategy:



As part of our Strategic Change, we have taken the following strategies:

Cancellation of the lonapegsomatropin drug substance reserved under the Commitment and Pre-payment Agreement

Under our Initial Strategy, we had previously placed an order for the Reserved Drug Substance to be produced by the CDMO B scheduled in early 2023. To secure these batches, we have made prepayment under the Commitment and Pre-Payment Agreement, which only represented a fraction of the anticipated total cost. Had the production moved forward, we would have faced an additional substantial payment obligation, which would have significantly drained our financial resources for that year. Further, extra regulatory vetting time would be required to secure a separate import BLA for the Core Product with drug substance produced by the CDMO B, as the Core Product with drug substance produced by the CDMO A was used in pivotal clinical trials conducted in China and pursuant to the relevant regulatory requirements, only drug products with the drug substance produced by the same manufacturer tested in clinical trials could be allowed for sale upon the BLA approval.

Considering our cash position, the substantial upcoming financial obligation, the unpredictable and challenging nature of fundraising environment as well as the time and expense involved in seeking a separate BLA for the Core Product with drug substance from the CDMO B, we determined that cancelling the Reserved Drug Substance to be produced by the CDMO B was necessary and in the best interest of our company. In February 2023, we exercised the right to cancel the commitment to purchase the Reserved Drug Substance under the Commitment and Pre-payment Agreement. As such, we shall compensate Ascendis Pharma for its losses pursuant to the relevant agreement, provided that Ascendis Pharma shall use commercially reasonable efforts to mitigate the losses and that such losses are evidenced by supporting documents and are detailed in the invoice. For the year ended December 31, 2023, we recorded a loss from a discontinued procurement contract in an amount of RMB109.0 million in relation to the foregoing cancellation. For more details, see “Financial Information – Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income – Other Gains and Losses, Net.”

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Termination of the Land Use Right Transfer Agreement

Under our Initial Strategy where we planned to build our in-house manufacturing capabilities, we entered into the Land Related Agreements with the Suzhou Industrial Park Planning and Construction Committee in January 2022, pursuant to which we made payment of RMB9.2 million (including the land deposit of RMB1.8 million) and acquired land use rights of approximately 25,000 square meters in Suzhou. By committing to our Strategic Change, we believe we are able to realize local manufacturing earlier by collaborating with a local CDMO while substantially reducing the initial capital investment. As such, we exercised the termination right under the Land Use Right Transfer Agreement and submitted an application of land return with relevant governmental authorities of Suzhou Industrial Park, requesting the termination of the Land Related Agreements and returning of the land use rights to Suzhou Industrial Park Administration Committee.

In relation to the land return, upon approval of land return by relevant governmental authorities, we may incur a termination loss of approximately RMB1.8 million due to the non-refundable nature of the land deposit, and after communication, we have been informed by the relevant governmental authorities that land reclamation is needed to get the approval of land return. In relation to the land reclamation, we expect that we may incur an estimated cost of approximately RMB13.6 million based on the assessment of land reclamation work as of the Latest Practicable Date and that the relevant work is expected to be completed by the end of 2024. In July 2024, we entered into a construction agreement with a vendor for land reclamation, setting a tentative completion deadline of December 2024. As of the Latest Practicable Date, the land reclamation project was on track. As advised by our PRC Legal Adviser, the foregoing land return would not affect our legal rights to apply for land use rights with governmental authorities in the future. For more details, see “Risk Factors – Risks Related to Our Business Operations – We may in the future be subject to disputes, legal proceedings or arbitration claims in the ordinary course of our business, and the court ruling or arbitration award may not be favorable to us.”

With tightening global financial conditions amid uncertain outlook, we reasonably believe that we have made proactive adaptation by canceling the lonapegsomatropin drug substance reserved under the Commitment and Pre-payment Agreement and terminating the Land Use Right Transfer Agreement, which we believe can yield benefits in excess of costs. Going forward, we will regularly assess risks and vulnerabilities from various drivers of change, such as economic, environmental and societal factors to implement proactive adjustment initiatives and prevent potential losses.

- (2) Pre-PPQ lonapegsomatropin drug substance (“Pre-PPQ DS”) obtained pursuant to the Cost Sharing and Volume Commitment Agreement

We intend to use the Pre-PPQ DS for both ongoing and future R&D endeavors, including but not limited to that, (i) we have utilized the Pre-PPQ DS in our in-house development of the dual chamber device (DCD) technology in the form of prefilled syringe as a drug delivery system for the lonapegsomatropin drug substance, which included testing various process conditions and parameters to create a prototype for the local manufacturing; and (ii) we will utilize the Pre-PPQ DS to test analytical methods ensuring our capability to perform quality control on the locally manufactured drug product; and (iii) we will utilize the Pre-PPQ DS as reference samples in comparability studies of the locally manufactured drug substance. See “– Commercial Supply and Manufacturing – Step 2: Collaborative Local Manufacturing with Local CDMO” for more details.

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COLLABORATIONS

Exclusive License Agreements with Ascendis Pharma

Background

In November 2018, we entered into three Exclusive License Agreements with Ascendis Pharma relating to lonapegsomatropin, TransCon CNP (navepegritide) and palopegteriparatide, respectively, which were subsequently amended in January 2021 due to the necessity to reflect the evolving cooperation progress between the parties in terms of technology transfer and Joint Commercialization Committee. Pursuant to the terms of each agreement, Ascendis Pharma granted us an exclusive (including as to Ascendis Pharma), royalty-free license under its applicable owned patents and other intellectual property for the purposes of developing, manufacturing and commercializing the applicable drug candidates in endocrinology in China (including Hong Kong, Macau and Taiwan). In addition, during the term of the Exclusive License Agreements, Ascendis Pharma is required to notify us prior to engaging in substantive discussions with a third party regarding the license to such third party by Ascendis Pharma or its affiliates of rights to develop or commercialize endocrine drugs in China (including Hong Kong, Macau and Taiwan) covered by the relevant Exclusive License Agreement, which we will refer to as a ROFN Opportunity. If we inform Ascendis Pharma that we wish to negotiate an agreement for such ROFN Opportunity, Ascendis Pharma and us shall enter into good faith negotiations to finalize the relevant license agreement. We are not obligated to make any royalty or milestone payments under the relevant Exclusive License Agreements, but have instead issued to Ascendis Pharma an aggregate of 40,000,000 Series A Preferred Shares as consideration for Ascendis Pharma to enter into these agreements. Ascendis Pharma is one of our Founding Shareholders. See “History, Development and Corporate Structure – Major Corporate Development and Shareholding Changes of Our Group” for more details. As a result of this arrangement, Ascendis Pharma’s interests are closely aligned with ours both in terms of bring endocrine drug candidates to patients in China (including Hong Kong, Macau and Taiwan) and beyond as well as growing our Company for financial success. See “Relationship with the Controlling Shareholders – Independence from Our Controlling Shareholders – Operational and Administrative Independence – Remote Risk of Termination or any Material Adverse Change of the Mutually Beneficial Relationship” for more details regarding the benefits of this licensing arrangement in lieu of cash payment as consideration to Ascendis Pharma.

Rights and Obligation

Each agreement obligates us to use diligent efforts to develop and commercialize lonapegsomatropin, TransCon CNP (navepegritide) and palopegteriparatide, as applicable, in China (including Hong Kong, Macau and Taiwan). We are solely responsible for any clinical trial activities in China (including Hong Kong, Macau and Taiwan) for the foregoing licensed product, and for obtaining regulatory approval for each licensed product in China (including Hong Kong, Macau and Taiwan). We and Ascendis Pharma shall each conduct the R&D activities as allocated to the respective party under the applicable research and technical development plans, and we shall reimburse Ascendis Pharma for its costs incurred with respect to its employees and approved service providers.

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Ascendis Pharma must provide product supply to us for use in conducting clinical trials in China (including Hong Kong, Macau and Taiwan) pursuant to separate Clinical Supply Agreements entered into concurrently with each Exclusive License Agreement. Additionally, we and Ascendis Pharma will negotiate in good faith the terms and conditions governing the commercial supply of each licensed product to us.

Under each Exclusive License Agreement, Ascendis Pharma, as the licensor, agreed not to, directly or through third parties, research, develop, manufacture or commercialize applicable competing products in China (including Hong Kong, Macau and Taiwan), specifically, long-acting products or product candidates that are being developed and/or commercialized for use in all human indications (excluding diabetes (and certain related metabolic disorders), obesity and ophthalmology) that contains a hGH, CNP or PTH, as the case may be. We, as licensee under the Exclusive License Agreements, agreed not to use or exploit the patents and technical information (such as know-hows, discoveries, techniques) controlled by Ascendis Pharma unless expressly permitted under the licenses granted to us, and not to grant any license to third parties our interest in any inventions or intellectual property arising out of the activities conducted under the Exclusive License Agreements (i) outside China (including Hong Kong, Macau and Taiwan) for the development and/or commercialization of any product for use in the treatment of endocrinology disorders; and (ii) relating to Ascendis Pharma's platform technology (including Ascendis Pharma's proprietary chemistry, materials and methodologies for transiently covalently coupling a substrate of interest to various carriers via a transient conjugation linker, thereby allowing release of the transiently linked substrate in a controlled manner over time for a therapeutic or prophylactic effect) outside China (including Hong Kong, Macau and Taiwan) for any purpose (collectively, the "Licensee Restricted Activities").

We and Ascendis Pharma will each solely own inventions and related intellectual property resulting from activities we each solely conduct pursuant to each agreement, and will jointly own any inventions and related intellectual property developed jointly. After the first regulatory approval of the licensed products in China (including Hong Kong, Macau and Taiwan), if requested by us, Ascendis Pharma shall transfer to us (or one or more sublicensed affiliates designated by us) the licensed product patents in China (including Hong Kong, Macau and Taiwan) in accordance with each Exclusive License Agreement at no additional cost, subject to our Shareholders' approval in accordance with our Amended and Restated Shareholders Agreement, if applicable. To facilitate our commercialization of the relevant drug candidates, once approved, we currently expect to require Ascendis Pharma to transfer such licensed product patents to us in China upon obtaining the relevant regulatory approval. We granted Ascendis Pharma a non-exclusive, royalty-free, fully-paid, perpetual, irrevocable license under our rights in any such inventions to develop and commercialize products outside of China (including Hong Kong, Macau and Taiwan), which Ascendis Pharma has the right to convert such non-exclusive license to an exclusive license on terms to be negotiated between the parties in good faith. Subject to Ascendis Pharma transferring to us the licensed patents after the regulatory approval of the licensed products in China (including Hong Kong, Macau and Taiwan) if requested by us where we would have the first right to prosecute the licensed patents, Ascendis Pharma has the first right to prosecute the licensed patents. We have first

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right to enforce the licensed patents in China (including Hong Kong, Macau and Taiwan) within our licensed field, and Ascendis Pharma has such right in the rest of the world or in China (including Hong Kong, Macau and Taiwan) outside of our licensed field.

Each Exclusive License Agreement continues to be in effect for as long as a valid claim of an applicable licensed patent exists in China (including Hong Kong, Macau and Taiwan). The current valid claim of the applicable licensed patent is projected to expire in 2035, 2040 and 2037, respectively, for lonapegsomatropin, TransCon CNP (navepegritide) and palopegteriparatide. The valid term of applicable licensed patent is expected to further extend upon the approval of the currently pending patent applications and future new patent applications in relation to the licensed product. See “– Intellectual Property” for more details. We may terminate each Exclusive License Agreement for convenience upon 90 days’ prior written notice to Ascendis Pharma or by notice to Ascendis Pharma upon bankruptcy or insolvency-related events involving Ascendis Pharma that have continued for 60 days undismissed, unbonded and undischarged. Additionally, in the event that Ascendis Pharma commits a material breach of any of the terms of each Exclusive License Agreement on its part to be performed or observed, we shall have the right to terminate such agreement, in whole or in part, by giving 60 days’ written notice to Ascendis Pharma, unless such material breach is cured within the notice period.

On the other hand, in the event that we commit a material breach of our material obligations under each Exclusive License Agreement (including the conduct of Licensee Restricted Activities as discussed above, the failure to reimburse Ascendis Pharma for its costs incurred in connection with the R&D activities) and such material breach causes material loss by Ascendis that exceeds US\$20 million, Ascendis Pharma shall have the right to terminate such agreement, in whole or in part, by giving 90 days’ written notice to us, unless such material breach is cured within the notice period or the loss to Ascendis Pharma is reduced below an agreed money threshold. Further, Ascendis Pharma may terminate an Exclusive License Agreement upon 30 days’ notice if we participate in a challenge of any of the patents licensed to us under such agreement, and upon bankruptcy or insolvency-related events involving us that have continued for 60 days undismissed, unbonded and undischarged. Ascendis Pharma may also terminate the relevant Exclusive License Agreement(s) upon immediate written notice to us, if we undergo a change of control in favor of (i) pharmaceutical or biotechnology companies commercializing long-acting products that compete with lonapegsomatropin, palopegteriparatide or TransCon CNP (navepegritide), as applicable, within and outside of China (including Hong Kong, Macau and Taiwan) as of the date of such change of control, or (ii) in the case of lonapegsomatropin, specified large players in the pharmaceutical industry to the extent they are conducting clinical development and/or commercialization of a long-acting product that compete with lonapegsomatropin.

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Dispute Resolution

Dispute, controversy or claim related to matters over the material aspects of the development of the Licensed Products shall be resolved by the Joint Development Committee (JDC) by unanimous vote, with each Ascendis Subsidiaries and the Company having one vote. If after reasonable discussion and consideration of each of the parties' views on a particular matter before the JDC, the JDC is unable to reach a decision by unanimous vote on that matter, then the Company shall have final decision-making authority, provided such unilateral decision, among other things, will not materially impair any rights or assets of Ascendis Subsidiaries and results in a material expansion of activities allocated to Ascendis Subsidiaries.

Dispute, controversy or claim related to matters over the material aspects of the commercialization of the Licensed Products shall be resolved by the Joint Commercialization Committee (JCC) by unanimous vote, with each Ascendis Subsidiaries and the Company having one vote. If after reasonable discussion and consideration of each of the parties' views on a particular matter before the JCC, the JCC is unable to reach a decision by unanimous vote on that matter, then the disputed matter shall be escalated to a discussion between the chief executive officers of each of the parties. If such discussions are terminated without a settlement, then the Company shall have final decision-making authority acting in good faith, provided such unilateral decision, among other things, will not have a negative effect on the development, manufacture or commercialization of the Licensed Products by Ascendis Subsidiaries outside China (including Hong Kong, Macau and Taiwan).

In the event of any controversy, claim or other dispute arising out of or relating to compliance with the Exclusive License Agreements, or the validity, breach, termination or interpretation of the Exclusive License Agreements, such dispute shall be first referred to the chief executive officers of the parties for resolution. In the event that the chief executive officers cannot resolve such dispute within thirty (30) days of the receipt of such written notice, either party may initiate the binding arbitration conducted under the auspices of the International Chamber of Commerce accordance with the then prevailing Rules of Arbitration of the International Chamber of Commerce in San Francisco, California, applying the substantive law of the state of Delaware, USA, without reference to its conflict of laws principles, and shall not be governed by the United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention). Other contractual arrangements between the Company and Ascendis Subsidiaries including Cost Sharing and Volume Commitment Agreement, Commitment and Pre-Payment Agreement, and Commercial Supply Agreement apply for the same aforementioned dispute resolution mechanism.

Notwithstanding above, any dispute that involves the validity, infringement or claim interpretation of a patent that is issued: (a) in the United States shall be subject to actions before the United States Patent and Trademark Office and/or submitted exclusively to the federal court located in the jurisdiction of the district where any of the defendants resides; and (b) in any other country shall be brought before an appropriate regulatory or administrative body or court in that country.

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Further Letter Agreement in relation to China Phase 2 trial

In August 2021, without compromising our exclusive rights and responsibilities for the development and commercialization regarding TransCon CNP (navepegritide) in China (including Hong Kong, Macau and Taiwan), we entered into a letter agreement with Ascendis Pharma to specify the roles and responsibilities between both parties in anticipation of the upcoming China Phase 2 trial. Pursuant to this letter agreement, the two companies will jointly conduct the China Phase 2 trial, with Ascendis Pharma acting as trial sponsor and us acting as the exclusive authorized agent. In November 2022, the two companies entered into an amendment to this letter agreement, under which we became the sole sponsor for the OLE period of the China Phase 2 trial to reflect the updated roles and responsibilities between both parties as the sponsorship for the OLE period of China Phase 2 trial was transferred from Ascendis Pharma to us (the letter agreement and the subsequent amendment, collectively referred to as the “Letter Agreement”). Pursuant to the Letter Agreement, we and Ascendis Pharma shall reasonably cooperate and coordinate with each other in the conduct of the China Phase 2 trial. We and Ascendis Pharma shall establish a joint task force comprised of an equal representative functions from each party and the joint task force shall meet regularly to discuss the strategy and review the progress of the China Phase 2 trial. We and Ascendis Pharma shall be responsible for the portion of the costs incurred in connection with the conduct of the China Phase 2 trial based on the allocation as set forth in the Letter Agreement, and among others, Ascendis Pharma shall be responsible for the costs for investigational medicinal products, while we will reimburse Ascendis Subsidiaries for the packing, labeling and shipment to China. Subsequent to the entry of the foregoing amendment, we became the sole sponsor for the OLE portion of the China Phase 2 trial as it commenced in January 2023.

Strategic Cooperation with China Alliance on Rare Diseases on A National Patient Registry and Diagnosis Consensus of ACH in China

We supported the founding of Achondroplasia Advisory Board in June 2019 under the governance of CHARD, a national, non-profit, cooperative exchange platform for rare diseases by entering into a donation agreement with CHARD. Pursuant to the donation agreement, the funds we donated shall be managed under the CHARD’s Rare Disease Management Special Fund and used for pre-determined purposes, which primarily include the training of medical personnel related to rare diseases, academic conferences, expert lectures, promotion of rare disease registration systems, rare diseases related healthcare education, CHARD’s operational expenses and other related purposes. The specific use of the funds shall be jointly negotiated between CHARD and us annually. CHARD is responsible for supporting the operation of the Achondroplasia Advisory Board and all operational expenses shall be funded by the Rare Disease Management Special Fund.

In December 2020, we entered into a five-year strategy cooperation with CHARD on a national patient registry and diagnosis consensus of ACH in China, the ApproaCH project, under a funding agreement dated December 2020 between us and CHARD (the “ApproaCH Agreement”). Under the ApproaCH project, a national patient registry study, the ApproaCH Registry Study, was initiated in April 2021 and achieved the first wave screening and

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enrollment in October 2021, which has reached its targeted enrollment number of 380 patients and completed an initial 154 follow-ups as of December 31, 2023. According to the ApproaCH agreement, we provided funding for the ApproaCH Registry Study, with the purpose of assessing the growth and development indicators, natural disease processes and the complications associated with ACH patients, as well as evaluating their quality of life and the economic burden of ACH patients, by analyzing epidemiological information of registered ACH patients in China. The goal of the ApproaCH Registry Study is to establish a Chinese ACH patient cohort and establish ACH data platform or system to further understand the natural history and current standard of care, and publish study reports and papers. CHARD is responsible for the preparation, planning and implementation of the ApproaCH Registry Study, including arranging researcher consultation from time to time, research conferences, and working with CHARD's ACH experts and 17 hospitals across the country during the implementation of the project. CHARD is also responsible for designing and developing study protocol, establishing and managing the ACH database and ensuring the compliance of the data collection. CHARD owns the rights to the original data from the ACH patient cohort and the economic burden study. CHARD is the sole owner of all data, study results and intellectual property rights generated by the ApproaCH project and we shall not use the intellectual property rights generated by the project without the written consent of CHARD. Research data shall not be made public and research paper based on the ApproaCH project shall not be published without the written consent of CHARD.

Strategic Cooperation with Peking University Health Science Center on A Cohort Study on HP

In July 2021, we entered into a strategic cooperation agreement with Peking University Health Science Center to initiate the PaTHway R study, the first registry study for HP patients in China and one of the largest epidemiological surveys for this disease worldwide. The PaTHway R study aims to enhance the understanding among the public and professionals regarding the etiology, treatment options, disease burdens of HP and was kicked off in January 2022. Pursuant to the strategic cooperation agreement, the Peking University Health Science Center is responsible for study protocol design, project management and execution, data management, statistical analysis, etc. The study protocol shall be approved by the project expert committee, and patient data shall be collected from 500 patients with HP from eight regions across China enrolled to the study according to the study protocol. The study shall be carried out in accordance with the study protocol and the standard operating procedures and will be audited by us, to support a final research report. The Peking University Health Science Center shall ensure that the research project is compliant with the laws and regulations and shall be responsible for obtaining the necessary approvals from the relevant regulatory authorities and conducting necessary filings. We are responsible for providing support for funding, supervision and management, and should assist in identifying clear and defined research objectives, research background information and the first draft of study protocol. The Peking University Health Science Center is the owner of all intellectual properties associated with the project, but will provide and license the desensitized data generated from the project to us for our product research, development and other commercial use.

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Key Arrangements in relation to Our Local Manufacturing Capabilities for the Core Product

In July 2023, we entered into a Technology Transfer Master Plan of the Core Product with Ascendis Pharma, which has marked the commencement of the Technology Transfer with respect to the manufacturing of the Core Product from Ascendis Pharma to us and sets forth the obligations of both parties under the Exclusive License Agreement with respect to the Technology Transfer. On December 18, 2023, we entered into a collaboration agreement with WuXi Biologics, our designated local CDMO, to strengthen our commercialization capabilities and establish localized manufacturing capabilities to secure the supply of our Core Product. Pursuant to such agreement, WuXi Biologics will be involved in the Technology Transfer and Localization as the local CDMO of manufacturing technology, and we will entrust WuXi Biologics with the local commercial supply of lonapegsomatropin drug substance. WuXi Biologics will leverage its technologies and expertise to provide us with efficient and cost-effective local manufacturing solutions for the Core Product. Completion of the Technology Transfer and Localization, which is expected to be in 2026, will confer to us the technical capabilities to manufacture the Core Product drug substance in collaboration with WuXi Biologics. The commercialization of the Core Product produced by WuXi Biologics will start once we obtain the approval of Local BLA, which is expected to occur in 2028.

Entry into Strategic Collaboration Agreement with Shanghai Pharmaceutical

On October 30, 2023, to advance the expected commercialization of our Core Product and other products, we entered into a strategic collaboration agreement with Shanghai Pharmaceutical. Pursuant to such agreement, Shanghai Pharmaceutical will leverage its expertise and capabilities to assist us to establish the necessary management framework in line with the GSP.

BUSINESS DEVELOPMENT

We will continue to select, develop, and market paradigm-shifting therapeutic drugs that have the potential to fulfill current unmet medical needs. We aim to bridge global innovation to bring endocrine therapies to Chinese patients, and plan to become the partner of choice in endocrinology for China (including Hong Kong, Macau and Taiwan). Thus far, we have a proven track record of collaborating with Ascendis Pharma, which underscores our credibility with global biopharmaceutical and biotechnology companies and paves the way for long-term collaborations. We intend to expand our pipeline portfolio through strategic in-licensing, collaborations and partnerships with Ascendis Pharma and other biopharmaceutical companies. Under the Exclusive License Agreements with Ascendis Pharma, we hold a right of first negotiation on certain future Ascendis Pharma products within the endocrine disease area for China (including Hong Kong, Macau and Taiwan). This will enable us to source, develop and commercialize additional drug candidates that are based on the unique transient conjugation technology (TransCon) and have the potential to be highly differentiated endocrine therapies. We plan to collaborate with Ascendis Pharma to evaluate future potential drug candidates and

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exercise our right for those products that address unmet medical needs and possess strong commercial potential in China (including Hong Kong, Macau and Taiwan). See “– Collaborations – Exclusive License Agreements with Ascendis Pharma” for more details.

Beyond Ascendis Pharma, we plan to leverage our platform and network to pursue business development opportunities with other potential biopharmaceutical partners with endocrine drugs, drug candidates or technologies and platforms that may be synergistic or complementary to our portfolio and/or our capabilities. We believe our relationships with our Shareholders and a group of strategic and life sciences focused Sophisticated Investors will contribute to our success in building value-creating partnerships. In the long-term, we plan to leverage our infrastructure in endocrinology to become the partner of choice for endocrine treatment looking to enter China (including Hong Kong, Macau and Taiwan).

We plan to fully exploit our extensive knowledge in endocrinology and our deep understanding of the medical need and technology, and through identifying and executing attractive licensing and collaboration opportunities or through mergers and acquisitions, we seek to pursue business development opportunities to further expand our portfolio with other potential biopharmaceutical partners with endocrine drugs, drug candidates or technologies that may be synergistic or complementary to our portfolio.

Our scaled operation and platform, integrated with a commercial team that targets the same group of doctors and call points in the endocrinology specialty, is highly synergistic with strong operating leverage to maximize the value of additional endocrine products looking to enter China (including Hong Kong, Macau and Taiwan):

- *Synergistic clinical stage products with potential.* We prioritize bringing in drugs or drug candidates based on their clinical profile, degree of novelty and validation, technology differentiation, the unmet medical needs of the target disease and respective commercial potential in China (including Hong Kong, Macau and Taiwan).
- *Marketed endocrine products with only light commercialization effort required and attractive cashflow or margin.* We are strategically seeking to in-license or acquire rights to drugs that are either already launched or in late-stage development in regulated markets such as the United States and the European Union that may be synergistic or complementary to our portfolio.

As a complementary measure, we will opportunistically look to establish internally developed pipeline of promising therapies, with local CDMO support or through mergers and acquisitions of research-driven biotech companies, when the products’ target or MoA fit with our overall product offering suite and target large market opportunities.

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EMPLOYEES

As of the Latest Practicable Date, we employed a total of 57 full-time employees, all based in China, including a total of 16 employees with a Ph.D. degree or an M.D. degree. The following table sets forth a breakdown of our employees by function as of the Latest Practicable Date:

Function	Number	% of Total
Clinical R&D	22	39
Manufacturing (including manufacturing related R&D)	7	12
Commercialization (including Medical Affairs)	10	17
Others	18	32
Total	57	100

Employee Agreements with Key Management and Research Staff

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-compete agreement that prohibits the employee from competing with us, directly or indirectly, during his or her employment and for two years after the termination of his or her employment. The contracts also typically include undertakings regarding assignment of inventions and discoveries made during the course of his or her employment. See “Directors and Senior Management” for further details regarding the terms of confidentiality and employment agreements with our key management.

As of the Latest Practicable Date, neither our Company nor any of our subsidiaries have any labor union. We believe that we maintain a good working relationship with our employees and we have not experienced any significant labor disputes or any significant difficulty in recruiting staff for our operations.

Recruitment, Training and Development

We recruit our employees based on their qualifications and potential. We provide new employee training to our employees and periodic on-the-job training to enhance the skills and knowledge of our employees.

Employee Benefits

The remuneration package of our employees includes salary, benefits, bonus and incentive share options. Our compensation programs are designed to remunerate our employees based on their performance, measured against specified objective criteria. As required by laws and regulations in China, we participate in various employee social security plans that are

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organized by municipal and provincial governments, including housing, pension, medical insurance and unemployment insurance. We are required under PRC law to make contributions to employee benefit plans at specified percentages of the salaries, bonuses and certain allowances of our employees, up to a maximum amount specified by the local government from time to time.

INTELLECTUAL PROPERTY

We own the intellectual property rights to exclusively develop, manufacture, and commercialize our Core Product and other drug candidates in China (including Hong Kong, Macau and Taiwan). We were granted an exclusive and royalty-free license (with the right to grant sub-licenses) under the Exclusive License Agreements to develop, manufacture (i.e., any manufacturing activity of the licensed products, or ingredients thereof, including manufacturing for pre-clinical or clinical use, or commercial sale, testing, handling, packaging and storage, ongoing stability tests and regulatory activities related to any of the foregoing), have made, use, sell, offer for sale, import, export or otherwise commercialize our pipeline drug candidates in endocrinology in China (including Hong Kong, Macau and Taiwan). Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our drug candidates and our core technologies and other know-how and to operate without infringing, misappropriating or otherwise violating the proprietary and intellectual rights of others and to prevent others from infringing, misappropriating or otherwise violating our proprietary or intellectual property rights. To protect our proprietary and intellectual property position, we have gained exclusive licensed rights in Mainland China, Hong Kong, Macau and Taiwan to issued patents and patent applications related to our drug candidates that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position, which we generally seek to protect through contractual obligations with third parties. We were not involved in any intellectual property infringement claims or proceedings during the Track Record Period and up to the Latest Practicable Date.

As of the Latest Practicable Date, we have exclusive licenses from Ascendis Pharma to 36 issued patents (including a platform patent which covers Lonapegsomatropin, TransCon CNP (navepegritide) and Palopegteriparatide) in China (including Hong Kong, Macau and Taiwan), and 47 pending patent applications in China (including Hong Kong, Macau and Taiwan). Our patent and patent application portfolio includes the following:

Lonapegsomatropin. We have exclusively licensed from Ascendis Pharma eight issued patents and four patent applications in China (including Hong Kong, Macau and Taiwan) relating to lonapegsomatropin. The issued patents are projected to expire in 2035.

TransCon CNP (navepegritide). We have exclusively licensed from Ascendis Pharma 19 issued patents and 12 patent applications in China (including Hong Kong, Macau and Taiwan) relating to TransCon CNP (navepegritide). The issued patents are projected to expire in 2040.

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Palopegteriparatide. We have exclusively licensed from Ascendis Pharma 10 issued patents and 24 patent applications in China (including Hong Kong, Macau and Taiwan) relating to palopegteriparatide. The issued patents are projected to expire in 2037.

Auto-Injector. We have exclusively licensed from Ascendis Pharma two issued patents and seven patents applications in China (including Hong Kong, Macau and Taiwan) relating to the auto-injector. The issued patents are projected to expire in 2038.

The table below sets forth an overview of material granted patents in connection with our drug candidate as of the Latest Practicable Date. See “Appendix IV – Statutory and General Information – B. Further Information about Our Business” for further details.

Patent Application/ Publication Number	Scope of Protection	Jurisdiction	Applicant	Application Date	Status	Expiration date	Rights of the Company
<i>Lonapegsomatropin</i>							
CN101980725B	Cycloheximide bridging agent	CN	ASCENDIS PHARMA AS	January 30, 2009	Granted	January 30, 2029	The Company was granted by the Applicant an exclusive, royalty-free licence (with the right to grant sub-licences) under this patent to develop, manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize licensed product in the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the excluded indications in the PRC, including Hong Kong, Macau and Taiwan.
CN102014965B	PEGylated recombinant human growth hormone compounds	CN	Ascendis Pharma Endocrinology Division	April 29, 2009	Granted	April 29, 2029	
CN102989001B	hGH prodrugs	CN	Ascendis Pharma Endocrinology Division	April 29, 2009	Granted	April 29, 2029	The Company was granted by the Applicant an exclusive, royalty-free licence (with the right to grant sub-licences) under this patent to develop, manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize licensed product in the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the excluded indications in the PRC, including Hong Kong, Macau and Taiwan.
HK1179899	hGH prodrugs	HK	Ascendis Pharma Endocrinology Division	April 29, 2009	Granted	April 29, 2029	
HK 18100073.0	Polymeric human growth hormone prodrug	HK	Ascendis Pharma Endocrinology Division	November 17, 2015	Granted	November 17, 2035	The Company was granted by the Applicant an exclusive, royalty-free licence (with the right to grant sub-licences) under this patent to develop, manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize licensed product in the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the excluded indications in the PRC, including Hong Kong, Macau and Taiwan.
HK 18103805.9	Long- Acting Growth Hormone Dosage Forms	HK	Ascendis Pharma Endocrinology Division	November 20, 2015	Granted	November 20, 2035	
HK1152239A1	Growth Hormone (rhGH)	HK	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S	April 29, 2009	Granted	April 29, 2029	The Company was granted by the Applicant an exclusive, royalty-free licence (with the right to grant sub-licences) under this patent to develop, manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize licensed product in the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the excluded indications in the PRC, including Hong Kong, Macau and Taiwan.
HK1209445A1	Pharmaceutical formulation comprising a long-acting growth hormone (hGH)	HK	ASCENDIS PHARMA A/S	October 8, 2013	Granted	October 8, 2033	

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Patent Application/ Publication Number	Scope of Protection	Jurisdiction	Applicant	Application Date	Status	Expiration date	Rights of the Company
<i>TransCon CNP</i>							
<i>(navepegritide)</i>							
CN101980725B	Cycloheximide bridging agent	CN	ASCENDIS PHARMA AS	January 30, 2009	Granted	January 30, 2029	The Company was granted by the Applicant an exclusive, royalty-free licence (with the right to grant sub-licences) under this patent to develop, manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize licensed product in the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the excluded indications in the PRC, including Hong Kong, Macau and Taiwan.
HK1152240	Cycloheximide bridging agent	HK	ASCENDIS PHARMA AS	January 30, 2009	Granted	January 30, 2029	
CN107405409B	CNP prodrug or pharmaceutically acceptable salts thereof	CN	Ascendis Pharma Growth Disorders	January 8, 2016	Granted	January 8, 2036	
HK1246666B	CNP prodrug or pharmaceutically acceptable salts thereof	HK	Ascendis Pharma Growth Disorders	January 8, 2016	Granted	January 8, 2036	
CN108472380B	Controlled-release CNP agonist	CN	Ascendis Pharma Growth Disorders	January 5, 2017	Granted	January 5, 2037	
CN 114306629 B (Divisional patent of the CN108472380B)	Controlled-release CNP agonist	CN	Ascendis Pharma Growth Disorders	January 5, 2017	Granted	January 5, 2037	
HK40069215A	Controlled-release CNP agonist	HK	ASCENDIS PHARMA GROWTH DISORDERS A/S	January 5, 2017	Granted	January 5, 2037	
MAEJ/007651	Controlled-release CNP agonist	Macau	ASCENDIS PHARMA GROWTH DISORDERS A/S	January 5, 2017	Granted	January 5, 2037	
HK1259384A	Controlled-release CNP agonist	HK	Ascendis Pharma Growth Disorders	January 5, 2017	Granted	January 5, 2037	
CN108472383B	Controlled-release CNP agonists with low NPR-C binding	CN	Ascendis Pharma Growth Disorders	January 5, 2017	Granted	January 5, 2037	
HK1257769B	Controlled-release CNP agonists with low NPR-C binding	HK	ASCENDIS PHARMA GROWTH DISORDERS A/S	January 4, 2019	Granted	January 4, 2039	
HK1262973A	Controlled-release CNP agonists with low NPR-C binding	HK	Ascendis Pharma Growth Disorders	January 5, 2017	Granted	January 5, 2037	
J/006504	Controlled-release CNP agonists with low NPR-C binding	Macau	Ascendis Pharma Growth Disorders	January 5, 2017	Granted	January 5, 2037	
HK 17103600.7	Hyperbranched polymer conjugates via non-enzymatic cleavable linker	HK	ASCENDIS PHARMA	October 1, 2004	Granted	October 1, 2024	

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Patent Application/ Publication Number	Scope of Protection	Jurisdiction	Applicant	Application Date	Status	Expiration date	Rights of the Company
HK 18100069.6	CNP prodrug	HK	Ascendis Pharma Growth Disorders	January 8, 2016	Granted	January 8, 2036	
CN109843295B	CNP combination therapy	CN	Ascendis Pharma Growth Disorders	September 28, 2017	Granted	September 28, 2037	
HK40008972A1	CNP combination therapy	HK	Ascendis Pharma Growth Disorders	September 28, 2017	Granted	September 28, 2037	
CN113423384B (2020800134620)	Pharmaceutical formulation comprises a CNP conjugate	CN	ASCENDIS PHARMA GROWTH DISORDERS A/S	February 10, 2020	Granted	February 10, 2040	
HK40052552B	Dry pharmaceutical formulations of CNP conjugates	HK	ASCENDIS PHARMA GROWTH DISORDERS A/S	November 9, 2021	Granted	November 9, 2041	
<i>Palopegeteriparatide</i>							
CN101980725B	Cycloheximide bridging agent	CN	ASCENDIS PHARMA AS	January 30, 2009	Granted	January 30, 2029	The Company was granted by the Applicant an exclusive, royalty-free licence (with the right to grant sub-licences) under this patent to develop, manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize licensed product in the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the excluded indications in the PRC, including Hong Kong, Macau and Taiwan.
HK1152240	Cycloheximide bridging agent	HK	ASCENDIS PHARMA AS	January 30, 2009	Granted	January 30, 2029	
CN109069659B	PTH prodrugs	CN	Ascendis Pharma Bone Diseases	February 28, 2017	Granted	February 28, 2037	
HK40000751A1	PTH prodrugs	HK	Ascendis Pharma Bone Diseases	February 28, 2017	Granted	February 28, 2037	
CN109789221B	Pharmaceutical composition	CN	Ascendis Pharma Bone Diseases	September 28, 2017	Granted	September 28, 2037	
CN109789188B	PTH compounds with low peak-to-trough ratios	CN	Ascendis Pharma Bone Diseases	September 28, 2017	Granted	September 28, 2037	
CN109789189B (Just received Notice of Allowance)	Controlled release compounds	CN	Ascendis Pharma Bone Diseases	September 28, 2017	Granted	September 28, 2037	
HK40007776A	Dosage regimen for a controlled-release PTH compound	HK	ASCENDIS PHARMA BONE DISEASES A/S	October 18, 2019	Granted	October 18, 2039	
MAEJ/006797	Pharmaceutical formulation comprising long-acting growth hormone	Macau	ASCENDIS PHARMA BONE DISEASES A/S	September 28, 2017	Granted	September 28, 2037	
MAEJ/007897	Dosage regimen for a controlled-release PTH compound	Macau	Ascendis Pharma Bone Diseases A/S	September 28, 2017	Granted	September 28, 2037	

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Patent Application/ Publication Number	Scope of Protection	Jurisdiction	Applicant	Application Date	Status	Expiration date	Rights of the Company
<i>Auto-Injector</i>							
CN110769873B	Autoinjector	CN	Ascendis Pharma GmbH	May 23, 2018	Granted	May 23, 2038	The Company was granted by the Applicant an exclusive, royalty-free licence (with the right to grant sub-licences) under this patent to develop, manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize licensed product in the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the excluded indications in the PRC, including Hong Kong, Macau and Taiwan.
CN110809484B	Autoinjector	CN	Ascendis Pharma GmbH	June 29, 2018	Granted	June 29, 2038	

Pursuant to the Exclusive License Agreements, upon the first regulatory approval of a licensed product in endocrinology in China (including Hong Kong, Macau and Taiwan), we are entitled to request Ascendis Pharma to transfer the ownership of the patents in relation to the corresponding licensed products in China (including Hong Kong, Macau and Taiwan) to us, without incurring additional costs. As such, we shall, at our own expense and in our sole discretion, have the first right to file, prosecute, maintain and defend such patents. We intend to exercise such option to request Ascendis Pharma to transfer the ownership of the patents in relation to the Core Product upon obtaining the expected BLA approval in mid-2025. See “Appendix IV – Statutory and General Information – B. Further Information about Our Business – 2. Intellectual Property Rights of Our Group” for details of the licensed product patents in China (including Hong Kong, Macau and Taiwan) which we expect to request Ascendis Pharma to transfer to us. Even without such ownership transfer, we will still maintain an effective control over the patent rights of the Licensed Products in China (including Hong Kong, Macau and Taiwan) with an exclusive license under the Exclusive License Agreements which enable us to develop, manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize our pipeline drug candidates in endocrinology in China (including Hong Kong, Macau and Taiwan). Therefore, we believe any failure to obtain ownership of relevant patents from Ascendis Pharma will not directly hamper our business, financial

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conditions or results of operations. We currently do not own or have any exclusive license to any patents or patent applications in any jurisdictions outside of China (including Hong Kong, Macau and Taiwan) for lonapegsomatropin, TransCon CNP (navepegritide), and palopegteriparatide. See “– Collaborations – Exclusive License Agreements with Ascendis Pharma” for more details regarding our exclusive license arrangements with Ascendis Pharma.

We performed due diligence on Ascendis Pharma’s intellectual property rights before entering into the license agreements with them, but we cannot guarantee that such rights will not be challenged or that they will provide meaningful exclusivity or competitive advantage or otherwise enable us to successfully exploit the licensed drug candidates. See “Risk Factors – Key Risks Related to Our Business, Business Operations, Intellectual Property, Regulatory Approval of Our Drug Candidates, Commercialization and Financial Prospects – Our in-licensed patents and patent applications or any patents and patent applications that we own or in-license in the future may be subject to priority disputes or to inventorship disputes and similar proceedings. If we or our licensors are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the development, manufacture and commercialization of one or more of our drug candidates.”

The term of a patent depends upon the laws of the country in which it is issued. Generally, a patent term is 20 years from the earliest filing date of a non-provisional patent application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to inventions are effective for 20 years, and utility models are effective for 10 years and designs are effective for 15 years from the date of application. The patent compensation system has been effective from June 1, 2021, which may benefit issued patents in China. For patents relating to new drugs approved for marketing in the PRC, the patent term may be extended upon request of the patent holder by up to five years as determined by the competent patent authorities, in order to compensate for the time spent for drug marketing registration and approval procedures, and with such compensation the patent term after the relevant new drug marketing authorization is approved shall not exceed 14 years.

To mitigate the risks of patent expiration and obtain the necessary intellectual property protection to support the development and commercialization of our drug candidates in China (including Hong Kong, Macau and Taiwan), we will apply for patent term extension under relevant patent laws and through the patent compensation system, once the relevant drug candidates receive marketing approval in China. In addition to the issued patents, we have rights to patent applications in China (including Hong Kong, Macau and Taiwan) for each of our drug candidates. Such patent applications, if approved, will confer us additional patent protections in relation to the applicable drug candidates. Further, under the Exclusive License Agreements, we will own all right, title, and interest and to any and all patents that are conceived or generated solely by the employees, agents or service providers of our Company or affiliates. As such, we may perform and continue our research and development efforts and take ownership of self-developed patents during and after the patent terms, thereby creating a patent portfolio that offers sustainable patent protection in China (including Hong Kong, Macau and Taiwan) all the way long. Even if patent term extensions and the patent

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compensation system were not available for the issued patents, we can continue to develop, manufacture and commercialize our drug candidates under the exclusive capacity conferred by the patents to be issued from the currently pending patent applications and potential self-developed patent applications. Further, under the Exclusive License Agreements, we also control the technical information (i.e., any and all know-how, data, inventions, discoveries, findings, methods, proprietary information, processes, techniques, materials and other information and technology) required to develop, manufacture and commercialize our drug candidates, and the licensed use of such technical information will remain effective as long as the Exclusive License Agreements are not terminated.

We conduct our business mainly under the brand name of “VISEN Pharmaceuticals” (维昇药业). As of the Latest Practicable Date, we had 124 registered trademarks and 3 pending trademark applications in China (including Hong Kong, Macau and Taiwan). We have one domain name, which is *www.visenpharma.com*.

The table below sets forth the registered trademarks that we deemed material to our business.

No.	Trademark	Owner	Class	Place of Registration	Expiry Date	Registration Number
1	VISEN	VISEN Shanghai	35	PRC	September 6, 2033	46448849
2	VISEN	VISEN Shanghai	35	PRC	April 13, 2032	50914244
3	VISEN	VISEN Shanghai	5	PRC	October 6, 2031	51329106
4	VISEN	VISEN Shanghai	10	PRC	February 6, 2032	58107493
5	维昇	VISEN Shanghai	10	PRC	September 13, 2033	63503436
6	维昇	VISEN Shanghai	5	PRC	October 27, 2032	54815389
7	维昇	VISEN Shanghai	35	PRC	January 6, 2033	54827259
8	维昇	VISEN Shanghai	35	PRC	May 20, 2032	54836276
9	维臻高	VISEN Shanghai	5	PRC	January 27, 2032	58118622
10	维昇笔	VISEN Shanghai	10	PRC	January 27, 2032	58120354
11	VISENPHM	VISEN Shanghai	35	PRC	August 6, 2029	35290153
12	VISENPHM	VISEN Shanghai	5	PRC	August 6, 2029	35301061

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No.	Trademark	Owner	Class	Place of Registration	Expiry Date	Registration Number
13	VISENMED	VISEN Shanghai	5	PRC	August 20, 2029	35440861
14	VISENMED	VISEN Shanghai	35	PRC	August 13, 2029	35444832
15		VISEN Shanghai	10	PRC	May 13, 2034	75054451
16	VISEN	VISEN HK	5, 10 & 35	HK	July 27, 2031	305701509
17	维臻高 (Series)	VISEN HK	5	HK	July 27, 2031	305701383
18	维昇 (Series)	VISEN HK	5, 10 & 35	HK	July 27, 2031	305701491

See “Risk Factors – Other Risks Related to Our Intellectual Property” for other risks related to our intellectual property, and “Appendix IV – Statutory and General Information – B. Further Information about Our Business” for further details regarding our intellectual property rights.

As advised by our legal advisor as to the intellectual property laws, with the support of the freedom-to-operate searches and analysis on our Core Product and other drug candidates in China (including Hong Kong, Macau and Taiwan), (a) no particular findings has caused or casted doubt on our possession of sufficient rights under the Exclusive License Agreements enabling us to manufacture, import, commercialize, use, or sell the Core Product and other drug candidates in China (including Hong Kong, Macau and Taiwan); (b) no third-party issued patents have been identified that would be infringed upon by us in relation to the manufacturing, importation, commercialization, use, or sale of the Core Product and other drug candidates in China (including Hong Kong, Macau and Taiwan); (c) Ascendis Pharma is the registered owner of patents and patent applications for the Core Product and other drug candidates in China (including Hong Kong, Macau and Taiwan); and (d) existing registered patents have conferred sufficient protection to the Core Product and other drug candidates in China (including Hong Kong, Macau and Taiwan), regardless of the pending status of patent applications in relation to the Core Product and other drug candidates. Taking into account the foregoing, our Directors believe, which is concurred by our legal advisor as to the intellectual property laws, that we possess the essential patent rights and have sufficient intellectual property protection in relation to the Core Product and other drug candidates in China (including Hong Kong, Macau and Taiwan).

With the same basis set forth above and independent due diligence conducted by the Joint Sponsors, nothing has come to the Joint Sponsors’ attention that would reasonably cause Joint Sponsors to cast doubt on the Directors’ view.

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PERMITS, LICENSES AND OTHER APPROVALS

During the Track Record Period and as of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations. As of the Latest Practicable Date, all of our three drug candidates received notice for approval of clinical trials (臨床試驗通知書) issued by the NMPA.

LEGAL PROCEEDINGS AND COMPLIANCE

Our Directors confirm that, as of the Latest Practicable Date, we were not a party to any material legal or administrative proceedings in connection with intellectual property rights or otherwise, and we are not aware of any claims or proceedings contemplated by Governmental Authorities or third parties which could materially and adversely affect our business. In addition, as of the Latest Practicable Date, other than those disclosed elsewhere in the Directors and Senior Management, our Directors are not involved in any actual or threatened material claims or litigation.

SUPPLIERS

Our major suppliers primarily provide us (i) the clinical supplies of our endocrine drug candidates; (ii) operational services such as patient registry; (iii) certain research and development services which we outsource to third-party CROs; and (iv) lessors of our leased properties. We have established stable relationships with many of our key suppliers.

Purchases from our five largest suppliers, for 2022, 2023 and the four months ended April 30, 2024 were RMB87.4 million, RMB30.0 million and RMB8.2 million, respectively, representing 53%, 45% and 48% of our total purchase cost for the respective period. Purchases from our largest supplier for 2022, 2023 and the four months ended April 30, 2024 were RMB63.5 million, RMB17.7 million and RMB3.9 million, respectively, representing 39%, 26% and 23% of our purchase cost for the respective period.

Save for Ascendis Pharma, all of our five largest suppliers during the Track Record Period are Independent Third Parties, and none of our Directors, their respective associates nor any Shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as at the Latest Practicable Date, has 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, we order supplies and services on a purchase order basis and have set up CRO bidding and management processes to enable us to obtain better terms and conditions.

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The following table sets forth certain information of our five largest suppliers during the Track Record Period:

Five largest suppliers for the four months ended April 30, 2024	Supplier background	Products/services purchased	Business relationship since	Typical credit term and payment method	Purchase amount	Percentage of total purchases
<i>RMB'000</i>						
Ascendis Pharma Endocrinology Division A/S	A global pharmaceutical Company headquartered in Denmark focusing on endocrinology rare diseases, wholly owned by Ascendis Pharma A/S	Clinical supply of the Core Product, Clinical Consulting, Cost Sharing for the Core Product	2018	30-60 days, wire transfer	3,900	23%
Ascendis Pharma Growth Disorders A/S	A global pharmaceutical Company headquartered in Denmark focusing on growth disorders diseases, wholly owned by Ascendis Pharma A/S	Clinical supply of TransCon CNP (navepegritide), Clinical Consulting	2018	30-60 days, wire transfer	2,090	12%
Supplier A	A company engaged in the development of real estate properties. The company's focus is on the development of various types of properties, which includes residential, commercial, or mixed-use projects. It has a registered capital of approximately US\$78.0 million	Office lease relating to the office in Beijing	2021	N/A, wire transfer	818	5%

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Five largest suppliers for the four months ended April 30, 2024	Supplier background	Products/services purchased	Business relationship since	Typical credit term and payment method	Purchase amount	Percentage of total purchases
					<i>RMB'000</i>	
Supplier B	A company based in Shanghai, China. Its business scope includes property leasing, property information consulting, and corporate investment. The company provides services related to the leasing of properties, offering solutions for individuals and businesses in search of rental properties. It has a registered capital of approximately US\$100.9 million	Office lease relating to the office in Shanghai	2021	N/A, wire transfer	679	4%
Supplier C	A leading CRO headquartered in Hangzhou, providing full-service for the global biopharmaceutical and medical device industries. It had revenue of approximately RMB7,384.0 million and more than 9,500 employees in 2023 according to its annual report	<ul style="list-style-type: none"> • Core Product: safety evaluation, clinical trial execution, and central image, CSR preparation • Palopegteriparatide: assist us with data management, safety information collection and biostatic analysis • TransCon CNP (navepegritide): pharmacovigilance service for safety evaluation 	2019	60 days, wire transfer	679	4%
Total					<u>8,166</u>	<u>48%</u>

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Five largest suppliers for the Year 2023	Supplier background	Products/services purchased	Business relationship since	Typical Credit Term and Payment Method	Purchase amount	Percentage of total purchases
					(RMB'000)	
Ascendis Pharma Endocrinology Division A/S	A global pharmaceutical Company headquartered in Denmark focusing on endocrinology rare diseases, wholly owned by Ascendis Pharma A/S	Clinical supply of the Core Product, Clinical Consulting, Cost Sharing for the Core Product	2018	30-60 days, wire transfer	17,712	26%
Supplier B	A company based in Shanghai, China. Its business scope includes property leasing, property information consulting, and corporate investment. The company provides services related to the leasing of properties, offering solutions for individuals and businesses in search of rental properties. It has a registered capital of approximately US\$100.9 million	Office lease relating to the office in Shanghai	2021	N/A, wire transfer	4,092	6%
Ascendis Pharma Growth Disorders A/S	A global pharmaceutical Company headquartered in Denmark focusing on growth disorders diseases, wholly owned by Ascendis Pharma A/S	Clinical supply of TransCon CNP (navepegritide), Clinical Consulting	2018	30-60 days, wire transfer	3,301	5%
Supplier A	A company engaged in the development of real estate properties. The company's focus is on the development of various types of properties, which includes residential, commercial, or mixed-use projects. It has a registered capital of approximately US\$78.0 million	Office lease relating to the office in Beijing	2021	N/A, wire transfer	2,480	4%

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Five largest suppliers for the Year 2023	Supplier background	Products/services purchased	Business relationship since	Typical Credit Term and Payment Method	Purchase amount	Percentage of total purchases
					<i>(RMB'000)</i>	
Supplier D	A well-structured, multidisciplinary comprehensive medical education center affiliated to a university, with 10 university hospitals and 11 hospitals serving as teaching hospitals as of September 1, 2023	Patient registry study for HP patients	2021	30 days, wire transfer	2,378	4%
			Total		29,963	45%

Five largest suppliers for the Year 2022	Supplier background	Products/services purchased	Business relationship since	Typical Credit Term and Payment Method	Purchase amount	Percentage of total purchases
					<i>(RMB'000)</i>	
Ascendis Pharma Endocrinology Division A/S	A global pharmaceutical Company headquartered in Denmark focusing on endocrinology rare diseases, wholly owned by Ascendis Pharma A/S	Clinical supply of the Core Product, Clinical Consulting, Cost Sharing for the Core Product	2018	30-60 days, wire transfer	63,499	39%
Ascendis Pharma Bone Diseases A/S	A global pharmaceutical Company headquartered in Denmark focusing on bone diseases, wholly owned by Ascendis Pharma A/S	Clinical supply of palopegteriparatide, Clinical Consulting	2018	30-60 days, wire transfer	6,576	4%
Supplier D	A well-structured, multi-disciplined comprehensive medical education center affiliated to a university, with 10 university hospitals and 11 hospitals serving as teaching hospitals as of September 1, 2023	Patient registry study for HP patients	2021	30 days, wire transfer	6,440	4%

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Five largest suppliers for the Year 2022	Supplier background	Products/services purchased	Business relationship since	Typical Credit Term and Payment Method	Purchase amount	Percentage of total purchases
					<i>(RMB'000)</i>	
Supplier E	A company providing construction services headquartered in Suzhou. It has a registered capital of RMB50 million	Construction unit relating to Suzhou Industrial Park	2022	60 days, wire transfer	5,503	3%
Supplier C	A leading CRO headquartered in Hangzhou, providing full-service for the global biopharmaceutical and medical device industries. It had revenue of approximately RMB7,384.0 million and more than 9,500 employees in 2023 according to its annual report	<ul style="list-style-type: none"> • Core Product: safety evaluation, clinical trial execution, and central image, CSR preparation • Palopegteriparotide: assist us with data management, safety information collection and biostatic analysis • TransCon CNP (navepegtride): pharmacovigilance service for safety evaluation 	2019	60 days, wire transfer	5,355	3%
Total					<u>87,353</u>	<u>53%</u>

CUSTOMERS

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales before the commercialization of one or more of our drug candidates.

COMPETITION

The pharmaceutical industry is highly competitive and subject to rapid and significant change, and we anticipate direct competition from other organizations developing LAGH therapies and other types of endocrine therapies. This would include companies such as Novo Nordisk A/S, Anhui Anke Biotechnology (Group) Co., Ltd, GeneScience Pharmaceutical Co., Ltd., Xiamen Amoytop Biotech Co., Ltd., Shanghai United Sai'er Biology Engineering Co., Ltd., I-Mab Biopharma Co., Ltd., as well as other major multinational pharmaceutical companies, China-based innovative biopharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies, universities, and other

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research institutions. Many of our competitors have greater resources, as well as larger R&D functions and more experienced marketing and manufacturing organizations. As a result, these companies may be more effective in selling and marketing their products or obtaining regulatory approval more rapidly than we are able to if their drug candidates are in clinical development.

Additionally, our competitors may succeed in developing, acquiring or licensing technologies and drug products that are superior to, or more effectively marketed than, the drug candidates that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive. For additional information regarding the companies that may be competitive with our drug candidates currently in development, see “– Our Drug Pipeline.” Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or therapies that are more effective, safer or less costly than our current or future drug candidates, or obtain regulatory approval for their products more rapidly than we may obtain approval for our drug candidates.

QUALITY MANAGEMENT SYSTEM

We believe that an effective quality management system is critical to ensuring the quality of our products and maintaining our reputation and success. Our senior management team is actively involved in formulating internal quality control policies and monitoring our overall quality control process. We have established comprehensive quality control procedures and protocols that span across the entire clinical development lifecycle.

We have established an independent quality management system and devote significant attention to quality control and assurance for the clinical development of our drug candidates. Our quality management team monitors and drives our quality performance, allocates sufficient resources to implement the quality management system and sets the quality governance mechanism. We also conduct regular training so that our quality management team understands the regulatory requirements applicable to the operation of our business.

The primary responsibilities of our quality management team include the following:

- establishing a robust quality management system for our line functions to ensure that all our operational activities conform with global and local regulatory requirements; continuously assessing and evaluating the system for optimization and improvement;
- developing and implementing audit plans for investigator site audits, internal process audits and vendor audits to ensure our compliance with applicable regulatory requirements;

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- establishing and maintaining integrated risk-based quality review and evaluation strategy and metrics and coordinating and performing risk evaluations for our Company and individual projects to ensure adequate quality metrics and timely reporting to our senior management team;
- maintaining our vendor management system, which includes establishing appropriate processes for the assessment of vendors, monitoring their performance, reviewing and approving quality agreements and other duties; and
- ensuring patient safety and well-being during our clinical trials and the credibility of our clinical trial data.

RISK MANAGEMENT

We recognize that risk management is critical to the success of our business operation. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the Chinese and global pharmaceutical markets, our ability to develop, manufacture and commercialize our drug candidates, and our ability to compete with other pharmaceutical companies. See "Risk Factors" for a discussion of various risks and uncertainties we face. We also face various market risks. In particular, we are exposed to credit, liquidity, interest rate and currency risks that arise in the normal course of our business. See "Financial Information – Financial Risk Disclosure" for a discussion of these market risks.

We have adopted a consolidated set of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis. Our audit committee, and ultimately our Directors, supervise the implementation of our risk management policies. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated by us and reported to our Directors.

The following key principles outline our approach to risk management and internal control:

- Our governance committee which is comprised of senior management and functional heads will oversee and manage the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) reviewing and approving our corporate risk tolerance; (iii) monitoring the most significant risks associated with our business operation and our management's handling of such risks; (iv) reviewing our corporate risk in the light of our corporate risk tolerance; and (v) monitoring and ensuring the appropriate application of our risk management framework across our Company.

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- Our Chief Executive Officer is responsible for (i) formulating and updating our risk management policy and target; (ii) reviewing and approving major risk management issues of our Company; (iii) promulgating risk management measures; (iv) providing guidance on our risk management approach to the relevant departments in our Company; (v) reviewing the relevant departments' reporting on key risks and providing feedback; (vi) supervising the implementation of our risk management measures by the relevant departments; (vii) ensuring that the appropriate structure, processes and competences are in place across our Company; and (viii) reporting to our Directors on our material risks.
- The relevant departments in our Company, including without limitation the finance department, the legal and compliance department and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to formalize risk management across our Company and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) prepare a risk management report annually for our Chief Executive Officer's review; (iv) continuously monitor the key risks relating to their operation or function; (v) implement appropriate risk responses where necessary; and (vi) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

We consider that our Directors and senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control. See "Directors and Senior Management" for details regarding their qualification and experiences.

INTERNAL CONTROL

We have engaged an independent internal control consultant to review and provide remedial advice on our internal control and risk management. The internal control consultant has conducted a review procedure on our internal control system in certain aspects, including financial reporting and disclosure controls, corporate level controls, information system control management and other procedures for our operations. The internal control consultant conducted its work in June and July 2023 and has not identified any deficiencies in our risk management and internal control system in the review that would have had a material adverse impact on our business, financial condition or results of operations.

Our Directors are responsible for establishing and ensuring effective internal controls to safeguard our Shareholder's 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.

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During the Track Record Period, we have regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operation, such as contract management policy, risk management and protection of intellectual property. We provide periodic training about these measures and procedures to our employees as part of our employee training program. In addition, we monitor the implementation of these measures and procedures.
- Our Directors (who are responsible for monitoring the corporate governance of our Company) with help from our legal advisers, will also periodically review our compliance status with all relevant laws and regulations after the [REDACTED].
- We have established an audit committee effective upon the [REDACTED] which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and renders advice in respect of financial reporting as well as oversees internal control procedures of our Company.
- We maintain strict anti-corruption policies among our employees and we believe we will therefore be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry. We strictly prohibit bribery or other improper payments in any of our business operations. This prohibition applies to all business activities, anywhere in the world, whether involving government officials or healthcare professionals. Improper payments prohibited by this policy include bribes, kickbacks, excessive gifts or entertainment, or any other payment made or offered to obtain an undue business advantage. We keep accurate books and records that reflect transactions and asset dispositions in reasonable detail. Requests for false invoices or payment of expenses that are unusual, excessive or inadequately described are rejected and promptly reported. Misleading, incomplete or false entries in our books and records are never acceptable. We will also ensure that any future commercialization team personnel comply with applicable legal requirements, which include restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.
- We have established procedures to protect the confidentiality of personal information of stakeholders, including but not limited, employees and healthcare professionals. In general, we do not have access to patients' personal data. We maintain policies which require our personnel to be trained on collecting, processing and safeguarding personal information and require our CROs to have data protection measures in place and related clauses in our agreements with them under which they are responsible for safeguarding data in their possession. Access to clinical trial data has been strictly limited to authorized personnel only according to the GCP and

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relevant regulations. Additionally, we require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Data are to be used only for the intended use, as agreed by the patients and consistent with the consent form and no use of data falls outside the scope of the consent form will be permitted without obtaining consent from patients.

- We have engaged several PRC law firms to advise us on and keep us abreast with PRC laws and regulations. We will continue to arrange various training to be provided by external legal advisers from time to time when necessary and/or any appropriate accredited institution to update our Directors, senior management, and relevant employees on the latest PRC laws and regulations.
- Our Directors believe that compliance creates sustainable value for us and are dedicated to cultivating a compliance culture among all of our employees. To ensure such compliance culture is embedded into everyday workflow and set the expectations for individual behavior across the organization, we regularly conduct internal compliance checks and inspections, adopt strict accountability internally and conduct compliance training.

LAND AND PROPERTIES

Headquartered in Shanghai, we also have offices in Beijing, Suzhou and Taipei. We have leased and occupied approximately 893.07 square meters of office space in China (including Hong Kong, Macau and Taiwan) as of the date of this document. The relevant lease agreements have lease expiration dates ranging from December 14, 2024 to August 28, 2026. We do not anticipate undue difficulty in renewing our leases upon their expiration, and we do not anticipate any material impact on our operations if we fail to renew any of the leases.

The following table sets forth a summary of our leased properties and land use right as of the Latest Practicable Date.

<u>Location</u>	<u>Type of Property</u>	<u>Gross Floor Area (sq.m)</u>	<u>Property Leased/ Land Use Right</u>	<u>Expiry Date</u>
Beijing, China	Office	266.46	Leased	June 14, 2026
Shanghai, China	Office	482.04	Leased	September 30, 2025
Shanghai, China	Office	64.49	Leased	December 14, 2024
Shanghai, China	Warehouse	45	Leased	September 30, 2025
Shanghai, China	Registered Address	/	Leased	August 28, 2026

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<u>Location</u>	<u>Type of Property</u>	<u>Gross Floor Area (sq.m)</u>	<u>Property Leased/ Land Use Right</u>	<u>Expiry Date</u>
Suzhou, China	Office	10	Leased	December 26, 2024
Taiwan, China	Office	25.08	Leased	March 31, 2025

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our insurance policies cover AEs in our clinical trials, including personal injury and property loss incurred in any clinical trials conducted or funded by our Company. See “Risk Factors – We have limited insurance coverage, and any claims beyond our insurance coverage may result in us incurring substantial costs and a diversion of resources.”

SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

We are subject to various social, health, safety and environmental laws and regulations and our operations are regularly inspected by local government authorities. We believe we have adequate policies and SOPs ensuring compliance with all social, health, safety and environmental protection regulations. Particularly, we believe our continued growth rests on integrating social values into our business. We intend to create a lasting positive environmental, social and governance (“ESG”) impact on our future customers, suppliers and the broader community whom our operation may impact. We acknowledge our responsibilities on environmental protection, social responsibilities and are aware of the climate-related issues that may have impact on our business. We are committed to complying with ESG reporting requirements upon [REDACTED].

Our Board has the collective and overall responsibility for establishing, adopting and reviewing the ESG vision, policy and target of our Group, and evaluating, determining and addressing our ESG-related risks at least once a year. Our Board may assess the ESG risks and review our existing strategy, target and internal controls, and suggest for enhancements for our ESG management schemes. Our management team is generally responsible for carrying out the ESG policies in executing our Company’s business operations. Furthermore, we will form an ESG working group that will work on ESG requirements of our suppliers, including giving priority to suppliers with environmentally friendly products and services. Our ESG working group will also closely monitor environmental and social risks in our supply chain. Finally, our Board will also engage independent third parties to evaluate potential ESG risks faced by our Company, provide comment on our ESG Policy and strategies, and set targets so that the ESG Policy will be up-to-date.

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We monitor ESG-related risks and opportunities that may impact our business, strategy and financial performance and evaluate the magnitude of resulting impact by taking into consideration the relevant matters stipulated in Appendix C2 to the Listing Rules and applicable laws, regulations and industry standards. We will also take environmental protection as an important part in employee training, and continue to raise the awareness of energy conservation and environmental protection of all employees in the Group, helping us achieve a green, healthy and sustainable development.

Sets forth below details of our ESG focus on our business operations:

- *Manufacturing activities.* We are committed to integrating ESG principles into anticipated manufacturing activities, especially when engaging with CDMOs. In selecting WuXi Biologics preparing for anticipated manufacturing activities, we take into consideration the ESG management policies including manufacturing measures and procedures adopted by it. We align with the ESG goals and work closely with Wuxi Biologics and any other CDMOs to ensure that our manufacturing activities are sustainable and adhere to the ESG standards.
- *Clinical trials.* We are committed to managing chemical waste effectively during clinical trials. We follow standard protocols to ensure that waste is disposed of in a manner that minimizes environmental impact. We also ensure that our clinical trials are conducted ethically, with focus on patient safety.
- *Product safety.* In anticipation of the commercialization of drug candidates, we will place a high priority on our product safety by adhering to rigorous testing and quality control measures to ensure the safety and efficacy of our products and following transparent reporting practices to keep stakeholders informed about product safety issues.
- *Drug pricing.* We recognize the importance of fair drug pricing in its ESG policies. In anticipation of the commercialization of drug candidates, we strive to set drug prices based on the value they provide to patients, taking into account factors such as the cost of development, the therapeutic benefits of the drug, and the need for accessibility and affordability.
- *Supply chain management.* We are committed to integrating ESG principles into our supply chain management. In anticipation of the commercialization of drug candidates, we will work closely with our suppliers to ensure they meet the shared business ethics and sustainability standards.

We strive to provide a safe working environment for our employees. We have implemented work safety guidelines setting out safety practices, accident prevention and accident reporting. When we engage in manufacturing activities in the future, we will implement company-wide environmental, health and safety policies and operating procedures. We expect our expenses in relation to environmental compliance matters to increase going forward as we implement these policies and procedures.

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Corporate social responsibility is also a key part of our core growth philosophy which, along with our focus on sustainability, diversity and public interests, is expected to generate value for our Shareholders. As such, we are committed to incorporating corporate social responsibility principles into our operational decisions and practices. For instance, in 2020, we entered into a five-year strategy cooperation under a funding agreement with CHARD, a national, non-profit, cooperative exchange platform for rare diseases, to support the founding of Achondroplasia Advisory Board. We also invested in various other corporate social responsibility efforts, including making donations to organizations such as hospitals, universities and foundations that combat COVID-19, and sponsoring medical conferences. In 2022, 2023 and the four months ended April 30, 2024, respectively, we spent approximately RMB2.5 million, RMB1.9 million and RMB0.1 million, in regards to the foregoing corporate social responsibility activities.

We are subject to environmental protection and occupational health and safety laws and regulations in China. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines, penalties or damages or incur costs that could have a material adverse effect on the success of our business. See “Risk Factors – Other Risks Related to Obtaining Regulatory Approval of Our Drug Candidates and Other Legal Compliance Matters – If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines, penalties or damages or incur costs that could have a material adverse effect on the success of our business” on the potential impact of such risks. However, since we focused on provide treatment in selected endocrinology diseases and have not yet commenced the commercial manufacturing during the Track Record Period, we did not incur material environmental compliance expenses during such period and we do not expect the expenses of such compliance to be material going forward. We will make continuous endeavors to contribute a better environment by limiting the emission of greenhouse gas, appealing employees to live an eco-friendly lifestyle and so on.

As advised by our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or results of operations and had complied with laws, rules or regulations during ordinary business operation in relation to ESG, safety and environmental protection, in all material aspects in the PRC, including but not limited to Good Clinical Trial Practice for Drugs (《藥物臨床試驗質量管理規範》), Notice on Issuing the Administration Rules of Drug Clinical Trial Institution (《關於發佈藥物臨床試驗機構管理規定的公告》), Environmental Protection Law of PRC (《中華人民共和國環境保護法》), Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), Environmental Impact Assessment Law of PRC (《中華人民共和國環境影響評價法》), Administrative Measures for Pollutant Discharge Licensing (for Trial Implementation) (《排污許可管理辦法(試行)》), Regulation on Pollutant Discharge Permit Administration (《排污許可管理條例》), Fire Prevention Law of the PRC (《中華人民共和國消防法》) and others.

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

OUR CONTROLLING SHAREHOLDERS

As at the Latest Practicable Date, Ascendis Pharma A/S, through its wholly-owned subsidiaries, Ascendis Pharma Endocrinology Division, Ascendis Pharma Growth Disorders and Ascendis Pharma Bone Diseases (collectively, “Ascendis Subsidiaries”), was indirectly interested in an aggregate of approximately 39.95% of the Shares in the Company. Immediately after the completion of the [REDACTED] (assuming the [REDACTED] is not exercised and no Shares are issued under the [REDACTED] Share Award Scheme), Ascendis Pharma A/S, through the Ascendis Subsidiaries, will be indirectly interested in approximately [[REDACTED]%] of the Shares in the Company.

As at the Latest Practicable Date, Vivo Plenilune IX Limited, or Vivo Capital was interested in approximately 35.09% of the Shares in the Company. Immediately after the completion of the [REDACTED] (assuming the [REDACTED] is not exercised and no Shares are issued pursuant to the [REDACTED] Share Award Scheme), Vivo Capital will be interested in [[REDACTED]%] of the total issued share capital of our Company. Vivo Capital is a wholly-owned subsidiary of Vivo Capital Fund IX (Cayman), L.P., which is in turn controlled by its general partner, Vivo Capital IX (Cayman), LLC. (collectively, “Vivo Funds”).

Accordingly, Ascendis Pharma A/S, the Ascendis Subsidiaries, and Vivo Funds will be the Controlling Shareholders of the Company after the [REDACTED].

DELINEATION OF BUSINESS

Business of Our Group

We are a late-stage, near-commercialization biopharmaceutical company focused on providing treatments in selected endocrinology diseases in China (including Hong Kong, Macau and Taiwan). As of the Latest Practicable Date, we had a pipeline of three endocrine drug candidates, namely lonapegsomatropin, TransCon CNP (navepegritide) and palopegteriparatide, among which, lonapegsomatropin has completed Phase 3 pivotal trial for the treatment of PGHD in China, and the other two drug candidates are being studied in clinical trials in China.

Delineation from Ascendis Pharma

Ascendis Pharma A/S is a biopharmaceutical company that has been listed on Nasdaq (Ticker Symbol: ASND) since 2015. Applying its transient conjugation technology (TransCon), Ascendis Pharma currently has a pipeline of three independent endocrine rare disease drug candidates (lonapegsomatropin, TransCon CNP (navepegritide) and palopegteriparatide (excluding the rights granted to our Company in China (including Hong Kong, Macau and Taiwan))). Among the three drug candidates, lonapegsomatropin is commercially available in the United States, having received marketing approval from the FDA in 2021. Lonapegsomatropin has also received marketing approval from the EMA in 2022 and is undergoing clinical development in Japan. Palopegteriparatide was also approved by the EMA and the FDA in November 2023 and August 2024, respectively, for the treatment of adult patients with chronic hypoparathyroidism (“HP”) and was commercially launched in certain European countries in January 2024.

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

As disclosed in the section headed “Business – Collaborations – Exclusive License Agreements with Ascendis Pharma” in this document, our Company obtained from Ascendis Pharma an exclusive, royalty-free license under its applicable owned patents and other intellectual property to develop, manufacture and commercialize lonapegsomatropin, TransCon CNP (navepegritide) and palopegteriparatide (collectively, “Licensed Products”) in China (including Hong Kong, Macau and Taiwan), specifically, long-acting products or product candidates that are being developed and/or commercialized for use in all human indications (excluding diabetes (and certain related metabolic disorders), obesity and ophthalmology) that contains a hGH, CNP or PTH, as the case may be. While our drug candidates are in-licensed from Ascendis Pharma, there is a clear delineation of business between our Company and Ascendis Pharma, as the licenses granted to our Company in China (including Hong Kong, Macau and Taiwan) are exclusive so that no one other than our Company (except where our Company grants sublicenses to its affiliates in China (including Hong Kong, Macau and Taiwan)) can develop, manufacture and commercialize the Licensed Product in China (including Hong Kong, Macau and Taiwan), and Ascendis Pharma has agreed not to compete with our Company in China (including Hong Kong, Macau and Taiwan) in respect of the Licensed Products.

Ascendis Non-Compete Undertaking

Pursuant to the Exclusive License Agreements, during the term of the respective Exclusive License Agreement, neither the Ascendis Subsidiaries (being parties to the Exclusive License Agreements) nor its affiliates shall conduct, or intentionally enable, or participate in, or license or otherwise authorize any third party to conduct, enable or participate in, the research, development, manufacture or commercialization of any Competing Product in China (including Hong Kong, Macau and Taiwan). A “Competing Product” shall mean a long-acting product (a product that is intended to be administered to a subject, once a week or less frequently than once a week in the case of hGH and CNP, and once a day or less frequently than once a day in the case of PTH) developed and/or commercialized for use in the all human indications (subject to certain exceptions (including diabetes (and certain related metabolic disorders), obesity and ophthalmology)) that contains a hGH, CNP or PTH, as the case may be.

In addition, under the Shareholders’ Agreement, each of the Ascendis Subsidiaries (being parties to the Shareholders’ Agreement) undertakes and covenants to our Company that, it will not, without our prior written consent, either on its own account or through any of his/its controlled affiliates, or in conjunction with or on behalf of any other person: (i) carry out or be engaged in the research, development, manufacturing or commercialization of any product for the treatment of any diseases involving hyper- or hyposecretion of hormones in China (including Hong Kong, Macau and Taiwan) (the “Competing Business”); (ii) directly or indirectly own any interest in a third party engaged in the Competing Business other than holding in aggregate less than ten percent (10%) of the issued share capital of any entity engaged in the Competing Business as a passive investor; (iii) solicit or entice away or attempt to solicit or entice away from any member of our Group, any person or entity who is a customer, client, employee, representative, agent or correspondent of our Group or in the habit of dealing with our Group, or (iv) provide services to any entity engaged in the Competing Business in any form. Such non-compete undertaking shall terminate upon the termination of each of the Exclusive License Agreements.

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

Right of First Negotiation

In addition, during the term of the Exclusive License Agreements, Ascendis Pharma is required to notify our Company prior to engaging in substantive discussions with third parties regarding the license to such third parties by Ascendis Pharma or its affiliates under the Ascendis platform technology (including Ascendis Pharma’s proprietary chemistry, materials and methodologies for transiently covalently coupling a substrate of interest to various carriers *via* a transient conjugation linker, thereby allowing release of the transiently linked substrate in a controlled manner over time for a therapeutic or prophylactic effect) of rights to develop or commercialize endocrine product(s) in China (including Hong Kong, Macau and Taiwan) (a “ROFN Opportunity”). No later than 20 business days after receipt of such notice, the Company shall notify Ascendis Pharma whether it wishes to enter into negotiations with Ascendis Pharma to negotiate an agreement for our Company to obtain the right corresponding to such ROFN Opportunity. If our Company does not timely notify Ascendis Pharma that it wishes to negotiate for the ROFN Opportunity, or notifies Ascendis Pharma that it is not interested in the ROFN Opportunity, Ascendis Pharma shall be free to engage with third parties discussions of such ROFN Opportunity. If the Company timely notifies Ascendis Pharma that it wishes to negotiate an agreement for such ROFN Opportunity, the parties shall enter into good faith negotiations not to exceed 90 days with the goal of finalizing the terms of and executing the relevant license agreement. If after the expiration of such ninety (90)-day period (the “ROFN Negotiation Stop Date”), the Parties have not executed the relevant license agreement, Ascendis Pharma shall be free to engage with third parties discussions of such ROFN Opportunity provided that Ascendis Pharma shall not grant such ROFN Opportunity to a third party on terms more favorable to such third party than last offered by Ascendis Pharma to our Company for an additional one 180 days after the ROFN Negotiation Stop Date.

Apart from the aforesaid business, Ascendis Pharma is also advancing oncology as its second therapeutic area of focus which is different in nature from our Group’s business.

On the bases of the above, the Directors believe that the Group’s businesses and Ascendis Pharma’s businesses are clearly delineated and do not directly or indirectly compete with each other.

Delineation from Vivo

Vivo Funds are under the management of Vivo Capital LLC. Founded in 1996, Vivo Capital LLC is a global investment firm focused on healthcare with approximately US\$5.8 Billion in assets under management as of December 31, 2023, and provides a multi-fund Investment platform, covering private equity including buyout, venture capital, and public equity. Vivo Capital LLC and funds managed by Vivo Capital LLC (collectively, “Vivo”) invest broadly in healthcare across all fund strategies, including biotechnology, pharmaceuticals, medical devices, and healthcare services, with a focus on the largest healthcare markets.

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

Interest in the Investee

As of the Latest Practicable Date, among all investee portfolio companies in which Vivo holds 10% or more equity interest, only one portfolio investee company (the “**Investee**”) engages in the research and development of endocrinology therapies/drugs. As of the Latest Practicable Date, Vivo holds [22.74]% equity interest in the Investee on a fully-diluted basis.

We do not consider that the business of the Investee competes or is likely to compete with the business of our Group. To the best knowledge of the Company, the Investee is a China-based rare disease therapeutics company and currently has a drug product for the treatment of pediatric patient with congenital adrenal hyperplasia (CAH) in China. CAH is an endocrine rare disease resulting from the deficiency of one of the enzymes required for cortisol synthesis in the adrenal cortex. The Directors believe that the Investee’s businesses are clearly delineated from the Group’s businesses for the following reasons:

- Different therapeutic focus. To the knowledge of the Directors, the Investee does not plan to engage in the development of drugs/therapies for GHD, HP or ACH;
- Different management and operational team. To the knowledge of the Directors, our Directors and senior management do not hold any position in the Investee. Moreover, there is no overlapping personnel in the research and development teams of our Group and the Investee; and
- Corporate governance. Our Company has adopted and will adopt certain corporate governance measures to manage the conflicts of interest as set forth in “– Corporate governance measures” as below.

In addition, while Vivo may acquire interests in certain businesses that operate in the healthcare sector, Vivo normally provides financial capital in its portfolio companies. The business decisions of each Vivo’s portfolio company are solely made by the directors and senior management of such portfolio company.

Save as disclosed above, as of the Latest Practicable Date, none of our Controlling Shareholders, have any interest in any other company which is principally engaged in a business similar to the principal business of the Company, and accordingly is not subject to disclosure pursuant to Rule 8.10 of the Listing Rules.

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDERS

The Directors are of the view that the Group is able to carry on its business independently from the Controlling Shareholders (including their close associates) following completion of the [REDACTED] for the following reasons:

Operational and Administrative Independence

The Company has a full-time management team and team of staff to carry out its own operation independent of the Controlling Shareholders. The support functions comprising accounting, administration, corporate secretarial, compliance and human resource management will also continue to be handled by a team of staff employed directly by the Company and are separated from the Controlling Shareholders. In addition, we have established our internal organizational and management structure which includes Shareholders’ meetings, our Board and other committees and formulated the terms of reference of these bodies in accordance with the requirements of the applicable laws and regulations, the Listing Rules and the Articles of Association, so as to establish a regulated and effective corporate governance structure with independent departments, each with specific area of responsibilities.

During ordinary and usual course of business, the Group has entered into transactions with Ascendis Subsidiaries, including the Exclusive License Agreements, the Clinical Supply Agreements, the Cost Sharing and Volume Commitment Agreement and Commercial Supply Agreement. See “Connected Transactions” for details. Such transactions were and will be conducted in the ordinary and usual course of business of the Group, on an arm’s length basis and on normal commercial terms.

Effective Control over the Development, Regulatory and Commercialization Activities

With respect to the development of the Company’s products, pursuant to the Exclusive License Agreements, our Group is solely responsible for any clinical trial activities carried out as part of our development and commercialization activities in China (including Hong Kong, Macau and Taiwan). The parties shall also agree to a R&D plan that sets forth the parties respective research and technical development plan activities, which may be amended by the joint development committee established by both parties in accordance with the Exclusive License Agreements. Apart from the products supplied by Ascendis Pharma under the Clinical Supply Agreements for use in conducting clinical trials and the assistance provided by Ascendis Pharma under the Exclusive License Agreements, our Group procures equipment, materials and services that are essential for its R&D activities, from its suppliers that are independent from Ascendis Pharma. For details of the Clinical Supply Agreements and Exclusive License Agreements, see “Connected Transactions.” The development of Licensed Products will be monitored by a joint development committee with equal representation of the Company and Ascendis Pharma. All decisions of such committee shall be made by unanimous vote. If the committee is unable to reach consensus on certain matter, with certain specific pre-agreed exceptions, our Company shall have the final decision-making authority. For details regarding the R&D activities conducted by the Company as of the date of this document, please

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

refer to sections headed “Business – Research and Development”, “Business – Our Drug Pipeline – Lonapegsomatropin – A Long-Acting hGH Replacement Therapy for PGHD – Our R&D Work”, “Palopegteriparatide – A PTH Replacement Therapy Addressing the Underlying Cause of HP – Our R&D Work” and “TransCon CNP (navepegritide) – A Disease-Modifying Therapy for ACH – Our R&D Work.”

In terms of regulatory filings, the Company has the sole responsibility for obtaining and maintaining, and shall own, all regulatory approvals for Licensed Product developed under each Exclusive License Agreement from regulatory authorities in each of the jurisdictions in China (including Hong Kong, Macau and Taiwan). Where reasonably requested by us, Ascendis Pharma would provide assistance to us to support the obtaining and maintenance of regulatory approvals of the Licensed Products in China (including Hong Kong, Macau and Taiwan). For details, see “Connected Transactions – Exclusive License Agreements.”

The commercialization of Licensed Products in China (including Hong Kong, Macau and Taiwan) will be monitored by a joint commercialization committee with equal representation of the Company and Ascendis Pharma, the current marketing authorization holder. All decisions of such committee shall be made by unanimous vote. If the committee is unable to reach consensus on certain matter, with certain specific pre-agreed exceptions, our Company shall have the final decision-making authority acting in good faith. As a late-stage, near-commercialization biopharmaceutical company, the Company has taken solid strides towards realizing independent commercialization capabilities, as evidenced by (i) the commercialization team it built up internally; and (ii) the know-how and expertise it accumulated from designing the tailor-made programs for commercialization, patient awareness and market access in China. For details, please see the section headed “Business – Commercialization Plan, Patient Support and Market Access.”

On the basis of the above, our Directors are of the view that, the Company retains effective control over the development, regulatory and commercialization activities of its products in China (including Hong Kong, Macau and Taiwan), and the Company has all requisite resources and is capable of carrying on the business of R&D, application for registration and clinical trials in China (including Hong Kong, Macau and Taiwan) independently of Ascendis Pharma.

Mutual and Established Relationship

The roles of Ascendis Pharma, as our global partner, and us are mutually beneficial and complementary to each other. On one hand, the licenses in China (including Hong Kong, Macau and Taiwan) granted by Ascendis Pharma, provide us with the exclusive rights to develop, manufacture and commercialize the Licensed Products, which have been validated in the global development programs conducted by Ascendis Pharma. On the other hand, the licensing arrangement also enables us to utilize the know-how, data, materials and other information relating to the global clinical trials conducted by Ascendis Pharma to optimize the design of our clinical trials in China (including Hong Kong, Macau and Taiwan). The continuous communication with and ongoing support from Ascendis Pharma will also benefit our R&D activities.

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

As the sole strategic long-term partner of Ascendis Pharma in China (including Hong Kong, Macau and Taiwan), we provide an exclusive channel through which Ascendis Pharma and us collaboratively commercialize the endocrinology products, so as to unlock and tap into the vast market in China (including Hong Kong, Macau and Taiwan) with unmet medical needs. The successful commercialization of the Licensed Products to address the needs of the local markets in China (including Hong Kong, Macau and Taiwan) will advance our mutual goal of extending the footprint of TransCon drug candidate portfolio globally. We are able to provide exclusive benefits for Ascendis Pharma in following aspects. We have established an experienced China-based leadership team and a strong in-house operational team. Our Company leverages its endocrinology expertise, R&D and regulatory capabilities to help Chinese patients access our drug candidates. In addition, in anticipation of the potential BLA/NDA approval and subsequent commercial launch of our drug candidates, we started building up a focused and specialized commercialization team with strong expertise in endocrinology, to drive medical activities in the market of China (including Hong Kong, Macau and Taiwan) in accordance with local rules and regulations, and we believe our key commercialization leadership members, who have substantial experience and strong track records relevant to our pipeline drug candidates, can leverage their expertise launching endocrine drugs in China (including Hong Kong, Macau and Taiwan). For details, see "Business – Commercialization Plan, Patient Support and Market Access."

Remote Risk of Termination or any Material Adverse Change of the Mutually Beneficial Relationship

The risk of Ascendis Pharma terminating the Exclusive License Agreements and the Clinical Supply Agreements is remote, as Ascendis Pharma has limited termination rights under the agreements. Each of the Exclusive License Agreements became effective on November 7, 2018 and shall continue indefinitely and for so long as a valid claim of a licensed patent exists in China (including Hong Kong, Macau and Taiwan). Ascendis Pharma may only terminate the relevant Exclusive License Agreement for certain specified material breaches thereof by us, if we challenge the validity of any patents licensed to us under such agreements, or upon bankruptcy or insolvency-related events involving us, in each case subject to specified notice periods, and upon immediate written notice in the event we undergo a change of control in favor of certain kinds of, or certain specified, competitors. The Clinical Supply Agreements will automatically terminate upon the termination of the Exclusive License Agreements.

More importantly, Ascendis Pharma's interests are closely aligned with ours both in terms of bringing endocrine drug candidates to patients in China (including Hong Kong, Macau and Taiwan) and beyond as well as growing our Company for financial success. Accordingly, termination or any adverse change of the existing relationship will be detrimental to the interest of Ascendis Pharma as well. We believe that Ascendis Pharma and we currently cooperate smoothly and we will continue to maintain our collaborative relationship with Ascendis Pharma in the future. Our Directors are not aware of any circumstances which indicates that our long-term relationship with Ascendis Pharma is likely to be terminated or materially and adversely change.

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

Anticipated Decrease of Reliance in the Future

It is industry norm that the licensee may have certain extent of reliance on licensing partners, among others, (i) for conducting clinical trials, and (ii) for the supply of drug candidates to support clinical development, manufacturing and commercialization of the licensed product candidates. While we benefit from Ascendis Pharma’s ongoing support to our R&D activities, clinical supplies, manufacturing and commercialization activities, we do not believe that we have undue reliance on Ascendis Pharma. Our transactions with Ascendis Pharma are conducted based on normal commercial terms and are consistent with market and industry standard.

While we have entered into commercial supply agreement with Ascendis Pharma for the supply of packaged products of lonapegsomatropin in the short term, we plan to enable local commercial production of one or potentially more of our drug candidates upon completion of technology transfer and obtaining necessary drug manufacturing licenses. Transitioning our supply chain to local commercial production may also enable our Company to better control the quality and consistency of the supply of our drug candidates and improve the certainty and cost-effectiveness of production. We plan to implement a three-step drug procurement and manufacturing plan to realize the commercialization of lonapegsomatropin as early as possible. In the short term, we plan to source the commercial drug supply from our collaboration partner, Ascendis Pharma. We have successfully reached a commercial supply agreement for the commercial supply of the Core Product by Ascendis Pharma in October 2023. Please refer to “Connected Transactions” for more details. In the medium term, we intend to collaborate with WuXi Biologics, our designated local CDMO in China, for the commercial production of lonapegsomatropin. In July 2023, we entered into the Technology Transfer Master Plan of the Core Product with Ascendis Pharma, signifying the commencement of technology transfer from Ascendis Pharma to us for the manufacturing of the Core Product. In December 2023, we entered into a collaboration agreement with the WuXi Biologics, pursuant to which WuXi Biologics will serve as the local CDMO of the Technology Transfer to conduct the process development and validation achieving the localization of the manufacturing technology. Completion of the Technology Transfer and Localization, which is expected to be in 2026, will confer to us the technical capabilities to manufacture the lonapegsomatropin drug substance in collaboration with WuXi Biologics. We are also developing the DCD technology in the form of prefilled syringe as a drug delivery system for the lonapegsomatropin drug substance. Once this development is finished, WuXi Biologics will have the capability to produce the Core Product. For more information regarding the DCD, please refer to “Business – Research and Development – CMC Development Programs – Dual Chamber Device Technology Development.” The commercialization of the Core Product produced by WuXi Biologics will start once we obtain the approval of Local BLA, which is expected to occur in 2028. In the long term, we plan to establish our in-house manufacturing capabilities.

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

In addition, beyond Ascendis Pharma, we plan to leverage our platform and network to pursue business development opportunities with other potential biopharmaceutical partners with endocrine drugs, drug candidates or technologies and platforms that may be synergistic or complementary to our portfolio and/or our capabilities. We plan to fully exploit our extensive knowledge in endocrinology and our deep understanding of the medical need and technology, and through identifying and executing attractive licensing and collaboration opportunities or through mergers and acquisitions, we seek to pursue business development opportunities to further expand our portfolio with other potential biopharmaceutical partners with endocrine drugs, drug candidates or technologies that may be synergistic or complementary to our portfolio. For details, see “Business – Business Development.”

Effective Control over Manufacturing Drug Product Supply, Commercialization and IP Protection

As mentioned above, in the short term, we plan to source the commercial drug supply of drug products of lonapegsomatropin from our collaboration partner, Ascendis Pharma. Concurrently, our Company has taken proactive steps to establish independent control over the local manufacturing and supply of the drug products of lonapegsomatropin by partnering with WuXi Biologics in the Technology Transfer and Localization and the development of the DCD technology, which will equip us with the necessary technology and expertise to produce the drug product. For more information regarding the Technology Transfer and Localization, please refer to “Business – Commercial Supply and Manufacturing – Step 2: Collaborative Local Manufacturing with Local CDMO.” Upon successful completion of the Technology Transfer and Localization and the approval of the Manufacturing BLA, the Company will gain the capability to locally produce the drug products of lonapegsomatropin. This includes acquiring the framework, steps, and processes essential for the production of the drug products of lonapegsomatropin. As outlined in our agreement with WuXi Biologics, they will adhere to the production methods, procedural standards, and operational workflows specified by the Company for manufacturing the drug products of lonapegsomatropin. Furthermore, the Company will maintain control over the production pace of the drug product, ensuring that all aspects of production align with the Company’s standards and strategic objectives. Additionally, the Company will deploy specialists to be on-site to promptly address any issues that arise during the manufacturing process.

Other than mentioned above, the Company also has effective control on the commercialization, and IP protection of the lonapegsomatropin, TransCon CNP and palopegteriparatide in China. For details, please refer to “Business – Commercialization Plan, Patient Support and Market Access” and “Business – Intellectual Property.”

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

Effective Management of the Conflicts of Interests

In addition, following the [REDACTED], any transactions between the Company and Ascendis Pharma will constitute connected transactions of the Company and will therefore be subject to the requirements of the Listing Rules and corporate governance measures in relation to connected transactions, including that any Directors holding overlapping positions with the Ascendis Pharma will abstain from voting on the relevant board resolutions. Please see “– Corporate Governance Measures” in this section for further information.

On the basis of the above, the Directors are of the view that the arrangements contemplated under the Exclusive License Agreements, the Clinical Supply Agreements and the Cost Sharing and Volume Commitment Agreement will not affect the Company’s ability to operate independently and the Group’s operations are independent from the Ascendis Pharma.

Financial Independence

Our Group has an independent financial system and makes financial decisions according to our Group’s own business needs and neither our Controlling Shareholders nor their close associates may intervene with our use of funds. Our Directors believe that, the Company is also able to independently secure [REDACTED] from [REDACTED] that are independent from the Controlling Shareholders. Please refer to “History, Development and Corporate Structure – [REDACTED] Investments.”

As at the Latest Practicable Date, there were no loans or guarantees provided by the Controlling Shareholders to or for the benefit of the Group.

On the basis of the foregoing, the Company is financially independent from the Controlling Shareholders.

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

Independence of Directors and Management

The Board consists of nine Directors, comprising one executive Director, five non-executive Directors and three independent non-executive Directors. See “Directors and Senior Management” for further details. The table below sets forth the overlapping director/management between our Company on the one hand and our Controlling Shareholders (including their close associates) on the other hand:

Name	Position in our Company	Material position in the Controlling Shareholders (including close associates)
Mr. Michael Wolff JENSEN	Chairman of the Board, Non-Executive Director	Executive vice president, chief legal officer of Ascendis Pharma A/S Chairman of the board of directors in the following companies: Ascendis Pharma Bone Diseases Ascendis Pharma, Ophthalmology Division A/S Ascendis Pharma Oncology Division A/S Ascendis Pharma Growth Disorders Ascendis Pharma Endocrinology Division
Mr. Jan Møller MIKKELSEN	Non-Executive Director	President, chief executive officer, board member and executive director of Ascendis Pharma A/S Executive manager and member of the board of directors in: Ascendis Pharma Bone Diseases Ascendis Pharma, Ophthalmology Division A/S Ascendis Pharma Oncology Division A/S Ascendis Pharma Growth Disorders Ascendis Pharma Endocrinology Division Member of the board of directors in Ascendis Pharma, Inc. and Ascendis Pharma Endocrinology Inc.
Mr. Fu Shan	Non-Executive Director	Joint chief executive officer and the Greater China chief executive officer of Vivo Capital LLC
Mr. Michael J. CHANG	Non-Executive Director	Managing partner of Vivo Capital LLC

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

The Directors are of the view that the Board of Directors and the senior management of the Group are able to function independently of the Controlling Shareholders and their close associates for the following reasons:

- our CEO and Executive Director, Mr. LU An-bang, currently does not hold any management positions in our Controlling Shareholders or any of their close associates. Mr. Lu is responsible for overall development strategy and business direction of our Group, as well as the day to day management of our Group’s operations;
- more than half of the members of the Board, including Mr. LU An-bang, Mr. CAO Yibo and all the independent non-executive Directors, will be entirely independent of Controlling Shareholders; and the independent non-executive Directors will be entitled to engage professional advisers at our cost for advice on matters relating to any potential conflict of interest arising out of any transaction to be entered into between our Company and our Directors or their respective associates;
- each of the overlapping Directors are non-executive Directors who does not participate in the daily operation and management of our Company, and only participates in the decision-making process for significant matters, such as our operational strategy (subject to measures conflicts of interest to avoid and address as described below);
- save as disclosed above, none of the members of the senior management of Company (including our CEO, Chief Commercial Officer and Executive Advisor) have any ongoing role with the Controlling Shareholders;
- should there be a potential conflict of interest or a connected transaction (as defined under the Listing Rules) between the Company (on one hand) and Ascendis Pharma or Vivo Capital (including the Vivo Funds) (on the other hand), the relevant overlapping Directors from Ascendis Pharma or Vivo Capital (including the Vivo Funds), will abstain from voting on the relevant board resolution(s) of the Company;
- each of our Directors is aware of his/her fiduciary duties and responsibilities under the Listing Rules as a director, which require that he/she acts in the best interests of our Company and our Shareholders as a whole; and
- 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” in this section for further information.

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

CORPORATE GOVERNANCE MEASURES

We will comply with the provisions of the Corporate Governance Code set forth in Appendix C1 to the Listing Rules, which sets out the principles of good corporate governance.

Our Directors believe that there are adequate corporate governance measures in place to manage existing and potential conflicts of interest. In order to further avoid potential conflicts of interest, we have implemented the following measures:

- where a board meeting or Shareholders' meeting is to be held for considering proposed transactions in which any of our Directors or Controlling Shareholders or any of their respective close associates has a material interest, the relevant Director or Controlling Shareholder will not vote on the relevant resolutions;
- we have established internal control mechanisms to identify connected transactions. Upon the [REDACTED], if we enter into connected transactions with any Controlling Shareholder or any of their associates, we will comply with the applicable Listing Rules;
- the independent non-executive Directors will review, on an annual basis, whether there are any conflicts of interests between our Group and any Controlling Shareholder (the "Annual Review") and provide impartial and professional advice to protect the interests of our minority Shareholders;
- our Controlling Shareholders will undertake to provide all information necessary, including all relevant financial, operational and market information and any other necessary information as required by the independent non-executive Directors for the Annual Review;
- our Company will disclose decisions on matters reviewed by the independent non-executive Directors either in its annual reports or by way of announcements;
- where our Directors reasonably request the advice of independent professionals, such as financial advisors, the appointment of such independent professionals will be made at our Company's expenses; and
- we have appointed Somerley Capital Limited as our compliance advisor to provide advice and guidance to us in respect of compliance with the applicable laws and regulations, as well as the Listing Rules, including various requirements relating to corporate governance.

CONNECTED TRANSACTIONS

OVERVIEW

We set out below certain transactions with connected persons which will constitute continuing connected transactions of our Group under Chapter 14A of the Listing Rules.

CONNECTED PERSONS

We have entered into and will continue to engage in certain transactions with the following connected persons, which will constitute our continuing connected transactions upon [REDACTED]:

<u>Connected Person(s)</u>	<u>Connected Relationship</u>
Ascendis Pharma Endocrinology Division	One of the Controlling Shareholders. Pursuant to Rule 14A.07(1) of the Listing Rules, Ascendis Pharma Endocrinology Division is a connected person of our Company.
Ascendis Pharma Growth Disorders	One of the Controlling Shareholders. Pursuant to Rule 14A.07(1) of the Listing Rules, Ascendis Pharma Growth Disorders is a connected person of our Company.
Ascendis Pharma Bone Diseases	One of the Controlling Shareholders. Pursuant to Rule 14A.07(1) of the Listing Rules, Ascendis Pharma Bone Diseases is a connected person of our Company.

CONNECTED TRANSACTIONS

CONTINUING CONNECTED TRANSACTIONS

As the Company is a pre-revenue biopharmaceutical company, the revenue ratio is not applicable. The assets ratio remains applicable and does not produce any anomalous result. As an alternative to the revenue ratio and profit ratio, we have applied a percentage ratio test based on the total amount of research and development costs and administrative expenses of our Group.

Summary of Our Continuing Connected Transactions

No.	Nature of Transactions	Relevant Listing Rules	Connected Person(s)	Waiver Sought
<i>Cost Sharing and Volume Commitment Agreement</i>				
1.	Cost sharing and volume commitment Agreement with Ascendis Pharma Endocrinology Division	14A.76 de minimis transactions	Ascendis Pharma Endocrinology Division	Not applicable
<i>Exclusive License Agreements</i>				
1.	License Agreement with Ascendis Pharma Endocrinology Division (Lonapegsomatropin)	14A.34, 14A.35, 14A.36, 14A.52 and 14A.105	Ascendis Pharma Endocrinology Division	Requirements as to announcement, circular, independent shareholders’ approval and contract term not exceeding three years under Chapter 14A of the Listing Rules
2.	License Agreement with Ascendis Pharma Growth Disorders (TransCon CNP (navepegritide))	14A.34, 14A.35, 14A.36, 14A.52 and 14A.105	Ascendis Pharma Growth Disorders	Requirements as to announcement, circular, independent shareholders’ approval and contract term not exceeding three years under Chapter 14A of the Listing Rules

CONNECTED TRANSACTIONS

No.	Nature of Transactions	Relevant Listing Rules	Connected Person(s)	Waiver Sought
3.	License Agreement with Ascendis Pharma Bone Diseases (palopegteriparatide)	14A.34, 14A.35, 14A.36, 14A.52 and 14A.105	Ascendis Pharma Bone Diseases	Requirements as to announcement, circular, independent shareholders' approval and contract term not exceeding three years under Chapter 14A of the Listing Rules
<i>Clinical Supply Agreements</i>				
1.	Products supplied by Ascendis Pharma Endocrinology Division (Lonapegsomatropin)	14A.34, 14A.35, 14A.36 and 14A.105	Ascendis Pharma Endocrinology Division	Requirement as to announcement under Chapter 14A of the Listing Rules
2.	Products supplied by Ascendis Pharma Growth Disorders (TransCon CNP (navepegritide))	14A.34, 14A.35, 14A.36 and 14A.105	Ascendis Pharma Growth Disorders	Requirements as to announcement, circular under Chapter 14A of the Listing Rules
3.	Products supplied by Ascendis Pharma Bone Diseases (palopegteriparatide)	14A.34, 14A.35, 14A.36 and 14A.105	Ascendis Pharma Bone Diseases	Requirements as to announcement, circular under Chapter 14A of the Listing Rules
<i>Commercial Supply Agreement</i>				
	Commercial Supply Agreement	14A.34, 14A.35, 14A.36 and 14A.105	Ascendis Pharma Endocrinology Division	Requirements as to announcement, circular, independent shareholders' approval under Chapter 14A of the Listing Rules

CONNECTED TRANSACTIONS

FULLY EXEMPT CONTINUING CONNECTED TRANSACTION

Cost Sharing and Volume Commitment Agreement

Principal terms

Ascendis Pharma A/S has entered into a tech transfer and manufacturing services agreement (“Agreement”) in 2019 with a Swiss contract development and manufacturing organization which is capable of producing drug substances in large scale, which is an Independent Third Party (the “Overseas CDMO B”) regarding the supply of lonapegsomatropin drug substance, and has been engaged in a scale up project (the “Scale-up Project”) with Overseas CDMO B regarding lonapegsomatropin drug substance production capacity for the years 2022-2026 inclusive. When Ascendis Pharma A/S entered into the Tech Transfer Agreement with Overseas CDMO B in 2019, it was contemplated that the Scale-up Project would be completed in 2023. Once the Scale-up Project is completed, certain capacity will be made available to Ascendis Pharma Endocrinology Division by Overseas CDMO B until 2026 (“Ascendis Reserved Capacity”).

On December 14, 2021, our Company entered into the cost sharing and volume commitment agreement (the “Cost Sharing and Volume Commitment Agreement”) with Ascendis Pharma Endocrinology Division. Pursuant to the Cost Sharing and Volume Commitment Agreement, our Company will have the right to reserve from Ascendis Pharma Endocrinology Division the volume of lonapegsomatropin drug substance that does not exceed 25% of the Ascendis Reserved Capacity until 2026, for future production of the Core Product to be supplied by Ascendis Pharma Endocrinology Division. The Company agreed to pay Ascendis Pharma Endocrinology Division an amount calculated as 25% of the costs incurred by it in connection with the Scale-up Project, which mainly includes the cost of materials used in the Scale-up Project, the payment made by Ascendis Pharma Endocrinology Division to Overseas CDMO B for Ascendis Reserved Capacity (including the one-time technology transfer fee) and the internal resources costs incurred by Ascendis Pharma Endocrinology Division for the daily operation of the Scale-up Project. This arrangement ensures that the Company will be able to access the lonapegsomatropin drug substance once the increased production capacity resulting from the Scale-up Project becomes available.

The Company also obtained 25% ownership of the Pre-PPQ drug substance from Ascendis Pharma Endocrinology Division under such agreement, which is a byproduct of the Pre-PPQ stage of the manufacturing process. The purpose of the Pre-PPQ stage is to test and validate the drug substance manufacturing process, and the resulting product is not intended for commercial use. The Company intends to use the Pre-PPQ Drug Substance for both ongoing and future R&D endeavors, including but not limited to that, (i) the Company have utilized the Pre-PPQ Drug Substance in the in-house development of the dual chamber device (DCD) technology in the form of prefilled syringe as a drug delivery system for the lonapegsomatropin drug substance, which included testing various process conditions and parameters to create a prototype for the local manufacturing; (ii) the Company will utilize the Pre-PPQ Drug Substance to test analytical methods ensuring our capability to perform quality control on the locally manufactured drug product, and (iii) the Company will utilized the Pre-PPQ Drug Substance as reference samples in comparability studies of the locally manufactured drug substance. These endeavors collectively will contribute to the establishment of the Company’s

CONNECTED TRANSACTIONS

local commercial manufacturing capability. The Pre-PPQ drug substance, valued at RMB56.5 million according to Ascendis Pharma Endocrinology Division’s invoice, represents 54% of the total consideration paid by the Company to Ascendis Pharma Endocrinology Division under the Cost Sharing and Volume Commitment Agreement.

The term of the Cost Sharing and Volume Commitment Agreement commenced on December 14, 2021 and shall expire on December 31, 2026. A substantial part of the cost of Scale-up Project has incurred in 2021. It is expected that beyond 2023, the Company would not incur further costs under such cost sharing arrangement.

Pricing policy

The amount to be paid to Ascendis Pharma Endocrinology Division shall be determined by 25% of the actual costs incurred by Ascendis Pharma Endocrinology Division for the Scale-up Project (the “Project Costs”), which mainly comprise the cost of materials used in the Scale-up Project, the payment made by Ascendis Pharma Endocrinology Division to Overseas CDMO B for Ascendis Reserved Capacity (including the one-time technology transfer fee) and the internal resources costs incurred by Ascendis Pharma Endocrinology Division for the daily operation of the Scale-up Project. Ascendis Pharma Endocrinology Division shall on quarterly basis submit to our Company a calculation of the Project Costs for the preceding financial quarter. In addition, our Company has the right to engage external accounting firms to audit the Project Costs and our payment under the cost sharing arrangement. If the audit reveals any discrepancies that require adjustments, Ascendis Pharma Endocrinology Division shall reimburse the Company for any overpayments, as detailed in the audit report. Our Company’s total payment in connection with the Scale-up Project shall not exceed 25% of the total estimated cost in the Cost Sharing and Volume Commitment Agreement without our Company’s prior written consent.

Historical amounts

For the years ended December 31, 2022, 2023 and the four months ended April 30, 2024, the amounts paid by the Group to Ascendis Pharma Endocrinology Division under the cost sharing arrangement was approximately RMB21.6 million, RMB8.5 million, with no payments made for the four months ended April 30, 2024.

Annual Caps

It is expected that no further costs will be incurred under such cost sharing arrangement beyond 2023. As such, the estimated caps would be 0 for the three years ending December 31, 2026.

Listing Rules implications

The Cost Sharing and Volume Commitment Agreement is entered into in the ordinary and usual course of business of our Group on normal commercial terms. The highest applicable percentage ratio calculated for such transactions, is expected to be less than 0.1%. As such, this transaction will be fully-exempt from the reporting, annual review, announcement and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

CONNECTED TRANSACTIONS

NON-EXEMPT AND PARTIALLY-EXEMPT CONTINUING CONNECTED TRANSACTIONS

Exclusive License Agreements

Principal terms

On November 7, 2018, our Company entered into three Exclusive License Agreements (as amended on January 4, 2021) with Ascendis Pharma Endocrinology Division, Ascendis Pharma Growth Disorders and Ascendis Pharma Bone Diseases (collectively, “Ascendis Subsidiaries”), respectively. Pursuant to the Exclusive License Agreements, the Company obtained from Ascendis Subsidiaries exclusive, royalty-free licenses under their applicable owned patents and other intellectual property or technical information to develop, manufacture and commercialize lonapegsomatropin with its auto-injector, TransCon CNP (navepegritide) with its injector and palopegteriparatide with its injector (collectively, the “Licensed Products”), in China (including Hong Kong, Macau and Taiwan) for use in the treatment and/or prevention of any disease, condition or disorder of any human indication (subject to certain exceptions, including diabetes (and certain related metabolic disorders), obesity and ophthalmology). The Company also obtained a right of first negotiation to license from Ascendis Subsidiaries the rights to develop or commercialize certain additional pharmaceutical products for the treatment of endocrine disorders. Each of the Exclusive License Agreements became effective on November 7, 2018 and will remain in effect for an indefinite period until the expiration of the last valid claim of a licensed patent in China (including Hong Kong, Macau and Taiwan) or an early termination by either party. Each of the Exclusive License Agreements may be terminated by either party for the other party’s uncured material breach or bankruptcy, by Ascendis Subsidiaries for a change of control of the Company or if the Company or its affiliates challenges (or assists a third party in challenging) in a court the validity, enforceability or scope of certain patents and patent applications as specified in the Exclusive License Agreements, unless some exceptions apply, or by the Company for convenience upon advanced notice. The Company shall own all right, title and interest in and to any and all data, results, improvements and inventions, in connection with the research, development, manufacturing, or commercialization activities conducted with respect to the Licensed Products (the “Program IP”), conceived or generated solely by employees, agents or service providers of the Company and its affiliates, and the Company and Ascendis Subsidiaries (or their affiliates) shall each own an undivided fifty percent (50%) rights, title and interest in and to any and all Program IP conceived or generated during the course of, and in connection with each of the Exclusive License Agreements by employees, agents or service providers of both parties.

As a one-time, non-refundable consideration of the rights and license granted by Ascendis Subsidiaries under the respective Exclusive License Agreement, the Company issued to: (i) Ascendis Pharma Endocrinology Division 20,000,000 Series A Preferred Shares corresponding to a total value of US\$20.0 million; (ii) Ascendis Pharma Growth Disorders 7,500,000 Series A Preferred Shares corresponding to a total value of US\$7.5 million; and (iii) Ascendis Pharma Bone Diseases 12,500,000 Series A Preferred Shares corresponding to a total value of US\$12.5 million. See “History, Development and Corporate Structure – Major Corporate Development and Shareholding Changes of Our Group – Our Company – Series A Financing” for more details.

CONNECTED TRANSACTIONS

In August 2021, without compromising our exclusive rights and responsibilities for the development and commercialization regarding TransCon CNP (navepegritide) in China (including Hong Kong, Macau and Taiwan), our Company entered into a letter agreement with Ascendis Pharma Growth Disorders to specify the roles and responsibilities between both parties in anticipation of the upcoming China Phase 2 trial. Pursuant to this letter agreement, the two companies will jointly conduct the China Phase 2 trial, with Ascendis Pharma Growth Disorders acting as trial sponsor and us acting as the exclusive authorized agent. In November 2022, the two companies entered into an amendment to this letter agreement under which we became the sole sponsor for the OLE period of the China Phase 2 trial to reflect the updated roles and responsibilities between both parties as the sponsorship for the OLE period of China Phase 2 trial was transferred from Ascendis Pharma to us (the letter agreement and the subsequent amendment, collectively referred to as the “Letter Agreement”). Pursuant to the Letter Agreement, we and Ascendis Subsidiaries shall reasonably cooperate and coordinate with each other in the conduct of the China Phase 2 trial of TransCon CNP (navepegritide). Subsequent to the entry of the foregoing amendment, we became the sole sponsor for the OLE portion of the China Phase 2 trial as it commenced in January 2023.

Ascendis Subsidiaries’ Expenses Arrangement and Pricing Policy

Under the Exclusive License Agreements, the Company and Ascendis Subsidiaries agreed to conduct certain R&D activities allocated to themselves respectively under a research and technical development plan mutually agreed by the parties in accordance with the terms of the Exclusive License Agreements (the “Research and Technical Development Plan”), and the Company will pay or reimburse (as applicable) Ascendis Subsidiaries for the costs and expenses actually incurred by Ascendis Subsidiaries in carrying out the research and technical development activities as set out in the respective Research and Technical Development Plans in connection with each of the Licensed Products (“Ascendis Subsidiaries’ Expenses”). The Ascendis Subsidiaries’ Expenses comprise:

- (i) the out-of-pocket cost incurred by Ascendis Subsidiaries of having any R&D activities performed by approved service providers in accordance with the applicable Research and Technical Development Plan;
- (ii) Ascendis Subsidiaries’ FTE costs, which is determined based on the number of FTE used by Ascendis Subsidiaries and the applicable FTE rate ranging from Euros (€200,000) to Euros (€300,000) per FTE, depending on Ascendis Subsidiaries’ interests in the share capital of the Company, pursuant to the Exclusive License Agreements; and
- (iii) any other costs or expenses identified and included in the applicable Research and Technical Development Plan.

CONNECTED TRANSACTIONS

Under the Exclusive License Agreements, if our Company plans to manufacture the Licensed Products (excluding Ascendis Subsidiaries' proprietary linkers) in China (including Hong Kong, Macau and Taiwan), the Company and Ascendis Subsidiaries will perform a technology transfer of such know-how of Ascendis Subsidiaries necessary to permit the Company to manufacture the Licensed Products in China (including Hong Kong, Macau and Taiwan), in accordance with a technology transfer plan as mutually agreed by the parties. The Company shall reimburse Ascendis Subsidiaries' FTE costs, travel costs and costs of all materials transferred in connection with the performance of the relevant Technology Transfer and Localization. See "Business – Overview – CMC R&D and Local BLA for local manufacturing" for more details regarding the latest status of the technology transfer.

In addition, the Company will also pay Ascendis Subsidiaries at FTE rate for the assistance as reasonably requested by us and provided by Ascendis Subsidiaries to support the obtaining and maintenance of regulatory approvals of the Licensed Products in China (including Hong Kong, Macau and Taiwan). Ascendis Subsidiaries will designate an individual (the "Ascendis Alliance Manager") to ensure communication and alignment between Ascendis Subsidiaries and our Company regarding activities carried out under the Exclusive License Agreements. Our Company shall bear the cost for any additional services conducted by such Ascendis Alliance Manager that is not otherwise reimbursed by our Company at the applicable FTE rate (the "Ascendis Alliance Manager Expenses"), provided that the prior agreement of our Company and Ascendis Subsidiaries on the scope of such additional services is required. During the Track Record Period, the assistance we requested and received from Ascendis Subsidiaries primarily included general and administrative support, as well as R&D consulting services, mainly for the following activities: (i) for lonapegsomatropin, (a) the pharmacovigilance and biometry for data analysis including statistical programming and statistical analysis, and (b) the regulatory strategy advice and documentation support to prepare for our Import BLA submission package with the NMPA; (ii) for TransCon CNP (navepegritide) and palopegteriparatide, the pharmacovigilance and biometry for data analysis including statistical programming and statistical analysis. In connection with our expected R&D and regulatory activities of three drug candidates, we expect to procure R&D consulting services from Ascendis Pharma mainly for the following activities: (i) for lonapegsomatropin, (a) the technology transfer of lonapegsomatropin drug substance from Ascendis Pharma to us, and (b) consulting the technology localization process that involves the lonapegsomatropin drug substance manufacturing scale-up; (ii) for TransCon CNP (navepegritide) and palopegteriparatide, the support of data programming and statistical analysis, and the regulatory strategy advice and documentation support in connection with our expected NDA with the NMPA.

The applicable FTE rate under the Exclusive License Agreements was determined based on our arms' length negotiation with Ascendis Subsidiaries, and consistent with the market rate charged by personnel with similar seniority and experience.

CONNECTED TRANSACTIONS

In addition, we and Ascendis Subsidiaries shall be responsible for the portion of the costs incurred in connection with the conduct of the China Phase 2 trial of TransCon CNP (navepegritide) based on the allocation as set forth in the Letter Agreement, and among others, Ascendis Subsidiaries shall be responsible for the costs for investigational medicinal products, while we will reimburse Ascendis Subsidiaries for the packing, labeling and shipment to China.

Subject to the terms of the Exclusive License Agreements and the Letter Agreement, our Group may enter into specific agreements with Ascendis Subsidiaries to set out specific terms and conditions in relation to various matters under the Exclusive License Agreements, including but not limited to commercial supply, FTE costs, supplies for regulatory filing, etc.

For further details of the Exclusive License Agreements, please see “Business – Collaborations – Exclusive License Agreements with Ascendis Pharma.”

Reasons for and benefits of the transactions

As the Company is a clinical stage biopharmaceutical company, the licenses granted by Ascendis Subsidiaries are essential to our R&D process as they provide us with the exclusive rights to develop, manufacture and commercialize the Licensed Products, which have been validated in the global development programs conducted by Ascendis Subsidiaries. The licensing arrangement also enables us to utilize the know-how, data, materials and other information relating to the global clinical trials conducted by Ascendis Subsidiaries to optimize the design of our clinical trials in China (including Hong Kong, Macau and Taiwan). The continuous communication with and ongoing support from Ascendis Subsidiaries would also benefit our R&D activities.

Historical amounts

The following table sets forth historical transaction amounts incurred by the Group in connection with the disbursement arrangement under the respective Exclusive License Agreement with respect to each of the Licensed Products for the Track Record Period:

	Year Ended December 31		Four months ended April 30
	2022	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
FTE costs			
Lonapegsomatropin	8,566	8,112	3,257
TransCon CNP (navepegritide)	440	3,059	2,090
Palopegteriparatide	1,320	895	70
Sub-total	10,326	12,066	5,417
Other⁽¹⁾			
Lonapegsomatropin	33,367	1,149	643
Sub-total	33,367	1,149	643
Total	43,693	13,215	6,060

(1) Relates to supplies for regulatory filing, i.e. purchasing of QC testing samples.

CONNECTED TRANSACTIONS

Annual caps

The following table sets out our estimated caps for the disbursement arrangement under the respective Exclusive License Agreement with respect to each of the Licensed Products for the three years ending December 31, 2026:

	Year Ending December 31		
	2024	2025	2026
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
FTE Costs			
Lonapegsomatropin	18,863	11,792	9,132
TransCon CNP (navepegritide)	7,609	7,452	3,186
Palopegteriparatide	1,115	8,282	7,295
Sub-total	27,587	27,527	19,613
Other⁽¹⁾			
Lonapegsomatropin⁽²⁾	16,739	4,000	–
TransCon CNP (navepegritide)	–	10,000	–
Palopegteriparatide	–	16,840	600
Sub-total	16,739	30,840	600
Total	44,326	58,367	20,213

- (1) Relates to supplies for regulatory filing and materials for Technology Transfer and Localization purpose
- (2) Under the Exclusive License Agreement, we have established the preliminary framework for a purchase agreement concerning materials intended for Technology Transfer and Localization upon the successful completion of the [REDACTED]. Currently, only initial arrangements have been made under this framework, with no additional actions taken at this stage. Following the completion of the [REDACTED] and subsequent negotiations between both parties, the Company plans to acquire the necessary materials for the Technology Transfer and Localization under this purchase agreement in the manner as disclosed in “Future Plans and Use of [REDACTED].”

Basis of cap

In arriving at the above annual caps, we have considered the following factors:

- (i) the historical amounts of the Ascendis Subsidiaries’ Expenses paid by our Group to Ascendis Subsidiaries under the respective Research and Technical Development Plan in respect of each Licensed Product;
- (ii) the number of FTE expected to be used by Ascendis Subsidiaries to perform the activities under the respective Research and Technical Development Plan and by the Ascendis Alliance Manager to support our regulatory approvals including but not limited to, gathering global regulatory files, coordinating the required documentation from CDMOs for the NMPA, conducting a gap analysis of clinical data and comparing China-specific clinical data with global clinical data, reviewing and providing advisory services on CSR, offering CMC technical consulting related to product specifications for China and offering CMC technical consulting related to the drug tests mandated by the NMPA, which is commensurate with the development and regulatory submission status of each Licensed Product;

CONNECTED TRANSACTIONS

- (iii) the expenses to be incurred in connection with the product registration testing associated with the verification of lonapegsomatropin to support our BLA filing to the NMPA for the treatment of PGHD which was accepted by the NMPA on March 7, 2024. In connection with such filing, we expect to incur a substantial amount of expenses that relate to (x) product QC testing, which mainly includes the provision of sampling products, the provision of testing services, expenses in connection with the regulatory registration of pharmaceutical excipients and packaging materials, and technical support in relation to the registration process; and (y) regulatory registration of medical device, which mainly relates to the document preparation and testing of medical device. We also expect to incur expenses in 2024, 2025 and 2026 relating to consulting service in connection with the indication expansion of lonapegsomatropin and the local production project of lonapegsomatropin. Furthermore, considering the Company's upcoming Technology Transfer and Localization from Ascendis Pharma, it is anticipated that there will be expenses incurred for the procurement of materials required for this project in 2024 and 2025 under the purchase agreement framework upon the successful completion of the [REDACTED];
- (iv) the expenses to be incurred in connection with the development and regulatory filing of TransCon CNP (navepegritide) in China. Specifically, we expect to incur a higher amount of expenses in 2025, as compared to that in 2024 and 2026, in connection with the preparation of NDA filing in China since 2024. We expect expenses relating to the regulatory filing to be similar in nature as items (x) and (y) in paragraph (iii) above;
- (v) the expenses to be incurred in connection with the development and regulatory filing of palopegteriparatide in China. Specifically, we expect to file a NDA with the NMPA for palopegteriparatide in the first half of 2025. In connection with such filing, we expect to incur a substantial amount of expenses in 2025, which will be similar in nature as items (x) and (y) in paragraph (iii) above; and
- (vi) among the expenses mentioned in paragraph (iii), testing services and technical support would be charged at the applicable FTE rate, and the supplies for the regulatory filing purpose and Technical Transfer purpose will be charged at a price equal to Ascendis Subsidiaries' fully-burdened cost.

Listing Rules implications

Pursuant to Rules 14A.81 to 14A.83 of the Listing Rules, the transactions (i.e., the disbursement arrangement) under the Exclusive License Agreements should be aggregated. The Exclusive License Agreements are entered into in the ordinary and usual course of business of our Group on normal commercial terms, and the highest applicable percentage ratio calculated for such transactions, on an aggregate basis, is expected to be more than 5% on an annual basis. As such, these transactions will be subject to the reporting, annual review, announcement and independent shareholders' approval requirements under Chapter 14A of the Listing Rules.

CONNECTED TRANSACTIONS

Waiver from strict compliance with contractual term requirements

Under Rule 14A.52 of the Listing Rules, a [REDACTED] issuer is required to set a contractual term not exceeding three years. It is impracticable and difficult for us to set a contractual term not exceeding three years in respect of the Exclusive License Agreements. Therefore, the Company applied to the Stock Exchange for, and the Stock Exchange [has granted] to the Company, a waiver under Rule 14A.52 of the Listing Rules from strict compliance with the contractual term requirements for the following reasons:

- (i) it is impractical and difficult for the Company to set a term of not exceeding three years in respect of the Exclusive License Agreements, as each of the Licensed Products has a product life cycle of more than three years from its development stage since in-licensing to commercialization;
- (ii) the indefinite term of the Exclusive License Agreements can secure long-term, exclusive cooperative relationship with Ascendis Pharma, which provides strategic benefits for us to engage in development, manufacturing and commercialization of the Licensed Products in China (including Hong Kong, Macau and Taiwan). In addition, the exclusive term to cooperate with Ascendis Pharma safeguards the interests of our Company and Shareholders as a whole by providing our Company with relevant exclusivity in the relevant area of business;
- (iii) If the Exclusive License Agreements are subject to renewal every three years, we may face the unnecessary and substantial risks of failing to renew such agreement upon expiry and bringing disruptions to the development, manufacturing and commercialization of the Licensed Products, and losing our competitive advantages. This may even prevent us from carrying on our business, bringing uncertainty to our continued operation; and
- (iv) our Directors consider that the terms of the Exclusive License Agreements are consistent with normal business practices for agreements of a similar nature in the biotechnology industry and are in the best interest of our Group and our Shareholders as a whole, because (x) the indefinite term of the Exclusive License Agreement can secure long-term license rights for us, thus avoiding unnecessary disruptions to our business and enable long-term development and continuity of our operations; and (y) as confirmed by Frost & Sullivan, it is common in the biotechnology industry where similar long-term licensing arrangement are adopted.

Based on the above, the Directors are of the view that it is normal business practice for agreements of this type to be of an indefinite term. Based on the aforementioned, the Joint Sponsors agree with the Directors' view and concur that it is consistent with normal business practice for the Exclusive License Agreements to have an indefinite term.

CONNECTED TRANSACTIONS

Clinical Supply Agreements

Principal terms

On November 7, 2018, concurrently with the execution of the Exclusive License Agreements, our Company entered into three clinical supply agreements (as amended on August 20, 2021) (the “Clinical Supply Agreements”, each a “Clinical Supply Agreement”) with Ascendis Pharma Endocrinology Division, Ascendis Pharma Growth Disorders and Ascendis Pharma Bone Diseases with respect to each of Licensed Products, respectively. Pursuant to the respective Clinical Supply Agreement, for use in conducting clinical trials in China (including Hong Kong, Macau and Taiwan), we agreed to procure from:

- (1) Ascendis Pharma Endocrinology Division, the lonapegsomatropin drug products and the auto-injector;
- (2) Ascendis Pharma Growth Disorders, the TransCon CNP (navepegritide) drug products; and
- (3) Ascendis Pharma Bone Diseases, the palopegteriparatide drug products and the injector.

Each Clinical Supply Agreement is effective from the date of the agreement and will remain in effect until its termination. Each of the Clinical Supply Agreements may be terminated by: (x) mutual consent of the parties, (y) either party in the event of the other party’s bankruptcy, insolvency, assignment for the benefit of creditors, or uncured material breach or (z) by the Company for convenience upon advanced notice. Each Clinical Supply Agreement will also immediately terminate when the corresponding Exclusive License Agreement is terminated. It is expected that no further amounts will be incurred under the Clinical Supply Agreement after December 31, 2025. As such, the Clinical Supply Agreements would be terminated upon mutual consent following the final delivery of products thereunder.

As a supplement to the Clinical Supply Agreements, on June 15, 2021, our Group, Ascendis Pharma A/S and Ascendis Subsidiaries entered into a quality agreement, which specifies the roles and responsibilities of our Group and Ascendis Pharma with respect to the manufacturing, handling, storage and distribution of Licensed Products used in clinical trials.

Pricing policy

The purchase prices of the Licensed Products under each Clinical Supply Agreement (the “Clinical Supply Price”) shall be equal to Ascendis Subsidiaries’ fully-burdened cost for supplying the Licensed Products (including the costs of purchasing from third-party suppliers and Ascendis Subsidiaries’ internal overhead costs attributed to products purchased by the Company), subject to price adjustments which may be required to comply with transfer pricing requirements actually issued by relevant taxing authorities in applicable jurisdictions with respect to the relevant Licensed Products.

CONNECTED TRANSACTIONS

Reasons for and benefits of the transactions

Ascendis Pharma A/S is applying its platform technology to build a leading, fully integrated, global biopharmaceutical company focused on making a meaningful difference in patients’ lives. Our pipeline products are developed based on the rights we in-licensed from Ascendis Subsidiaries. The products required for our clinical trials in China (including Hong Kong, Macau and Taiwan), and those required in Ascendis Subsidiaries’ global clinical trials, share similar characteristics and requirements. A stable supply of products for use in clinical trials is of crucial importance to our business. The Directors are of the view that Ascendis Subsidiaries has been providing the Group with high quality and stable supply of the products for use in clinical trials during the Track Record Period, and it will be in the interests of our Group to continue procuring clinical supplies from Ascendis Subsidiaries.

Historical amounts

The following table sets forth historical transaction amounts paid by the Group to Ascendis Subsidiaries under the respective Clinical Supply Agreement with respect to each of the Licensed Products for the Track Record Period:

	Year Ended December 31		Four months ended April 30
	2022	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Lonapegsomatropin	–	–	–
TransCon CNP (navepegritide)	714	243	–
Palopegteriparatide	5,256	451	–
Total	5,970	694	–

Pursuant to the letter agreement entered into between Ascendis Subsidiaries and our Company in August 2021 with respect to the China Phase 2 trial, Ascendis Subsidiaries would be responsible for the costs and expenses in connection with the clinical supply for the China Phase 2 trial (including the expenses for transporting the investigational medicinal products from Ascendis Subsidiaries to our Company then to the clinical sites). In November 2022, we and Ascendis Subsidiaries entered into an amendment to this letter agreement, pursuant to which we became the sole sponsor for the OLE period of the China Phase 2 trial and we and Ascendis Subsidiaries shall reasonably cooperate and coordinate with each other in the conduct of the China Phase 2 trial. Subsequent to the entry of the foregoing amendment, we became the sole sponsor for the OLE portion of the China Phase 2 trial as it commenced in January 2023. As such, we incurred such reimbursement amounts for TransCon CNP (navepegritide) in 2022 and 2023.

CONNECTED TRANSACTIONS

Annual caps

The following table sets out our estimated caps for the aggregate Clinical Supply Price under the respective Clinical Supply Agreement with respect to each of the Licensed Products for the three years ending December 31, 2026:

	Year Ending December 31		
	2024	2025	2026
	RMB'000	RMB'000	RMB'000
Lonapegsomatropin	–	–	–
TransCon CNP (navepegritide)	–	–	–
Palopegteriparatide	2,943	259	–
Total	2,943	259	–

Basis of cap

In arriving at the above annual caps, we have considered the following factors:

- (i) the historical transaction amounts paid by our Group to Ascendis Subsidiaries under the respective Clinical Supply Agreement;
- (ii) the estimated costs to be incurred by Ascendis Subsidiaries for supplying the products to our Group including, among which, the estimated market price of materials which Ascendis Subsidiaries would procure from third-party suppliers for supplying such products; and
- (iii) the anticipated amounts of products for the use in clinical trial programs of palopegteriparatide in 2024, 2025 and 2026, that is commensurate with the development status of these drug candidates. As the Company plans to use the PPQ samples produced by the local CDMO for the purpose of indication expansion, it is expected that no amounts would be incurred with respect to Lonapegsomatropin for the years ended December 31, 2024, 2025 and 2026. As the clinical supplies for the current China Phase 2 trial has been procured in 2023, it is expected that no amounts would be incurred with respect to TransCon CNP (navepegritide) for the years ended December 31, 2024, 2025 and 2026. It is expected that no further amounts will be incurred under the Clinical Supply Agreement after December 31, 2025.

Listing Rules Implications

Pursuant to Rules 14A.81 to 14A.83 of the Listing Rules, the transactions under the Clinical Supply Agreements shall be aggregated. The transactions contemplated under the Clinical Supply Agreements are conducted in the ordinary and usual course of business on normal commercial terms and the highest applicable percentage ratio calculated for such transactions, on an aggregate basis, is expected to be more than 0.1% but less than 5% on an annual basis. As such, these transactions will be exempted from the independent shareholders' approval requirements and would require compliance with the reporting and announcement requirements and annual review requirements under Chapter 14A of the Listing Rules.

CONNECTED TRANSACTIONS

Commercial Supply Agreement

Principal terms

On October 23, 2023, our Company entered into a commercial supply agreement (the “Commercial Supply Agreement”) with Ascendis Pharma Endocrinology Division, pursuant to which the Company agreed to purchase, and Ascendis Pharma Endocrinology Division agreed to sell, lonapegsomatropin drug packages (the “Drug Packages”), some additional product items intended for display purposes during marketing events (the “Demo Product”) and the auto-injectors (the “Auto-Injectors”). Upon receiving instructions from the Company to manufacture the relevant products, Ascendis Pharma Endocrinology Division will proceed with the manufacturing process and deliver the relevant products to the Company. In line with the planned commercialization process of our Core Product, the transaction contemplated hereunder would be completed in 2026. For further details of the commercialization of our Core Product, please refer to the section headed “Business – Commercial Supply and Manufacturing.”

Pricing policy

The price to be paid for the Drug Packages and the Demo Product will be the manufacturing costs that may be incurred by Ascendis Pharma Endocrinology Division plus an additional 20% mark up. As advised by Frost & Sullivan, the pricing structure of the Drug Packages and the Demo Product adheres to industry standards. The estimated total purchase price of the Drug Packages is RMB64.0 million (EUR8.1 million) and the estimated total purchase price of the Demo Product is RMB0.7 million (EUR0.08 million). Pursuant to the Commercial Supply Agreement, within 14 calendar days upon receiving the invoice from Ascendis Pharma Endocrinology Division after signing the Commercial Supply Agreement, the Company must pay Ascendis Pharma Endocrinology Division a non-refundable pre-payment of RMB39.2 million (EUR5.0 million) for manufacturing costs and commitments related to Drug Packages. For the Demo Product, when the Company instructs Ascendis Pharma Endocrinology Division to manufacture such products, the Company shall pay Ascendis Pharma Endocrinology Division a non-refundable prepayment equal to 50% of the estimate price of the relevant Demo Product upon receipt of the corresponding invoice from Ascendis Pharma Endocrinology Division and shall pay the rest 50% of the estimate price upon receipt of the corresponding invoice from Ascendis Pharma Endocrinology Division 40 calendar days prior to the expected delivery of the Demo Product.

A pre-payment of RMB39.2 million (EUR5.0 million) was made by the Company for the Drug Packages in November 2023. The remaining purchase price of the Drug Packages will be paid in two installments: (i) upon the Company’s notification to Ascendis Pharma Endocrinology Division instructing them to manufacture the Drug Packages, the Company will pay RMB4.0 million (EUR0.5 million) to Ascendis Pharma Endocrinology Division; (ii) prior to the final delivery of the Drug Packages, the Company will pay Ascendis Pharma Endocrinology Division RMB20.8 million (EUR2.6 million) upon receiving the relevant invoices from Ascendis Pharma Endocrinology Division. No payment has been made for the Demo Product by the Company to Ascendis Pharma Endocrinology Division as of the Latest Practicable Date.

CONNECTED TRANSACTIONS

The amount to be paid to Ascendis Pharma Endocrinology Division for the Auto-Injectors shall be determined by the manufacturing costs incurred by Ascendis Pharma Endocrinology Division plus an additional 20% mark up for the Auto-Injectors. The fees for each batch of the Auto-Injectors will be settled in the way below: (i) within 30 days of the Company's notification to Ascendis Pharma Endocrinology Division instructing Ascendis Pharma Endocrinology Division to manufacture the requested amount of the Auto-Injectors and the receipt of the corresponding invoice from Ascendis Pharma Endocrinology Division, the Company shall pay Ascendis Pharma Endocrinology Division a non-refundable pre-payment of 50% of the estimate price per each item; (ii) upon confirming of the expected delivery date and receiving the receipt of Ascendis Pharma Endocrinology Division's estimated total purchase price for the requested amount of the Auto-Injectors, the Company shall make the rest payment to Ascendis Pharma Endocrinology Division within 30 days upon receipt of the invoice from Ascendis Pharma Endocrinology Division.

The Commercial Supply Agreement contains a true-up clause, pursuant to which Ascendis Pharma Endocrinology Division will notify the Company of the final total purchase price 180 days after the final delivery of the products. If the final total purchase price surpasses the payments made by the Company, the Company will transfer the remaining amount to Ascendis Pharma Endocrinology Division within 30 days. If the payments made by the Company exceed the final total purchase price, Ascendis Pharma Endocrinology Division will reimburse the excess amount to the Company within 30 days. Our Company has the right to engage external accounting firms to audit the purchase price and our payment for the products under the Commercial Supply Agreement.

The consideration was determined after arm's length negotiations between us and Ascendis Pharma Endocrinology Division, taking into account various factors including but not limited to (i) the manufacturing costs; (ii) the reasonable profit margin, among others. The Company have performed the following to form the basis of determining the consideration: (i) conducted market research to analyze pricing trends; (ii) examined the pricing strategies employed by similar products in the industry; (iii) analyzed the profit margins of comparable products in the market; (iv) considered the prevailing market conditions and economic factors. Having considered the above, the Company is of the view that the consideration is fair and reasonable.

Reasons for and benefits of the transactions

Entering into the Commercial Supply Agreement with Ascendis Pharma Endocrinology Division ensures a consistent and reliable supply of lonapegsomatropin drug packages. This is crucial for meeting the initial market demand for our lonapegsomatropin products and guaranteeing continuous access for our patients and healthcare providers. By securing this stable supply chain, we can better manage our inventory and plan more effectively for future growth and market expansion, paving the way for our collaborative local manufacturing with Local CDMO.

CONNECTED TRANSACTIONS

Historical amounts

No delivery has been made by Ascendis Pharma Endocrinology Division under the Commercial Supply Agreement during the Track Record Period.

Annual Caps

The following table sets out our estimated caps for the Commercial Supply Agreement for the three years ending December 31, 2026:

	Year Ended December 31,		
	2024	2025	2026
	RMB'000	RMB'000	RMB'000
Drug Package and Demo Product			
Purchase	–	64,665 ⁽¹⁾	–
Auto-Injectors Purchase	800	1,000	3,200

Note:

- (1) The amount includes a pre-payment of RMB39.2 million (EUR5.0 million) made by the Company in 2023 for the purchase of the Drug Packages.

Basis of Cap

In arriving at the above annual caps, we have considered the payment and delivery schedule under the Commercial Supply Agreement as detailed in the paragraph “Pricing Policy” above. Anticipating the receipt of the BLA approval for our Core Product for PGHD in China in 2025, to fulfill the initial market demands for our Core Product, most of the transaction amounts for the purchase of Drug Package and Demo Product would be incurred in 2025.

Listing Rules implications

The Commercial Supply Agreement is entered into in the ordinary and usual course of business of our Group on normal commercial terms, and the highest applicable percentage ratio calculated for such transactions is expected to be more than 5% on an annual basis. As such, these transactions will be subject to the reporting, annual review, announcement and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

CONNECTED TRANSACTIONS

WAIVER APPLICATION FOR THE EXCLUSIVE LICENSE AGREEMENTS, THE CLINICAL SUPPLY AGREEMENTS AND THE COMMERCIAL SUPPLY AGREEMENT

We expect the transactions contemplated under the Exclusive License Agreements, the Clinical Supply Agreements and the Commercial Supply Agreement, as disclosed above will be carried out on a continuing basis and will extend over a period of time, and our Directors consider that strict compliance with the announcement, circular and/or independent shareholders' approval (as applicable) requirements under the Listing Rules would be impractical, unduly burdensome and would impose unnecessary administrative costs on our Company.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver to us under Rule 14A.105 of the Listing Rules from compliance with the announcement and/or independent shareholders' approval requirements (if applicable) in respect of the Exclusive License Agreements, the Clinical Supply Agreements and the Commercial Supply Agreement.

DIRECTORS' CONFIRMATION

Our Directors (including independent non-executive Directors) are of the view that (1) the continuing connected transactions as disclosed in this section have been and will be entered into in the ordinary and usual course of business on normal commercial terms which are fair and reasonable and in the interests of our Company and our Shareholders as a whole; (2) the terms of the Exclusive License Agreements are considered normal business practice for agreements of their types; and (3) the proposed monetary annual caps in respect of these continuing connected transactions are fair and reasonable and in the interests of our Company and our Shareholders as a whole.

JOINT SPONSORS' CONFIRMATION

Based on the documentation and data provided by the Company and the Joint Sponsors' participation in the due diligence and discussions with both the management of the Company and the representatives from Ascendis Pharma, the Joint Sponsors are of the view that (i) the non-exempt and partially-exempt continuing connected transactions set out above have been entered into in the ordinary and usual course of business of the Group on normal commercial terms, which are fair and reasonable and in the interests of the Company and the Shareholders as a whole; (ii) the terms of the Exclusive License Agreements are considered normal business practice for agreements of their types; and (iii) the proposed annual caps for the non-exempt continuing connected transactions as described above are fair and reasonable and in the interests of the Shareholders as a whole.

DIRECTORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board comprises nine Directors, including one executive Director, five non-executive Directors and three independent non-executive Directors.

The following table sets out information in respect of our Directors:

Name	Age	Position	Date of joining our Group	Date of appointment as Director	Roles and responsibilities
Mr. Michael Wolff JENSEN	53	Chairman of the Board, Non-Executive Director	January 8, 2021	January 8, 2021	Providing overall guidance on strategic planning, business direction and management of the Company
Mr. Jan Møller MIKKELSEN	65	Non-Executive Director	November 7, 2018	November 7, 2018	Participating in formulating the Company’s corporate and business strategies
Mr. FU Shan (付山)	56	Non-Executive Director	November 1, 2018	November 1, 2018	Participating in formulating the Company’s corporate and business strategies
Mr. LU An-bang (盧安邦)	57	Executive Director, Chief Executive Officer	November 7, 2018	November 7, 2018	Overall strategic planning, business direction and day-to-day operational management of the Company
Mr. Michael J. CHANG	41	Non-Executive Director	December 1, 2023	December 1, 2023	Participating in formulating the Company’s corporate and business strategies
Mr. CAO Yibo (曹弋博)	41	Non-Executive Director	January 8, 2021	January 8, 2021	Participating in formulating the Company’s corporate and business strategies

DIRECTORS AND SENIOR MANAGEMENT

<u>Name</u>	<u>Age</u>	<u>Position</u>	<u>Date of joining our Group</u>	<u>Date of appointment as Director</u>	<u>Roles and responsibilities</u>
Dr. YAO Zhengbin (Bing)	58	Independent non-executive Director	April 1, 2021	April 1, 2021	Supervising and providing independent judgment to our Board
Mr. CHAN Peng Kuan (陳炳鈞)	61	Independent non-executive Director	April 1, 2021	April 1, 2021	Supervising and providing independent judgment to our Board
Ms. NI Hong (倪虹)	52	Independent non-executive Director	April 1, 2021	April 1, 2021	Supervising and providing independent judgment to our Board

Executive Director

Mr. LU An-bang (盧安邦), aged 57, was appointed as a Director and Chief Executive Officer of the Company on November 7, 2018. He was re-designated as an Executive Director on March 27, 2021. Mr. Lu is responsible for the overall strategic planning, business direction and day-to-day operational management of the Company. He has been the director of VISEN Shanghai since February 2019, the director of VISEN HK since October 2019, the director of VISEN BVI since November 2020, and the director of VISEN Suzhou since June 2021.

Mr. Lu has over 31 years of experience in global biopharmaceutical development with a proven track record of commercialization and operational success in China. Prior to joining our Group, Mr. Lu worked at Takeda Pharmaceutical Company Limited, where he served as the general manager, president and the head of greater China consecutively from October 2010 to September 2017. Prior to Takeda, Mr. Lu worked at Servier from September 1994 to September 2010, among which, during May 2006 to September 2010, Mr. Lu served as the general manager of Servier (Tianjin), mainly responsible for the overall development of Mainland China or PRC.

Mr. Lu obtained his Bachelor’s degree in Pharmacy from Taipei Medical University in June 1989. He received his pharmacist certificate in October 1989 and Pharmacist Civil Servant Examination Certificate from the Examination Yuan of Taiwan in April 1990.

DIRECTORS AND SENIOR MANAGEMENT

Non-Executive Directors

Mr. Michael Wolff JENSEN, aged 53, was appointed as a Director and the Chairman of the Board of our Company on January 8, 2021. He was re-designated as a non-executive Director on March 27, 2021. Mr. Jensen is responsible for providing overall guidance on strategic planning, business direction and management of the Company. He has been the director of VISEN BVI and the director of VISEN HK since February 2021, the director of VISEN Shanghai since May 2021, the director of VISEN Suzhou since June 2021, and the director of VISEN Taiwan since December 2021.

Mr. Jensen currently works at Ascendis Pharma A/S, a company listed on Nasdaq (stock code: ASND) and has served as the senior vice president from 2013 to 2023, the executive vice president since 2023, the chief legal officer since June 2013 and the chairman of the board of directors from January 2008 to May 2021. From 2013 to May 2021, he served as the chairman of the board of directors of XSpray Pharma AB, a company listed on Nasdaq Stockholm AB (stock code: XSPRAY). Mr. Jensen served as chairman of a Danish private sports manufacturing goods company from November 2016 to June 2019. He has served as the chairman of the board of directors of Vicore Pharma Holding AB, a company listed on Nasdaq Stockholm AB (stock code: VICO) from May 2020 to March 2022.

From December 2011 to June 2019, Mr. Jensen served as a board member and the chairman of the board of directors of Eurocine Vaccines AB, a company listed on Spotlight Stock Market (stock code: EUCI). From October 2010 to June 2013, Mr. Jensen served as senior legal adviser and the head of partnerships in France office for the renewable business division of Ørsted A/S (formerly known as Dong Energy A/S), a company listed on the NASDAQ OMX Copenhagen (stock code: CPH). From 2003 to 2008, he served as executive vice president and chief financial officer of LifeCycle Pharma A/S, now Veloxis Pharmaceuticals A/S, a company formerly listed on the NASDAQ OMX Copenhagen (stock code: VELO) until January 2020. Prior to joining Veloxis Pharmaceuticals A/S, Mr. Jensen served as the general counsel and chief financial officer of Genmab A/S, a company listed on Nasdaq Global Select Market and the Copenhagen Stock Exchange (stock code: GMAB), a publicly traded biotechnology company from 2000 to 2003.

Mr. Jensen obtained his Master of Laws degree from University of Copenhagen in 1997.

Mr. Jan Møller MIKKELSEN, aged 65, was appointed as a Director on November 7, 2018. He was re-designated as a non-executive Director on March 27, 2021. Mr. Mikkelsen is responsible for participating in formulating the Company’s corporate and business strategies. He has been the director of VISEN Shanghai since February 2019, the director of VISEN HK since October 2019, the director of VISEN BVI since November 2020, and the director of VISEN Suzhou since June 2021.

DIRECTORS AND SENIOR MANAGEMENT

Mr. Mikkelsen currently serves as the chairman of the board of directors of Hummingbird Bioscience Holdings Limited. Mr. Mikkelsen founded Ascendis Pharma A/S (Nasdaq: ASND) and has served as president and chief executive officer as well as board member since December 2007. From 2002 to 2006, Mr. Mikkelsen served as the president and chief executive officer of LifeCycle Pharma A/S, now Veloxis Pharmaceuticals A/S, a company listed on the NASDAQ OMX Copenhagen (stock code: VELO). From 2000 to 2002, Mr. Mikkelsen was the president of the pharmaceutical division of Maxygen, Inc. Prior to that, Mr. Mikkelsen co-founded ProFound Pharma A/S, a biopharmaceutical company that was later acquired by Maxygen, Inc., and served as co-chief executive officer from 1999 to 2000. Prior to that, Mr. Mikkelsen held various positions at Novo Nordisk A/S, a global healthcare company, including vice president of protein discovery. Mr. Mikkelsen currently serves as a member of the advisory board of Inspirion Delivery Technologies, a specialty pharmaceutical company.

Mr. Mikkelsen received a Cand. Scient. degree in Biochemistry from the University of Odense, Denmark in July 1985, and pursued his post-doctoral research at Children’s Hospital in Oakland, CA from July 1985 to January 1986.

Mr. FU Shan (付山), aged 56, was appointed as a Director on November 2018, and re-designated as a non-executive Director on March 27, 2021. Mr. Fu is responsible for participating in formulating the Company’s Corporate and business strategies. He has been the director of VISEN HK since November 2018, the director of VISEN Shanghai since February 2019, the director of VISEN BVI since November 2020, and the director of VISEN Suzhou since June 2021.

Mr. Fu has served as joint chief executive officer and the greater China chief executive officer of Vivo Capital LLC since October 2013. Since July 2018, Mr. Fu has served as a non-executive director of Sinovac Biotech Ltd., a company listed on the NASDAQ Global Market (stock code: SVA). Since January 2016, Mr. Fu has served as a non-executive director in TOT BIOPHARM International Company Limited, a company listed on the Stock Exchange (stock code: 1875). From June 2021 to March 2024, Mr. Fu served as a director of Genetron Holdings Limited (a company previously listed on the NASDAQ Global Market (stock code: GTH) and delisted in March 2024). From February 2018 to March 2023, he served as a non-executive director in InnoCare Pharma Limited, a company listed on the Stock Exchange (stock code: 9969). From June 2008 to October 2013, Mr. Fu was the senior managing director of the Beijing branch of Blackstone (Shanghai) Equity Investment Management Company Limited. From June 2003 to March 2008, he worked at China National Development and Reform Commission and served as the director of general office and the director of policy and regulations department. Prior to that, he was the director of policy and foreign investment department in the State Economic and Trade Commission of China.

Mr. Fu received his Bachelor of Arts degree in history from Peking University in July 1988. He obtained his Master’s degree in history from Peking University in July 1991.

DIRECTORS AND SENIOR MANAGEMENT

Mr. Michael J. CHANG, aged 41, was appointed as a non-executive Director on December 1, 2023. Mr. Chang is responsible for participating in formulating the Company’s corporate and business strategies.

Mr. Chang worked in Vivo Capital LLC since August 2012 and now is a managing partner of Vivo Capital LLC. Prior to joining Vivo Capital, Mr. Chang worked at Johnson & Johnson, a company listed on NYSE (stock code: JNJ), serving as a senior manager from August 2008 to September 2010 and a part-time consultant in 2011. From August 2006 to July 2008, Mr. Chang served as a consultant in Strategy & (formerly known as Booz & Company Inc.) Prior to that, Mr. Chang worked as an analyst in the healthcare team of Fletcher Spaght Inc. from July 2005 to May 2006.

Mr. Chang obtained his Bachelor’s degree in Economics from Harvard College in 2005, and obtained an M.B.A. from Harvard Business School in 2012.

Mr. CAO Yibo (曹弋博), aged 41, was appointed as a Director on January 8, 2021 and re-designated as a non-executive Director on March 27, 2021. Mr. Cao is responsible for participating in formulating the Company’s Corporate and business strategies. He has been the director of VISEN BVI and VISEN HK since February 2021, the director of VISEN Shanghai since May 2021, and the director of VISEN Suzhou since June 2021.

Mr. Cao works at Hongshan and has served as the managing director since July 2017. Mr. Cao joined Vivo Capital LLC in August 2011 and left as a managing director in July 2017. Since December 2020, Mr. Cao has served as a director of Beijing Microread Genetics Co., Ltd., a company listed on the National Equities Exchange and Quotations (stock code: 873723).

Mr. Cao obtained his Bachelor’s degree in pharmacy and his Master’s degree in science (majored in clinical pharmacy) from Peking University in July 2005 and July 2007, respectively.

Independent Non-executive Directors

Dr. YAO Zhengbin (Bing), aged 58, was appointed as an independent non-executive Director effective as of April 1, 2021, and is primarily responsible for supervising and providing independent judgment to the Board. Dr. Yao has also been serving in the capacity as an independent director of our subsidiary VISEN BVI since April 2021.

Dr. Yao is currently serving as the chief executive officer and chairman of the board of the ArriVent BioPharma, Inc., a company listed on the Nasdaq (stock code: AVBP) since June 2021. Dr. Yao has also been serving as a director of Alumis Inc, a company listed on the Nasdaq (stock code: ALMS), developing therapeutics for autoimmune diseases since June 2021. Dr. Yao has served as a director of NexImmune, Inc., a company listed on the Nasdaq (stock code: NEXI), from January 2017 to August 2024, the chief executive officer and president of Viela Bio, Inc., a company listed on Nasdaq (“Viela”, stock code: VIE) from February 2018 to March 2021, and the chairman of the board of Viela Bio, Inc. from January 2019 to March 2021, until it was acquired by Horizon Therapeutics Public Limited Company (“Horizon”, Nasdaq: HZNP). Dr. Yao previously served as senior vice president of Respiratory, Inflammation and Autoimmune at MedImmune, a subsidiary of AstraZeneca, and senior vice president and head of Immuno-Oncology Franchise, AstraZeneca

DIRECTORS AND SENIOR MANAGEMENT

Plc, a company primarily listed on the London Stock Exchange (stock code: AZN). He has held various positions including vice president of research and senior director of discovery biology at Tanox, Inc. before it was acquired by Genentech.

Dr. Yao received his Master’s in Science degree in immunology from Anhui Medical University in Anhui, China in July 1989 and Ph.D. degree in microbiology and immunology from the University of Iowa in June 1994.

Dr. Yao, in his capacity as the then chairman/chief executive officer/president of Viela, along with each of the former Viela board members, one of Viela’s large shareholders and others, was named as a co-defendant in a class action initiated in February 2023 by certain former stockholders of Viela which alleges various breaches of fiduciary duties in connection with Viela’s acquisition by Horizon Therapeutics PLC. As of the latest Practicable Date, the case was dismissed with prejudice by the Court of Chancery of the State of Delaware. Such former shareholders of Viela have appealed the decision to the Delaware Supreme Court, where the case is currently pending.

Given (1) all of the cases were brought against Viela’s board as a whole, instead of targeting Dr. Yao in his personal capacity as the then chairman/chief executive officer/president of Viela; (2) the court has not made any judgment, ruling or decision against Viela, its board or Dr. Yao; and (3) it is not uncommon to see securities actions in connection with public mergers and acquisitions in the U.S. and there are plaintiffs law firms that pursue these types of actions on a regular basis regardless of the underlying substance of the matter, the Company is of the view that the securities actions do not affect Dr. Yao’s suitability to act as a director of the Company.

Mr. CHAN Peng Kuan (陳炳鈞), aged 61, was appointed as an independent non-executive Director effective as of April 1, 2021, and is primarily responsible for supervising and providing independent judgment to the Board. Mr. Chan has also been serving in the capacity as an independent director of our subsidiary VISEN BVI since April 2021.

Mr. Chan has served as an independent non-executive director at JW (Cayman) Therapeutics Co. Ltd (stock code: 2126) since August 2024, CANbridge Pharmaceuticals Inc. (stock code: 1228) and Yonghe Medical Group Co., Ltd. (stock code: 2279) since June 2021, respectively, all of which are listed on the Stock Exchange. Mr. Chan has also served as an independent non-executive director at Yincheng International Holding Co., Ltd., a company listed on the Stock Exchange (stock code: 1902) since February 2019. From October 2017 to May 2019, Mr. Chan served as the chief financial officer of Elegance Optical Int’l Holdings Ltd, a company listed on the Stock Exchange (stock code: 907). From January 2012 to September 2017, he served as the chief operating officer at CITIC Merchant Co., Limited. Prior to that, he worked at Piper Jaffray Asia Limited from January 2011 to November 2011 and served as the head of Asia CIG and Cleantech at the investment banking department. From March 2005 to January 2011, he worked at BNP Paribas Capital (Asia Pacific) Limited with his last position as the managing director of corporate finance – greater China coverage department. From August 2000 to December 2004, Mr. Chan served as an executive director of Sanyuan Group Limited (三元集團有限公司) (“Sanyuan Group”), a company delisted from the Stock Exchange in December 2009 (stock code: 0140), which principally engaged in property investment and bio-pharmaceuticals, with the mission of restructuring its business activities and materialising its debt restructuring plan.

DIRECTORS AND SENIOR MANAGEMENT

Mr. Chan obtained his Bachelor of Commerce degree from University of Canterbury in New Zealand in May 1989 and his Master of Applied Finance degree from Macquarie University in Australia in November 1998. Mr. Chan is a Chartered Accountant of the Chartered Accountants Australia and New Zealand and a Certified Public Accountant of the Hong Kong Institute of Certified Public Accountants.

Mr. Chan was a director of the following companies, which were involuntarily wound up:

<u>Name of Company</u>	<u>Place of incorporation</u>	<u>Principal business activity immediately before being voluntarily wound up or struck off</u>	<u>Voluntarily wound up or being struck off</u>	<u>Reason</u>
Pacific Engineering Limited	Hong Kong	a company principally engaged in the trading of the sea sand	Involuntarily wound up on May 11, 2006 due to winding up order	This company had been making loss and a creditor filed a petition to wind up this company which was subsequently dissolved by compulsory winding up.
Infinity Properties Limited	Hong Kong	a property holding company	Involuntarily wound up on January 31, 2007 due to winding up order	This company was wound up as a result of the debt restructuring agreement reached between Sanyuan Group Limited (a then listed company on the Stock Exchange and the holding company of this company) and the relevant lending bank. This company was dissolved by compulsory winding up as a result thereof.

DIRECTORS AND SENIOR MANAGEMENT

<u>Name of Company</u>	<u>Place of incorporation</u>	<u>Principal business activity immediately before being voluntarily wound up or struck off</u>	<u>Voluntarily wound up or being struck off</u>	<u>Reason</u>
Propland Limited	Hong Kong	a property holding company	Involuntarily wound up on October 6, 2006 due to winding up order	same as above
V & O Company Limited	Hong Kong	a property holding company	Involuntarily wound up on October 6, 2006 due to winding up order	same as above

Mr. Chan was appointed on August 31, 2000 as a director of each of Pacific Engineering Limited, Infinity Properties Limited, Propland Limited and V & O Company Limited (collectively, the "Relevant Companies"), all of which were incorporated in Hong Kong and wholly-owned subsidiaries of Sanyuan Group.

As a result of the debt restructuring agreement reached between Sanyuan Group Limited (三元集團有限公司) and the relevant lending bank, winding up petitions were filed to wind up Infinity Properties Limited, Propland Limited and V&O Company Limited on December 23, 2004 and the respective winding-up orders were granted against those companies on February 23, 2005.

There was no wrongful act on the part of Mr. Chan leading to the winding up of the Relevant Companies.

Mr. Chan has confirmed that, (i) he was not involved in the daily operations of the Relevant Companies at any time; and (ii) during the course of the liquidation of the Relevant Companies, there was no allegation of fraud or other impropriety, judgment debt or disqualification order made against him.

Considering the facts as stated above, the Company is of the view that his past involvement as a director in four involuntarily wound-up companies do not affect Mr. Chan's suitability to act as an independent non-executive Director. Based on the aforementioned facts and independent due diligence conducted by the Joint Sponsors, nothing material has come to the Joint Sponsors' attention to disagree with the Company's view on the suitability of Mr. Chan to act as an Independent Non-Executive Director of the Company.

DIRECTORS AND SENIOR MANAGEMENT

Ms. NI Hong (倪虹), aged 52, was appointed as an independent non-executive Director effective as of April 1, 2021, and is primarily responsible for supervising and providing independent judgment to the Board. Ms. Ni has also been serving in the capacity as an independent director of our subsidiary VISEN BVI since April 2021.

Ms. Ni has served as independent director of Zhihu Inc., a company listed on the New York Stock Exchange (stock code: ZH), since March 2021, Acotec Scientific Holdings Limited, a company listed on the Stock Exchange (stock code: 6669), since August 2021, ATA Creativity Global (formerly known as ATA Inc.), a company listed on Nasdaq (stock code: AACG) since January 2008, Ucloudlink Group Inc., a company listed on Nasdaq (stock code: UCL) since June 2020 and Digital China Holdings Limited, a company listed on the Stock Exchange (stock code: 0861), from September 2010 to June 2024.

Ms. Ni served as an independent non-executive director of Digital China Holdings Limited, a company listed on the Stock Exchange (stock code: 0861), from September 2010 to June 2024, an executive director of COGOBUY Group, a company listed on the Stock Exchange (stock code: 400), from March 2015 to June 2020 and a non-executive director from June 2020 to June 2022. Previously, Ms. Ni worked as a practicing attorney at Skadden, Arps, Slate, Meagher & Flom LLP in New York and Hong Kong, specializing in corporate finance.

Ms. Ni obtained her Juris Doctor degree from the University of Pennsylvania Law School in May 1998 and her bachelor’s degree in applied economics and business management from Cornell University in May 1994.

SENIOR MANAGEMENT

The following table sets forth information about our senior management:

<u>Name</u>	<u>Age</u>	<u>Position</u>	<u>Date of joining our Group</u>	<u>Date of appointment as Senior Management</u>	<u>Roles and responsibilities</u>
Mr. LU An-bang (盧安邦)	57	Executive Director, Chief Executive Officer	November 7, 2018	November 7, 2018	Overall management of the business of the Company
Dr. CHEN Jun (陳軍)	54	Chief Commercial Officer	April 1, 2021	April 1, 2021	Overall management of the drug commercialization of the Company

DIRECTORS AND SENIOR MANAGEMENT

<u>Name</u>	<u>Age</u>	<u>Position</u>	<u>Date of joining our Group</u>	<u>Date of appointment as Senior Management</u>	<u>Roles and responsibilities</u>
Mr. WU Jian (吳建)	49	Executive Advisor	January 4, 2022	January 4, 2022	Capital market activities, investor relations, and strategy formulation and enforcement of the Company

Mr. LU An-bang (盧安邦), aged 57, was appointed as a Director and Chief Executive Officer of the Company on November 7, 2018. He was re-designated as an Executive Director on March 27, 2021. Mr. Lu is responsible for the strategic planning, business direction and day-to-day operational management of the Company. Please refer to the sub-section headed “– Board of Directors – Executive Directors” in this section for his biography.

Dr. CHEN Jun (陳軍), aged 54, was appointed as the Chief Commercial Officer of our Company on April 1, 2021 and is responsible for the overall management of the drug commercialization of our Group.

Dr. Chen has served as vice president of diabetes portfolio business unit at Eli Lilly China from July 2018 to March 2021. From May 2016 to July 2018, he was vice president of diabetes business group of Medtronic in greater China. From January 2002 to April 2016, Dr. Chen served at various management roles at Novo Nordisk USA and China where his final position was vice president of marketing at Novo Nordisk China from October 2010 to April 2016. He was an associate at McKinsey & Company from 2000 to 2002. Prior to that, Dr. Chen was pharmaceutical scientist at Merck & Co. and its affiliate company Merial Ltd. from 1997 to 2000.

Dr. Chen received his Bachelor’s degree in molecular biology from the University of Science and Technology of China in July 1992, and his Ph.D. degree from Purdue University in the U.S. in May 1997.

Mr. WU Jian (吳建), aged 49, was appointed as the Executive Advisor of our Company on January 4, 2022 and is responsible for capital market activities, investor relations, and strategy formulation and enforcement of our Group.

DIRECTORS AND SENIOR MANAGEMENT

Prior to joining the Group, Mr. Wu has served as the head of equity capital markets and executive director of the corporate finance and capital markets services division of ICBC International Holdings Limited from August 2015 to March 2021. From December 2013 to August 2015, Mr. Wu was the director of the global capital market department of China Merchants Securities (HK) Co., Ltd.. From May 2011 to April 2013, Mr. Wu was the head of China ECM of the equity capital markets of investment banking department of Daiwa Capital Markets Hong Kong Limited. From January 2010 to May 2011, Mr. Wu was the vice president of investment banking department of BOCOM International Holdings Company Limited. From February 2008 to October 2009, Mr. Wu was an associate in the global banking division of Deutsche Bank, Hong Kong Branch. Mr. Wu served as a senior software engineer at BEA Systems, Inc. from July 2002 to September 2006.

In January 2008, Mr. Wu received his Master of Business Administration degree from the University of Oxford, the United Kingdom. In May 2002, Mr. Wu received his Master’s degree in information management and systems from University of California, Berkeley, the United States. In June 1998, Mr. Wu received his Bachelor’s degree in management information systems from the Tsinghua University.

Directors’ and Senior Management’s Interests

Save as disclosed above in this section, none of our Directors or senior management has been a director of any public company the securities of which are listed on any securities market in Hong Kong or overseas in the three years immediately preceding the date of this document.

Save as disclosed above in this section, to the best of the knowledge, information and belief of our Directors having made all reasonable enquiries, there was no other matter with respect to the appointment of our Directors that needs to be brought to the attention of our Shareholders and there was no information relating to our Directors that is required to be disclosed pursuant to Rules 13.51(2)(h) to (v) of the Listing Rules as of the Latest Practicable Date.

As of the Latest Practicable Date, save for the interests in the Shares of our Company held indirectly by Mr. LU An-bang, which are disclosed in the paragraphs headed “Appendix IV – Statutory and General Information – C. Further Information about Our Directors and Substantial Shareholders” in this document, none of our Directors held any interest in the securities within the meaning of Part XV of the SFO.

Save as disclosed above in this section, as of the Latest Practicable Date, none of our Directors or senior management is related to other Directors or senior management of our Company.

DIRECTORS AND SENIOR MANAGEMENT

COMPANY SECRETARY

Ms. Chan Sze Ting (陳詩婷) has been appointed as the company secretary of the Company on [REDACTED]. Ms. Chan currently serves as a director of the Company Secretarial Services of Tricor Services Limited, a member of Vistra Group.

Ms. Chan has over 18 years of experience in the corporate secretarial field and has been providing professional corporate services to Hong Kong listed companies as well as multinational, private and offshore companies.

Ms. Chan is a Chartered Secretary, a Chartered Governance Professional and a Fellow of both The Hong Kong Chartered Governance Institute and The Chartered Governance Institute in the United Kingdom. Ms. Chan holds a bachelor of laws degree from the University of London.

CORPORATE GOVERNANCE

Board Committees

The Board has established the following committees, namely the audit committee, the remuneration committee and the nomination committee. The committees operate in accordance with respective terms of reference established by our Board.

Audit Committee

The Company has established the audit committee of the Board with written terms of reference in compliance with Rule 3.21 of the Listing Rules and Appendix C1 to the Listing Rules (the “Corporate Governance Code”). The primary duties of our audit committee include the review and supervision of the Group’s financial reporting system, monitoring the internal control procedures and risk management, review of the Group’s financial information, review of the relationship with the external auditor of the Company and performance of the corporate governance functions delegated by the Board.

Our audit committee consists of two independent non-executive Directors and one non-executive Director and the chairman is Mr. CHAN Peng Kuan who holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules. Our audit committee consists of the following members:

Mr. CHAN Peng Kuan (chairman)

Mr. FU Shan

Dr. YAO Zhengbin (Bing)

DIRECTORS AND SENIOR MANAGEMENT

Remuneration Committee

The Company has established the remuneration committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and the Corporate Governance Code. The primary duties of the remuneration committee include making recommendations to the Board on the Company’s policy and structure for the remuneration of the Directors and senior management; and reviewing and approving the remuneration packages of all Directors and senior management with reference to corporate goals and objectives resolved by our Board from time to time. Our remuneration committee consists of the following members:

Ms. NI Hong (chairwoman)
Mr. CHAN Peng Kuan
Mr. LU An-Bang

Nomination Committee

The Company has established the nomination committee with written terms of reference in compliance with the Corporate Governance Code. The primary duties of the nomination committee include reviewing the structure, size and composition of our Board, assessing the independence of our independent non-executive Directors, identifying individuals suitably qualified to be a member of the Board and making recommendation to our Board on matters relating to the appointment or re-appointment of Directors. Our nomination committee consists of the following members:

Mr. Michael Wolff JENSEN (chairman)
Dr. YAO Zhengbin (Bing)
Ms. NI Hong

Corporate Governance Code

We have adopted certain corporate governance measures in compliance with the Corporate Governance Code. We aim to achieve a high standard of corporate governance, which is crucial to safeguard the interests of the Shareholders. To accomplish this, we expect to comply with the Corporate Governance Code after the [REDACTED].

Board Diversity Policy

In order to enhance the effectiveness of the 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 the 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 the Board, including but not limited to gender, age, cultural and educational background, or professional experience. The ultimate decision of the appointment will be based on merit and the contribution which the selected candidates will bring to the Board.

DIRECTORS AND SENIOR MANAGEMENT

The Board comprises nine members, including one executive Director, five non-executive Directors and three independent non-executive Directors. Our Directors have a balanced mix of knowledge, skills, perspectives and experience, including overall management and strategic development, business, science, investment, accounting and consulting. They obtained professional and academic qualifications including business administration, law, economics and science. Taking into account our existing business model and specific needs as well as the different background of our Directors, the composition of the Board satisfies our board diversity policy, and the Board and the nomination committee of the Company will assess the Board composition regularly.

Our nomination committee is responsible for reviewing the diversity of the Board. After [REDACTED], our nomination committee will continue to monitor and evaluate the implementation of the board diversity policy from time to time to ensure its continued effectiveness and we will disclose in our corporate governance report about the implementation of the board diversity policy, including any measurable objectives set for implementing the board diversity policy and the progress on achieving these objectives on an annual basis. We will also continue to take steps to promote gender diversity at all levels of our Company, including but without limitation at the Board and senior management levels.

KEY TERMS OF EMPLOYMENT AGREEMENTS WITH OUR SENIOR MANAGEMENT AND KEY PERSONNEL

We normally enter into: (i) an employment contract; (ii) a non-disclosure agreement; and (iii) a non-competition agreement with our senior management members and other key personnel. Below sets forth the key terms of these contracts we enter into with our senior management and other key personnel.

Term

We normally enter into an employment contract with a term up to 3 years with our senior management members and other key personnel.

Confidentiality

Scope of confidential information. The scope of confidential information include, without limitation:

- i. confidential information relating to the processes, products, specifications, organization, finances, operations, planning research and/or development programs, marketing, business forecasts, procurement, requirements, customer lists and accounts;
- ii. any other confidential information relating to products produced or marketed, or contemplated to be produced or marketed, by the Company or any member thereof;

DIRECTORS AND SENIOR MANAGEMENT

- iii. any business records, papers, reports, notebooks, calendars, documents, drawings, charts, samples, or similar forms of tangibly recorded data, containing any of the above information;
- iv. any information, data or records, including the types described above which by agreement with the Company are to be kept confidential or secret; and
- v. all copies of the above information.

Confidential obligation. During and after the employment with the Company, the employee shall not disclose or communicate any of the confidential information to any competitor or other third party or use or refer to any of the confidential information for any purpose, or remove materials containing any of the confidential information from the Company's premises, except as necessary for the employee to properly perform services for the Company during his/her service, or required by relevant laws and regulations or administrative authorities. All confidential information of previous employers, including any invention, discovery, secret or confidential information, knowledge or data of any third party to which the employee may be under an obligation of secrecy shall not be disclosed to or used for the benefit of the Company.

Confidential period. The confidentiality obligation shall continue to be in effect after 5 years upon termination of the employment.

Non-Competition Covenants

Non-competition obligation. During the term of the employment contract and within 24 months from the employee's departure from the Company, the employee shall not: (i) serve in or provide services to enterprises that compete with the Group; (ii) produce and operate any other same or similar products or businesses that compete with the Group; (iii) establish or participate in, or purchase stakes of entities that compete with the Group; or (iv) contact with clients of the Group which is not for the benefits of the Group.

Non-solicitation obligation. During the term of the employment contract and within 24 months from the employee's departure from the Company, the employee shall not either for themselves or for any other person or entity (i) directly or indirectly entice, induce, remand, persuade, recruit or encourage, or attempt to entice, induce, remand, persuade, recruit or encourage any of our employees to leave the Company, or (ii) otherwise encourage or induces any other staff of the Company to serve in other organizations.

Compensation for Breach of Covenants

If the employee breaches the confidentiality covenants or non-competition covenants, our Group shall be entitled to seeking a specified amount of compensation from the defaulting employee.

DIRECTORS AND SENIOR MANAGEMENT

REMUNERATION OF DIRECTORS AND SENIOR MANAGEMENT

For details on the service contracts and appointment letters signed between the Company and our Directors, please refer to the section “Statutory and General Information – C. Further Information about Our Directors and Substantial Shareholders” in Appendix IV to this document. Our Directors and senior management receive compensation in the form of salaries, allowances, bonuses and other benefits in kind, including our contribution to the pension scheme. The aggregate amount of remuneration (including salaries, bonuses, allowances and benefits in kind, contributions to pension scheme, discretionary bonus and bonus based on performance) that was paid by our Group to our Directors for each of the two years ended December 31, 2022 and 2023 and the four months ended April 30, 2024 was RMB62.5 million (including share grant), RMB19.1 million (including share grant) and RMB18.2 million (including share grant), respectively. Please refer to Note 9 of the Accountants’ Report in Appendix I to this document on the Directors’ and chief executive’s remuneration for the Track Record Period.

The aggregate amount of remuneration (including salaries, allowances and benefits in kind, contributions to pension scheme, discretionary bonus and bonus based on performance) paid to our five highest paid individuals for the two years ended December 31, 2022 and 2023 and the four months ended April 30, 2024 was approximately RMB97.3 million, RMB38.6 million and RMB26.0 million, respectively.

During the Track Record Period, (i) no remuneration was paid to our Directors or the five highest paid individuals as an inducement to join, or upon joining our Group, (ii) no compensation was paid to, or receivable by, our Directors or past Directors or the five highest paid individuals for the loss of office as director of any member of our Group or any other office in connection with the management of the affairs of any member of our Group, and (iii) none of our Directors waived any emoluments. Our Directors’ remuneration is determined with reference to the relevant Director’s experience and qualifications, level of responsibility, performance and the time devoted to our business, and the prevailing market conditions.

Except as disclosed in this document, no Director has been paid in cash or shares or otherwise by any person either to induce him to become, or to qualify him as a Director, or otherwise for service rendered by him in connection with the promotion or formation of us.

SHARE SCHEMES

We have adopted the Share Schemes, including the Equity Incentive Plan and the [REDACTED] Share Award Scheme. For further details, please see “Statutory and General Information – D. Equity Incentive Plan” and “Statutory and General Information – E. [REDACTED] Share Award Scheme” in Appendix IV to this document.

DIRECTORS AND SENIOR MANAGEMENT

COMPLIANCE ADVISER

The Company has appointed Somerley Capital Limited as its compliance adviser pursuant to Rule 3A.19 of the Listing Rules. In compliance with Rule 3A.23 of the Listing Rules, the Company must consult with and, if necessary, seek advice from the compliance adviser on a timely basis in the following circumstances:

- before the publication of any regulatory announcement, circular or financial report;
- where a transaction, which might be a notifiable or connected transaction or constitute price sensitive information of our Company, is contemplated including share issues and share repurchases;
- where we propose to apply 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
- where the Stock Exchange makes an inquiry of us in respect of unusual price movement and [REDACTED] or other issues under Rule 13.10 of the Listing Rules.

The terms of appointment of the compliance adviser will commence on the [REDACTED] and end on the date on which the Company distributes its annual report in respect of its financial results for the first full financial year commencing after the [REDACTED].

COMPETITION

Each of our Directors confirms that as of the Latest Practicable Date, he or she did not have any interest in a business which competes or is likely to compete, directly or indirectly, with our business and requires disclosure under Rule 8.10 of the Listing Rules.

From time to time our non-executive Directors may serve on the boards of both private and public companies within the broader healthcare and biopharmaceutical industries. However, as these non-executive Directors are not members of our executive management team, we do not believe that their interests in such companies as directors would render us incapable of carrying on our business independently from the other companies in which these non-executive Directors may hold directorships from time to time.

DIRECTORS AND SENIOR MANAGEMENT

CONFIRMATION FROM OUR DIRECTORS

Rule 3.09D of the Listing Rules

Each of our Directors confirms that he or she (i) has obtained the legal advice referred to under Rule 3.09D of the Listing Rules, and (ii) understands his or her obligations as a director of a [REDACTED] under the Listing Rules.

Rule 3.13 of the Listing Rules

Each of the independent non-executive Directors has confirmed (i) his/her independence as regards each of the factors referred to in Rules 3.13(1) to (8) of the Listing Rules, (ii) he/she has no past or present financial or other interest in the business of the Company or its subsidiaries or any connection with any core connected person of the Company under the Listing Rules as of the Latest Practicable Date, and (iii) that there are no other factors that may affect his/her independence at the time of his/her appointments.

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following completion of the [REDACTED], assuming the [REDACTED] is not exercised and no Shares are issued under the [REDACTED] Share Award Scheme, 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 to us 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 share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group. Our Directors are not aware of any arrangement which may at a subsequent date result in a change of control of our Company:

Name of Substantial Shareholder	Capacity/ Nature of Interest	Total number of Shares/underlying shares as at the Latest Practicable Date ⁽¹⁾	Approximate percentage of interest in our Company as at the Latest Practicable Date	Total number of Shares/underlying shares immediately after completion of the [REDACTED] ⁽²⁾	Approximate percentage of interest in our Company immediately after completion of the [REDACTED] ⁽²⁾
Ascendis Pharma A/S ⁽³⁾	Interest in controlled corporation	41,136,364	39.95%	[REDACTED]	[REDACTED]%
Ascendis Pharma Endocrinology Division ⁽³⁾	Beneficial interest	20,568,182	19.97%	[REDACTED]	[REDACTED]%
Ascendis Pharma Growth Disorders ⁽³⁾	Beneficial interest	7,713,068	7.49%	[REDACTED]	[REDACTED]%
Ascendis Pharma Bone Diseases ⁽³⁾	Beneficial interest	12,855,114	12.48%	[REDACTED]	[REDACTED]%
Vivo Capital IX (Cayman), LLC. ⁽⁴⁾	Interest in controlled corporation	36,136,364	35.09%	[REDACTED]	[REDACTED]%
Vivo Capital Fund IX (Cayman), L.P. ⁽⁴⁾	Interest in controlled corporation	36,136,364	35.09%	[REDACTED]	[REDACTED]%
Vivo Plenilune IX Limited ⁽⁴⁾	Beneficial interest	36,136,364	35.09%	[REDACTED]	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Notes:

- (1) The number of Shares held assuming that all of the Preferred Shares have been converted into the Shares on a one-to-one basis.
- (2) Based on the assumption that the [REDACTED] is not exercised and no Shares are issued under the [REDACTED] Share Award Scheme.
- (3) As of the Latest Practicable Date, (i) Ascendis Pharma Endocrinology Division directly held 20,568,182 Shares, consisting of 20,000,000 Series A Preferred Shares and 568,182 Series B Preferred Shares; (ii) Ascendis Pharma Growth Disorders directly held 7,713,068 Shares, consisting of 7,500,000 Series A Preferred Shares and 213,068 Series B Preferred Shares; and (iii) Ascendis Pharma Bone Diseases directly held 12,855,114 Shares, consisting of 12,500,000 Series A Preferred Shares and 355,114 Series B Preferred Shares. Each of Ascendis Pharma Endocrinology Division, Ascendis Pharma Growth Disorders and Ascendis Pharma Bone Diseases is a wholly-owned subsidiary of Ascendis Pharma A/S. As such, under the SFO, Ascendis Pharma A/S is deemed to be interested in the total amount of Shares held by Ascendis Pharma Endocrinology Division, Ascendis Pharma Growth Disorders and Ascendis Pharma Bone Diseases.
- (4) As of the Latest Practicable Date, Vivo Plenilune IX Limited, or Vivo Capital directly held 36,136,364 Shares, consisting of 35,000,000 Series A Preferred Shares and 1,136,364 Series B Preferred Shares. Vivo Plenilune IX Limited is a wholly-owned subsidiary of Vivo Capital Fund IX (Cayman), L.P., which is in turn controlled by its general partner, Vivo Capital IX (Cayman), LLC. As such, under the SFO, Vivo Capital IX (Cayman), LLC. and Vivo Capital Fund IX (Cayman), L.P. are deemed to be interested in the total number of Shares held by Vivo Plenilune IX Limited.

Except as disclosed above, our Directors are not aware of any other person who will, immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised and no Shares are issued under the [REDACTED] Share Award Scheme), have an interest or short position in our Shares or underlying Shares which would fall to be disclosed to us under the provisions of Divisions 2 and 3 of Part XV of the SFO, or, will be, directly or indirectly, interested in 10% or more of the issued voting shares of our Company or any other member of our Group.

SHARE CAPITAL

AUTHORIZED AND ISSUED SHARE CAPITAL

The following is a description of the authorized and issued share capital of our Company in issue and to be issued as fully paid or credited as fully paid immediately following the completion of the [REDACTED].

As at the Latest Practicable Date, our authorized share capital was US\$50,000.00 divided into: (i) 386,363,636 Shares, (ii) 20,000,000 non-voting Shares, (iii) 80,000,000 Series A Preferred Shares, and (iv) 13,636,364 Series B Preferred Shares.

As of the date of this document, our issued share capital consisted of (i) 80,000,000 Series A Preferred Shares, (ii) 9,340,500 non-voting Shares, and (iii) 13,636,364 Series B Preferred Shares. The Preferred Shares and non-voting Shares will be converted into Shares on a one-to-one basis by way of re-designation before [REDACTED].

Assuming the [REDACTED] is not exercised and no Shares are issued under the [REDACTED] Share Award Scheme, the share capital of our Company immediately following the completion of the [REDACTED] will be as follows:

<u>Description of Shares</u>	<u>Number of Shares</u>	<u>Aggregate nominal value of Shares</u> <i>(US\$)</i>	<u>Approximate percentage of issued share capital</u>
Shares in issue (including the Shares on re-designation of the Preferred Shares and non-voting Shares)	102,976,864	10,297.7	[REDACTED]%
Shares to be issued under the [REDACTED]	<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]</u> %
Total	<u><u>[REDACTED]</u></u>	<u><u>[REDACTED]</u></u>	<u><u>[REDACTED]</u></u> %

SHARE CAPITAL

Assuming the [REDACTED] is exercised in full and no Shares are issued under the [REDACTED] Share Award Scheme, the share capital of our Company upon completion of the [REDACTED] will be as follows:

<u>Description of Shares</u>	<u>Number of Shares</u>	<u>Aggregate nominal value of Shares</u> <i>(US\$)</i>	<u>Approximate percentage of issued share capital</u> <i>(%)</i>
Shares in issue (including the Shares on re-designation of the Preferred Shares and non-voting Shares)	102,976,864	10,297.7	[REDACTED]%
Shares to be issued under the [REDACTED]	<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]%</u>
Total	<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]%</u>

ASSUMPTIONS

The above tables assume that the [REDACTED] becomes unconditional, that Shares are issued pursuant to the [REDACTED], and that the Preferred Shares and non-voting Shares are converted into Shares on a one-to-one basis.

RANKING

The [REDACTED] are shares in the share capital of our Company and rank equally with all Shares currently in issue or to be issued (including all Preferred Shares and non-voting Shares re-designated into Shares upon completion of the [REDACTED]) and, in particular, will rank in full for all dividends or other distributions declared, made or paid on the Shares in respect of a record date which falls after the date of this document.

SHARE CAPITAL

CIRCUMSTANCES UNDER WHICH GENERAL MEETINGS ARE REQUIRED

Pursuant to the Cayman Companies Act and the terms of the Articles of Association, our Company may from time to time by ordinary resolution of Shareholders (i) increase its share capital; (ii) consolidate and divide its share capital into Shares of larger amount; and (iii) cancel any Shares which have not been taken or agreed to be taken. In addition, our Company may, subject to the provisions of the Cayman Companies Act, reduce its share capital or capital redemption reserve by its Shareholders passing a special resolution. For further details, please refer to the section headed “Appendix III – Summary of the Constitution of Our Company and Cayman Islands Company Law – Summary of the Constitution of the Company – 2. Articles of Association – 2.5. Alteration of Capital” in this document.

SHARE SCHEMES

We have adopted the Equity Incentive Plan and the [REDACTED] Share Award Scheme. For further details, please see the sections headed “Appendix IV – Statutory and General Information – D. Equity Incentive Plan” and “Appendix IV – Statutory and General Information – E. [REDACTED] Share Award Scheme” to this document.

GENERAL MANDATE TO ISSUE SHARES

Subject to the [REDACTED] becoming unconditional, our Directors [have been granted] a general unconditional mandate to allot, issue and deal with Shares with a total nominal value of not more than the sum of: (i) 20% of the aggregate nominal value of the Shares in issue immediately following completion of the [REDACTED] (excluding any Shares which may be issued pursuant to the exercise of the [REDACTED]); and (ii) the aggregate nominal value of Shares repurchased by the Company under the authority referred to in “– General Mandate to Repurchase Shares” in this section.

This general mandate to issue Shares will expire at the earliest of: (i) the conclusion of the next annual general meeting of our Company unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions; or (ii) the expiration of the period within which our Company’s next annual general meeting is required by the Memorandum of Association and Articles of Association or any other applicable laws to be held; or (iii) the date on which it is varied or revoked by an ordinary resolution of our Shareholders in general meeting. For further details on this general mandate, please see the section headed “Appendix IV – Statutory and General Information – A. Further Information about Our Group – 4. Resolutions Passed by Our Shareholders” in this document.

SHARE CAPITAL

GENERAL MANDATE TO REPURCHASE SHARES

Subject to the [REDACTED] becoming unconditional, our Directors [have been granted] a general unconditional mandate to exercise all the powers of our Company to repurchase our own securities with nominal value of up to 10% of the aggregate nominal value of our Shares in issue immediately following the completion of the [REDACTED] (excluding any Shares which may be allotted and issued pursuant to the exercise of the [REDACTED]). The repurchase mandate only relates to repurchases made on the Stock Exchange, or on any other stock exchange on which our Shares are listed (and which are recognized by the SFC and the Stock Exchange for this purpose), and which are in accordance with the Listing Rules.

This general mandate to repurchase Shares will expire at the earliest of: (i) the conclusion of the next annual general meeting of our Company unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions; or (ii) the expiration of the period within which our Company’s next annual general meeting is required by the Memorandum of Association and Articles of Association or any other applicable laws to be held; or (iii) the date on which it is varied or revoked by an ordinary resolution of our Shareholders passed in a general meeting. For further details of the repurchase mandate, please see the section headed “Appendix IV – Statutory and General Information – A. Further Information about Our Group – 4. Resolutions Passed by Our Shareholders” in this document.

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You should read the following discussion and analysis in conjunction with our audited consolidated financial information including the notes thereto, included in the Accountants’ Report in Appendix I to this document. Our audited consolidated financial information has been prepared in accordance with International Financial Reporting Standards.

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance that involve risks and uncertainties. These statements are based on assumptions and analysis made by us in light of our experience and perception of historical events, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this document, including those set forth under the sections headed “Risk Factors” and “Forward-Looking Statements” in this document.

OVERVIEW

We are a late-stage, near-commercialization biopharmaceutical company focused on providing treatments in selected endocrinology diseases in China (including Hong Kong, Macau and Taiwan). Since our inception, we have built a pipeline of three drug candidates targeting selected endocrine diseases, all of which were in-licensed from our collaboration partner, Ascendis Pharma. We currently have no product approved for commercial sale and have not generated any revenue from product sales. We have incurred operating losses in each year since inception and during the Track Record Period. Our total comprehensive losses were RMB288.9 million, RMB249.5 million and RMB60.3 million in 2022, 2023 and the four months ended April 30, 2024, respectively. Substantially all of our operating losses resulted from R&D expenses, administrative expenses and other gains and losses, net. We expect to incur significant expenses and operating losses for at least the next several years as we further our clinical R&D efforts, continue the clinical development of, seek regulatory approval for, and perform CMC development activities for our drug candidates, launch commercialization of our pipeline products, and add personnel necessary to operate our business. Subsequent to the [REDACTED], we expect to incur costs associated with operating as a [REDACTED]. We expect that our financial performance will fluctuate from period to period due to the development status of our drug candidates, regulatory approval timeline and commercialization of our drug candidates after approval.

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BASIS OF PREPARATION

Our Company was incorporated as an exempted company with limited liability in the Cayman Islands on November 1, 2018. Our Company, as the holding company of our business, indirectly owns VISEN Shanghai in China that is principally engaged in the research and clinical development of our drug candidates. See “History, Development and Corporate Structure” for more details. The consolidated financial information of our Group has been prepared in accordance with IFRSs, which comprise all standards and interpretations approved by the International Accounting Standards Board. All IFRSs effective for the accounting period commencing from January 1, 2024, together with the relevant transitional provisions, have been early adopted by our Group in the preparation of the consolidated financial information. The consolidated financial information has been prepared under the historical cost convention. The consolidated financial information of our Group is presented in RMB and all values are rounded to the nearest thousand except when otherwise indicated.

SIGNIFICANT FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations have been, and are expected to continue to be, affected by a number of factors, many of which may be beyond our control. A discussion of the key factors is set out below.

Our Ability to Successfully Develop Our Drug Candidates

Our business and results of operations depend on our ability to successfully develop and seek regulatory approval of our drug candidates. As of the Latest Practicable Date, we had three drug candidates in our development pipeline, including our Core Product, lonapegsomatropin, and two other drug candidates, TransCon CNP (navepegritide) and palopegteriparatide. Leveraging our clinical development capabilities, we provide patients in China (including Hong Kong, Macau and Taiwan) with access to the following endocrine solutions: (i) our Core Product, lonapegsomatropin, has completed the Phase 3 pivotal trial in China for the treatment of PGHD and the BLA filing was accepted by the NMPA on March 7, 2024; (ii) TransCon CNP (navepegritide) has completed the double-blind period of Phase 2 clinical trial in China for the treatment of ACH and the last patient last visit of OLE period of this trial was completed in April 2024; and (iii) palopegteriparatide is currently undergoing development in China Phase 3 pivotal trial for the treatment of adult patients with HP and has completed the double-blind period of this trial in January 2023. See “Business – Our Drug Pipeline” for more details regarding the development status of our drug candidates. Whether our drug candidates can demonstrate favorable safety and efficacy clinical trial results, and whether we can obtain the requisite regulatory approvals for our drug candidates in time, are crucial for our business and results of operations.

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Our Ability to Successfully Commercialize Our Drug Candidates

Subject to us successfully developing and obtaining regulatory approval of our drug candidates, our business and results of operations depend on our ability to commercialize our drug candidates. Our pipeline comprises three late-stage clinical drug candidates. Although we currently have no product approved for commercial sale and have not generated any revenue from product sales, we expect to commercialize one or more of our drug candidates over the coming years. Our ability to generate revenue from our drug candidates depends on the successful commercialization of the drug candidates, which may require significant marketing efforts in accordance with local rules and regulations. If our drug candidates are approved but fail to achieve the degree of market acceptance, we may not be able to generate revenue as expected. See “Business – Commercialization Plan, Patient Support and Market Access” for our commercialization plans and “Risk Factors – Other Risks Related to Manufacturing and Commercialization of Our Drug Candidates” for more details regarding the risks related to commercialization of our drug candidates.

Cost Structure

Our business and results of operations are significantly affected by our cost structure, which was comprised primarily of R&D expenses, administrative expenses and other gains and losses, net, during the Track Record Period.

R&D activities are central to our business. Our R&D costs consisted of contracting costs, raw materials and consumables, staff costs, share-based payment expenses, depreciation and amortization, cost sharing and others. Our current R&D activities primarily relate to the clinical development of our Core Product, lonapegsomatropin for the treatment of PGHD, and our two key drug candidates, TransCon CNP (navepegritide) and palopegteriparatide, addressing pediatric and adult endocrine diseases respectively. We expect our R&D costs to increase for the foreseeable future as we continue to progress the clinical development of and to conduct CMC activities with respect to our current and future drug candidates.

Our administrative expenses consisted of staff costs, depreciation of right-of-use assets, and property, plant and equipment, amortization, consulting and legal service fees, human resources and recruitment service fees, share-based payment expenses and others. We expect our administrative expenses to increase in the future to support our drug development efforts, commercialization, CMC and manufacturing activities with respect to our drug candidates, if approved.

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We expect our cost structure to evolve as we continue to develop and expand our business. As we continue to progress and expand our pipeline and gradually bring our product pipeline to commercialization, we expect to incur additional costs in relation to, among other things, our R&D, manufacturing, and medical activities in accordance with local rules and regulations. We also anticipate an increase in the legal, compliance, accounting, insurance, and investor and public relations expenses as a result of becoming a [REDACTED] in Hong Kong.

Funding for Our Operations

During the Track Record Period, we funded our operations through private equity financing. Going forward, in the event of the successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with revenue generated from sales of our commercialized drug products. However, with the continuing expansion of our business we may require further funding through public or private equity offerings, debt financing or other sources. Any changes in our ability to fund our operations will affect our cash flow and results of operations. See “– Liquidity and Capital Resources” for more details.

MATERIAL ACCOUNTING POLICY INFORMATION AND ESTIMATES

We have identified certain accounting policies that are significant to the preparation of our consolidated financial statements. Some of our accounting policies involve subjective assumptions and estimates, as well as complex judgments relating to accounting items. The estimates and underlying assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The estimates and underlying assumptions are reviewed on an on-going basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods. When reviewing our consolidated financial statements, you should consider (i) our material accounting policy information; (ii) the judgments and other uncertainties affecting the application of such policies; and (iii) the sensitivity of reported results to changes in conditions and assumptions.

We set forth below those accounting policies that we believe are of critical importance to us or involve the most significant estimates and judgments used in the preparation of our consolidated financial statements. Our material accounting policy information and estimates, which are important for an understanding of our financial condition and results of operations, are set forth in detail in notes 2 and 3 to the Accountants’ Report in Appendix I to this document.

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Material Accounting Policies

Research and Development Costs

All research costs are charged to profit or loss as incurred. Expenditure incurred on projects to develop new products is capitalized and deferred only when 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. Product development expenditure which does not meet these criteria is expensed when incurred.

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.

Our Group 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 representing the Group's obligation to make lease payments to lessor 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 (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease term and the estimated useful lives of the assets, as follows:

Office premises	2 to 3 years
Land use right	30 years

If ownership of the leased asset transfers to our Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

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(b) Lease Liabilities

Lease liabilities are recognized at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees.

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 the lease payments (e.g., a change to future payments resulting from a change in an index or rate used to determine such lease payments) or a change in the assessment of an option to purchase the underlying asset.

Lease liabilities are presented in separate lines as current and non-current liabilities on the consolidated statements of financial position.

(c) Short-Term Leases

We apply the short-term lease recognition exemption to its short-term leases of office premises (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 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 amortized cost, fair value through other comprehensive income, and fair value through profit or loss.

Financial assets classified and measured at amortized cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss. We did not have any financial assets measured at fair value at the end of each reporting period.

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Subsequent Measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial Assets at Amortized Cost (Debt Instruments)

Financial assets at amortized cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognized in profit or loss when the asset is derecognized, modified or impaired.

Share-based Payments

We operate an equity incentive plan for the purpose of providing incentives and rewards to eligible participants who contribute to the success of our operations. 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 is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using the market approach, further details of which are given in note 22 to Accountants’ Report 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 (in share reward reserve), 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 reporting 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 these conditions being met is assessed as part of our best estimate of the number of equity instruments that will ultimately vest. 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.

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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 we 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.

Government Grants

Government grants are recognized 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 fully recognized as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed.

DESCRIPTION OF SELECTED COMPONENTS OF STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

The table below sets forth our consolidated statements of profit or loss and other comprehensive income for the periods indicated derived from our consolidated statements of profit or loss and other comprehensive income set forth in the Accountants’ Report in Appendix I to this document:

	Year Ended		Four Months Ended	
	December 31,		April 30,	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Other income	5,764	11,356	2,567	5,835
Other gains and losses, net	77,184	(106,695)	(113,590)	805
Research and development costs	(179,546)	(57,690)	(3,805)	(25,771)
Administrative expenses	(177,449)	(79,944)	(22,248)	(35,146)
Finance costs	(619)	(317)	(126)	(66)
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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	Year Ended		Four Months Ended	
	December 31,		April 30,	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Loss before tax	(288,967)	(249,570)	(138,997)	(60,131)
Income tax expense	—	—	—	—
Loss for the year/period	(288,967)	(249,570)	(138,997)	(60,131)
Exchange differences on translation of the financial statements of subsidiaries	69	106	(63)	(189)
Total comprehensive loss for the year/period	<u>(288,898)</u>	<u>(249,464)</u>	<u>(139,060)</u>	<u>(60,320)</u>

Other Income

During the Track Record Period, our other income mainly consisted of government grants and other subsidies related to income and bank interest income.

Government grants have been received from the PRC local Governmental Authorities to support the subsidiary’s operating activities. There are no unfulfilled conditions related to these government grants. The establishment of the incentive programs and grant of such subsidies are subject to the government’s discretion and the receipt of such subsidies is thus unpredictable. Bank interest income comprised interest from bank deposits.

The following table sets forth a breakdown of our other income for the periods indicated:

	Year Ended		Four Months Ended	
	December 31,		April 30,	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Other income				
Government grants and other subsidies related to income	197	211	209	3,088
Bank interest income	5,567	11,145	2,358	2,747
Total	<u>5,764</u>	<u>11,356</u>	<u>2,567</u>	<u>5,835</u>

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Other Gains and Losses, Net

During the Track Record Period, our other gains and losses mainly consisted of (i) foreign exchange losses and gains; (ii) grants; (iii) donations; and (iv) loss from discontinued procurement contract.

During the Track Record Period, we held much of our cash and cash equivalents in US dollars, and foreign exchange losses and gains represented the exchange differences of the value of the foreign currency we held against the RMB resulted from fluctuations in exchange rates. Grants mainly related to our grants to CHARD for rare diseases with cooperation on a national patient registry and diagnosis consensus of ACH in the PRC. Donations related to our donations to non-profit making organizations for the purpose of epidemic relief and public welfare. Loss from discontinued procurement contract related to our cancellation of the commitment to purchase the previously reserved drug substance under a commitment and pre-payment agreement with Ascendis Pharma. In light of our commercial supply strategy adjustment, on February 1, 2023, we exercised the right to cancel the commitment to purchase the reserved drug substance under the commitment and pre-payment agreement. As such, we shall compensate Ascendis Pharma for its losses pursuant to the relevant agreement, provided that Ascendis Pharma shall use commercially reasonable efforts to mitigate the losses and that such losses are evidenced by supporting documents and are detailed in the invoice.

The following table sets forth a breakdown of our other gains and losses for the periods indicated:

	Year Ended		Four Months Ended	
	December 31,		April 30,	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Other Gains and Losses, Net				
Net foreign exchange gains/(losses)	79,782	4,706	(3,874)	947
Grants	(1,488)	(1,407)	(517)	(142)
Donations	(1,007)	(473)	(193)	–
Loss on the disposal of property, plant and equipment	(103)	(242)	–	–
Loss on termination of a lease contract	–	(273)	–	–
Loss from a discontinued procurement contract	–	(109,006)	(109,006)	–
Total	77,184	(106,695)	(113,590)	805

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Research and Development Costs

Our R&D costs consisted of: (i) contracting costs; (ii) raw materials and consumables; (iii) staff costs; (iv) share-based payment expenses; (v) depreciation and amortization; (vi) cost sharing; and (vii) others. Contracting costs and raw materials and consumables were mainly related to engaging with CROs and facilitating projects. Staff costs consisted of wages and salaries, bonuses and other employee benefits. Share-based payment expenses were incurred from our grant of restricted share units in 2021 and 2022. Depreciation and amortization mainly represented the depreciation of our leases under IFRS 16 and plant, property and equipment. Cost sharing represented the costs incurred by us in connection with the Cost Sharing and Volume Commitment Agreement we signed with Ascendis Pharma Endocrinology Division in 2021. Others mainly included consulting service fees and general expenses incurred for the purpose of R&D. The following table sets forth breakdowns by activity of our R&D costs for the periods indicated:

	Year ended		Four Months Ended	
	December 31,		April 30,	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Contracting costs	48,798	27,757	9,459	9,113
Raw materials and consumables	37,176	4,354	2,142	950
Staff costs	41,529	36,599	13,813	11,515
Share-based payment expenses	15,108	(29,334)	(29,719)	893
Depreciation and amortization	3,929	3,625	1,304	934
Cost sharing	21,566	8,451	4,905	–
Others	11,440	6,238	1,901	2,366
Total	179,546	57,690	3,805	25,771

The R&D costs incurred for our Core Product, lonapegsomatropin, amounted to RMB106.2 million, RMB28.7 million, RMB1.9 million and RMB12.7 million in 2022, 2023 and the four months ended April 30, 2023 and 2024, respectively, accounting for 59.1%, 49.8%, 50.0% and 49.2% of our total R&D costs, respectively, for the same periods. The decrease of R&D costs for lonapegsomatropin in 2023 was primarily due to (i) the decrease of RMB27.4 million in raw materials and consumables cost mainly due to the centralized procurement of quality control testing samples for the Core Product in 2022; (ii) the reversal of certain share-based payment expenses of RMB17.9 million mainly in relation to the retirement and resignation of relevant employees; (iii) the decrease of RMB13.1 million in lonapegsomatropin drug substance cost sharing amount we incurred under the Cost Sharing and Volume Commitment Agreement due to the completion of relevant project; and (iv) the decrease of RMB12.8 million in contracting cost mainly as a result of the completion of Phase

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3 pivotal trial in April 2022. The increase of R&D costs for lonapegsomatropin in the four months ended April 30, 2024 as compared to the same period in 2023 was primarily due to the reversal of certain share-based payment expenses of RMB14.6 million mainly in relation to the departure of relevant employee in the four months ended April 30, 2023 and delay in reaching certain milestone under the Equity Incentive Plan.

We incurred RMB17.8 million, RMB9.4 million, RMB0.6 million and RMB6.2 million on the development of TransCon CNP (navepegritide) in 2022, 2023 and the four months ended April 30, 2023 and 2024, respectively. The decrease of the R&D costs for TransCon CNP (navepegritide) in 2023 was primarily due to the reversal of certain share-based payment expenses of RMB10.1 million mainly in relation to the retirement of relevant employees. The increase in the four months ended April 30, 2024 as compared to the same period in 2023 was primarily due to the reversal of certain share-based payment expenses of RMB4.6 million mainly in relation to the departure of relevant employees in the four months ended April 30, 2023 and delay in reaching certain milestone under the Equity Incentive Plan.

We incurred RMB55.5 million, RMB19.6 million, RMB1.3 million and RMB6.9 million on the development of palopegteriparatide in 2022, 2023 and the four months ended April 30, 2023 and 2024, respectively. The decrease of the R&D costs for palopegteriparatide in 2023 was primarily due to (i) the reversal of certain share-based payment expenses of RMB16.4 million mainly in relation to the retirement and resignation of relevant employees; (ii) the decrease of RMB11.6 million in contracting costs mainly resulting from the completion of the double-blind period of Phase 3 pivotal trial of palopegteriparatide in China in January 2023; and (iii) the decrease of RMB5.1 million in raw materials and consumables mainly resulting from the centralized procurement of drugs for clinical use in 2022 to meet the demands of China Phase 3 pivotal trial. The increase in the four months ended April 30, 2024 as compared to the same period in 2023 was primarily due to the reversal of certain share-based payment expenses of RMB10.5 million mainly in relation to the departure of relevant employees in the four months ended April 30, 2023 and delay in reaching certain milestone under the Equity Incentive Plan, partially offset by a decrease in contracting costs of RMB3.6 million mainly as a result of the completion of the double-blind period of Phase 3 pivotal trial of palopegteriparatide in China in January 2023.

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Administrative Expenses

Our administrative expenses consisted of: (i) staff costs; (ii) share-based payment expenses; (iii) depreciation and amortization; (iv) consulting and legal service fees; (v) human resources and recruitment service fees; and (vi) others. Staff costs consisted of wages and salaries, bonuses and other employee benefits. Share-based payment expenses consisted of administrative expenses associated with our grant of restricted share units in 2021 and 2022. Depreciation and amortization mainly represented the depreciation of our lease under IFRS 16 and plant, property and equipment and amortization of intangible assets. Consulting and legal service fees included fees relating to legal, consulting and translation services. Human resources and recruitment service fees included fees in connection with recruitment activities. Others mainly included traveling expenses and general expenses incurred for administrative purposes.

The table below sets forth a breakdown of our administrative expenses for the periods indicated:

	Year ended December 31,		Four Months Ended April 30,	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Staff costs	49,823	42,305	21,353	9,880
Share-based payment expenses	78,400	17,068	(4,866)	20,779
Depreciation and amortization	3,576	3,371	1,185	878
Consulting and legal service fees	13,022	6,346	1,361	955
Human resources and recruitment service fees	4,136	850	124	120
Others	28,492	10,004	3,091	2,534
Total	177,449	79,944	22,248	35,146

Finance Costs

Our finance costs represented interest on lease liabilities. We recorded finance costs of RMB0.6 million, RMB0.3 million, RMB0.1 million and RMB0.1 million in 2022, 2023 and the four months ended April 30, 2023 and 2024, respectively.

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[REDACTED]

Our [REDACTED] represented expenses incurred for our proposed [REDACTED] and [REDACTED]. We recorded [REDACTED] of RMB[REDACTED], RMB[REDACTED], RMB[REDACTED] and RMB[REDACTED] in 2022, 2023 and the four months ended April 30, 2023 and 2024, respectively.

Income Tax

Our 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. We recorded no income tax expense during the Track Record Period, due to our loss before taxation.

Cayman Islands

Under the current laws of the Cayman Islands, our Company is not subject to tax on income or capital gains. In addition, upon payments of dividends by our Company to its shareholders, no Cayman Islands withholding tax is imposed on our Company.

British Virgin Islands

Under the current laws of BVI, our subsidiary incorporated in BVI is not subject to tax on income or capital gains. In addition, upon payments of dividends to us, no BVI withholding tax is imposed on the subsidiary.

Hong Kong

Our subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the statutory rate of 16.5% on any estimated assessable profits arising in Hong Kong during the Track Record Period. No Hong Kong profits tax was provided for as we did not generate any assessable profits arising in Hong Kong during the Track Record Period.

China

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations, our subsidiaries which operate in China are subject to income tax at a rate of 25% on the taxable income during the Track Record Period. Pursuant to the Corporate Income Tax Law, VISEN Shanghai enjoyed super deduction of 175% and 200% on qualifying R&D expenditures from January 2022 to October 2022 and from November 2022 to April 2024, respectively, during the Track Record Period.

Taiwan

The subsidiary incorporated in Taiwan is subject to Taiwan profits tax. The first TWD120,000 of assessable profits of this subsidiary are not subject to tax and the remaining assessable profits are taxed at 20%. No Taiwan profits tax was provided for as we did not generate any assessable profits arising in Taiwan during the Track Record Period.

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PERIOD-TO-PERIOD COMPARISON OF RESULTS OF OPERATIONS

Four Months Ended April 30, 2024 Compared to Four Months Ended April 30, 2023

Other Income

Our other income increased from RMB2.6 million for the four months ended April 30, 2023 to RMB5.8 million for the four months ended April 30, 2024, primarily due to an increase of RMB2.9 million in government grants and other subsidies related to recognition of deferred income from local government.

Other Gains and Losses, Net

We recorded net losses of RMB113.6 million for the four months ended April 30, 2023, and recorded net gains of RMB0.8 million for the four months ended April 30, 2024. The change was primarily due to (i) the loss from a discontinued procurement contract recorded in the amount of RMB109.0 million in the four months ended April 30, 2023 in relation to our cancellation of the commitment to purchase the previously reserved drug substance under the commitment and pre-payment agreement in February 2023; and (ii) the net foreign exchange gains of RMB0.9 million in the four months ended April 30, 2024 as compared to net foreign exchange losses of RMB3.9 million in the same period in 2023 as a result of the US dollars exchange rate appreciation and EUR exchange rate depreciation against the Renminbi in the four months ended April 30, 2024, yielding foreign exchange gains for the Group’s cash and cash equivalents denominated in US dollars and payables denominated in EUR.

Research and Development Costs

Our R&D costs increased from RMB3.8 million for the four months ended April 30, 2023 to RMB25.8 million for the four months ended April 30, 2024, primarily due to the reversal of certain share-based payment expenses of RMB29.7 million mainly in relation to the departure of relevant employees in the four months ended April 30, 2023 and delay in reaching certain milestone under the Equity Incentive Plan.

Administrative Expenses

Our administrative expenses increased from RMB22.2 million for the four months ended April 30, 2023 to RMB35.1 million for the four months ended April 30, 2024, primarily due to the reversal of share-based payments in the four months ended April 30, 2023.

Finance Costs

Our finance costs remained relatively stable at RMB0.1 million for the four months ended April 30, 2023 and 2024.

FINANCIAL INFORMATION

[REDACTED]

Our [REDACTED] increased from RMB[REDACTED] for the four months ended April 30, 2023 to RMB[REDACTED] for the four months ended April 30, 2024, primarily due to the increased professional services provided by the Joint Sponsors, legal counsels and other professional service providers in relation to the [REDACTED].

Loss for the Period

As a result of the foregoing, our loss for the period decreased from RMB139.0 million for the four months ended April 30, 2023 to RMB60.1 million for the four months ended April 30, 2024.

Year Ended December 31, 2023 Compared to Year Ended December 31, 2022

Other Income

Our other income increased from RMB5.8 million in 2022 to RMB11.4 million in 2023, primarily due to an increase of RMB5.6 million in bank interest income as the interest rate increased for deposits denominated in the US dollars.

Other Gains and Losses, Net

We recorded net gains of RMB77.2 million in 2022, and recorded net losses of RMB106.7 million in 2023. The change was primarily due to (i) the loss from a discontinued procurement contract recorded in the amount of RMB109.0 million in relation to our cancellation of the commitment to purchase the previously reserved drug substance under the commitment and pre-payment agreement in February 2023; and (ii) a decrease of RMB75.1 million in net foreign exchange gains in 2023 as a result of the US dollars exchange rate appreciation against the Renminbi by a relatively small margin and less cash and cash equivalent denominated in US dollars.

Research and Development Costs

Our R&D costs decreased from RMB179.5 million in 2022 to RMB57.7 million in 2023, primarily due to the decrease of R&D costs for lonapegsomatropin, TransCon CNP (navepegritide) and palopegteriparatide of RMB77.5 million, RMB8.4 million and RMB35.9 million, respectively.

Administrative Expenses

Our administrative expenses decreased from RMB177.4 million in 2022 to RMB79.9 million in 2023, primarily due to the decrease in share-based payments and the consulting and legal service fees.

FINANCIAL INFORMATION

Finance Costs

Our finance costs decreased from RMB0.6 million in 2022 to RMB0.3 million in 2023, due to a decrease in the interest on lease liabilities in relation to the decrease of our lease liabilities.

[REDACTED]

Our [REDACTED] increased from RMB[REDACTED] in 2022 to RMB[REDACTED] in 2023, primarily due to the increased professional services provided by the Joint Sponsors, legal counsels and other professional service providers in relation to the [REDACTED].

Loss for the Year

As a result of the foregoing, our loss for the year decreased from RMB289.0 million in 2022 to RMB249.6 million in 2023.

DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The table below sets forth selected information from our consolidated statements of financial position as of the dates indicated, which have been derived from the Accountants’ Report in Appendix I to this document:

	As of December 31,		As of
	2022	2023	April 30,
	<i>RMB’000</i>	<i>RMB’000</i>	2024
			<i>RMB’000</i>
NON-CURRENT ASSETS			
Property, plant and equipment	2,352	876	551
Right-of-use assets	14,812	12,379	11,158
Intangible assets	1,415	567	301
Amount advanced to a related party	–	39,193	39,193
Prepayments and other receivables	11,103	16,660	17,596
	29,682	69,675	68,799
CURRENT ASSETS			
Prepayments and other receivables	15,961	16,972	16,418
Amount advanced to a related party	69,171	9,367	9,375
Cash and cash equivalents	626,458	347,782	299,683
	711,590	374,121	325,476

FINANCIAL INFORMATION

	As of December 31,		As of
	2022	2023	April 30,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
CURRENT LIABILITIES			
Trade and other payables	49,460	37,582	33,366
Deferred income	2,900	2,900	–
Amounts due to related parties	30,311	8,790	6,344
Lease liabilities	4,668	2,552	1,785
Total current liabilities	87,339	51,824	41,495
Net current assets	624,251	322,297	283,981
Total assets less current liabilities	653,933	391,972	352,780
NON-CURRENT LIABILITIES			
Lease liabilities	1,328	1,097	554
Total non-current liabilities	1,328	1,097	554
Net assets	652,605	390,875	352,226
EQUITY			
Equity attributable to owners of the Company			
Share capital	70	70	70
Treasury shares	(6)	(6)	(6)
Reserves	652,541	390,811	352,162
Total equity	652,605	390,875	352,226

FINANCIAL INFORMATION

Net Current Assets

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

	As of December 31,		As of	As of
	2022	2023	April 30,	July 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
CURRENT ASSETS				
Prepayments and other receivables	15,961	16,972	16,418	13,299
Amount advanced to a related party	69,171	9,367	9,375	10,218
Cash and cash equivalents	626,458	347,782	299,683	270,020
Total current assets	711,590	374,121	325,476	293,537
CURRENT LIABILITIES				
Trade and other payables	49,460	37,582	33,366	31,699
Deferred income	2,900	2,900	–	–
Amounts due to related parties	30,311	8,790	6,344	8,522
Lease liabilities	4,668	2,552	1,785	2,368
Total current liabilities	87,339	51,824	41,495	42,589
Net current assets	624,251	322,297	283,981	250,948

We had net current assets of RMB250.9 million as of July 31, 2024, being the latest practicable date for the purpose of liquidity disclosure in this document, which decreased from RMB284.0 million as of April 30, 2024, primarily due to a decrease of RMB29.7 million in cash and cash equivalents as a result of the operating costs associated with our R&D and administrative activities.

Our net current assets decreased from RMB322.3 million as of December 31, 2023 to RMB284.0 million as of April 30, 2024, primarily due to a decrease of RMB48.1 million in cash and cash equivalents as a result of the operating costs associated with our R&D and administrative activities.

Our net current assets decreased from RMB624.3 million as of December 31, 2022 to RMB322.3 million as of December 31, 2023, primarily due to a decrease of RMB278.7 million in cash and cash equivalents as a result of the operating costs associated with our R&D and administrative activities and a decrease of RMB59.8 million in amount advanced to a related party.

FINANCIAL INFORMATION

Prepayments and Other Receivables

Our prepayments and other receivables included rental deposits, value-added tax recoverable, prepayments for R&D services, other prepayments and deferred share issue costs. Value-added tax recoverable represented value-added taxes incurred in clinical development, office renovation and procurement of plant, property and equipment. The table below sets forth a breakdown of our prepayments and other receivables as of the dates indicated:

	As of December 31,		As of
	2022	2023	April 30,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Non-current:			
Value-added tax recoverable	9,440	16,137	17,100
Rental deposits	1,663	523	496
	11,103	16,660	17,596
Current:			
Prepayments for research and development services	6,951	5,308	4,997
Deferred share issue costs	5,669	6,053	5,671
Other prepayments	1,855	824	838
Bank interest receivable	1,391	4,036	4,094
Rental deposits	41	697	764
Other receivables	54	54	54
	15,961	16,972	16,418
Total	27,064	33,632	34,014

FINANCIAL INFORMATION

Our prepayments and other receivables remained relatively stable at RMB33.6 million and RMB34.0 million as of December 31, 2023 and April 30, 2024, respectively. Our prepayments and other receivables increased from RMB27.1 million as of December 31, 2022 to RMB33.6 million as of December 31, 2023, primarily due to an increase of RMB6.7 million in value-added tax recoverable mainly in relation to our research and development activities, partially offset by a decrease of RMB1.6 million in prepayments for research and development services as a result of our completion of the Phase 3 pivotal trial of the Core Product in April 2022. As of July 31, 2024, RMB5.2 million, representing 15.3% of the prepayments and other receivables as of April 30, 2024 was subsequently settled. The rest of the unsettled prepayments and other receivables primarily consist of deposit, prepayments for future clinical trials, bank interest receivable, defer issue costs and value-added tax recoverable, representing approximately 83.2% of the prepayments and other receivables as of April 30, 2024.

Cash and Cash Equivalents

Our cash and cash equivalents consisted of cash on hand and at banks, and short-term highly liquid deposits. Our cash and cash equivalents decreased from RMB626.5 million as of December 31, 2022 to RMB347.8 million as of December 31, 2023 and further to RMB299.7 million as of April 30, 2024, primarily due to the operating costs associated with our R&D and administrative activities, payment for the loss resulted from discontinued procurement contract related to our cancellation of the commitment to purchase the previously reserved drug substance under a commitment and pre-payment agreement with Ascendis Pharma and prepayments for future commercial supply of drug products.

Amount Advanced to a Related Party

Our amount advanced to a related party, as non-current asset and of trade nature, increased from nil as of December 31, 2022 to RMB39.2 million as of December 31, 2023 and remained the same as of April 30, 2024, as we made a payment of RMB39.2 million to Ascendis Pharma for relevant drug products in November 2023 pursuant to the Commercial Supply Agreement entered in October 2023. See “Connected Transactions – Non-Exempt and Partially-Exempt Continuing Connected Transactions – Commercial Supply Agreement – Pricing Policy” for more details.

Our amount advanced to a related party, as current asset and of trade nature, decreased from RMB69.2 million as of December 31, 2022 to RMB9.4 million as of December 31, 2023 and remained relatively stable as of April 30, 2024, primarily due to the write-off of the prepayment recorded in 2022 for the purchase of previously reserved drug substance under a commitment and pre-payment agreement with Ascendis Pharma, as we canceled our commitment to purchase such drug substance in 2023.

FINANCIAL INFORMATION

Trade and Other Payables

Our trade and other payables primarily consisted of trade payables, accrued expenses for R&D services, salary and discretionary bonus payables, other payables, accrued [REDACTED] and other taxes payable. The table below sets forth a breakdown of our trade and other payables as of the dates indicated:

	<u>As of December 31,</u>		<u>As of</u>
	<u>2022</u>	<u>2023</u>	<u>April 30,</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<u>2024</u>
			<i>RMB'000</i>
Trade payables	3,740	669	166
Accrued expenses for research and development services	8,790	8,078	8,593
Salary and discretionary bonus payables	11,815	13,316	5,992
Other payables	14,582	2,590	1,660
Accrued [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Other taxes payable	2,569	1,852	2,589
Total	<u>49,460</u>	<u>37,582</u>	<u>33,366</u>

Trade and other payables decreased from RMB37.6 million as of December 31, 2023 to RMB33.4 million as of April 30, 2024, primarily due to a decrease of RMB7.3 million in salary and discretionary bonus payables as a result of payments for 2023 year-end performance bonus, partially offset by an increase of RMB3.3 million in accrued [REDACTED].

Trade and other payables decreased from RMB49.5 million as of December 31, 2022 to RMB37.6 million as of December 31, 2023, primarily due to (i) a decrease of RMB12.0 million in other payables as we made payments for consulting and design fees in 2023; and (ii) a decrease of RMB3.1 million in trade payables, partially offset by an increase of RMB3.1 million in accrued [REDACTED].

The following table sets forth an ageing analysis of our trade payables as of the dates indicated, based on the invoice date:

	<u>As of December 31,</u>		<u>As of April 30,</u>
	<u>2022</u>	<u>2023</u>	<u>2024</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Within 3 months	<u>3,740</u>	<u>669</u>	<u>166</u>

As of July 31, 2024, RMB0.2 million, representing 100.0% of the trade payables as of April 30, 2024 was subsequently settled.

FINANCIAL INFORMATION

Amounts Due to Related Parties

Our amounts due to related parties decreased from RMB8.8 million as of December 31, 2023 to RMB6.3 million as of April 30, 2024, primarily due to the settlement of our payment for R&D consulting services from Ascendis Pharma relating to our three drug candidates.

Our amounts due to related parties decreased from RMB30.3 million as of December 31, 2022 to RMB8.8 million as of December 31, 2023, primarily due to the settlement of our payment for the centralized procurement of quality control testing samples for the Core Product and costs incurred by us in connection with the Cost Sharing and Volume Commitment Agreement we signed with Ascendis Pharma.

LIQUIDITY AND CAPITAL RESOURCES

Overview

Our primary uses of cash are to fund the R&D of our Core Product and other pipeline programs, administrative expenses and other recurring expenses. During the Track Record Period, we incurred negative cash flows from our operations and substantially all of our operating cash outflows resulted from our R&D costs and administrative expenses. Our net cash used in operating activities was RMB246.5 million, RMB271.3 million and RMB46.5 million in 2022, 2023 and the four months ended April 30, 2024, respectively. For further details, please refer to the sub-section headed “– Cash Flows” in this section.

Our operating cash flow will continue to be affected by our R&D expenses and administrative expenses. We expect to improve our net operating cash outflows position following the approval and commercialization of our drug candidates in the future. During the Track Record Period and up to the Latest Practicable Date, we funded our working capital requirements through proceeds from private equity financing. Our management closely monitors uses of cash and cash equivalents and strives to maintain a robust liquidity for our operations. Going forward, we believe our liquidity requirements will be satisfied by a combination of [REDACTED] from the [REDACTED] and cash generated from our operations. As of April 30, 2024, our cash and cash equivalents amounted to RMB299.7 million.

FINANCIAL INFORMATION

Cash Flows

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

	Year Ended December 31,		Four Months Ended April 30,	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Net cash flows used in operating activities	(246,549)	(271,310)	(88,467)	(46,534)
Net cash flows used in investing activities	(1,766)	(520)	(245)	–
Net cash flows used in financing activities	(7,949)	(6,952)	(2,266)	(1,376)
Net decrease in cash and cash equivalents	(256,264)	(278,782)	(90,978)	(47,910)
Cash and cash equivalents at beginning of the year/period	882,653	626,458	626,458	347,782
Cash and cash equivalents at end of the year/period	626,458	347,782	535,417	299,683

Operating Activities

During the Track Record Period, we incurred negative cash flows from our operations. Substantially all of our operating cash outflows have resulted from our R&D costs and administrative expenses.

In the four months ended April 30, 2024, our net cash used in operating activities was RMB46.5 million, which was primarily attributable to our loss before tax of RMB60.1 million, adjusted for non-cash items and changes in working capital. Positive adjustments primarily included share-based payment expenses of RMB21.7 million. Negative adjustments mainly included (i) a decrease in trade and other payables of RMB4.2 million and (ii) a decrease in deferred income of RMB2.9 million.

In 2023, our net cash used in operating activities was RMB271.3 million, which was primarily attributable to our loss before tax of RMB249.6 million, adjusted for non-cash items and changes in working capital. Positive adjustments primarily included loss from discontinued procurement contract of RMB69.2 million. Negative adjustments mainly included (i) a reversal of share-based payment expenses of RMB12.3 million; (ii) a decrease in amounts due to related parties of RMB21.5 million; (iii) an increase in amount advanced to a related party of RMB48.6 million and (iv) a decrease in trade and other payables of RMB12.1 million.

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In 2022, our net cash used in operating activities was RMB246.5 million, which was primarily attributable to our loss before tax of RMB289.0 million, adjusted for non-cash items and changes in working capital. Positive adjustments primarily included: (i) share-based payment expenses of RMB93.5 million; (ii) increase in amounts due to related parties of RMB7.1 million; (iii) depreciation of right-of-use assets of RMB4.9 million; and (iv) increase in trade and other payables of RMB4.4 million. Negative adjustments mainly included an increase in amount advanced to a related party of RMB69.2 million.

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. In view of our net operating cash outflows throughout the Track Record Period, we plan to improve such position through the following initiatives: (i) advance our pipeline drug candidates towards commercialization to generate revenue from product sales. Specifically, subject to regulatory communications and marketing approval, we expect to receive BLA approval for our Core Product for PGHD in China in the mid 2025 and subsequently launch the Core Product commercially; (ii) after the commercialization of our drug candidates, we plan to closely monitor and manage the settlement of our trade receivables to avoid credit losses. We will also closely monitor the settlement of our trade payables to achieve better cash flow position; and (iii) in addition, we will continue to implement comprehensive measures to effectively control our operating costs and better utilize our idle cash. For example, we have set up a comprehensive budget management mechanism covering all types of costs and expenses incurred in our daily operations, and strictly manage our budgets at the project and business department levels.

Investing activities

In the four months ended April 30, 2024, our net cash used in investing activities was nil.

In 2023, our net cash used in investing activities was RMB0.5 million, which was due to the purchase of items of property, plant and equipment.

In 2022, our net cash used in investing activities was RMB1.8 million, which was primarily due to the purchase of items of property, plant and equipment of RMB1.5 million.

Financing activities

In the four months ended April 30, 2024, our net cash used in financing activities was RMB1.4 million, which was due to lease payments and related interests of RMB1.4 million.

In 2023, our net cash used in financing activities was RMB7.0 million, which was primarily due to: (i) lease payments and related interests of RMB4.9 million; and (ii) payment of [REDACTED] of RMB[REDACTED].

In 2022, our net cash used in financing activities was RMB7.9 million, which was primarily due to: (i) lease payments and related interests of RMB5.8 million; and (ii) payment of [REDACTED] of RMB[REDACTED].

FINANCIAL INFORMATION

WORKING CAPITAL

Our Directors are of the opinion that, taking into account the financial resources available to our Group, including cash and cash equivalents and the estimated [REDACTED] from the [REDACTED], we have sufficient working capital to cover at least 125% of our costs, including R&D costs and administrative expenses for at least the next 12 months from the expected date of this document.

Our cash burn rate refers to the average monthly (i) net cash used in operating activities, including clinical development and business development activities; (ii) capital expenditures; and (iii) lease payments. We had cash and cash equivalents of RMB299.7 million as of April 30, 2024. We estimate that we will receive [REDACTED] of approximately HK\$[REDACTED], equivalent to RMB[REDACTED], after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], assuming no [REDACTED] is exercised and assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the low-end of the indicative [REDACTED] range in this document. We estimate that our cash and cash equivalents as of April 30, 2024 will be able to maintain our financial viability for [REDACTED] months or, if we take into account [REDACTED]% of the estimated [REDACTED] from the [REDACTED] (namely, the portion allocated for our working capital and other general corporate purposes), [REDACTED] months or, if we also take into account the estimated [REDACTED] from the [REDACTED], [REDACTED] months. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing, if needed, with a minimum buffer of 12 months.

CASH OPERATING COSTS

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

	Year Ended December 31,		Four Months Ended April 30,	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Costs Relating to Research and Development of Our Core Product, Lonapegsomatropin				
Contracting costs	27,318	13,075	2,770	6,147
Raw materials and consumables	20,705	10,662	10,088	466
Staff costs	18,163	16,065	5,811	6,547
Cost sharing	32,630	17,986	14,440	–
Others	7,896	2,708	1,410	2,304
Subtotal	106,712	60,496	34,519	15,464

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	Year Ended December 31,		Four Months Ended April 30,	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Costs Relating to Research and Development of Other Drug Candidates				
Contracting costs	25,458	18,038	4,951	4,629
Raw materials and consumables	5,200	5,271	3,174	893
Staff costs	22,504	18,816	7,478	7,385
Others	3,526	2,954	741	422
Subtotal	56,688	45,079	16,344	13,329
Workforce employment cost⁽¹⁾	47,179	38,174	15,916	14,050
Direct production cost	–	–	–	–
Others⁽²⁾	47,713	39,632	14,815	7,021
Total	258,292	183,381	81,594	49,864

Notes:

- (1) Workforce employment costs represented non-R&D staff costs, mainly including salaries and social insurance contributions.
- (2) Mainly consisted of consulting expense, [REDACTED], travelling expense and other miscellaneous costs.

INDEBTEDNESS

The following table sets forth the breakdown of our indebtedness as of the dates indicated:

	As of December 31,		As of April 30,	As of July 31,
	2022	2023	2024	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(unaudited)</i>
Current				
Lease liabilities	4,668	2,552	1,785	2,368
Non-current				
Lease liabilities	1,328	1,097	554	896
Total	5,996	3,649	2,339	3,264

FINANCIAL INFORMATION

Except as presented above, we did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, unutilized bank facilities, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities as of the Latest Practicable Date. Our Directors confirm that there has not been any material change in our indebtedness since the Latest Practicable Date up to the date of this document. Our Directors confirm that as of the Latest Practicable Date, there was no material covenant on any of our outstanding debt and there was no breach of any covenant during the Track Record Period and up to the Latest Practicable Date. Our Directors further confirm that our Group did not experience any difficulty in obtaining bank loans and other borrowings, default in payment of bank loans and other borrowings or breach of covenants during the Track Record Period and up to the Latest Practicable date.

CAPITAL EXPENDITURES

The following table sets forth our capital expenditures for the periods indicated:

	Year Ended December 31,		Four Months Ended April 30,	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Purchases of items of property, plant and equipment	1,484	520	245	–
Payment for acquisition of land use right	282	–	–	–
Total	1,766	520	245	–

Our historical capital expenditures during the Track Record Period primarily included expenditure associated with the purchase of property, plant and equipment which mainly consists of furniture and equipment and leasehold improvements. We funded our capital expenditure requirements during the Track Record Period through equity financing.

CAPITAL COMMITMENTS

As of December 31, 2022 and 2023 and April 30, 2024, we had no capital commitments contracted for but not yet provided.

FINANCIAL INFORMATION

CONTINGENT LIABILITIES

As of December 31, 2022 and 2023 and April 30, 2024, we did not have any contingent liabilities. We confirm that as of the Latest Practicable Date, there had been no material changes or arrangements to our contingent liabilities.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet transactions.

KEY FINANCIAL RATIO

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

	As of December 31,		As of
	2022	2023	April 30,
			2024
Current ratio ⁽¹⁾	8.15	7.22	7.84

Note:

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

Our current ratio increased from 7.22 as of December 31, 2023 to 7.84 as of April 30, 2024, mainly due to a decrease in our current liabilities from RMB51.8 million as of December 31, 2023 to RMB41.5 million as of April 30, 2024, which was primarily due to (i) a decrease of RMB4.2 million in trade and other payables; (ii) a decrease of RMB2.9 million in deferred income; and (iii) a decrease of RMB2.4 million in amounts due to related parties.

Our current ratio decreased from 8.15 as of December 31, 2022 to 7.22 as of December 31, 2023, mainly due to a decrease in our current assets from RMB711.6 million as of December 31, 2022 to RMB374.1 million as of December 31, 2023, which was primarily due to a decrease of RMB278.7 million in cash and cash equivalents as a result of the operating costs associated with our R&D and administrative activities, payment for the loss resulted from discontinued procurement contract related to our cancellation of the commitment to purchase the previously reserved drug substance under a commitment and pre-payment agreement with Ascendis Pharma and prepayments for future commercial supply of drug products. See “– Discussion of Certain Selected Items from the Consolidated Statements of Financial Position – Net Current Assets.”

FINANCIAL INFORMATION

RELATED-PARTY TRANSACTIONS

During the Track Record Period, we purchased investigational medicinal products as well as R&D services primarily from our related parties, and entered into agreements, in accordance with published prices and conditions agreed by us and the related parties.

The below table sets forth the transactions with related parties during the Track Record Period.

	Year Ended December 31,		Four Months Ended April 30,	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
	<i>(unaudited)</i>			
Purchase of trial drugs and cost sharing				
Ascendis Pharma				
Endocrinology Division	50,667	8,451	4,905	–
Ascendis Pharma Growth Disorders	714	243	–	–
Ascendis Pharma Bone Diseases	5,256	451	–	–
	<u>56,637</u>	<u>9,145</u>	<u>4,905</u>	<u>–</u>
Purchase of services				
Ascendis Pharma				
Endocrinology Division	12,832	9,261	1,678	3,900
Ascendis Pharma Growth Disorders	440	3,059	290	2,090
Ascendis Pharma Bone Diseases	1,320	895	253	70
	<u>14,592</u>	<u>13,215</u>	<u>2,221</u>	<u>6,060</u>
Loss from a discontinued procurement contract				
Ascendis Pharma				
Endocrinology Division	–	109,006	109,006	–

FINANCIAL INFORMATION

The below table sets forth the outstanding balances with related parties during the Track Record Period as of the dates indicated:

	As of December 31,		As of April 30,
	2022	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Amounts due to related parties			
Trade payables			
Ascendis Pharma Endocrinology			
Division	23,623	230	2,129
Ascendis Pharma Bone Diseases	480	–	42
Ascendis Pharma Growth Disorders	138	109	1,465
	24,241	339	3,636
Accrued expenses			
Ascendis Pharma Endocrinology			
Division	2,145	6,785	2,523
Ascendis Pharma Bone Diseases	2,014	401	29
Ascendis Pharma Growth Disorders	714	1,265	156
	4,873	8,451	2,708
Other payables			
Ascendis Pharma Endocrinology			
Division	776	–	–
Ascendis Pharma Bone Diseases	265	–	–
Ascendis Pharma Growth Disorders	156	–	–
	1,197	–	–
	30,311	8,790	6,344
Amount advanced to a related party			
Prepayments – current			
Ascendis Pharma Endocrinology	69,171	9,367	9,375
Prepayments – non-current			
Ascendis Pharma Endocrinology	–	39,193	39,193

FINANCIAL INFORMATION

The outstanding balances above are unsecured, non-interest-bearing and repayable on demand. The outstanding balances due to related parties and advanced to a related party were business trade in nature. Our Directors confirm that our related party transactions during the Track Record Period were conducted on an arm's length basis, and that such transactions, in the aggregate, would not distort the results of operations over the Track Record Period or make the historical results over the Track Record Period not reflective of our expectations for future performance.

Details of our transactions with and the outstanding balances with related parties during the Track Record Period are set out in note 25 to the Accountants' Report in Appendix I to this document.

FINANCIAL RISK DISCLOSURE

We are exposed to a variety of financial risks, including foreign currency risk, credit risk and liquidity risk, as set out below. We regularly monitor our exposure to these risks and as at the Latest Practicable Date, did not hedge or consider necessary to hedge any of these risks.

Foreign Currency Risk

Foreign currency risk means the risk resulting from changes in foreign currency exchange rates.

We have transactional currency exposures, arising from purchases by operating units in currencies other than the units' functional currencies. The majority of our cash and cash equivalents are denominated in foreign currencies and are exposed to foreign currency risk. We currently do not have a foreign currency hedging policy. However, our management monitors foreign exchange exposure and will consider appropriate hedging measures in the future should the need arise. See note 28 to the Accountants' Report in Appendix I to this document for further details, including relevant sensitivity analysis.

Credit Risk

For financial assets included in prepayments and other receivables, our management makes periodic collective assessment as well as individual assessment on the recoverability of other receivables based on historical settlement records and past experience. Our Directors believe that there is no material credit risk inherent in our outstanding balance of other receivables.

As of the end of the Track Record Period, cash and cash equivalents were deposited in financial institutions without significant credit risk. See note 28 to the Accountants' Report in Appendix I to this document for further details.

FINANCIAL INFORMATION

Liquidity Risk

In the management of the liquidity risk, we monitor and maintain a level of cash and cash equivalents deemed adequate by our management to finance the operations and mitigate the effects of fluctuations in cash flows. See note 28 to the Accountants' Report in Appendix I to this document for further details.

DIVIDEND

No dividend has been paid or declared by our Company since its date of incorporation and up to the end of the Track Record Period. Any declaration and payment as well as the amount of dividends will be subject to our Memorandum of Association and the Cayman Companies Act. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Investors should not purchase our ordinary shares with the expectation of receiving cash dividends. The declaration and payment of dividends in the future will be determined by our Board of Directors, in its discretion, or the Shareholders in general meeting, and will depend on a number of factors, including our earnings, capital requirements, and overall financial condition. As advised by our Cayman counsel, under the Cayman Companies Act, a Cayman Islands company may pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be paid if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business. There is no assurance that dividends of any amount will be declared to be distributed in any year.

DISTRIBUTABLE RESERVES

As of April 30, 2024, we did not have any distributable reserves.

[REDACTED] INCURRED AND TO BE INCURRED

[REDACTED] mainly comprise legal and other professional fees paid and payable to the professional parties, commissions payable to the [REDACTED], and printing and other expenses for their services rendered in relation to the [REDACTED] and the [REDACTED]. [REDACTED] for the [REDACTED] are estimated to be approximately HK\$[REDACTED] million, including (i) [REDACTED] (including but not limited to commissions and fees) of approximately HK\$[REDACTED] million and (ii) [REDACTED] of approximately HK\$[REDACTED] million, comprising (a) fees and expenses of legal advisors and accountants of approximately HK\$[REDACTED] million and (b) other fees and expenses of approximately HK\$[REDACTED] million, at an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the [REDACTED], which represents approximately [REDACTED]% of the gross [REDACTED] we expect to receive from this [REDACTED] assuming no Shares are issued pursuant to the [REDACTED] and no Shares are issued under the [REDACTED] Share Award Scheme. RMB[REDACTED] million (HK\$[REDACTED] million) was recognized and charged to our consolidated statements of profit or loss and other comprehensive income as of April 30, 2024. After April 30, 2024, approximately HK\$[REDACTED] million is expected to be charged to our consolidated statements of profit or loss and other comprehensive income, and approximately HK\$[REDACTED] million is expected to be charged against equity upon the [REDACTED]. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

FINANCIAL INFORMATION

UNAUDITED [REDACTED] STATEMENT OF ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

The following unaudited [REDACTED] statement of adjusted consolidated net tangible assets of the Group prepared in accordance with Rule 4.29 of the Listing Rules is set out below to illustrate the effect of the [REDACTED] on the consolidated net tangible assets of our Group attributable to our owners as of April 30, 2024 as if the [REDACTED] had taken place on such date.

The unaudited [REDACTED] statement of adjusted consolidated net tangible assets has been prepared for illustrative purposes only and because of its hypothetical nature, it may not give a true and fair picture of the consolidated net tangible assets of our Group attributable to our owners as of April 30, 2024 or at any further date following the [REDACTED].

The following unaudited [REDACTED] statement of adjusted consolidated net tangible assets of our Group is prepared based on the audited consolidated net tangible liabilities of our Group attributable to our owners as of April 30, 2024 as derived from the Accountants’ Report set out in Appendix I to this document and adjusted as described below.

Audited consolidated net tangible assets of our Group attributable to our owners as of April 30, 2024	Estimated [REDACTED] from the [REDACTED]	Unaudited [REDACTED] adjusted consolidated net tangible assets attributable to our owners as of April 30, 2024	Unaudited [REDACTED] adjusted consolidated net tangible assets attributable to our owners per share as of April 30, 2024
<i>RMB'000</i> (Note 1)	<i>RMB'000</i> (Note 2)	<i>RMB'000</i>	<i>RMB</i> <i>HK\$</i> (Note 3) (Note 4)
Based on [REDACTED] [HK\$[REDACTED]] per [REDACTED]	[351,925]	[REDACTED]	[REDACTED] [REDACTED] [REDACTED]
Based on [REDACTED] [HK\$[REDACTED]] per [REDACTED]	[351,925]	[REDACTED]	[REDACTED] [REDACTED] [REDACTED]
Based on [REDACTED] [HK\$[REDACTED]] per [REDACTED]	[351,925]	[REDACTED]	[REDACTED] [REDACTED] [REDACTED]

Notes:

- (1) The consolidated net tangible assets of the Group attributable to equity holders of the Company as at April 30, 2024 was equal to the audited net assets attributable to owners of the Company as at April 30, 2024 of RMB[352,226,000] after deducting of intangible assets of RMB[301,000] as at April 30, 2024 set out in the Accountants’ Report in Appendix I to this document.

FINANCIAL INFORMATION

- (2) The estimated [REDACTED] from the [REDACTED] are based on an [REDACTED] of [HK\$[REDACTED]], [HK\$[REDACTED]] and [HK\$[REDACTED]], after deduction of the [REDACTED] fees and other related expenses payable by the Company (excluding the [REDACTED] that have been charged to profit or loss as of April 30, 2024) and does not take into account any Shares which may be issued upon the exercise of the [REDACTED].
- (3) The unaudited pro forma adjusted consolidated net tangible assets per Share is arrived at after adjustments referred in note 2 above and on the basis of [REDACTED] Shares in issue, assuming that the [REDACTED] has been completed on April 30, 2024 but does not take into account (i) any Shares which may be sold pursuant to the exercise of the [REDACTED], or (ii) any Shares which may be issued under the [REDACTED] share incentive scheme.
- (4) For the purpose of this unaudited [REDACTED] statement of adjusted net tangible assets, the balances stated in RMB are converted into HKD at the rate of RMB1.00 to [HKD1.0982].
- (5) No adjustment has been made to the unaudited [REDACTED] adjusted consolidated net tangible assets to reflect any [REDACTED] results or other transactions of the Group entered into subsequent to April 30, 2024.

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that, up to the date of this document, there has been no material adverse change in our financial or [REDACTED] position since April 30, 2024 (being the date on which the latest consolidated financial information of our Group was prepared) and there has been no event since April 30, 2024 which would materially affect the information shown in our consolidated financial statements included in the Accountants’ Report in Appendix I to this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors confirm that, as at 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” for details of our future plans.

USE OF [REDACTED]

Assuming an [REDACTED] of HK\$[REDACTED], being the mid-point of the [REDACTED], and after deducting estimated [REDACTED] fees and the estimated [REDACTED] in connection with the [REDACTED] and [REDACTED], and the [REDACTED] is not exercised, we estimate that the aggregate [REDACTED] from the [REDACTED] will be approximately HK\$[REDACTED], or HK\$[REDACTED] if the [REDACTED] is exercised in full.

In line with our strategies, we intend to use the [REDACTED] we will receive from the [REDACTED] for the following purposes, subject to changes in light of our evolving business needs and changing market conditions:

- (a) Approximately HK\$[REDACTED] (representing [REDACTED]% of [REDACTED]) to fund the ongoing BLA registration of imported Core Product, ongoing and planned research and development and BLA registration of locally manufactured Core Product, planned clinical trial on new indication expansion, and planned commercial launch of our Core Product, lonapegsomatropin, of which:
 - (i) Approximately HK\$[REDACTED] (representing [REDACTED]% of [REDACTED]) to fund the ongoing BLA registration of imported Core Product (the “Import BLA”) subsequent to the acceptance of our BLA filing by the NMPA in March 2024 to support our efforts in obtaining the marketing approval to import and commercialize lonapegsomatropin sourced from Ascendis Pharma, primarily including (1) labor costs of our clinical development, regulatory affairs and CMC personnel who will continue to support us in obtaining the Import BLA approval, (2) costs incurred in relation to requests from the CDE of the NMPA for additional information or clarification, such as test methods development and validation, (3) costs incurred in purchasing drug substance and drug product samples to prepare for the pre-approval quality control testing conducted by the NMPA and (4) costs incurred in routine NMPA GCP site inspection.

FUTURE PLANS AND USE OF [REDACTED]

- (ii) Approximately HK\$[REDACTED] (representing [REDACTED]% of [REDACTED]) to fund the ongoing and planned research and development and BLA registration of locally manufactured Core Product for PGHD (the “Local BLA”), which will enable us to commercialize the locally manufactured lonapegsomatropin in China, of which:
- (1) Approximately HK\$[REDACTED] (representing [REDACTED]% of [REDACTED]) to fund the pharmaceutical/CMC studies required by the NMPA for the purpose of Local BLA registration of PGHD, which cover the lonapegsomatropin drug substance and drug product development. For the lonapegsomatropin drug substance, from 2024 to 2026, by collaborating with Ascendis Pharma and WuXi Biologics, we will conduct the lab-scale drug substance study, drug substance analytical method transfer, development and validation, the engineering run and the process validation studies for the purpose of Local BLA registration. For the drug product development, from 2024 to 2026, by collaborating with WuXi Biologics, we expect to conduct the DCD development and process characterization studies, process scale-up and process validation studies to ensure at-scale production of DCD products for the purpose of Local BLA registration.
 - (2) Approximately HK\$[REDACTED] (representing [REDACTED]% of [REDACTED]) to fund the Local BLA registration. The activities in relation to such registration cover drug testing by the National Institutes for Food and Drug Control of locally produced products against the proposed quality standards, generating stability data of the drug substance and drug product to support the Local BLA filing, and the preparation and submission of the Local BLA dossier.
- (iii) Approximately HK\$[REDACTED] (representing [REDACTED]% of [REDACTED]) to fund the planned clinical studies of the Core Product for the treatment of an additional indication, idiopathic short stature, which will require a supplemental application to the NMPA. The activities in relation to such approval include R&D personnel costs and costs related to clinical trial activities, including clinical drug supplies, as well as contracting costs with third parties such as CROs and SMOs. We intend to conduct a multi-center, randomized, open-label, active-controlled, parallel-group Phase 2b/3 trial to investigate the efficacy and safety of Core Product in children with ISS. We plan to finalize the study design, develop the study protocol, and conduct pre-IND communication with NMPA shortly following the completion of the [REDACTED]. If we proceed as planned, we expect to make IND filing in 2025. See “Business – Our Drug Pipeline – Lonapegsomatropin – A Long-Acting hGH Replacement Therapy for PGHD – Future Clinical Development Plan” for more details.

FUTURE PLANS AND USE OF [REDACTED]

- (iv) Approximately HK\$[REDACTED] (representing [REDACTED]% of [REDACTED]) to fund the payment for the commercial supply of lonapegsomatropin from Ascendis Pharma pursuant to the existing Commercial Supply Agreement, and potential future commercial supply agreement for our commercial sale of lonapegsomatropin in China under the Import BLA, before our collaborative local manufacturing capability is established.

- (b) Approximately HK\$[REDACTED] (representing [REDACTED]% of [REDACTED]) to fund the ongoing China Phase 3 pivotal trial and planned commercial launch of palopegteriparatide, including to fund the ongoing China Phase 3 pivotal trial, of palopegteriparatide for the treatment of adult HP and the preparation of regulatory filings, and once approved, the commercialization of palopegteriparatide in China for the treatment of adult HP.

- (c) Approximately HK\$[REDACTED] (representing [REDACTED]% of [REDACTED]) to fund the ongoing OLE portion of China Phase 2 trial of TransCon CNP (navepegritide) for the treatment of ACH.

- (d) Approximately HK\$[REDACTED] (representing [REDACTED]% of [REDACTED]) to fund our working capital and other general corporate purposes.

If the [REDACTED] is set at the high point or the low point of the [REDACTED] (assuming the [REDACTED] is not exercised and no Shares are issued under the [REDACTED] Share Award Scheme), the [REDACTED] will increase or decrease by approximately HK\$[REDACTED], respectively. We will apply the additional or reduced [REDACTED] to the above purposes on a pro-rata basis.

If the [REDACTED] is exercised in full, we will receive additional [REDACTED] of approximately HK\$[REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the [REDACTED].

If the [REDACTED] are not immediately applied to the above purpose, we will only deposit those [REDACTED] into short-term interest-bearing accounts at licensed commercial banks and/or other authorized financial institutions (as defined under the Securities and Futures Ordinance or applicable laws and regulations in other jurisdictions).

We currently have no specific plans as to how the [REDACTED] from this [REDACTED] will be allocated beyond the uses specified above, and therefore management will retain discretion to allocate the remainder of the [REDACTED] of this [REDACTED] among these uses.

FUTURE PLANS AND USE OF [REDACTED]

This expected use of the [REDACTED] from this [REDACTED] represents our intentions based upon our current plans and business conditions. As of the Latest Practicable Date, we could not predict with certainty all of the particular uses for the [REDACTED] to be received upon the completion of this [REDACTED] or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our drug development programs, the status of and results from pre-clinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our drug candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the [REDACTED] from this [REDACTED] and may change the allocation of use of these [REDACTED] among the uses described above. An [REDACTED] will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the [REDACTED].

We will issue an appropriate announcement if there is any material change in the abovementioned use of [REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

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HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

APPENDIX I

ACCOUNTANTS’ REPORT

The following is the text of a report received from the independent reporting accountants, Ernst & Young, Certified Public Accountants, Hong Kong, prepared for the purpose of incorporation in this Document.

[To insert the firm’s letterhead with official address]

ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF VISEN PHARMACEUTICALS, MORGAN STANLEY ASIA LIMITED AND JEFFERIES HONG KONG LIMITED

INTRODUCTION

We report on the historical financial information of VISEN Pharmaceuticals (the “Company”) and its subsidiaries (together, the “Group”) set out on pages I-[●] to [●], which comprises the consolidated statements of profit or loss and other comprehensive income, statements of changes in equity and statements of cash flows of the Group for each of the years ended 31 December 2022 and 2023 and the four months ended 30 April 2024 (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 30 April 2024 and material accounting policy information and other explanatory information (together, the “Historical Financial Information”). The Historical Financial Information set out on pages I-[●] to [●] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [Date] (the “Document”) in connection with the initial [REDACTED] of the shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

DIRECTORS’ RESPONSIBILITY FOR THE HISTORICAL FINANCIAL INFORMATION

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information, and for such internal control as the directors determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

REPORTING ACCOUNTANTS’ RESPONSIBILITY

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 *Accountants’ Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

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ACCOUNTANTS’ REPORT

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

OPINION

In our opinion, the Historical Financial Information gives, for the purposes of the accountants’ report, a true and fair view of the financial position of the Group and the Company as at 31 December 2022 and 2023 and 30 April 2024 and of the financial performance and cash flows of the Group for each of the Relevant Periods in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information.

REVIEW OF INTERIM COMPARATIVE FINANCIAL INFORMATION

We have reviewed the interim comparative financial information of the Group which comprises the consolidated statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the four months ended 30 April 2023 and other explanatory information (the “Interim Comparative Financial Information”). The directors of the Company are responsible for the preparation of the Interim Comparative Financial Information in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information. Our responsibility is to express a conclusion on the Interim Comparative Financial Information based on our review. We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the HKICPA. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has come to our attention that causes us to believe that the Interim Comparative Financial Information, for the purposes of the accountants’ report, is not prepared, in all material respects, in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information.

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ACCOUNTANTS' REPORT

REPORT ON MATTERS UNDER THE RULES GOVERNING THE LISTING OF SECURITIES ON THE STOCK EXCHANGE AND THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-4 have been made.

Dividends

We refer to note 12 to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

[●]

Certified Public Accountants

Hong Kong

[Date]

I. HISTORICAL FINANCIAL INFORMATION

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The financial statements of the Group for the Relevant Periods, on which the Historical Financial Information is based, were audited by Ernst & Young in accordance with Hong Kong Standards on Auditing issued by the Hong Kong Institute of Certified Public Accountants (the “Underlying Financial Statements”).

The Historical Financial Information is presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	Notes	Year ended 31 December		Four months ended 30 April	
		2022	2023	2023	2024
		RMB'000	RMB'000	RMB'000	RMB'000
				<i>(Unaudited)</i>	
Other income	5	5,764	11,356	2,567	5,835
Other gains and losses, net	6	77,184	(106,695)	(113,590)	805
Research and development costs		(179,546)	(57,690)	(3,805)	(25,771)
Administrative expenses		(177,449)	(79,944)	(22,248)	(35,146)
Finance costs	8	(619)	(317)	(126)	(66)
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
LOSS BEFORE TAX	7	(288,967)	(249,570)	(138,997)	(60,131)
Income tax expense	11	–	–	–	–
LOSS FOR THE YEAR/PERIOD		<u>(288,967)</u>	<u>(249,570)</u>	<u>(138,997)</u>	<u>(60,131)</u>
Attributable to:					
Owners of the Company		<u>(288,967)</u>	<u>(249,570)</u>	<u>(138,997)</u>	<u>(60,131)</u>
OTHER COMPREHENSIVE INCOME					
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:					
Exchange differences on translation of the financial statements of subsidiaries		<u>69</u>	<u>106</u>	<u>(63)</u>	<u>(189)</u>
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR/PERIOD, NET OF TAX		<u>69</u>	<u>106</u>	<u>(63)</u>	<u>(189)</u>
TOTAL COMPREHENSIVE LOSS FOR THE YEAR/PERIOD		<u>(288,898)</u>	<u>(249,464)</u>	<u>(139,060)</u>	<u>(60,320)</u>
Attributable to:					
Owners of the Company		<u>(288,898)</u>	<u>(249,464)</u>	<u>(139,060)</u>	<u>(60,320)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE COMPANY					
Basic and diluted	13	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>

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CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	<i>Notes</i>	As at 31 December		As at
		2022	2023	30 April
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
NON-CURRENT ASSETS				
Property, plant and equipment	14	2,352	876	551
Right-of-use assets	15	14,812	12,379	11,158
Intangible assets	16	1,415	567	301
Amount advanced to a related party	25	–	39,193	39,193
Prepayments and other receivables	17	11,103	16,660	17,596
Total non-current assets		29,682	69,675	68,799
CURRENT ASSETS				
Prepayments and other receivables	17	15,961	16,972	16,418
Amount advanced to a related party	25	69,171	9,367	9,375
Cash and cash equivalents	18	626,458	347,782	299,683
Total current assets		711,590	374,121	325,476
CURRENT LIABILITIES				
Trade and other payables	19	49,460	37,582	33,366
Deferred income		2,900	2,900	–
Amounts due to related parties	25	30,311	8,790	6,344
Lease liabilities	15	4,668	2,552	1,785
Total current liabilities		87,339	51,824	41,495
NET CURRENT ASSETS		624,251	322,297	283,981
TOTAL ASSETS LESS CURRENT LIABILITIES		653,933	391,972	352,780
NON-CURRENT LIABILITIES				
Lease liabilities	15	1,328	1,097	554
Total non-current liabilities		1,328	1,097	554
Net assets		652,605	390,875	352,226
EQUITY				
Equity attributable to owners of the Company				
Share capital	20	70	70	70
Treasury shares	20	(6)	(6)	(6)
Reserves	21	652,541	390,811	352,162
Total equity		652,605	390,875	352,226

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Share capital	Treasury shares	Share premium*	Share reward reserve*	Exchange fluctuation reserve*	Accumulated losses*	Total
	<i>RMB’000</i> <i>(note 20)</i>	<i>RMB’000</i> <i>(note 20)</i>	<i>RMB’000</i> <i>(note 21)</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
At 1 January 2022	77	(13)	1,523,253	217,661	(169)	(892,814)	847,995
Loss for the year	-	-	-	-	-	(288,967)	(288,967)
Other comprehensive income for the year:							
Exchange differences on translation of the financial statements of subsidiaries	-	-	-	-	69	-	69
Total comprehensive loss for the year	-	-	-	-	69	(288,967)	(288,898)
Cancellation of non- voting ordinary shares <i>(note 20)</i>	(7)	7	-	-	-	-	-
Equity-settled share- based payment	-	-	-	93,508	-	-	93,508
At 31 December 2022 and 1 January 2023	<u>70</u>	<u>(6)</u>	<u>1,523,253</u>	<u>311,169</u>	<u>(100)</u>	<u>(1,181,781)</u>	<u>652,605</u>
Loss for the year	-	-	-	-	-	(249,570)	(249,570)
Other comprehensive income for the year:							
Exchange differences on translation of the financial statements of subsidiaries	-	-	-	-	106	-	106
Total comprehensive loss for the year	-	-	-	-	106	(249,570)	(249,464)
Equity-settled share- based payment	-	-	-	(12,266)	-	-	(12,266)
At 31 December 2023	<u>70</u>	<u>(6)</u>	<u>1,523,253</u>	<u>298,903</u>	<u>6</u>	<u>(1,431,351)</u>	<u>390,875</u>

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	Share capital	Treasury shares	Share premium*	Share reward reserve*	Exchange fluctuation reserve*	Accumulated losses*	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
	<i>(note 20)</i>	<i>(note 20)</i>	<i>(note 21)</i>				
At 1 January 2023	70	(6)	1,523,253	311,169	(100)	(1,181,781)	652,605
Loss for the period	-	-	-	-	-	(138,997)	(138,997)
Other comprehensive loss for the period:							
Exchange differences on translation of the financial statements of subsidiaries	-	-	-	-	(63)	-	(63)
Total comprehensive loss for the period	-	-	-	-	(63)	(138,997)	(139,060)
Equity-settled share- based payment	-	-	-	(34,585)	-	-	(34,585)
At 30 April 2023 (unaudited)	70	(6)	1,523,253	276,584	(163)	(1,320,778)	478,960
At 1 January 2024	70	(6)	1,523,253	298,903	6	(1,431,351)	390,875
Loss for the period	-	-	-	-	-	(60,131)	(60,131)
Other comprehensive loss for the period:							
Exchange differences on translation of the financial statements of subsidiaries	-	-	-	-	(189)	-	(189)
Total comprehensive loss for the period	-	-	-	-	(189)	(60,131)	(60,320)
Equity-settled share- based payment	-	-	-	21,671	-	-	21,671
At 30 April 2024	70	(6)	1,523,253	320,574	(183)	(1,491,482)	352,226

* These accounts comprise the reserves of RMB652,541,000, RMB389,324,000 and RMB352,162,000 in the consolidated statements of financial position as at 31 December 2022 and 2023 and 30 April 2024, respectively.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

	<i>Notes</i>	Year ended		Four months ended	
		31 December		30 April	
		2022	2023	2023	2024
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
				<i>(Unaudited)</i>	
CASH FLOWS FROM OPERATING ACTIVITIES					
Loss before tax		(288,967)	(249,570)	(138,997)	(60,131)
Adjustments for:					
Bank interest income	5	(5,567)	(11,145)	(2,358)	(2,747)
Finance costs	8	619	317	126	66
Depreciation of property, plant and equipment	7	1,741	1,509	583	325
Depreciation of right-of-use assets	7	4,933	4,639	1,622	1,221
Amortisation of intangible assets	7	723	848	284	266
Loss on disposal of items of property, plant and equipment	7	91	242	–	–
Loss on termination of a lease contract	15	–	273	–	–
Loss from a discontinued procurement contract	6	–	69,171	109,006	–
Share-based payment expenses/(credit)	22	93,508	(12,266)	(34,585)	21,671
		(192,919)	(195,982)	(64,319)	(39,329)
Increase in prepayments and other receivables		(224)	(1,667)	(1,515)	(324)
Increase in amount advanced to a related party		(69,171)	(48,560)	–	(8)
Increase/(decrease) in amounts due to related parties and provision for a discontinued procurement contract		7,147	(21,521)	(18,534)	(2,446)
Increase/(decrease) in trade and other payables		4,442	(12,080)	(6,752)	(4,216)
Decrease in deferred income		–	–	–	(2,900)
Cash used in operations		(250,725)	(279,810)	(91,120)	(49,223)
Interest received		4,176	8,500	2,653	2,689
Net cash flows used in operating activities		(246,549)	(271,310)	(88,467)	(46,534)

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	Year ended		Four months ended	
	31 December		30 April	
	2022	2023	2023	2024
<i>Notes</i>	<u>RMB'000</u>	<u>RMB'000</u>	<u>RMB'000</u>	<u>RMB'000</u>
			<i>(Unaudited)</i>	
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchases of items of property, plant and equipment	(1,484)	(520)	(245)	–
Prepayment for acquisition of land use right	(282)	–	–	–
Net cash flows used in investing activities	<u>(1,766)</u>	<u>(520)</u>	<u>(245)</u>	<u>–</u>
CASH FLOWS FROM FINANCING ACTIVITIES				
Lease payments, including related interest	(5,783)	(4,945)	(2,003)	(1,376)
Payment of [REDACTED]	<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]</u>
Net cash flows used in financing activities	<u>(7,949)</u>	<u>(6,952)</u>	<u>(2,266)</u>	<u>(1,376)</u>
NET DECREASE IN CASH AND CASH EQUIVALENTS				
Effect of foreign exchange rate changes	69	106	(63)	(189)
Cash and cash equivalents at beginning of year	<u>882,653</u>	<u>626,458</u>	<u>626,458</u>	<u>347,782</u>
CASH AND CASH EQUIVALENTS AT END OF YEAR	<u>18</u>	<u>626,458</u>	<u>347,782</u>	<u>535,417</u>
				<u>299,683</u>

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ACCOUNTANTS’ REPORT

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

		As at 31 December		As at
	<i>Notes</i>	2022	2023	30 April
		<i>RMB’000</i>	<i>RMB’000</i>	2024
				<i>RMB’000</i>
NON-CURRENT ASSETS				
Investments in subsidiaries	<i>1</i>	1,019,940	1,192,898	1,214,569
Total non-current assets		<u>1,019,940</u>	<u>1,192,898</u>	<u>1,214,569</u>
CURRENT ASSETS				
Prepayments and other receivables	<i>17</i>	6,935	9,477	9,530
Amount due from a subsidiary	<i>25</i>	659	–	–
Cash and cash equivalents	<i>18</i>	440,425	232,841	231,216
Total current assets		<u>448,019</u>	<u>242,318</u>	<u>240,746</u>
CURRENT LIABILITIES				
Other payables	<i>19</i>	8,370	11,267	14,459
Amounts due to related party	<i>25</i>	9,535	–	–
Total current liabilities		<u>17,905</u>	<u>11,267</u>	<u>14,459</u>
NET CURRENT ASSETS		<u>430,114</u>	<u>231,051</u>	<u>226,287</u>
Net assets		<u>1,450,054</u>	<u>1,423,949</u>	<u>1,440,856</u>
EQUITY				
Share capital	<i>20</i>	70	70	70
Treasury shares	<i>20</i>	(6)	(6)	(6)
Reserves	<i>21</i>	1,449,990	1,423,885	1,440,792
Total equity		<u>1,450,054</u>	<u>1,423,949</u>	<u>1,440,856</u>

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II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE AND GROUP INFORMATION

VISEN Pharmaceuticals (the “Company”) was incorporated in the Cayman Islands as an exempted company with limited liability on 1 November 2018. The registered office address of the Company is P.O. Box 472, Harbour Place, 2nd Floor, 103 South Church Street, George Town, Grand Cayman KY1-1106, Cayman Islands.

The Company is an investment holding company. The Company and its subsidiaries (the “Group”) are principally engaged in developing and commercialising paradigm-shifting endocrine therapies. The address of the head office and principal place of business of the Company is Room 2605, 1788 Square, 1788 Nan Jing Road West, Shanghai, China.

As at the date of this report, the Company had direct and indirect interests in its subsidiaries, all of which are private limited liability companies (or, if incorporated outside Hong Kong, have substantially similar characteristics to a private company incorporated in Hong Kong), the particulars of which are as follows:

Name	Place and date of incorporation/ registration/ and place of operations	Nominal value of issued ordinary/ registered share capital	Percentage of equity attributable to the Company		Principal activities
			Direct	Indirect	
VISEN Pharmaceuticals HK Limited (“VISEN HK”) (note a)	Hong Kong, 13 November 2018	United States dollars (“USD”) 148,520,000	100%	–	Investment holding
VISEN Pharmaceuticals (BVI) Limited (“VISEN BVI”) (note b)	British Virgin Islands, 9 November 2020	USD2,050,000	100%	–	Investment holding
VISEN Pharmaceuticals (Shanghai) Co., Ltd. * (“VISEN Shanghai”) (維 昇藥業(上海) 有限公司) (note c)	People’s Republic of China (“PRC”), Chinese Mainland, 15 February 2019	USD113,000,000	–	100%	Developing and commercialising paradigm-shifting endocrine therapies in China
VISEN Pharmaceuticals (Suzhou) Co., Ltd. * (“VISEN Suzhou”) (維昇 藥業(蘇州) 有限公司) (note c)	PRC, Chinese Mainland, 11 June 2021	USD80,000,000	–	100%	Developing and commercialising paradigm-shifting endocrine therapies in China
VISEN Pharmaceuticals (Taiwan) Ltd. (“VISEN Taiwan”) (台灣維昇藥業 有限公司) (note d)	Taiwan, 28 December 2021	Taiwan dollars (“TWD”) 45,000,000	–	100%	Developing and commercialising paradigm-shifting endocrine therapies in Taiwan

Notes:

- The financial statements of this entity for the year ended 31 December 2022 prepared in accordance with the Small and Medium-sized Entity Financial Reporting Standard issued by the Hong Kong Institute of Certified Public Accountants were audited by Wong Chi Keung, Dennis, a certified public accountant registered in Hong Kong.
- No audited financial statements have been prepared for the entity for the years ended 31 December 2022 and 2023 as this entity was not subject to any statutory audit requirements under the relevant rules and regulations in its jurisdiction of incorporation.
- The statutory financial statements of these entities for the years ended 31 December 2022 and 2023 prepared in accordance with Accounting System for Business Enterprises were audited by Ernst & Young Hua Ming LLP Shanghai Branch, certified public accountants registered in the PRC.

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- d. The financial statements of this entity for the period ended 31 December 2022 and the year ended 31 December 2023 prepared in accordance with the International Financial Reporting Standards were audited by KPMG LLP, certified public accountants registered in Taiwan.
- * The English names of these entities represent the best effort made by the directors of the Company (the “Directors”) to translate the Chinese names as they have not been registered with any official English name.

The investments in subsidiaries in the Company’s statements of financial position represent:

	As at 31 December		As at 30 April
	2022	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Unlisted investments, at cost	1,019,940	1,192,898	1,214,569

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 (“IASB”).

All IFRSs effective for the accounting period commencing from 1 January 2024, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the Historical Financial Information throughout the Relevant Periods and in the period covered by the Interim Comparative Financial Information.

The Historical Financial Information has been prepared under the historical cost convention.

Basis of consolidation

The Historical Financial Information includes the financial information of the Company and its subsidiaries for the Relevant Periods. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

Generally, there is a presumption that a majority of voting rights results in control. When the Company has less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- the contractual arrangement with the other vote holders of the investee;
- rights arising from other contractual arrangements; and
- the Group’s voting rights and potential voting rights.

The financial statements of the subsidiaries are prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognises the related assets (including goodwill), liabilities, any non-controlling interest and the exchange fluctuation reserve; and recognises the fair value of any investment retained and any resulting surplus or deficit in profit or loss. The Group’s share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

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2.2 ISSUED BUT NOT YET EFFECTIVE IFRSs

The Group has not applied the following new and revised IFRSs, that have been issued but are not yet effective, in the Historical Financial Information. The Group intends to apply these new and revised IFRSs, if applicable, when they become effective.

Amendments to IAS 21	<i>Lack of Exchangeability</i> ¹
IFRS 18	<i>Presentation and Disclosure in Financial Statements</i> ³
IFRS 19	<i>Subsidiaries without Public Accountability: Disclosure</i> ³
Amendments to IFRS 9 and IFRS 7	<i>Amendments to the Classification and Measurement of Financial Instruments</i> ²
Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ⁴

¹ Effective for annual periods beginning on or after 1 January 2025

² Effective for annual periods beginning on or after 1 January 2026

³ Effective for annual/reporting periods beginning on or after 1 January 2027

⁴ 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 new and revised IFRSs upon initial application. IFRS 18 introduces new requirements on presentation within the statement of profit or loss, including specified totals and subtotals. It also requires disclosure of management-defined performance measures and includes new requirements for aggregation and disaggregation of financial information. The new requirements are expected to impact the Group’s presentation in the statement of profit or loss and other comprehensive income and disclosures of the Group’s financial performance. Other than IFRS 18, so far, the Group considers that IFRS 19 and the revised IFRSs are unlikely to have a significant impact on the Group’s results of operations and financial position.

2.3 MATERIAL ACCOUNTING POLICIES

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for a non-financial asset is required, the asset’s recoverable amount is estimated. An asset’s recoverable amount is the higher of the asset’s or cash-generating unit’s value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

An impairment loss is recognised only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each of the reporting periods as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to profit or loss in the period in which it arises.

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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, other than construction in progress, are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalised in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognises such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal annual rates used for this purpose are as follows:

Furniture and equipment	20% – 67%
Leasehold improvements	33% – 48%

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Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at the end of each of the reporting periods.

An item of property, plant and equipment including any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in profit or loss in the year/period the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress is stated at cost less any impairment losses, and is not depreciated. It is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

Intangible assets (other than goodwill)

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortised over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at the end of each of the reporting periods.

Software is amortised on a straight-line basis over the useful economic lives of 3 to 5 years.

Research and development costs

All research costs are charged to profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

Right-of-use assets are recognised at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Office premises	2 to 3 years
Land use right	30 years

If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

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(b) Lease liabilities

Lease liabilities are recognised at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees.

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 used to determine such lease payments) or a change in assessment of an option to purchase the underlying asset.

The Group’s lease liabilities are presented in a separate line on the consolidated statements of financial position.

(c) Short-term leases

The Group applies the short-term lease recognition exemption to its short-term leases of office premises (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, fair value through other comprehensive income, and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and the Group’s business model for managing them. With the exception of trade 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.

In order for a financial asset to be classified and measured at amortised cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest (“SPPI”) on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group’s business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortised cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

Purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace are recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset.

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Subsequent measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial assets at amortised cost (debt instruments)

Financial assets at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognised in profit or loss when the asset is derecognised, modified or impaired.

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.

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The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Financial assets at amortised cost, except for trade receivables, are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs.

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

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss and financial liabilities at amortised cost, as appropriate.

All financial liabilities are recognised initially at fair value and, in the case of financial liabilities at amortised cost, net of directly attributable transaction costs.

The Group's financial liabilities include trade and other payables and amounts due to related parties.

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at amortised cost (trade and other payables)

After initial recognition, trade and other payables are subsequently measured at amortised cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognised in profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in profit or loss.

Derecognition of financial liabilities

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in profit or loss.

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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.

Treasury shares

Own equity instruments which are reacquired and held by the Company or the Group (treasury shares) are recognised at cost and deducted from equity. No gain or loss is recognised in profit or loss on the purchase, sale, issue or cancellation of the Group's own equity instruments.

Cash and cash equivalents

Cash and cash equivalents in the consolidated statements of financial position comprise cash on hand and at banks, and short-term highly liquid deposits with a maturity of generally within three months that are readily convertible into known amounts of cash, subject to an insignificant risk of changes in value and held for the purpose of meeting short-term cash commitments.

For the purpose of the consolidated 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.

Provision

A provision is recognised when a present obligation (legal or constructive) has arisen as a result of a past event and it is probable that a future outflow of resources will be required to settle the obligation, provided that a reliable estimate can be made of the amount of the obligation.

Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognised outside profit or loss is recognised outside profit or loss, either in other comprehensive income or directly in equity.

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the reporting periods, taking into consideration interpretations and practices prevailing in the countries in which the Group operates.

Deferred tax is provided, using the liability method, on all temporary differences at the end of each of the reporting periods between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences; and
- in respect of taxable temporary differences associated with investments in subsidiaries, associates and joint ventures, 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, associates and joint ventures, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at the end of each of the reporting periods and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at the end of each of the reporting periods and are recognised to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the reporting periods.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Government grants

Government grants are recognised at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed.

Revenue recognition

Other income

Bank 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 an equity 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 is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using the market approach, further details of which are given in note 22 to the Historical Financial Information.

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The cost of equity-settled transactions is recognised in employee benefit expense, together with a corresponding increase in equity (in share reward reserve), over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognised for equity-settled transactions at the end of each of the reporting periods until the vesting date reflects the extent to which the vesting period has expired and the Group’s best estimate of the number of equity instruments that will ultimately vest. The charge or credit to profit or loss for a period represents the movement in the cumulative expense recognised as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group’s best estimate of the number of equity instruments that will ultimately vest. 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.

Other employee benefits

Pension scheme

The employees of 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 subsidiaries operating in Chinese Mainland are required to contribute a certain percentage of their payroll costs to the central pension scheme. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension scheme.

Housing fund – Chinese Mainland

The Group contributes on a monthly basis to a defined contribution housing fund plan operated by the local municipal government. Contributions to this plan by the Group 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 each of the reporting periods. Differences arising on settlement or translation of monetary items are recognised in profit or loss.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognised in other comprehensive income or profit or loss is also recognised in other comprehensive income or profit or loss, respectively).

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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.

The functional currencies of certain overseas subsidiaries are currencies other than RMB. As at the end of each of the reporting periods, the assets and liabilities of these entities are translated into RMB at the exchange rates prevailing at the end of each of the reporting periods and their statements of profit or loss and other comprehensive income are translated into RMB at the exchange rates that approximate to those prevailing at the dates of the transactions.

The resulting exchange differences are recognised in other comprehensive income and accumulated in the exchange fluctuation reserve, except to the extent that the differences are attributable to non-controlling interests. On disposal of a foreign operation, the cumulative amount in the reserve relating to that particular foreign operation is recognised in profit or loss.

For the purpose of the consolidated statement of cash flows, the cash flows of the overseas subsidiaries are translated into RMB at the exchange rates ruling at the dates of the cash flows. Frequently recurring cash flows of the overseas subsidiaries which arise throughout the reporting periods are translated into RMB at the weighted average exchange rates for the reporting periods.

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. 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

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3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group’s Historical Financial Information requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of each of the reporting periods, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Recognition of income taxes and deferred tax assets

Determining income tax provision involves judgment on the future tax treatment of certain transactions and when certain matters relating to the income taxes have not been confirmed by the local tax bureau. Management evaluates tax implications of transactions and tax provisions are set up accordingly. The tax treatments of such transactions are reconsidered periodically to take into account all changes in tax legislation. Deferred tax assets are recognised in respect of deductible temporary differences and unused tax losses. As those deferred tax assets can only be recognised to the extent that it is probable that future taxable profits will be available against which the deductible temporary differences and the losses can be utilised, management’s judgment is required to assess the probability of future taxable profits. Management’s assessment is revised as necessary and deferred tax assets are recognised if it becomes probable that future taxable profits will allow the deferred tax asset to be recovered.

Performance-based restricted share units

The Group estimates the number of share awards contingently issuable when determining the share-based expenses, which depends on the achievement of certain non-market performance targets of the Group under the Equity Incentive Plan (as defined in note 22 to the Historical Financial Information). This requires an estimation of the performance targets to be achieved by the Group, including completion of [REDACTED], commercialisation of products, local manufacturing, total sales and net profit target for the vesting period. The Group recorded RMB93,508,000, RMB(12,266,000) and RMB21,671,000 share-based payment expenses/(credit) during the years ended 31 December 2022 and 2023 and the four months ended 30 April 2024, respectively.

4. OPERATING SEGMENT INFORMATION

Operating segment information

For management purposes, the Group has only one reportable operating segment, which is developing and commercialising paradigm-shifting endocrine therapies. Since this is the only reportable operating segment of the Group, no further operating segment analysis thereof is presented.

Geographical information

Since nearly all of the Group’s non-current assets were located in Chinese Mainland, no geographical segment information in accordance with IFRS 8 *Operating Segments* is presented.

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5. OTHER INCOME

	Year ended 31 December		Four months ended 30 April	
	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
			(Unaudited)	
Government grants and other subsidies related to income (note)	197	211	209	3,088
Bank interest income	5,567	11,145	2,358	2,747
Total	5,764	11,356	2,567	5,835

Note: Government grants have been received from the PRC local government authorities to support a subsidiary’s operating activities. There are no unfulfilled conditions relating to these government grants.

6. OTHER GAINS AND LOSSES, NET

	Year ended 31 December		Four months ended 30 April	
	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
			(Unaudited)	
Net foreign exchange gains/(losses)	79,782	4,706	(3,874)	947
Grants (note i)	(1,488)	(1,407)	(517)	(142)
Donations (note ii)	(1,007)	(473)	(193)	–
Loss on disposal of property, plant and equipment	(103)	(242)	–	–
Loss on termination of a lease contract	–	(273)	–	–
Loss from a discontinued procurement contract (Note 25(a)(ii))	–	(109,006)	(109,006)	–
Total	77,184	(106,695)	(113,590)	805

Notes:

- i. During the years ended 31 December 2022 and 2023 and the four months ended 30 April 2023 and 2024, the Group paid RMB1,488,000, RMB1,407,000, RMB517,000 (unaudited) and RMB142,000, respectively, to a national cooperative exchange platform for rare diseases for sponsoring its research on diagnosis consensus of achondroplasia in the PRC.
- ii. During the years ended 31 December 2022 and 2023 and the four months ended 30 April 2023 and 2024, the Group donated RMB1,007,000, RMB473,000, RMB193,000 (unaudited) and nil, respectively, to non-profit making organisations for the purpose of epidemic relief and public welfare.

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7. LOSS BEFORE TAX

The Group’s loss before tax is arrived at after charging/(crediting):

	Year ended 31 December		Four months ended 30 April	
	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000	RMB’000
			(Unaudited)	
Depreciation of property, plant and equipment	1,741	1,509	583	325
Depreciation of right-of-use assets	4,933	4,639	1,622	1,221
Amortisation of intangible assets	723	848	284	266
Loss from a discontinued procurement contract	–	109,006	109,006	–
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Loss on disposal of items of property, plant and equipment	103	242	–	–
Auditors’ remuneration	180	146	–	–
Short-term lease payments	316	344	92	168
Loss on termination of a lease contract	–	273	–	–
Staff costs (including directors’ emoluments):				
– Salaries, discretionary bonuses, allowances and benefits in kind	86,295	75,200	33,511	20,260
– Pension scheme contributions	5,056	3,704	1,655	1,135
– Share-based payment expenses/(credit)	93,508	(12,266)	(34,585)	21,671
	<u>184,859</u>	<u>66,638</u>	<u>581</u>	<u>43,066</u>

8. FINANCE COSTS

	Year ended 31 December		Four months ended 30 April	
	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000	RMB’000
			(Unaudited)	
Interest on lease liabilities	<u>619</u>	<u>317</u>	<u>126</u>	<u>66</u>

9. DIRECTORS’ AND CHIEF EXECUTIVE’S REMUNERATION

Mr. LU An-bang and Dr. DONG Dandan were appointed as the executive directors of the Company with effect from 7 November 2018. Mr. FU Shan and Mr. Jan Møller MIKKELSEN were appointed as the non-executive directors of the Company with effect from 1 November 2018 and 7 November 2018, respectively. Mr. Michael Wolff JENSEN and Mr. CAO Yibo were appointed as the non-executive directors of the Company with effect from 8 January 2021. Dr. YAO Zhengbin, Mr. CHAN Peng Kuan and Ms. NI Hong were appointed as the independent non-executive directors of the Company with effect from 1 April 2021. Mr. Michael J. CHANG was appointed as the non-executive director of the Company and Dr. DONG Dandan resigned as the executive director with effect from 13 December 2023.

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Directors’ and chief executive’s remuneration for the Relevant Periods, disclosed pursuant to the Listing Rules, section 383(1)(a), (b), (c) and (f) of the Hong Kong Companies Ordinance and Part 2 of the Companies (Disclosure of Information about Benefits of Directors) Regulation, is as follows:

	Year ended 31 December		Four months ended 30 April	
	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000
Fees	1,035	1,080	351	363
Other emoluments:				
Salaries, allowances and benefits in kind	2,496	3,175	1,033	1,110
Discretionary bonuses	1,022	1,052	336	362
Pension scheme contributions	–	–	–	24
Share-based payment expenses	57,921	13,762	(1,833)	16,361
	61,439	17,989	(464)	17,857
	62,474	19,069	(113)	18,220

During the Relevant Periods and the four months ended 30 April 2023, a director was granted with restricted share units, in respect of his services to the Group, under the equity incentive plan of the Company, further details of which are set out in note 22 to the Historical Financial Information. The fair value of such restricted share units, which has been recognised in profit or loss over the vesting period, was determined as at the date of grant and the related expenses included in the Historical Financial Information for the Relevant Periods and the four months ended 30 April 2023 have been included in the above directors’ and chief executive’s remuneration disclosures. As the vesting condition of share awards granted to chief executive includes completion of [REDACTED], the estimated vesting date had been adjusted to reflect the management’s best estimation on the date of the completion of [REDACTED] as of the end of each of the Relevant Periods, which caused the reversal of share-based payment expenses during the four months ended 30 April 2023.

(a) Independent non-executive directors

The fees paid to independent non-executive directors were as follows:

	Year ended 31 December		Four months ended 30 April	
	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000
Dr. YAO Zhengbin	345	360	117	121
Mr. CHAN Peng Kuan	345	360	117	121
Ms. NI Hong	345	360	117	121
	1,035	1,080	351	363

There were no other emoluments payable to the independent non-executive directors during the Relevant Periods and the four months ended 30 April 2023.

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	Salaries, allowances and benefits in kind	Discretionary bonuses	Share-based payment expenses	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Four months ended 30 April 2023 (unaudited)				
Executive directors:				
Mr. LU An-bang*	1,033	336	(1,833)	(464)
Dr. DONG Dandan	–	–	–	–
	<u>1,033</u>	<u>336</u>	<u>(1,833)</u>	<u>(464)</u>
Non-executive directors:				
Mr. FU Shan	–	–	–	–
Mr. Jan Møller MIKKELSEN	–	–	–	–
Mr. Michael Wolff JENSEN	–	–	–	–
Mr. CAO Yibo	–	–	–	–
	<u>–</u>	<u>–</u>	<u>–</u>	<u>–</u>

	Salaries, allowances and benefits in kind	Discretionary bonuses	Pension scheme contributions	Share-based payment expenses	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Four months ended 30 April 2024					
Executive director:					
Mr. LU An-bang*	1,110	362	24	16,361	17,857
	<u>1,110</u>	<u>362</u>	<u>24</u>	<u>16,361</u>	<u>17,857</u>
Non-executive directors:					
Mr. FU Shan	–	–	–	–	–
Mr. Michael J. CHANG	–	–	–	–	–
Mr. Jan Møller MIKKELSEN	–	–	–	–	–
Mr. Michael Wolff JENSEN	–	–	–	–	–
Mr. CAO Yibo	–	–	–	–	–
	<u>–</u>	<u>–</u>	<u>–</u>	<u>–</u>	<u>–</u>

There was no arrangement under which a director waived or agreed to waive any remuneration during the Relevant Periods and the four months ended 30 April 2023.

* Mr. LU An-bang is also the chief executive of the Company, and his remuneration disclosed above included the services rendered by him as the chief executive.

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10. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees during the Relevant Periods included one director who is also the chief executive, details of whose remuneration are set out in note 9 above and none of the directors are included in the five highest paid employees during the four months ended 30 April 2023. Details of the remuneration of the remaining highest paid employees who are neither a director nor chief executive of the Company are as follows:

	Year ended 31 December		Four months ended 30 April	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Salaries, allowances and benefits in kind	7,786	7,771	2,968	2,591
Discretionary bonuses	4,300	4,272	1,518	1,421
Pension scheme contributions	145	146	73	61
Share-based payment expenses	23,603	8,426	2,437	4,114
	<u>35,834</u>	<u>20,615</u>	<u>6,996</u>	<u>8,187</u>

The number of non-director and non-chief executive highest paid employees whose remuneration fell within the following bands is as follows:

	Year ended 31 December		Four months ended 30 April	
	2022	2023	2023	2024
	<i>No. of employees</i>	<i>No. of employees</i>	<i>No. of employees</i>	<i>No. of employees</i>
			<i>(Unaudited)</i>	
Nil to HKD1,000,000	–	–	2	1
HKD1,000,001 to HKD1,500,000	–	–	1	1
HKD1,500,001 to HKD2,000,000	–	–	1	1
HKD2,500,001 to HKD3,000,000	–	1	–	–
HKD3,000,001 to HKD3,500,000	1	1	–	–
HKD3,500,001 to HKD4,000,000	–	–	1	–
HKD4,500,001 to HKD5,000,000	1	1	–	–
HKD5,000,001 to HKD5,500,000	–	–	–	1
HKD12,000,001 to HKD12,500,000	–	1	–	–
HKD14,000,001 to HKD14,500,000	1	–	–	–
HKD19,000,001 to HKD19,500,000	1	–	–	–
	<u>4</u>	<u>4</u>	<u>5</u>	<u>4</u>

During the Relevant Periods and the four months ended 30 April 2023, restricted share units were granted to the non-director and non-chief executive highest paid employees in respect of their services to the Group, further details of which are included in the disclosures in note 22 to the Historical Financial Information. The fair value of such restricted share units, which has been recognised in profit or loss over the vesting period, was determined as at the date of grant and the amounts included in the Historical Financial Information for the Relevant Periods and the four months ended 30 April 2023 are included in the above non-director and non-chief executive highest paid employees’ remuneration disclosures.

During the Relevant Periods and the four months ended 30 April 2023, no highest paid employees waived or agreed to waive any remuneration and no remuneration was paid by the Group to any of the five highest paid employees as an inducement to join or upon joining the Group or as compensation for loss of office.

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11. 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.

Cayman Islands

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains. In addition, upon payments of dividends by the Company to its shareholders, no Cayman Islands withholding tax is imposed on the Company.

British Virgin Islands

Under the current laws of the British Virgin Islands (“BVI”), the subsidiary incorporated in the BVI is not subject to tax on income or capital gains. In addition, upon payments of dividends to its shareholder, no BVI withholding tax is imposed on the subsidiary.

Hong Kong

The subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the statutory rate of 16.5% on any estimated assessable profits arising in Hong Kong during the Relevant Periods. No Hong Kong profits tax was provided for as the Group did not generate any assessable profits arising in Hong Kong during the Relevant Periods and the four months ended 30 April 2023.

Chinese Mainland

Pursuant to the Corporate Income Tax Law of the People’s Republic of China and the respective regulations (the “CIT Law”), the subsidiaries which operate in Chinese Mainland are subject to CIT at a rate of 25% on the taxable income during the Relevant Periods and the four months ended 30 April 2023.

Pursuant to the relevant CIT Laws, VISEN Shanghai enjoyed super deduction of 175% on qualifying research and development expenditures during the period from January 2022 to October 2022, and enjoyed super deduction of 200% on qualifying research and development expenditures during the period from November 2022 to April 2024.

Taiwan

The subsidiary incorporated in Taiwan is subject to Taiwan profits tax. The first TWD120,000 of assessable profits of this subsidiary are not subject to tax and the remaining assessable profits are taxed at 20%. No Taiwan profits tax was provided for as the Group did not generate any assessable profits arising in Taiwan during the Relevant Periods and the four months ended 30 April 2023.

A reconciliation of the tax expense applicable to loss before tax at the statutory rate for the country (or jurisdictions) in which the Company and its major subsidiaries are domiciled to the tax expense at the effective tax rate is as follows:

	Year ended 31 December		Four months ended 30 April	
	2022	2023	2023	2024
	RMB’000	RMB’000	RMB’000	RMB’000
			(Unaudited)	
Loss before tax	(288,967)	(249,570)	(138,997)	(60,131)
Tax at the statutory tax rate (25%)	(72,242)	(62,393)	(34,749)	(15,033)
Lower tax rate enacted by local authority	(6,195)	13,177	2,158	1,435
Tax effect of expenses not deductible for tax purposes	27,631	15,665	10,311	5,560
Income not subject to tax	(895)	(238)	(119)	(27)

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	<u>Year ended 31 December</u>		<u>Four months ended 30 April</u>	
	<u>2022</u>	<u>2023</u>	<u>2023</u>	<u>2024</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Additional deductible allowance for research and development expenses	(16,990)	(16,960)	(6,142)	(5,301)
Tax effect of tax losses and deductible temporary differences not recognised	<u>68,691</u>	<u>50,749</u>	<u>28,541</u>	<u>13,366</u>
Tax charge at the Group’s effective rate	<u><u>–</u></u>	<u><u>–</u></u>	<u><u>–</u></u>	<u><u>–</u></u>

The Group had tax losses in Chinese Mainland of RMB528,003,000 and RMB725,072,000 in aggregate as at 31 December 2022 and 2023 and RMB783,827,020.51 in aggregate as at 30 April 2024, respectively, that will expire in one to five years for offsetting against future taxable profits of the company in which the losses arose. The Group also had deductible temporary differences of RMB72,506,000, RMB72,984,000 and RMB65,892,000 as at 31 December 2022 and 2023 and 30 April 2024, respectively, which were mainly related to accrued expenses.

Deferred tax assets have not been recognised in respect of tax losses and deductible temporary differences as they have arisen in the subsidiaries that have been loss-making for some time and it is not considered probable that taxable profits in foreseeable future will be available against which the tax losses and deductible temporary differences can be utilised.

Since the Group did not fall within the scope of the Pillar Two model rules, the Pillar Two model rules did not have any impact to the Group during the Relevant Periods and the four months ended 30 April 2023.

12. DIVIDENDS

No dividend was paid or declared by the Company during the Relevant Periods and the four months ended 30 April 2023.

13. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE COMPANY

No loss per share information is presented as its inclusion, for the purpose of this report, is not considered meaningful.

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14. PROPERTY, PLANT AND EQUIPMENT

	Furniture and equipment	Leasehold improvements	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
As at 31 December 2022			
At 1 January 2022:			
Cost	1,320	3,659	4,979
Accumulated depreciation	(398)	(788)	(1,186)
Net carrying amount	<u>922</u>	<u>2,871</u>	<u>3,793</u>
At 1 January 2022, net of accumulated depreciation			
Cost	922	2,871	3,793
Additions	391	–	391
Disposal	(91)	–	(91)
Depreciation provided during the year	(474)	(1,267)	(1,741)
At 31 December 2022, net of accumulated depreciation	<u>748</u>	<u>1,604</u>	<u>2,352</u>
At 31 December 2022:			
Cost	1,585	3,659	5,244
Accumulated depreciation	(837)	(2,055)	(2,892)
Net carrying amount	<u>748</u>	<u>1,604</u>	<u>2,352</u>
	Furniture and equipment	Leasehold improvements	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
As at 31 December 2023			
At 1 January 2023:			
Cost	1,585	3,659	5,244
Accumulated depreciation	(837)	(2,055)	(2,892)
Net carrying amount	<u>748</u>	<u>1,604</u>	<u>2,352</u>
At 1 January 2023, net of accumulated depreciation			
Cost	748	1,604	2,352
Additions	69	206	275
Disposal	(14)	(228)	(242)
Depreciation provided during the year	(439)	(1,070)	(1,509)
At 31 December 2023, net of accumulated depreciation	<u>364</u>	<u>512</u>	<u>876</u>
At 31 December 2023:			
Cost	1,529	1,756	3,285
Accumulated depreciation	(1,165)	(1,244)	(2,409)
Net carrying amount	<u>364</u>	<u>512</u>	<u>876</u>

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	Furniture and equipment	Leasehold improvements	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
As at 30 April 2024			
At 1 January 2024:			
Cost	1,529	1,756	3,285
Accumulated depreciation	(1,165)	(1,244)	(2,409)
	<u>364</u>	<u>512</u>	<u>876</u>
Net carrying amount	<u>364</u>	<u>512</u>	<u>876</u>
At 1 January 2024, net of accumulated depreciation			
	364	512	876
Depreciation provided during the period	(97)	(228)	(325)
	<u>267</u>	<u>284</u>	<u>551</u>
At 30 April 2024, net of accumulated depreciation			
	267	284	551
At 30 April 2024:			
Cost	1,529	1,756	3,285
Accumulated depreciation	(1,262)	(1,472)	(2,734)
	<u>267</u>	<u>284</u>	<u>551</u>
Net carrying amount	<u>267</u>	<u>284</u>	<u>551</u>

As at 31 December 2022 and 2023 and 30 April 2024, there were no pledged property, plant and equipment.

15. LEASES

The Group as a lessee

The Group has lease contracts for land use right and various items of office premises used in its operations. Land use right has term for usage about 30 years and leases of office premises generally have lease terms between 2 and 3 years. Generally, the Group is restricted from assigning and subleasing the leased assets outside the Group.

(a) Right-of-use assets

The carrying amount of the Group’s right-of-use assets and the movements during the Relevant Periods are as follows:

	Land use right	Office premises	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
As at 31 December 2022			
As at 1 January 2022	–	10,223	10,223
Addition	9,522	–	9,522
Depreciation charge	(317)	(4,616)	(4,933)
	<u>9,205</u>	<u>5,607</u>	<u>14,812</u>
As at 31 December 2022	<u>9,205</u>	<u>5,607</u>	<u>14,812</u>

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	Land use right	Office premises	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
As at 31 December 2023			
As at 1 January 2023	9,205	5,607	14,812
Addition	–	3,070	3,070
Termination of a lease contract	–	(864)	(864)
Depreciation charge	(318)	(4,321)	(4,639)
	<u>8,887</u>	<u>3,492</u>	<u>12,379</u>
As at 31 December 2023	<u>8,887</u>	<u>3,492</u>	<u>12,379</u>
As at 30 April 2024			
As at 1 April 2024	8,887	3,492	12,379
Depreciation charge	(106)	(1,115)	(1,221)
	<u>8,781</u>	<u>2,377</u>	<u>11,158</u>
As at 30 April 2024	<u>8,781</u>	<u>2,377</u>	<u>11,158</u>

On 2 November 2023, the Group exercised the termination right in the land use right transfer agreement and submitted an application of land return (the “Application”). As of 30 April 2024 and up to the date of this report, the Application is still under ordinary review process by relevant governmental authority.

(b) Lease liabilities

The carrying amount of lease liabilities and the movements during the Relevant Periods are as follows:

	As at 31 December		As at 30 April
	2022	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Carrying amount at 1 January	11,160	5,996	3,649
New leases	–	2,872	–
Termination of a lease contract	–	(591)	–
Accretion of interest recognised during the year	619	317	66
Payments	(5,783)	(4,945)	(1,376)
	<u>5,996</u>	<u>3,649</u>	<u>2,339</u>
Carrying amount at 31 December	<u>5,996</u>	<u>3,649</u>	<u>2,339</u>
Analysed into:			
Current portion	4,668	2,552	1,785
Non-current portion	1,328	1,097	554
	<u>1,328</u>	<u>1,097</u>	<u>554</u>

The maturity analysis of lease liabilities is disclosed in note 28 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		Four months ended 30 April	
	2022	2023	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Depreciation of right-of-use assets	4,933	4,639	1,622	1,221
Interest on lease liabilities	619	317	126	66
Expenses relating to short-term leases	316	344	92	168
Loss on termination of a lease contract	–	273	–	–
Total amount recognised in profit or loss	5,868	5,573	1,840	1,455

(d) The total cash outflow for leases is disclosed in note 23(c) to the Historical Financial Information.

16. INTANGIBLE ASSETS

	Software
	<i>RMB'000</i>
As at 31 December 2022	
At 1 January 2022	
Cost	2,583
Accumulated amortisation	(445)
Net carrying amount	<u>2,138</u>
At 1 January 2022, net of accumulated amortisation	2,138
Amortisation provided during the year	(723)
At 31 December 2022, net of accumulated amortisation	<u>1,415</u>
At 31 December 2022	
Cost	2,693
Accumulated amortisation	(1,278)
Net carrying amount	<u>1,415</u>
As at 31 December 2023	
At 1 January 2023	
Cost	2,693
Accumulated amortisation	(1,278)
Net carrying amount	<u>1,415</u>
At 1 January 2023, net of accumulated amortisation	1,415
Amortisation provided during the year	(848)
At 31 December 2023, net of accumulated amortisation	<u>567</u>

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	<u>Software</u>
	<i>RMB’000</i>
At 31 December 2023	
Cost	2,693
Accumulated amortisation	<u>(2,126)</u>
Net carrying amount	<u><u>567</u></u>
As at 30 April 2024	
At 1 January 2024	
Cost	2,693
Accumulated amortisation	<u>(2,126)</u>
Net carrying amount	<u><u>567</u></u>
At 1 January 2024, net of accumulated amortisation	567
Amortisation provided during the period	<u>(266)</u>
At 30 April 2024, net of accumulated amortisation	<u><u>301</u></u>
At 30 April 2024	
Cost	2,693
Accumulated amortisation	<u>(2,392)</u>
Net carrying amount	<u><u>301</u></u>

17. PREPAYMENTS AND OTHER RECEIVABLES

The Group

	<u>As at 31 December</u>		<u>As at 30 April</u>
	<u>2022</u>	<u>2023</u>	<u>2024</u>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Non-current:			
Value-added tax recoverable	9,440	16,137	17,100
Rental deposits	<u>1,663</u>	<u>523</u>	<u>496</u>
	<u><u>11,103</u></u>	<u><u>16,660</u></u>	<u><u>17,596</u></u>
Current:			
Prepayments for research and development services	6,951	5,308	4,997
Deferred share issue costs	5,669	6,053	5,671
Other prepayments	1,855	824	838
Bank interest receivable	1,391	4,036	4,094
Other receivables	54	54	54
Rental deposits	<u>41</u>	<u>697</u>	<u>764</u>
	<u><u>15,961</u></u>	<u><u>16,972</u></u>	<u><u>16,418</u></u>

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The Company

	<u>As at 31 December</u>		<u>As at 30 April</u>
	<u>2022</u>	<u>2023</u>	<u>2024</u>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Current:			
Deferred share issue costs	5,669	6,053	5,671
Bank interest receivable	1,083	3,286	3,608
Prepayments	181	136	249
Rental deposit	2	2	2
	<u>6,935</u>	<u>9,477</u>	<u>9,530</u>

The financial assets included in the above balances relate to receivables for which there were no recent history of default and past due amounts. In addition, there is no significant change in the economic factors based on the assessment of the forward-looking information, so the directors of the Company are of the opinion that the ECLs in respect of these balances are minimal. The balances are interest-free and are not secured with collateral.

18. CASH AND CASH EQUIVALENTS

The Group

	<u>As at 31 December</u>		<u>As at 30 April</u>
	<u>2022</u>	<u>2023</u>	<u>2024</u>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Cash and bank balances	626,458	347,782	299,683
Denominated in			
RMB	296,809	190,035	197,445
USD	322,940	153,065	98,262
TWD	6,465	4,230	3,175
Hong Kong dollar (“HKD”)	244	452	801
	<u>626,458</u>	<u>347,782</u>	<u>299,683</u>

The Company

	<u>As at 31 December</u>		<u>As at 30 April</u>
	<u>2022</u>	<u>2023</u>	<u>2024</u>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Cash and bank balances	440,425	232,841	231,216
Denominated in			
RMB	146,648	148,081	147,054
USD	293,777	84,760	84,162
	<u>440,425</u>	<u>232,841</u>	<u>231,216</u>

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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. Short term time deposits are made for varying periods of between one day and three months depending on the immediate cash requirements of the Group, and earn interest at the respective short term time deposit rates. The bank balances are deposited with creditworthy banks with no recent history of default.

19. TRADE AND OTHER PAYABLES

The Group

	As at 31 December		As at 30 April
	2022	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade payables	3,740	669	166
Accrued expenses for research and development services	8,790	8,078	8,593
Salary and discretionary bonus payables	11,815	13,316	5,992
Other payables	14,582	2,590	1,660
Accrued [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Other taxes payable	2,569	1,852	2,589
	<u>49,460</u>	<u>37,582</u>	<u>33,366</u>

The Company

	As at 31 December		As at 30 April
	2022	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Accrued [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Other payables	406	190	93
	<u>8,370</u>	<u>11,267</u>	<u>14,459</u>

An ageing analysis of the trade payables and trade payables to related parties as at the end of each of the Relevant Periods, based on the invoice date, is as follows:

The Group

	As at 31 December		As at 30 April
	2022	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade payables			
Within 3 months	3,740	669	166
Trade payables to related parties (<i>Notes 25(b)</i>)			
Within 3 months	24,241	339	3,636
	<u>24,241</u>	<u>339</u>	<u>3,636</u>

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The Company

	As at 31 December		As at 30 April
	2022	2023	2024
	RMB’000	RMB’000	RMB’000
Trade payables to related parties (<i>Notes 25(b)</i>)			
Within 3 months	9,535	–	–

Trade and other payables are unsecured and non-interest-bearing. The carrying amounts of financial liabilities included in trade and other payables as at the end of each of the Relevant Periods approximated to their fair values due to their short-term maturities.

20. SHARE CAPITAL AND TREASURY SHARES

The Company was incorporated on 1 November 2018 with authorised share capital of USD50,000 divided into 500,000,000 ordinary shares with a par value of USD0.0001 each.

On 7 November 2018, the authorised share capital of the Company was changed to USD50,000 divided into: (i) 420,000,000 ordinary shares, and (ii) 80,000,000 Series A Preferred Shares, with a par value of USD0.0001 each.

On 8 January 2021, the authorised share capital of the Company was changed to USD50,000 divided into: (i) 386,363,636 ordinary shares, (ii) 20,000,000 non-voting ordinary shares, (iii) 80,000,000 Series A Preferred Shares, and (iv) 13,636,364 Series B Preferred Shares, with a par value of US\$0.0001 each.

On 16 November 2022, the authorised share capital of the Company was changed to USD50,000 divided into: (i) 397,023,136 ordinary shares, (ii) 9,340,500 non-voting ordinary shares, (iii) 80,000,000 Series A Preferred Shares, and (iv) 13,636,364 Series B Preferred Shares, with a par value of US\$0.0001 each.

Issued and fully paid:

	As at 31 December 2022 and 2023, 1 January 2024 and 30 April 2024		
	Number of shares in issue	Share capital	
		USD’000	RMB’000
Non-voting ordinary shares of USD0.0001 each	9,340,500	1	6
Series A Preferred Shares of USD0.0001 each	80,000,000	8	55
Series B Preferred Shares of USD0.0001 each	13,636,364	1	9
	102,976,864	10	70

A summary of movements in the Company’s share capital during the Relevant Periods is as follows:

	Number of shares in issue	Share capital
		RMB’000
As at 1 January 2022	113,636,364	77
Cancellation of non-voting ordinary shares*	(10,659,500)	(7)
As at 31 December 2022, 1 January 2023, 31 December 2023, 1 January 2024 and 30 April 2024	102,976,864	70

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Treasury shares:

	<u>Number of shares</u>	<u>Treasury shares</u> <i>RMB’000</i>
As at 1 January 2022	20,000,000	13
Cancellation of non-voting ordinary shares*	<u>(10,659,500)</u>	<u>(7)</u>
As at 31 December 2022, 1 January 2023, 31 December 2023, 1 January 2024 and 30 April 2024	<u>9,340,500</u>	<u>6</u>

* On 15 November 2022, the Company entered into share surrender agreements with VP EIP US LIMITED and VP EIP NUS LIMITED, pursuant to which these two entities surrendered for no consideration of totalling 10,659,500 non-voting ordinary shares of the Company. The surrendered shares were reserved for Equity Incentive Plan as set out in note 22 to the Historical Financial Information and had not been granted to any eligible award recipient before surrender. 10,659,500 non-voting ordinary shares of the Company were cancelled accordingly on 16 November 2022.

Preferred shares

On 7 November 2018, the Company issued 80,000,000 Series A convertible preferred shares (“Series A Preferred Shares”) to the investors of the Company at a price of USD1.00 per share with a par value of USD0.0001 each. The difference between the issue price and the par value of the shares issued amounting to USD79,992,000 (equivalent to RMB552,465,000) was recognised as share premium.

On 8 January 2021, the Company issued 13,636,364 series B convertible preferred shares (“Series B Preferred Shares”) to the series B investors of the Company at a price of USD11.00 per share with a par value of USD0.0001 each. The difference between the issue price and the par value of the shares issued amounting to USD149,998,640 (equivalent to RMB970,788,000) was recognised as share premium.

Series A Preferred Shares and Series B Preferred Shares (“Preferred Shares”) are accounted for as equity. The details of Series A Preferred Shares and Series B Preferred Shares are set out as follows:

Conversion features

Each holder of Preferred Shares shall have the right, at such holder’s sole discretion, at any time after the date of issuance, to convert Preferred Shares into such number of fully paid ordinary shares as determined by dividing the relevant issue price by the then-effective conversion price. The conversion prices for Preferred Shares are initially the respective Preferred Shares subscription price, resulting in an initial conversion ratio of 1:1, and shall be subject to adjustments to reflect share dividends, share splits, recapitalisation and other value adjustment events.

Each of the Preferred Shares shall automatically be converted into ordinary shares upon the closing of a firm-commitment [REDACTED] by the Company of its ordinary shares or a reverse merger of the Company with a [REDACTED] company, on a reputable securities exchange for a minimum [REDACTED] price as required by shareholders.

Liquidation preferences

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary or the consummation of a Deemed Liquidation Event (as defined below), all assets and funds of the Company legally available for distribution to the shareholders of the Company (after satisfaction of all creditors’ claims and claims that may be preferred by law) shall be distributed to the holders of Preferred Shares with an amount equal to the greater of (i) one times the applicable Preferred Share issue price, plus all declared but unpaid dividends thereon, and (ii) such amount per share as would have been payable had all Preferred Shares been converted into ordinary shares immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event (“Preference Amount”).

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If there are any assets or funds remaining after the aggregate Preferred Shares have been distributed or paid fully, the remaining assets and funds of the Company legally available for distribution shall be distributed among all holders of the ordinary shares and the non-voting ordinary shares, in proportion to the number of ordinary shares held by such holders (assuming the conversion of all non-voting ordinary shares into ordinary shares).

The following events (each a “Deemed Liquidation Event”) shall be deemed a liquidation, dissolution or winding up of the Company unless the holders of (i) at least sixty percent of the outstanding Series A Preferred Shares and (ii) at least fifty percent of the outstanding Series B Preferred Shares elect otherwise, (i) any acquisition, sale of shares, merger, consolidation or other similar transaction involving any subsidiary in which its shareholders do not retain a majority of the voting power in the surviving entity or the parent of the surviving entity (except any transaction effected solely to change the subsidiary’s domicile); or (ii) any sale, lease, transfer, exclusive license or disposition by the Company or any subsidiary of all or substantially all the assets or intellectual property of the subsidiaries, taken as a whole.

Based on the details of Preferred Shares set out above, the Preferred Shares include no contractual obligation: (i) to deliver a variable number of its own equity instruments; or (ii) to deliver cash or another financial asset to the holders of Preferred Shares ; or (iii) to exchange financial assets or financial liabilities with the holders of Preferred Shares under conditions that are potentially unfavourable to the Company. Accordingly, the Preferred Shares are recognised as equity.

21. RESERVES

The Group

The amounts of the Group’s reserves and the movements therein attributable to owners of the Company are presented in the consolidated statements of changes in equity on pages I-8 to I-10 of the Historical Financial Information.

Share premium

The share premium of the Group represents the difference between the issue price of convertible preferred shares and the par value of the shares issued. The Company can allot and issue shares by capitalising from the amount standing to the credit of the share premium account of the Company.

The Company

	Reserves			
	Share premium	Share reward reserve	Accumulated losses	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
At 1 January 2022	1,523,253	217,661	(409,531)	1,331,383
Profit and total comprehensive income for the year	–	–	25,099	25,099
Equity-settled share-based payment	–	93,508	–	93,508
At 31 December 2022 and 1 January 2023	1,523,253	311,169	(384,432)	1,449,990
Loss and total comprehensive loss for the year	–	–	(13,839)	(13,839)
Equity-settled share-based payment	–	(12,266)	–	(12,266)
At 31 December 2023 and 1 January 2024	1,523,253	298,903	(398,271)	1,423,885

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	Reserves			Total
	Share premium	Share reward reserve	Accumulated losses	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	
Loss and total comprehensive loss for the period	–	–	(4,764)	(4,764)
Equity-settled share-based payment	–	21,671	–	21,671
At 30 April 2024	<u>1,523,253</u>	<u>320,574</u>	<u>(403,035)</u>	<u>1,440,792</u>

22. SHARE-BASED PAYMENTS

The Company adopted an equity incentive plan (the “Equity Incentive Plan”) on 29 April 2019, as amended and restated by the Company on 8 January 2021 and 10 March 2021, respectively, for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group. Eligible participants of the Equity Incentive Plan may include any officer, directors, employees of the Company, and any individual consultants or advisors who render or have rendered bona fide services to the Company. The Equity Incentive Plan will automatically terminate on 28 April 2029.

In March 2021, the Company allotted and issued a total of 20,000,000 non-voting ordinary shares of the Company under the Equity Incentive Plan to certain special purpose vehicles in order to facilitate the administration of the plan. Details of the issuance of new shares of the Company related to the Equity Incentive Plan are set out in the section headed “History, Development and Corporate Structure” in the Document. On 15 March 2021, 30 August 2021, and 17 March 2022, the Company has granted restricted share units to 45, 5, and 11 grantees to subscribe for an aggregate of 6,340,000, 1,180,000, and 340,000 shares under the Equity Incentive Plan, respectively. These granted restricted share units will be vested in accordance with certain service conditions and non-market performance conditions. The subscription price for the restricted share units are all nil.

The restricted share units granted to grantees shall vest and become exercisable as to 25% of the total number of restricted share units granted on the first anniversary of the vesting commencement date, and the remaining 25%, 25% and 25% of the total number of the restricted share units granted shall vest and become exercisable on the second, third and fourth anniversaries of the vesting commencement date.

In addition to time-based vesting condition, the number of restricted share units which shall vest also depends on the performance targets, including completion of [REDACTED], commercialisation of products, local manufacturing, total sales and net profit target achieved by the Group during the vesting period.

The following restricted share units were outstanding under the Equity Incentive Plan during the years ended 31 December 2022 and 2023 and the four months ended 30 April 2024:

	Number of restricted share units
As at 1 January 2022	7,340,000
Granted during the year	340,000
Forfeited during the year	(37,500)
As at 31 December 2022 and 1 January 2023	<u>7,642,500</u>
Forfeited during the year	(1,167,500)
As at 31 December 2023, 1 January 2024 and 30 April 2024	<u><u>6,475,000</u></u>

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The fair value of the restricted share units granted on 30 August 2021 and 17 March 2022 is determined using the market approach – the multiple method which is price over research and development expense (“P/RD”). The following table lists the inputs to the method used:

	Restricted share units granted on 17 March 2022
Fair value at grant date (USD per share)	10.80
P/RD ratio	18.34
Expected volatility	48.61%
Risk-free interest rate	2.13%
Discount for lack of marketability	5.5%-21.0%

During the year ended 31 December 2022 and the four months ended 30 April 2024, share-based payment expenses of RMB93,508,000 and RMB21,671,000 were charged to profit or loss, respectively. During the year ended 31 December 2023 and the four months ended 30 April 2023, share-based payment expenses of RMB12,266,000 and RMB34,585,000 (unaudited) were credited to profit or loss mainly due to forfeiture of 1,167,500 restricted share units for retired and resigned employees.

23. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

During the years ended 31 December 2022 and 2023, and the four months ended 30 April 2024, other payables related to the purchase of property, plant and equipment were RMB245,000, nil and nil, respectively, which were non-cash transactions.

During the years ended 31 December 2022 and 2023 and the four months ended 30 April 2024, the Group had non-cash additions to right-of-use assets of nil, RMB2,872,000 and nil, respectively, and non-cash additions to lease liabilities of nil, RMB2,872,000 and nil, respectively, in respect of lease arrangements for office premises.

(b) Changes in liabilities arising from financing activities

	Accrued [REDACTED] included in other payables	Lease liabilities
	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2022	4,125	11,160
Changes from financing cash flows	(2,166)	(5,783)
Changes from operating cash flows	(11,404)	–
Accrued [REDACTED]	[REDACTED]	[REDACTED]
Deferred share issue costs	3,108	–
Accretion of interest	–	619
	<hr/>	<hr/>
At 31 December 2022 and 1 January 2023	7,964	5,996
Changes from financing cash flows	(2,007)	(4,945)
Changes from operating cash flows	(11,544)	–
Termination of a lease contract	–	(591)
Accrued [REDACTED]	[REDACTED]	[REDACTED]
Deferred share issue costs	384	–
Accretion of interest	–	317
New Leases	–	2,872
	<hr/>	<hr/>

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	Accrued [REDACTED] included in other payables	Lease liabilities
	<u>RMB’000</u>	<u>RMB’000</u>
At 31 December 2023 and 1 January 2024	11,077	3,649
Changes from financing cash flows	–	(1,376)
Changes from operating cash flows	(2,117)	–
Accrued [REDACTED]	[REDACTED]	[REDACTED]
Deferred share issue costs	(382)	–
Accretion of interest	–	66
	<u>14,366</u>	<u>2,339</u>
At 30 April 2024		
At 1 January 2023	7,964	5,996
Changes from financing cash flows	(263)	(2,003)
Changes from operating cash flows	(1,466)	–
Accrued [REDACTED]	[REDACTED]	[REDACTED]
Deferred issue costs	(571)	–
Accretion of interest	–	126
	<u>7,459</u>	<u>4,119</u>
At 30 April 2023		

(c) **Total cash outflow for leases**

The total cash outflow for leases included in the consolidated statements of cash flows is as follows:

	<u>Year ended 31 December</u>		<u>Four months ended 30 April</u>	
	<u>2022</u>	<u>2023</u>	<u>2023</u>	<u>2024</u>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(Unaudited)</i>	
Within operating activities	316	344	92	168
Within investing activities	282	–	–	–
Within financing activities	5,783	4,945	2,003	1,376
	<u>6,381</u>	<u>5,289</u>	<u>2,095</u>	<u>1,544</u>

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24. COMMITMENTS

At the end of each of the reporting periods, the Group did not have any significant contractual commitments.

25. RELATED PARTY TRANSACTIONS

(a) The Group had the following transactions with related parties during the Relevant Periods and the four months ended 30 April 2023:

	Year ended 31 December		Four months ended 30 April	
	2022	2023	2023	2024
	RMB'000	RMB'000	RMB'000	RMB'000
			(Unaudited)	
Purchase of trial drugs and cost sharing				
Ascendis Pharma Endocrinology Division A/S (“Ascendis Pharma Endocrinology”) (note i)	50,667	8,451	4,905	–
Ascendis Pharma Bone Diseases A/S (“Ascendis Pharma Bone Diseases”) (note i)	5,256	451	–	–
Ascendis Pharma Growth Disorders A/S (“Ascendis Pharma Growth Disorders”) (note i)	714	243	–	–
	<u>56,637</u>	<u>9,145</u>	<u>4,905</u>	<u>–</u>
Purchase of services				
Ascendis Pharma Endocrinology	12,832	9,261	1,678	3,900
Ascendis Pharma Growth Disorders	440	3,059	290	2,090
Ascendis Pharma Bone Diseases	1,320	895	253	70
	<u>14,592</u>	<u>13,215</u>	<u>2,221</u>	<u>6,060</u>
Loss from a discontinued procurement contract				
Ascendis Pharma Endocrinology (note ii)	–	109,006	109,006	–
	<u>–</u>	<u>109,006</u>	<u>109,006</u>	<u>–</u>

The purchases of goods and services from the related parties were made according to the published prices and conditions agreed by the Group and the related parties.

Notes:

- i Ascendis Pharma Endocrinology, Ascendis Pharma Growth Disorders and Ascendis Pharma Bone Diseases are wholly-owned subsidiaries of Ascendis Pharma A/S (“Ascendis Pharma”). Ascendis Pharma had significant influence on the Group as at 31 December 2022 and 2023 and 30 April 2023 and 2024.

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- ii In August 2022, the Group entered into a commitment and prepayment agreement (the “Agreement”) with Ascendis Pharma Endocrinology to purchase reserved drug substance. In September 2022, the Group prepaid Euros (“EUR”) 10,000,000 (equivalent to RMB69,171,000) to Ascendis Pharma Endocrinology and recorded prepayment of RMB69,171,000 as of 31 December 2022.

In February 2023, the Group exercised its right to cancel its commitment to purchase the reserved drug substance under the Agreement due to the change of its commercial supply strategy. The total loss resulting from the cancellation is EUR15,540,000 (equivalent to RMB109,006,000), comprised of (i) write-off of the prepayment of EUR10,000,000 (equivalent to RMB69,171,000) and (ii) provision of EUR5,540,000 (equivalent to RMB39,835,000) which was settled in December 2023. Details of the transaction are set out under the sections headed “FINANCIAL INFORMATION – DESCRIPTION OF SELECTED COMPONENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME – Other gains and losses, Net” in the Document.

- (b) Outstanding balances with related parties:

The Group

	As at 31 December		As at 30 April
	2022	2023	2024
	RMB’000	RMB’000	RMB’000
Amounts due to related parties:			
Trade payables			
– Ascendis Pharma Endocrinology	23,623	230	2,129
– Ascendis Pharma Bone Diseases	480	–	42
– Ascendis Pharma Growth Disorders	138	109	1,465
	<u>24,241</u>	<u>339</u>	<u>3,636</u>
Accrued expenses			
– Ascendis Pharma Endocrinology	2,145	6,785	2,523
– Ascendis Pharma Bone Diseases	2,014	401	29
– Ascendis Pharma Growth Disorders	714	1,265	156
	<u>4,873</u>	<u>8,451</u>	<u>2,708</u>
Other payables			
– Ascendis Pharma Endocrinology	776	–	–
– Ascendis Pharma Bone Diseases	265	–	–
– Ascendis Pharma Growth Disorders	156	–	–
	<u>1,197</u>	<u>–</u>	<u>–</u>
	<u>30,311</u>	<u>8,790</u>	<u>6,344</u>
Amount advanced to a related party:			
Prepayments-current:			
– Ascendis Pharma Endocrinology	69,171	9,367	9,375
Prepayments-non-current:			
– Ascendis Pharma Endocrinology	–	39,193	39,193

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	As at 31 December		As at 30 April
	2022	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Amount due from a subsidiary:			
– VISEN HK	659	–	–
Amount due to a related party:			
Trade payables			
– Ascendis Pharma Endocrinology	9,535	–	–

Amount due from a subsidiary and amount advanced to a related party are trade in nature, unsecured, non-interest-bearing and repayable on demand.

Amounts due to related parties are trade in nature, unsecured, non-interest-bearing and repayable on demand. The carrying amounts of amounts due to related parties as at the end of each of the Relevant Periods approximated to their fair values due to their short-term maturities.

(c) Compensation of key management personnel of the Group

	Year ended 31 December		Four months ended 30 April	
	2022	2023	2023	2024
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(Unaudited)</i>	
Salaries, allowances and benefits				
in kind	8,592	8,161	2,977	2,671
Discretionary bonuses	4,791	4,298	1,371	1,457
Independent non-executive				
directors’ fees	1,035	1,080	351	363
Pension scheme contributions	81	33	22	53
Share-based payment expenses	80,857	(5,372)	314	20,074
	<u>95,356</u>	<u>8,200</u>	<u>5,035</u>	<u>24,618</u>

Further details of directors’ and the chief executive’s emoluments are included in note 9 to the Historical Financial Information.

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26. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of each of the Relevant Periods are as follows:

The Group

As at 31 December 2022

Financial assets

	Financial assets at amortised cost
	<i>RMB’000</i>
Financial assets included in prepayments and other receivables	3,149
Cash and cash equivalents	626,458
	<u>629,607</u>

Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB’000</i>
Financial liabilities included in trade and other payables	35,076
Amounts due to related parties	30,311
	<u>65,387</u>

As at 31 December 2023

Financial assets

	Financial assets at amortised cost
	<i>RMB’000</i>
Financial assets included in prepayments and other receivables	5,310
Cash and cash equivalents	347,782
	<u>353,092</u>

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Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB’000</i>
Financial liabilities included in trade and other payables	22,414
Amounts due to related parties	8,790
	<u>31,204</u>

As at 30 April 2024

Financial assets

	Financial assets at amortised cost
	<i>RMB’000</i>
Financial assets included in prepayments and other receivables	5,408
Cash and cash equivalents	299,683
	<u>305,091</u>

Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB’000</i>
Financial liabilities included in trade and other payables	24,785
Amounts due to related parties	6,344
	<u>31,129</u>

The Company

As at 31 December 2022

Financial assets

	Financial assets at amortised cost
	<i>RMB’000</i>
Financial assets included in prepayments and other receivables	1,085
Amount due from a subsidiary	659
Cash and cash equivalents	440,425
	<u>442,169</u>

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Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB'000</i>
Financial liabilities included in other payables	8,370
Amount due to a related party	9,535
	<u>17,905</u>

As at 31 December 2023

Financial assets

	Financial assets at amortised cost
	<i>RMB'000</i>
Financial assets included in prepayments and other receivables	3,288
Cash and cash equivalents	232,841
	<u>236,129</u>

Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB'000</i>
Financial liabilities included in other payables	11,267

As at 30 April 2024

Financial assets

	Financial assets at amortised cost
	<i>RMB'000</i>
Financial assets included in prepayments and other receivables	3,610
Cash and cash equivalents	231,216
	<u>234,826</u>

Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB'000</i>
Financial liabilities included in other payables	14,459

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27. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

Fair values

All the carrying amounts of the Group’s financial instruments are those with carrying amounts that reasonably approximate to fair values. Management has assessed that the fair values of cash and cash equivalents, financial assets included in prepayments and other receivables (in the current portion), financial liabilities included in trade and other payables, amounts due to related parties and lease liabilities (in the current portion) approximate to their carrying amounts largely due to the short-term maturities of these instruments. The fair values of the other non-current financial assets and financial liabilities have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities. The Group did not have any financial assets or liabilities, other than stated above, measured at fair value at the end of each of the Relevant Periods.

The Group’s finance department headed by the finance manager is responsible for determining the policies and procedures for the fair value measurement of financial instruments. At the end of each of the Relevant Periods, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The directors review the results of the fair value measurement of financial instruments periodically for financial reporting.

The Group’s principal financial instruments comprise cash and cash equivalents. The main purpose of these financial instruments is to raise finance for the Group’s operations. The Group has various other financial assets and liabilities such as other receivables and trade and other payables, which arise directly from its operations.

The main risks arising from the Group’s financial instruments are foreign currency risk, credit risk and liquidity risk. The board of directors of the Company reviews and agrees policies for managing each of these risks and they are summarised below.

28. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

Foreign currency risk

The Group has transactional currency exposures. Such exposures arise from purchases by operating units in currencies other than the units’ functional currencies.

The following table demonstrates the sensitivity at the end of each of the Relevant Periods to a reasonably possible change in foreign currency exchange rates, with all other variables held constant, of the Group’s loss before tax (due to changes in the fair values of monetary assets and liabilities) and the Group’s equity.

	<u>Increase/ (decrease) in rate of foreign currency</u>	<u>Increase/ (decrease) in loss before tax</u>	<u>Increase/ (decrease) in equity</u>
	%	RMB’000	RMB’000
31 December 2022			
If RMB weakens against USD	5	(16,038)	16,038
If RMB strengthens against USD	(5)	16,038	(16,038)
If RMB weakens against EUR	5	1,504	(1,504)
If RMB strengthens against EUR	(5)	(1,504)	1,504
If RMB weakens against TWD	5	(320)	320
If RMB strengthens against TWD	(5)	320	(320)
31 December 2023			
If RMB weakens against USD	5	(7,698)	7,698
If RMB strengthens against USD	(5)	7,698	(7,698)
If RMB weakens against EUR	5	439	(439)
If RMB strengthens against EUR	(5)	(439)	439

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	<u>Increase/ (decrease) in rate of foreign currency</u>	<u>Increase/ (decrease) in loss before tax</u>	<u>Increase/ (decrease) in equity</u>
	%	RMB'000	RMB'000
If RMB weakens against HKD	5	(11)	11
If RMB strengthens against HKD	(5)	11	(11)
If RMB weakens against TWD	5	(209)	209
If RMB strengthens against TWD	(5)	209	(209)
30 April 2024			
If RMB weakens against USD	5	(4,913)	4,913
If RMB strengthens against USD	(5)	4,913	(4,913)
If RMB weakens against EUR	5	317	(317)
If RMB strengthens against EUR	(5)	(317)	317
If RMB weakens against HKD	5	(38)	38
If RMB strengthens against HKD	(5)	38	(38)
If RMB weakens against TWD	5	(155)	155
If RMB strengthens against TWD	(5)	155	(155)

Credit risk

For financial assets included in prepayments and other receivables, management makes periodic collective assessment as well as individual assessment on the recoverability of other receivables based on historical settlement records and past experience. The directors believe that there is no material credit risk inherent in the Group’s outstanding balance of other receivables.

As at the end of each of the Relevant Periods, cash and cash equivalents were deposited in financial institutions with good credit ratings and without significant credit risk.

Maximum exposure and year-end staging

The tables below show the credit quality and the maximum exposure to credit risk based on the Group’s credit policy, which is mainly based on past due information unless other information is available without undue cost or effort, and year-end staging classification as at the end of each of the Relevant Periods.

The amounts presented are gross carrying amounts for financial assets.

The Group

As at 31 December 2022

	<u>12-month ECLs</u>	<u>Lifetime ECLs</u>		<u>Total</u>
	<u>Stage 1</u>	<u>Stage 2</u>	<u>Stage 3</u>	
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Financial assets included in prepayments and other receivables – normal	3,149	–	–	3,149
Cash and cash equivalents – not yet past due	626,458	–	–	626,458
	<u>629,607</u>	<u>–</u>	<u>–</u>	<u>629,607</u>

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As at 31 December 2023

	12-month ECLs	Lifetime ECLs		Total
	Stage 1	Stage 2	Stage 3	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	
Financial assets included in prepayments and other receivables – normal	5,310	–	–	5,310
Cash and cash equivalents – not yet past due	347,782	–	–	347,782
	353,092	–	–	353,092
	353,092	–	–	353,092

As at 30 April 2024

	12-month ECLs	Lifetime ECLs		Total
	Stage 1	Stage 2	Stage 3	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	
Financial assets included in prepayments and other receivables – normal	5,408	–	–	5,408
Cash and cash equivalents – not yet past due	299,683	–	–	299,683
	305,091	–	–	305,091
	305,091	–	–	305,091

The Company

As at 31 December 2022

	12-month ECLs	Lifetime ECLs		Total
	Stage 1	Stage 2	Stage 3	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	
Financial assets included in prepayments and other receivables – normal	1,085	–	–	1,085
Amount due from a subsidiary – normal	659	–	–	659
Cash and cash equivalents – not yet past due	440,425	–	–	440,425
	442,169	–	–	442,169
	442,169	–	–	442,169

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As at 31 December 2023

	12-month ECLs	Lifetime ECLs		Total
	Stage 1	Stage 2	Stage 3	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	
Financial assets included in prepayments and other receivables – normal	3,288	–	–	3,288
Cash and cash equivalents – not yet past due	232,841	–	–	232,841
	236,129	–	–	236,129
	236,129	–	–	236,129

As at 30 April 2024

	12-month ECLs	Lifetime ECLs		Total
	Stage 1	Stage 2	Stage 3	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	
Financial assets included in prepayments and other receivables – normal	3,610	–	–	3,610
Cash and cash equivalents – not yet past due	231,216	–	–	231,216
	234,826	–	–	234,826
	234,826	–	–	234,826

Liquidity risk

The Group monitors and maintains a level of cash and cash equivalents deemed adequate by the management of the Group to finance the operations and mitigate the effects of fluctuations in cash flows.

The maturity profile of the Group’s financial liabilities as at the end of each of the Relevant Periods, based on the contractual undiscounted payments, is as follows:

	As at 31 December 2022			Total
	On demand	Less than 1 year	1 to 5 years	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	
Amounts due to related parties	30,311	–	–	30,311
Financial liabilities included in trade and other payables	35,076	–	–	35,076
Lease liabilities	–	4,915	1,350	6,265
	65,387	4,915	1,350	71,652
	65,387	4,915	1,350	71,652

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	As at 31 December 2023			
	On demand	Less than 1 year	1 to 5 years	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Amounts due to related parties	8,790	–	–	8,790
Financial liabilities included in trade and other payables	22,414	–	–	22,414
Lease liabilities	–	2,682	1,117	3,799
	<u>31,204</u>	<u>2,682</u>	<u>1,117</u>	<u>35,003</u>

	As at 30 April 2024			
	On demand	Less than 1 year	1 to 5 years	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Amounts due to related parties	6,344	–	–	6,344
Financial liabilities included in trade and other payables	24,785	–	–	24,785
Lease liabilities	–	1,865	559	2,424
	<u>31,129</u>	<u>1,865</u>	<u>559</u>	<u>33,553</u>

The maturity profile of the Company’s financial liabilities as at the end of each of the Relevant Periods, based on the contractual undiscounted payments, is as follows:

	As at 31 December 2022			
	On demand	Less than 1 year	1 to 5 years	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Financial liabilities included in other payables	8,370	–	–	8,370
Amount due to a related party	9,535	–	–	9,535
	<u>17,905</u>	<u>–</u>	<u>–</u>	<u>17,905</u>

	As at 31 December 2023			
	On demand	Less than 1 year	1 to 5 years	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Financial liabilities included in other payables	11,267	–	–	11,267
	<u>11,267</u>	<u>–</u>	<u>–</u>	<u>11,267</u>

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ACCOUNTANTS’ REPORT

	As at 30 April 2024			
	On demand	Less than 1 year	1 to 5 years	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Financial liabilities included in other payables	14,459	–	–	14,459
	<u>14,459</u>	<u>–</u>	<u>–</u>	<u>14,459</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.

29. EVENT AFTER THE RELEVANT PERIODS

No significant events have occurred to the Company, or the Group in respect of any period subsequent to 30 April 2024.

30. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Company, the Group or any of the companies now comprising the Group in respect of any period subsequent to 30 April 2024.

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

**APPENDIX III SUMMARY OF THE CONSTITUTION OF OUR COMPANY
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Set forth below is a summary of certain provisions of the Memorandum and Articles of Association of our Company and certain aspects of Cayman Companies Law.

SUMMARY OF THE CONSTITUTION OF THE COMPANY

1. Memorandum of Association

The Memorandum of Association of the Company was conditionally adopted on [●] 2024 and states, inter alia, that the liability of the members of the Company is limited, that the objects for which the Company is established are unrestricted and the Company shall have full power and authority to carry out any object not prohibited by the Companies Act or any other law of the Cayman Islands.

The Memorandum of Association is available for inspection at the address specified in Appendix V in the section headed "Documents Delivered to the Registrar of Companies in Hong Kong and on Display."

2. Articles of Association

The Articles of Association of the Company were conditionally adopted on [●] 2024 and include provisions to the following effect:

2.1. Classes of Shares

The share capital of the Company consists of ordinary shares. The capital of the Company at the date of adoption of the Articles is US\$50,000 divided into 500,000,000 Shares of par value US\$0.0001 each.

2.2. Directors

(a) Power to allot and issue Shares

Subject to the provisions of the Companies Act, the Memorandum of Association and the Articles of Association, and to any special rights conferred on the holders of any shares or class of shares, any share in the Company (whether forming part of the present capital or not) may be issued with or have attached thereto such rights or restrictions whether in regard to dividend, voting, return of capital or otherwise as the Company may by ordinary resolution determine or, if there has not been any such determination or so far as the same shall not make specific provision, as the Board of Directors may determine. Subject to the provisions of the Companies Act, the Listing Rules and the Memorandum of Association and the Articles of Association, and to any special rights conferred on the holders of any shares or attaching to any class of shares, shares may be issued

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on the terms that they may be, or at the option of the Company or the holder are, liable to be redeemed on such terms and in such manner, including out of capital, as the Board of Directors may deem fit.

(b) Power to dispose of the assets of the Company or any subsidiary

Subject to any exercise by the Board of the powers to appoint managers, the management of the business of the Company shall be vested in the Board which, in addition to the powers and authorities by the Articles of Association expressly conferred upon it, may exercise all such powers and do all such acts and things as may be exercised or done or approved by the Company and are not by the Articles of Association or by the Companies Act expressly directed or required to be exercised or done by the Company in general meeting, but subject nevertheless to the provisions of the Companies Act and of the Articles of Association and to any regulation from time to time made by the Company in general meeting not being inconsistent with such provisions or the Articles of Association, provided that no regulation so made shall invalidate any prior act of the Board which would have been valid if such regulation had not been made.

The Board may from time to time appoint a general manager, manager or managers of the Company and may fix his or their remuneration either by way of salary or commission or by conferring the right to participation in the profits of the Company or by a combination of two or more of these modes and pay the working expenses of any of the staff of the general manager, manager or managers who may be employed by him or them in connection with the conduct of the business of the Company. The Board may enter into such agreement or agreements with any such general manager, manager or managers upon such terms and conditions in all respects as the Board may in its absolute discretion think fit, including a power for such general manager, manager or managers to appoint an assistant manager or managers or other employees whatsoever under them for the purpose of carrying on the business of the Company.

(c) Compensation or payment for loss of office

Payment to any Director or past Director of any sum by way of compensation for loss of office or as consideration for or in connection with his retirement from office (not being a payment to which the Director is contractually entitled) must first be approved by the Company in general meeting.

(d) Loans to Directors

There are provisions in the Articles of Association prohibiting the making of loans to Directors or their respective close associates which are equivalent to the restrictions imposed by the Companies Ordinance.

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(e) Financial assistance to purchase Shares

Subject to all applicable laws, the Company may give financial assistance to Directors and employees of the Company, its subsidiaries or any holding company or any subsidiary of such holding company in order that they may buy shares in the Company or any such subsidiary or holding company, provided always that any such financial assistance shall only be made in accordance with any relevant code, rules or regulations issued by the Exchange or the Securities and Futures Commission of Hong Kong from time to time in force.

(f) Disclosure of interest in contracts with the Company or any of its subsidiaries

Subject to the Companies Act and the Articles of Association, no Director or proposed Director shall be disqualified by his or her office from contracting with the Company either as vendor, purchaser or otherwise nor shall any such contract or any contract or arrangement entered into by or on behalf of the Company with any person, company or partnership of or in which any Director shall be a member or otherwise interested be capable on that account of being avoided, nor shall any Director so contracting or being any member or so interested be liable to account to the Company for any profit so realised by any such contract or arrangement by reason only of such Director holding that office or the fiduciary relationship thereby established, provided that such Director shall, if his or her interest in such contract or arrangement is material, declare the nature of his or her interest at the earliest meeting of the Board at which it is practicable for him or her to do so, either specifically or by way of a general notice stating that, by reason of the facts specified in the notice, he or she is to be regarded as interested in any contracts of a specified description which may subsequently be made by the Company.

A Director shall not be entitled to vote on (nor shall be counted in the quorum in relation to) any resolution of the Board in respect of any contract or arrangement or any other proposal whatsoever in which he or she or any of his or her Close Associates has any material interest, and if he or she shall do so his or her vote shall not be counted (nor is he to be counted in the quorum for the resolution), but this prohibition shall not apply to any of the following matters, namely:

- (i) the giving of any security or indemnity either:
 - (a) to the Director or his Close Associate(s) in respect of money lent by him or any of them or obligations incurred or undertaken by him or any of them at the request of or for the benefit of the Company or any of its subsidiaries; or

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- (b) to a third party in respect of a debt or obligation of the Company or any of its subsidiaries for which the Director or his Close Associate(s) has himself/themselves assumed responsibility in whole or in part and whether alone or jointly under a guarantee or indemnity or by the giving of security;
- (ii) any proposal concerning an [REDACTED] of the shares, debentures or other securities of or by the Company or any other company which the Company may promote or be interested in for [REDACTED] or purchase where the Director or his Close Associate(s) is/are or is/are to be interested as a participant in the [REDACTED] or [REDACTED] of the [REDACTED];
- (iii) any proposal concerning any other company in which the Director or his Close Associate(s) is/are interested only, whether directly or indirectly, as an officer or executive or shareholder or in which the Director or his Close Associates are not in aggregate beneficially interested in 5% or more of the issued shares of any class of such company (or of any third company through which his interest or that of his Close Associates is derived) or of the voting rights;
- (iv) any proposal or arrangement concerning the benefit of employees of the Company or our subsidiaries including:–
 - (a) the adoption, modification or operation of any employees' share scheme or any share incentive or share option scheme under which the Director or his Close Associate(s) may benefit; or
 - (b) the adoption, modification or operation of a pension fund or retirement, death or disability benefit scheme which relates both to Director, his Close Associate(s) and employees of the Company or of any of our subsidiaries and does not provide in respect of any Director, or his Close Associate(s), as such any privilege or advantage not generally accorded to the class of persons to which such scheme or fund relates; and
- (v) any contract or arrangement in which the Director or his Close Associate(s) is/are interested in the same manner as other holders of shares or debenture or other securities of the Company by virtue only of his/their interest in shares or debentures or other securities of the Company.

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(g) Remuneration

The Directors shall be entitled to receive by way of ordinary remuneration for their services such sum as shall from time to time be determined by the Company in general meeting or by the Board, as the case may be, such sum (unless otherwise directed by the resolution by which it is voted) to be divided amongst the Directors in such proportions and in such manner as they may agree, or failing agreement, equally, except that in such event any Director holding office for less than the whole of the relevant period in respect of which the remuneration is paid shall only rank in such division in proportion to the time during such period for which he has held office. Such remuneration shall be in addition to any other remuneration to which a Director who holds any salaried employment or office in the Company may be entitled by reason of such employment or office.

The Directors shall be entitled to be paid all travelling, hotel and other expenses, reasonably incurred by them in or about the performance of their duties as Directors including their expenses of travelling to and from Board meetings, committee meetings or general meetings or otherwise incurred whilst engaged on the business of the Company or in the discharge of their duties as Directors.

The Board may grant special remuneration to any Director, who shall perform any special or extra services to or at the request of the Company. Such special remuneration may be made payable to such Director in addition to or in substitution for his ordinary remuneration as a Director, and may be made payable by way of salary, commission or participation in profits or otherwise as may be agreed.

The remuneration of the managing director, joint managing director, deputy managing director or an executive director or a Director appointed to any other office in the management of the Company may from time to time be fixed by the Board and may be by way of salary, commission, or participation in profits or otherwise or by all or any of those modes and with such other benefits (including share option and/or pension and/or gratuity and/or other benefits on retirement) and allowances as the Board may from time to time decide. Such remuneration shall be in addition to such ordinary remuneration as the recipient may be entitled to receive as a Director.

(h) Retirement, appointment and removal

The Board shall have power from time to time and at any time to appoint any person as a Director either to fill a casual vacancy or as an addition to the Board. Any Director so appointed shall hold office only until the first annual general meeting of the Company after his appointment and shall then be eligible for re-election at that meeting.

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The members of the Company may by ordinary resolution at any time remove any Director (including a Managing Director or other executive Director) before the expiration of his term of office notwithstanding anything in the Articles of Association or in any agreement between the Company and such Director and may by ordinary resolution elect another person in his stead. Any person so elected shall hold office during such time only as the Director in whose place he is elected would have held the same if he had not been removed.

The Company may from time to time in general meeting by ordinary resolution increase or reduce the number of Directors but so that the number of Directors shall not be less than one. Subject to the provisions of the Articles of Association and the Companies Act, the Company may also by ordinary resolution elect any person to be a Director either to fill a casual vacancy or as an addition to the existing Directors. No person shall, unless recommended by the Board, be eligible for election to the office of Director at any general meeting unless during the period, which shall be at least seven days, commencing no earlier than the day after the despatch of the notice of the meeting appointed for such election and ending no later than seven days prior to the date of such meeting, there has been given to the Secretary notice in writing by a member of the Company (not being the person to be proposed), entitled to attend and vote at the meeting for which such notice is given, of his intention to propose such person for election and also notice in writing signed by the person to be proposed of his willingness to be elected.

There is no shareholding qualification for Directors nor is there any specified age limit for Directors.

The office of a Director shall be vacated:

- (i) if he or she resigns his or her office by notice in writing to the Company at its registered office or its principal office in Hong Kong;
- (ii) if an order is made by any competent court or official on the grounds that he or she is or may be suffering from mental disorder or is otherwise incapable of managing his or her affairs and the Directors resolve that his or her office be vacated;
- (iii) if, without leave, he or she is absent from meetings of the Directors (unless an alternate Director appointed by him or her attends) for 12 consecutive months, and the Directors resolve that his or her office be vacated;
- (iv) if he or she becomes bankrupt or has a receiving order made against him or her or suspends payment or compounds with his or her creditors generally;

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- (v) if he or she ceases to be or is prohibited from being a Director by law or by virtue of any provision in the Articles of Association;
- (vi) if he or she is removed from office by notice in writing served upon him or her signed by not less than three-fourths in number (or, if that is not a round number, the nearest lower round number) of the Directors (including himself or herself) for the time being then in office; or
- (vii) if he or she shall be removed from office by an ordinary resolution of the members of the Company under the Articles of Association.

At every annual general meeting of the Company one-third of the Directors for the time being (or, if their number is not three or a multiple of three, then the number nearest to, but not less than, one-third) shall retire from office by rotation, provided that every Director (including those appointed for a specific term) shall be subject to retirement by rotation at least once every three years. The Directors to retire in every year will be those who have been longest in office since their last election but as between persons who became Directors on the same day those to retire shall (unless they otherwise agree between themselves) be determined by lot. Any Director appointed to fill a casual vacancy or as an addition to the existing Directors shall not be taken into account in determining which Directors are to retire by rotation. A retiring Director shall retain office until the close of the meeting at which he or she retires and shall be eligible for re-election thereat. The Company at any annual general meeting at which any Directors retire may fill the vacated office by electing a like number of persons to be Directors.

(i) Borrowing powers

The Directors may from time to time at their discretion exercise all the powers of the Company to raise or borrow or to secure the payment of any sum or sums of money for the purposes of the Company and to mortgage or charge its undertaking, property and assets (present and future) and uncalled capital or any part thereof.

(j) Proceedings of the Board

The Directors may meet together for the despatch of business, adjourn and otherwise regulate their meetings and proceedings as they think fit in any part of the world. Subject to limited exceptions, questions arising at any meeting shall be determined by a majority of votes. In the case of an equality of votes, the chairman of the meeting shall have a second or casting vote.

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2.3. Alteration to constitutional documents

No alteration or amendment to the Memorandum or Articles of Association may be made except by special resolution.

2.4. Variation of rights of existing shares or classes of shares

Subject to the Companies Act, if at any time the share capital is divided into different classes of shares, the rights attaching to the shares or any class of shares may (unless otherwise provided by the terms of issue of the shares of that class) be varied or abrogated only with the consent in writing of three-fourths of the voting rights of the holders of that class, or with the sanction of a Special Resolution passed at a separate general meeting of the holders of the shares of the class. To every such separate general meeting the provisions of the Articles of Association relating to general meetings of the Company shall *mutatis mutandis* apply, but so that:

- (a) the necessary quorum (other than at an adjourned meeting) shall be two persons (or in the case of a member being a corporation, its duly authorized representative) holding or representing by proxy not less than one-third of the issued shares of that class and at any adjourned meeting of such holders, two holders present in person (or in the case of a member being a corporation, its duly authorized representative) or by proxy (whatever the number of shares held by them) shall be a quorum;
- (b) every holder of shares of the class shall be entitled on a poll to one vote for every such share held by him; and
- (c) any holder of shares of the class present in person or by proxy or authorized representative may demand a poll.

The special rights conferred upon the holders of the shares of any class issued with preferred or other rights shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied or abrogated by the creation or issue of further shares ranking *pari passu* therewith or by the redemption or purchase of shares of any class by the Company.

2.5. Alteration of capital

The Company may, from time to time, whether or not all the shares for the time being authorised shall have been issued and whether or not all the shares for the time being issued shall have been fully paid up, by ordinary resolution, increase its share capital by the creation of new shares, such new capital to be of such amount and to be divided into shares of such respective amounts as the resolution shall prescribe.

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The Company may from time to time by ordinary resolution:

- (a) consolidate and divide all or any of its share capital into shares of larger or smaller amount than its existing shares. On any consolidation of fully paid shares and division into shares of larger amount, the Board may settle any difficulty which may arise as it thinks expedient and in particular (but without prejudice to the generality of the foregoing) may as between the holders of shares to be consolidated determine which particular shares are to be consolidated into each consolidated share, and if it shall happen that any person shall become entitled to fractions of a consolidated share or shares, such fractions may be sold by some person appointed by the Board for that purpose and the person so appointed may transfer the shares so sold to the purchaser thereof and the validity of such transfer shall not be questioned, and so that the net proceeds of such sale (after deduction of the expenses of such sale) may either be distributed among the persons who would otherwise be entitled to a fraction or fractions of a consolidated share or shares rateably in accordance with their rights and interests or may be paid to the Company for the Company's benefit;
- (b) divide its shares into several classes and without prejudice to any special rights previously conferred on the holders of existing shares attach thereto respectively any preferential, deferred, qualified or special rights, privileges, conditions or such restrictions which in the absence of any such determination by the Company in general meeting, as the Directors may determine;
- (c) cancel any shares which at the date of the passing of the resolution have not been taken or agreed to be taken by any person, and diminish the amount of its share capital by the amount of the shares so cancelled subject to the provisions of the Companies Act;
- (d) sub-divide its shares or any of them into shares of smaller amount than is fixed by the Memorandum of Association of the Company, subject nevertheless to the provisions of the Companies Act, and so that the resolution whereby any share is sub-divided may determine that, as between the holders of the shares resulting from such sub-division, one or more of the shares may have any such preferred or other special rights, over, or may have such deferred rights or be subject to any such restrictions as compared with the others as the Company has power to attach to unissued or new shares; and
- (e) convert all or any of its paid up shares into stock and reconvert that stock its paid up shares of any denomination.

The Company may by Special Resolutions reduce its share capital or any capital redemption reserve or any other undistributed reserve in any manner authorised and subject to any conditions prescribed by the Companies Act. The Company may apply its share premium account in any manner permitted by the Companies Act.

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2.6. Special resolution – majority required

A “special resolution” is defined in the Articles of Association to mean a resolution passed by the Requisite Majority of such members as, being entitled to do so, vote in person or, in the case of such members being corporations, by their respective duly authorised representatives or, where proxies are allowed, by proxy at a general meeting of the Company of which notice specifying the intention to propose the resolution as a Special Resolution has been duly given in accordance with the Articles of Association and where a poll is taken regard shall be had in computing a majority to the number of votes to which each member is entitled, or a resolution approved in writing by all of the members entitled to vote at a general meeting of the Company in one or more instruments each signed by one or more of the members and the effective date of the Special Resolution so adopted shall be the date on which the instrument or the last of such instruments if more than one is executed. “Requisite Majority” means (a) with respect to a Special Resolution to (i) amend the Memorandum and Articles of Association, (ii) to approve the voluntary winding-up of the Company, and (iii) to approve a variation of the rights attached to shares, a majority of at least three-fourths; and (b) with respect to all other Special Resolutions, a majority of at least two-thirds.

In contrast, an “ordinary resolution” is defined in the Articles of Association to mean a resolution passed by a simple majority of the votes of such members of the Company as, being entitled to do so, vote in person or, in the case of corporations, by their duly authorised representatives or, where proxies are allowed, by proxy at a general meeting held in accordance with the Articles of Association and includes an ordinary resolution approved in writing by all the members of the Company aforesaid.

2.7. Voting rights

Subject to any special rights, privileges or restrictions as to voting for the time being attached to any class or classes of shares, at any general meeting on a show of hands every member present in person (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy shall have one vote and on a poll every member present in person (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy shall have one vote for every share of which he is the holder which is fully paid or credited as fully paid (but so that no amount paid or credited as paid on a share in advance of calls or installments is treated for the foregoing purposes as paid on the share) for each share registered in his name in the register of members of the Company. Notwithstanding anything contained in the Articles of Association, where more than one proxy is appointed by a shareholder which is a clearing house (or its nominees), each such proxy shall have one vote on a show of hands.

On a poll, a member or a proxy entitled to more than one vote need not use all his votes or cast all his votes in the same way. Members of the Company must have the right to: (a) speak at general meetings of the Company; and (b) vote at a general meeting except where a member is required by the Listing Rules to abstain from voting to approve the matter under consideration. An example of such a circumstance is where a member has a material interest in the transaction or arrangement being voted upon.

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Where any member is, under the Listing Rules, required to abstain from voting on any particular resolution or restricted to voting only for or only against any particular resolution, any votes cast by or on behalf of such member whether by proxy or, as the case may be corporate representative in contravention of such requirement or restriction shall not be counted.

Where there are joint registered holders of any share, any one of such persons may vote at any meeting, either personally or by proxy, in respect of such share as if he were solely entitled thereto; but if more than one of such joint holders be present at any meeting personally or by proxy, that one of the said persons so present being the most or, as the case may be, the more senior shall alone be entitled to vote in respect of the relevant joint holding and, for this purpose, seniority shall be determined by reference to the order in which the names of the joint holders stand on the register in respect of the relevant joint holding.

A member in respect of whom an order has been made by any competent court or official on the grounds that he is or may be suffering from mental disorder or is otherwise incapable of managing his affairs may vote by any person authorised in such circumstances to do so, and such person may vote by proxy.

Save as expressly provided in the Articles of Association or as otherwise determined by the Board, no person other than a member duly registered and who shall have paid all sums for the time being due from him payable to the Company in respect of his shares shall be entitled to be present or to vote (save as proxy for another member), or to be reckoned in a quorum, either personally or by proxy at any general meeting.

At any general meeting a resolution put to the vote of the meeting shall be decided on a show of hands unless voting by way of a poll is required by the Listing Rules or (before or on the declaration of the result of the show of hands or on the withdrawal of any other demand for a poll) a poll is demanded:

- (a) by the chairman of such meeting; or
- (b) by at least three members present in person or in the case of a member being a corporation by its duly authorised representative or by proxy for the time being entitled to vote at the meeting; or
- (c) by a member or members present in person or in the case of a member being a corporation by its duly authorised representative or by proxy and representing not less than one-tenth of the total voting rights of all members having the right to vote at the meeting; or

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- (d) by a member or members present in person or in the case of a member being a corporation by its duly authorised representative or by proxy and holding shares in the Company conferring a right to vote at the meeting being shares on which an aggregate sum has been paid up equal to not less than one-tenth of the total sum paid up on all shares conferring that right; or
- (e) if required by the Listing Rules, by any Director or Directors who, individually or collectively, hold proxies in respect of shares representing five per cent. or more of the total voting rights at such meeting.

A demand by a person as proxy for a member or in the case of a member being a corporation by its duly authorised representative shall be deemed to be the same as a demand by a member.

Notwithstanding any other provision of the Articles of Association, where that shareholder is a recognised clearing house (within the meaning of the Securities and Futures Ordinance) or its nominee(s), it may authorise such person or persons as it thinks fit to act as its representative(s) or proxy(ies) at any shareholders' meetings or any meetings of any class of shareholders provided that, if more than one person is so authorised, the authorisation or proxy form must specify the number and class of shares in respect of which each such representative is so authorised. Each person so authorised will be deemed to have been duly authorised without the need of producing any documents of title, notarised authorisation and/or further evidence for substantiating the facts that it is duly authorised and will be entitled to exercise the same power on behalf of the recognised clearing house as that clearing house or its nominee(s) could exercise if it were an individual shareholder of the Company.

2.8. Annual general meetings and extraordinary general meetings

The Company shall in each financial year hold a general meeting as its annual general meeting in addition to any other meeting in that year and shall specify the meeting as such in the notices calling it. So long as the first annual general meeting of the Company is held within 18 months of its incorporation, it need not be held in the year of its incorporation or in the following years. The annual general meeting shall be held at such time and place as the Board shall appoint.

The Board may, whenever it thinks fit, convene an extraordinary general meeting. General meetings shall also be convened and resolutions may be added to a meeting agenda on the written requisition of any two or more members of the Company deposited at the principal office of the Company in Hong Kong or, in the event the Company ceases to have such a principal office, the registered office specifying the objects of the meeting and signed by the requisitionists, provided that such requisitionists held as at the date of deposit of the requisition not less than one-tenth of the paid up capital of the Company which carries the right of voting at general meetings of the Company, on a one vote per

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share basis in the share capital of the Company. General meetings may also be convened on the written requisition of any one member of the Company which is a recognised clearing house (or its nominee(s)) deposited at the principal office of the Company in Hong Kong or, in the event the Company ceases to have such a principal office, the registered office specifying the objects of the meeting and signed by the requisitioner, provided that such requisitioner held as at the date of deposit of the requisition not less than one-tenth of the paid up capital of the Company which carries the right of voting at general meetings of the Company. If the Board does not within 21 days from the date of deposit of the requisition proceed duly to convene the meeting to be held within a further 21 days, the requisitioner(s) themselves or any of them representing more than one-half of the total voting rights of all of them, may convene the general meeting in the same manner, as nearly as possible, as that in which meetings may be convened by the Board provided that any meeting so convened shall not be held after the expiration of three months from the date of deposit of the requisition, and all reasonable expenses incurred by the requisitioner(s) as a result of the failure of the Board shall be reimbursed to them by the Company.

2.9. *Accounts and audit*

The Board shall cause to be kept such books of account as are necessary to give a true and fair view of the state of the Company's affairs and to show and explain its transactions and otherwise in accordance with the Companies Act. The Board shall cause all such books of account to be retained for a minimum period of five years from the date of which they are prepared.

The Board shall from time to time determine whether, to what extent, at what times and places and under what conditions or regulations, the accounts and books of the Company, or any of them, shall be open to the inspection of the members (other than officers of the Company) and no member shall have any right of inspecting any accounts or books or documents of the Company except as conferred by the Companies Act or any other relevant law or regulation or as authorised by the Board or by the Company in general meeting.

The Board shall, commencing with the first annual general meeting, cause to be prepared and to be laid before the members of the Company at every annual general meeting a profit and loss account for the period, in the case of the first account, since the incorporation of the Company and, in any other case, since the preceding account, together with a balance sheet as at the date to which the profit and loss account is made up and a Directors' report with respect to the profit or loss of the Company for the period covered by the profit and loss account and the state of the Company's affairs as at the end of such period, an Auditors' report on such accounts prepared pursuant to the Articles of Association and such other reports and accounts as may be required by law. Copies of those documents to be laid before the members of the Company at an annual general meeting shall not less than 21 days before the date of the meeting be sent in the manner

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in which notices may be served by the Company as provided herein to every member of the Company and every holder of debentures of the Company, provided that the Company shall not be required to send copies of those documents to any person of whose address the Company is not aware or to more than one of the joint holders of any shares or debentures.

2.10. Auditors

The Company shall at each annual general meeting appoint one or more firms of auditors to hold office until the conclusion of the next annual general meeting on such terms and with such duties as may be agreed with the Board, but if an appointment is not made, the Auditors in office shall continue in office until a successor is appointed. A Director, officer or employee of any such Director, officer or employee shall not be appointed as Auditors of the Company. The Board may fill any casual vacancy in the office of Auditors but while any such vacancy continues the surviving or continuing Auditors (if any) may act. The appointment, removal and remuneration of the Auditors must be approved by a majority of the Company's members in the annual general meeting except that in any particular year the Company in general meeting may delegate the fixing of such remuneration to the Board and the remuneration of any Auditors appointed to fill any casual vacancy may be fixed by the Board.

The members may, at any general meeting convened and held in accordance with these Articles, remove the Auditors by Special Resolution at any time before the expiration of the term of office and shall, by ordinary resolution, at that meeting appoint new auditors in its place for the remainder of the term.

2.11. Notice of meetings and business to be conducted thereat

An annual general meeting and any extraordinary general meeting called for the passing of a Special Resolution shall be called by not less than 21 days' notice in writing and any other extraordinary general meeting shall be called by not less than 14 days' notice in writing. Subject to the requirement under the Listing Rules, the notice shall be inclusive of the day on which it is served or deemed to be served and of the day for which it is given, and shall specify the time, place, and agenda of the meeting, particulars of the resolutions to be considered at the meeting and in the case of special business (as defined in the Articles of Association) the general nature of that business. The notice convening an annual general meeting shall specify the meeting as such, and the notice convening a meeting to pass a Special Resolution shall specify the intention to propose the resolution as a Special Resolution. Notice of every general meeting shall be given to the Auditors and to all members other than such as, under the provisions hereof or the terms of issue of the shares they hold, are not entitled to receive such notice from the Company.

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Notwithstanding that a meeting of the Company is called by shorter notice than that mentioned above, it shall be deemed to have been duly called if it is so agreed:

- (a) in the case of a meeting called as an annual general meeting, by all members of the Company entitled to attend and vote thereat or their proxies; and
- (b) in the case of any other meeting, by a majority in number of the members having a right to attend and vote at the meeting, being a majority together holding not less than 95% in nominal value of the shares giving that right.

If, after the notice of a general meeting has been sent but before the meeting is held, or after the adjournment of a general meeting but before the adjourned meeting is held (whether or not notice of the adjourned meeting is required), the Directors, in their absolute discretion, consider that it is impractical or unreasonable for any reason to hold a general meeting on the date or at the time and place specified in the notice calling such meeting, it may change or postpone the meeting to another date, time and place.

The Directors also have the power to provide in every notice calling a general meeting that in the event of a gale warning or a black rainstorm warning is in force at any time on the day of the general meeting (unless such warning is cancelled at least a minimum period of time prior to the general meeting as the Directors may specify in the relevant notice), the meeting shall be postponed without further notice to be reconvened on a later date. Where a general meeting is so postponed, the Company shall endeavour to cause a notice of such postponement to be placed on the Company's website and published on the Stock Exchange's website as soon as practicable, but failure to place or publish such notice shall not affect the automatic postponement of such meeting.

Where a general meeting is postponed:

- (a) the Directors shall fix the date, time and place for the reconvened meeting and at least seven clear days' notice shall be given for the reconvened meeting; and such notice shall specify the date, time and place at which the postponed meeting will be reconvened and the date and time by which proxies shall be submitted in order to be valid at such reconvened meeting (provided that any proxy submitted for the original meeting shall continue to be valid for the reconvened meeting unless revoked or replaced by a new proxy); and
- (b) notice of the business to be transacted at the reconvened meeting shall not be required, nor shall any accompanying documents be required to be recirculated, provided that the business to be transacted at the reconvened meeting is the same as that set out in the notice of the original meeting circulated to the members of the Company.

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2.12. Transfer of shares

Any member may transfer all or any of his shares by an instrument of transfer in the usual or common form or in a form prescribed by the Exchange or in any other form approved by the Board and may be under hand or, if the transferor or transferee is a clearing house or its nominee(s), by hand or by machine imprinted signature or by such other manner of execution as the Board may approve from time to time.

The instrument of transfer shall be executed by or on behalf of the transferor and the transferee provided that the Board of Directors may dispense with the execution of the instrument of transfer by the transferee in any case which it thinks fit in its discretion to do so. The transferor shall be deemed to remain the holder of the share until the name of the transferee is entered in the register of members in respect thereof. Notwithstanding the foregoing, transfers of shares which are [REDACTED] on the Exchange may be effected by any method of transferring or [REDACTED] in securities permitted by the Listing Rules and which has been approved by the Board for such purpose.

Fully paid Shares shall be free from any restriction with respect to the right of the holder thereof to transfer such Shares (except when permitted by the Exchange). The Board of Directors may, in its absolute discretion, and without giving any reason therefor, refuse to register a transfer of any share (not being a fully paid up share) to a person of whom it does not approve, or any share issued under any share incentive scheme for employees upon which a restriction on transfer imposed thereby still subsists, and it may also, without prejudice to the foregoing generality, refuse to register a transfer of any share to more than four joint holders or a transfer of any share (not being a fully paid up share) on which the Company has a lien.

The Directors may also decline to register any transfer of any shares unless:

- (a) the instrument of transfer is lodged with the Company accompanied by the certificate for the shares to which it relates (which shall upon registration of the transfer be cancelled) and such other evidence as the Board may reasonably require to show the right of the transferor to make the transfer;
- (b) the instrument of transfer is in respect of only one class of shares;
- (c) the instrument of transfer is properly stamped (in circumstances where stamping is required); and
- (d) a fee of such maximum as the Exchange may from time to time determine to be payable (or such lesser sum as the Board may from time to time require) is paid to the Company in respect thereof.

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If the Directors refuse to register a transfer of any share they shall, within two months after the date on which the transfer was lodged with the Company, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, on 10 business days' notice (or on 6 business days' notice in the case of a rights issue) being given by advertisement published on the Stock Exchange's website, or, subject to the Listing Rules, by electronic communication in the manner in which notices may be served by the Company by electronic means as provided in the Articles of Association or by advertisement published in the newspapers, be suspended and the register of members of the Company closed at such times for such periods as the Directors may from time to time determine, provided that the registration of transfers shall not be suspended or the register closed for more than 30 days in any year (or such longer period as the members of the Company may by ordinary resolution determine provided that such period shall not be extended beyond 60 days in any year).

2.13. Power of the Company to purchase its own shares

The Company is empowered by the Companies Act and the Articles of Association to purchase its own shares subject to certain restrictions and the Directors may only exercise this power on behalf of the Company subject to the authority of its members in general meeting as to the manner in which they do so and to any applicable requirements imposed from time to time by the Stock Exchange and the Securities and Futures Commission of Hong Kong. Shares which have been repurchased will be treated as cancelled upon the repurchase.

2.14. Power of any subsidiary of the Company to own shares

There are no provisions in the Articles of Association relating to the ownership of shares by a subsidiary.

2.15. Dividends and other methods of distribution

Subject to the Companies Act and the Articles of Association, the Company in general meeting may declare dividends in any currency but no dividends shall exceed the amount recommended by the Directors. No dividend may be declared or paid other than out of profits and reserves of the Company lawfully available for distribution, including share premium.

Unless and to the extent that the rights attached to any shares or the terms of issue thereof otherwise provide, all dividends shall (as regards any shares not fully paid throughout the period in respect of which the dividend is paid) be apportioned and paid pro rata according to the amounts paid up on the shares during any portion or portions of the period in respect of which the dividend is paid. For these purposes, no amount paid up on a share in advance of calls shall be treated as paid up on the share.

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The Directors may from time to time pay to the members of the Company such interim dividends as appear to the Directors to be justified by the profits of the Company. The Directors may also pay half-yearly or at other intervals to be selected by them any dividend which may be payable at a fixed rate if they are of the opinion that the profits available for distribution justify the payment.

The Directors may retain any dividends or other monies payable on or in respect of a share upon which the Company has a lien, and may apply the same in or towards satisfaction of the debts, liabilities or engagements in respect of which the lien exists. The Directors may also deduct from any dividend or other monies payable to any member of the Company all sums of money (if any) presently payable by him or her to the Company on account of calls, instalments or otherwise.

No dividend shall carry interest against the Company.

Whenever the Directors or the Company in general meeting have resolved that a dividend be paid or declared on the share capital of the Company, the Directors may further resolve: (a) that such dividend be satisfied wholly or in part in the form of an allotment of shares credited as fully paid up on the basis that the shares so allotted are to be of the same class as the class already held by the allottee, provided that the members of the Company entitled thereto will be entitled to elect to receive such dividend (or part thereof) in cash in lieu of such allotment; or (b) that the members of the Company entitled to such dividend will be entitled to elect to receive an allotment of shares credited as fully paid up in lieu of the whole or such part of the dividend as the Directors may think fit on the basis that the shares so allotted are to be of the same class as the class already held by the allottee. The Company may upon the recommendation of the Directors by ordinary resolution resolve in respect of any one particular dividend of the Company that notwithstanding the foregoing a dividend may be satisfied wholly in the form of an allotment of shares credited as fully paid without offering any right to members of the Company to elect to receive such dividend in cash in lieu of such allotment.

Any dividend, interest or other sum payable in cash to a holder of shares may be paid by cheque or warrant sent through the post addressed to the registered address of the member of the Company entitled, or in the case of joint holders, to the registered address of the person whose name stands first in the register of members of the Company in respect of the joint holding or to such person and to such address as the holder or joint holders may in writing direct. Every cheque or warrant so sent shall be made payable to the order of the holder or, in the case of joint holders, to the order of the holder whose name stands first on the register of members of the Company in respect of such shares, and shall be sent at his, her or their risk and the payment of any such cheque or warrant by the bank on which it is drawn shall operate as a good discharge to the Company in respect of the dividend and/or bonus represented thereby, notwithstanding that it may subsequently appear that the same has been stolen or that any endorsement thereon has been forged. The Company may cease sending such cheques for dividend entitlements or dividend warrants by post if such cheques or warrants have been left uncashed on two

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consecutive occasions. However, the Company may exercise its power to cease sending cheques for dividend entitlements or dividend warrants after the first occasion on which such a cheque or warrant is returned undelivered. Any one of two or more joint holders may give effectual receipts for any dividends or other monies payable or property distributable in respect of the shares held by such joint holders.

Any dividend unclaimed for six years from the date of declaration of such dividend may be forfeited by the Directors and shall revert to the Company.

The Directors may, with the sanction of the members of the Company in general meeting, direct that any dividend be satisfied wholly or in part by the distribution of specific assets of any kind, and in particular of paid up shares, debentures or warrants to subscribe securities of any other company, and where any difficulty arises in regard to such distribution the Directors may settle it as they think expedient, and in particular may disregard fractional entitlements, round the same up or down or provide that the same shall accrue to the benefit of the Company, and may fix the value for distribution of such specific assets and may determine that cash payments shall be made to any members of the Company upon the footing of the value so fixed in order to adjust the rights of all parties, and may vest any such specific assets in trustees as may seem expedient to the Directors.

2.16. Proxies

Any member of the Company entitled to attend and vote at a meeting of the Company shall be entitled to appoint another person who must be an individual as his or her proxy to attend and vote instead of him or her and a proxy so appointed shall have the same right as the member to speak at the meeting. A proxy need not be a member of the Company.

Instruments of proxy shall be in common form or in such other form as the Directors may from time to time approve provided that it shall enable a member to instruct his or her proxy to vote in favour of or against (or in default of instructions or in the event of conflicting instructions, to exercise his or her discretion in respect of) each resolution to be proposed at the meeting to which the form of proxy relates. The instrument of proxy shall be deemed to confer authority to vote on any amendment of a resolution put to the meeting for which it is given as the proxy thinks fit. The instrument of proxy shall, unless the contrary is stated therein, be valid as well for any adjournment of the meeting as for the meeting to which it relates provided that the meeting was originally held within 12 months from such date.

The instrument appointing a proxy shall be in writing under the hand of the appointor or his or her attorney authorised in writing or if the appointor is a corporation either under its seal or under the hand of an officer, attorney or other person authorised to sign the same.

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The instrument appointing a proxy and (if required by the Directors) the power of attorney or other authority (if any) under which it is signed, or a notarially certified copy of such power or authority, shall be delivered at the registered office of the Company (or at such other place as may be specified in the notice convening the meeting or in any notice of any adjournment or, in either case, in any document sent therewith) not less than 48 hours before the time appointed for holding the meeting or adjourned meeting at which the person named in the instrument proposes to vote or, in the case of a poll taken subsequently to the date of a meeting or adjourned meeting, not less than 48 hours before the time appointed for the taking of the poll and in default the instrument of proxy shall not be treated as valid. No instrument appointing a proxy shall be valid after the expiration of 12 months from the date named in it as the date of its execution. Delivery of any instrument appointing a proxy shall not preclude a member of the Company from attending and voting in person at the meeting or poll concerned and, in such event, the instrument appointing a proxy shall be deemed to be revoked.

Notwithstanding any other provision of the Articles of Association, where that shareholder is a recognised clearing house (within the meaning of the Securities and Futures Ordinance) or its nominee(s), it may authorise such person or persons as it thinks fit to act as its representative(s) or proxy(ies) at any shareholders' meetings or any meetings of any class of shareholders provided that, if more than one person is so authorised, the authorisation or proxy form must specify the number and class of shares in respect of which each such representative is so authorised. Each person so authorised will be deemed to have been duly authorised without the need of producing any documents of title, notarised authorisation and/or further evidence for substantiating the facts that it is duly authorised and will be entitled to exercise the same power on behalf of the recognised clearing house as that clearing house or its nominee(s) could exercise if it were an individual shareholder of the Company.

2.17. Calls on shares and forfeiture of shares

The Directors may from time to time make calls upon the members of the Company in respect of any monies unpaid on their shares (whether on account of the nominal amount of the shares or by way of premium or otherwise) and not by the conditions of allotment thereof made payable at fixed times and each member of the Company shall (subject to the Company serving upon him or her at least 14 days' notice specifying the time and place of payment and to whom such payment shall be made) pay to the person at the time and place so specified the amount called on his or her shares. A call may be revoked or postponed as the Directors may determine. A person upon whom a call is made shall remain liable on such call notwithstanding the subsequent transfer of the shares in respect of which the call was made.

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A call may be made payable either in one sum or by instalments and shall be deemed to have been made at the time when the resolution of the Directors authorising the call was passed. The joint holders of a share shall be jointly and severally liable to pay all calls and instalments due in respect of such share or other monies due in respect thereof.

If a sum called in respect of a share shall not be paid before or on the day appointed for payment thereof, the person from whom the sum is due shall pay interest on the sum from the day appointed for payment thereof to the time of actual payment at such rate, not exceeding 20% per annum, as the Directors may determine, but the Directors shall be at liberty to waive payment of such interest wholly or in part.

If any call or instalment of a call remains unpaid on any share after the day appointed for payment thereof, the Directors may at any time during such time as any part thereof remains unpaid serve a notice on the holder of such shares requiring payment of so much of the call or instalment as is unpaid together with any interest which may be accrued and which may still accrue up to the date of actual payment.

The notice shall name a further day (not being less than 14 days from the date of service of the notice) on or before which, and the place where, the payment required by the notice is to be made, and shall state that in the event of non-payment at or before the time and at the place appointed, the shares in respect of which such call was made or instalment is unpaid will be liable to be forfeited.

If the requirements of such notice are not complied with, any share in respect of which such notice has been given may at any time thereafter, before payment of all calls or instalments and interest due in respect thereof has been made, be forfeited by a resolution of the Directors to that effect. Such forfeiture shall include all dividends and bonuses declared in respect of the forfeited shares and not actually paid before the forfeiture. A forfeited share shall be deemed to be the property of the Company and may be re-allotted, sold or otherwise disposed of.

A person whose shares have been forfeited shall cease to be a member of the Company in respect of the forfeited shares but shall, notwithstanding the forfeiture, remain liable to pay to the Company all monies which at the date of forfeiture were payable by him or her to the Company in respect of the shares, together with (if the Directors shall in their discretion so require) interest thereon at such rate not exceeding 20% per annum as the Directors may prescribe from the date of forfeiture until payment, and the Directors may enforce payment thereof without being under any obligation to make any allowance for the value of the shares forfeited, at the date of forfeiture.

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2.18. Inspection of register of members

The register of members of the Company shall be kept in such manner as to show at all times the members of the Company for the time being and the shares respectively held by them. The register may, on 10 business days' notice (or on 6 business days' notice in the case of a rights issue) being given by advertisement published on the Stock Exchange's website, or, subject to the Listing Rules, by electronic communication in the manner in which notices may be served by the Company by electronic means as provided in the Articles of Association or by advertisement published in the newspapers, be closed at such times and for such periods as the Directors may from time to time determine either generally or in respect of any class of shares, provided that the register shall not be closed for more than 30 days in any year (or such longer period as the members of the Company may by ordinary resolution determine provided that such period shall not be extended beyond 60 days in any year).

Any register of members kept in Hong Kong shall during normal business hours (subject to such reasonable restrictions as the Directors may impose) be open to inspection by any member of the Company without charge and by any other person on payment of fee not exceeding HK\$2.50 (or such higher amount as may from time to time be permitted under the Listing Rules) as the Directors may determine for each inspection.

2.19. Quorum for meetings and separate class meetings

No business shall be transacted at any general meeting unless a quorum is present when the meeting proceeds to business, but the absence of a quorum shall not preclude the appointment, choice or election of a chairman which shall not be treated as part of the business of the meeting.

Two members of the Company present in person or by proxy shall be a quorum provided always that if the Company has only one member of record the quorum shall be that one member present in person or by proxy.

A corporation being a member of the Company shall be deemed for the purpose of the Articles of Association to be present in person if represented by its duly authorised representative being the person appointed by resolution of the directors or other governing body of such corporation or by power of attorney to act as its representative at the relevant general meeting of the Company or at any relevant general meeting of any class of members of the Company.

The quorum for a separate general meeting of the holders of a separate class of shares of the Company is described in paragraph 2.4 above.

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2.20. Rights of minorities in relation to fraud or oppression

There are no provisions in the Articles of Association concerning the rights of minority shareholders in relation to fraud or oppression.

2.21. Procedure on liquidation

If the Company shall be wound up, and the assets available for distribution amongst the members of the Company as such shall be insufficient to repay the whole of the paid-up capital, such assets shall be distributed so that, as nearly as may be, the losses shall be borne by the members of the Company in proportion to the capital paid up, or which ought to have been paid up, at the commencement of the winding up on the shares held by them respectively. If in a winding up the assets available for distribution amongst the members of the Company shall be more than sufficient to repay the whole of the capital paid up at the commencement of the winding up, the excess shall be distributed amongst the members of the Company in proportion to the capital paid up at the commencement of the winding up on the shares held by them respectively. The foregoing is without prejudice to the rights of the holders of shares issued upon special terms and conditions.

If the Company shall be wound up, the liquidator may with the sanction of a special resolution of the Company and any other sanction required by the Companies Act, divide amongst the members of the Company in specie or kind the whole or any part of the assets of the Company (whether they shall consist of property of the same kind or not) and may, for such purpose, set such value as he or she deems fair upon any property to be divided as aforesaid and may determine how such division shall be carried out as between the members or different classes of members of the Company. The liquidator may, with the like sanction, vest the whole or any part of such assets in trustees upon such trusts for the benefit of the members of the Company as the liquidator, with the like sanction and subject to the Companies Act, shall think fit, but so that no member of the Company shall be compelled to accept any assets, shares or other securities in respect of which there is a liability.

2.22. Untraceable members

The Company shall be entitled to sell any shares of a member of the Company or the shares to which a person is entitled by virtue of transmission on death or bankruptcy or operation of law if: (a) all cheques or warrants, not being less than three in number, for any sums payable in cash to the holder of such shares have remained uncashed for a period of 12 years; (b) the Company has not during that time or before the expiry of the three-month period referred to in (d) below received any indication of the whereabouts or existence of the member; (c) during the 12-year period, at least three dividends in respect of the shares in question have become payable and no dividend during that period has been claimed by the member; and (d) upon expiry of the 12-year period, the Company has caused an advertisement to be published in the newspapers or subject to the Listing Rules, by electronic communication in the manner in which notices may be served by the

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Company by electronic means as provided in the Articles of Association, giving notice of its intention to sell such shares and a period of three months has elapsed since such advertisement and the Stock Exchange has been notified of such intention. The net proceeds of any such sale shall belong to the Company and upon receipt by the Company of such net proceeds it shall become indebted to the former member for an amount equal to such net proceeds.

SUMMARY OF CAYMAN ISLANDS COMPANIES ACT AND TAXATION

1. Introduction

The Companies Act is derived, to a large extent, from the older Companies Acts of England, although there are significant differences between the Companies Act and the current Companies Act of England. Set out below is a summary of certain provisions of the Companies Act, although this does not purport to contain all applicable qualifications and exceptions or to be a complete review of all matters of corporate law and taxation which may differ from equivalent provisions in jurisdictions with which interested parties may be more familiar.

2. Incorporation

The Company was incorporated in the Cayman Islands as an exempted company with limited liability on 1 November 2018 under the Companies Act. As such, its operations must be conducted mainly outside the Cayman Islands. The Company is required to file an annual return each year with the Registrar of Companies of the Cayman Islands and pay a fee which is based on the size of its authorised share capital.

3. Share Capital

The Companies Act permits a company to issue ordinary shares, preference shares, redeemable shares or any combination thereof.

The Companies Act provides that where a company issues shares at a premium, whether for cash or otherwise, a sum equal to the aggregate amount of the value of the premia on those shares shall be transferred to an account called the "share premium account." At the option of a company, these provisions may not apply to premia on shares of that company allotted pursuant to any arrangement in consideration of the acquisition or cancellation of shares in any other company and issued at a premium. The Companies Act provides that the share premium account may be applied by a company, subject to the provisions, if any, of its memorandum and articles of association, in such manner as the company may from time to time determine including, but without limitation:

- (a) paying distributions or dividends to members;
- (b) paying up unissued shares of the company to be issued to members as fully paid bonus shares;

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- (c) in the redemption and repurchase of shares (subject to the provisions of section 37 of the Companies Act);
- (d) writing-off the preliminary expenses of the company;
- (e) writing-off the expenses of, or the commission paid, or discount allowed on, any issue of shares or debentures of the company; and
- (f) providing for the premium payable on redemption or purchase of any shares or debentures of the company.

No distribution or dividend may be paid to members out of the share premium account unless immediately following the date on which the distribution or dividend is proposed to be paid the company will be able to pay its debts as they fall due in the ordinary course of business.

The Companies Act provides that, subject to confirmation by the Grand Court of the Cayman Islands, a company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, by special resolution reduce its share capital in any way.

Subject to the detailed provisions of the Companies Act, a company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, issue shares which are to be redeemed or are liable to be redeemed at the option of the company or a shareholder. In addition, such a company may, if authorised to do so by its articles of association, purchase its own shares, including any redeemable shares. However, if the articles of association do not authorize the manner of purchase, a company cannot purchase any of its own shares unless the manner of purchase has first been authorised by an ordinary resolution of the company. The articles of association may provide that the manner of purchase may be determined by the directors of the company. At no time may a company redeem or purchase its shares unless they are fully paid. A company may not redeem or purchase any of its shares if, as a result of the redemption or purchase, there would no longer be any member of the company holding shares. A payment out of capital by a company for the redemption or purchase of its own shares is not lawful unless immediately following the date on which the payment is proposed to be made, the company shall be able to pay its debts as they fall due in the ordinary course of business.

There is no statutory restriction in the Cayman Islands on the provision of financial assistance by a company to another person for the purchase of, or subscription for, its own or its holding company's shares. Accordingly, a company may provide financial assistance if the directors of the company consider, in discharging their duties of care and to act in good faith, for a proper purpose and in the interests of the company, that such assistance can properly be given. Such assistance should be on an arm's-length basis.

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4. Dividends and Distributions

With the exception of section 34 of the Companies Act, there are no statutory provisions relating to the payment of dividends. Based upon English case law which is likely to be persuasive in the Cayman Islands in this area, dividends may be paid only out of profits. In addition, section 34 of the Companies Act permits, subject to a solvency test and the provisions, if any, of the company's memorandum and articles of association, the payment of dividends and distributions out of the share premium account (see paragraph 3 above for details).

5. Shareholders' Suits

The Cayman Islands courts can be expected to follow English case law precedents. The rule in *Foss v. Harbottle* (and the exceptions thereto which permit a minority shareholder to commence a class action against or derivative actions in the name of the company to challenge (a) an act which is ultra vires the company or illegal, (b) an act which constitutes a fraud against the minority where the wrongdoers are themselves in control of the company, and (c) an action which requires a resolution with a qualified (or special) majority which has not been obtained) has been applied and followed by the courts in the Cayman Islands.

6. Protection of Minorities

In the case of a company (not being a bank) having a share capital divided into shares, the Grand Court of the Cayman Islands may, on the application of members holding not less than one-fifth of the shares of the company in issue, appoint an inspector to examine into the affairs of the company and to report thereon in such manner as the Grand Court shall direct.

Any shareholder of a company holding fully-paid shares may petition the Grand Court of the Cayman Islands which may make a winding up order if the court is of the opinion that it is just and equitable that the company should be wound up.

Claims against a company by its shareholders must, as a general rule, be based on the general laws of contract or tort applicable in the Cayman Islands or their individual rights as shareholders as established by the company's memorandum and articles of association.

The English common law rule that the majority will not be permitted to commit a fraud on the minority has been applied and followed by the courts of the Cayman Islands.

7. Disposal of Assets

The Companies Act contains no specific restrictions on the powers of directors to dispose of assets of a company. As a matter of general law, every officer of a company, which includes a director, managing director and secretary is required, in exercising his or her powers and discharging his or her duties must do so honestly and in good faith with a view to the best interests of the company and exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.

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8. Accounting and Auditing Requirements

The Companies Act requires that a company shall cause to be kept proper books of account with respect to:

- (a) all sums of money received and expended by the company and the matters in respect of which the receipt and expenditure takes place;
- (b) all sales and purchases of goods by the company; and
- (c) the assets and liabilities of the company.

A company is required to keep such books of account as are necessary to give a true and fair view of the state of the company's affairs and to explain its transactions and shall cause all books of account to be retained for a minimum period of 5 years from the date on which they are prepared.

9. Register of Members

An exempted company may, subject to the provisions of its articles of association, maintain its principal register of members and any branch registers at such locations, whether within or without the Cayman Islands, as its directors may from time to time think fit. There is no requirement under the Companies Act for an exempted company to make any returns of members to the Registrar of Companies of the Cayman Islands. The names and addresses of the members are, accordingly, not a matter of public record and are not available for public inspection. However, (i) an exempted company shall make available, at its registered office, in electronic form or any other medium, such register of members, including any branch register of members, as may be required of it upon service of an order or notice by the Tax Information Authority pursuant to the Tax Information Authority Act (As Revised) of the Cayman Islands, and (ii) unless exempted, a company has an obligation to maintain a register of its beneficial owners pursuant to the Beneficial Ownership Transparency Act 2023 (As Revised), and such register may be accessed by certain authorities as set out in the legislation.

10. Register of Directors

A register containing the names and addresses of its directors and officers must be maintained at the registered office in the Cayman Islands, and the company must notify the Registrar of Companies of any change in such directors or officers including a change of the name of such directors or officers within sixty days of any such change.

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11. Register of Mortgages and Charges

A company must maintain a register of all mortgages and charges specifically affecting property of the company, and shall enter in such register in respect of each mortgage or charge a short description of the property mortgaged or charged, the amount of charge created and the names of the mortgagees or persons entitled to such charge. The register of mortgages and charges shall be open to inspection by any creditor or member of the company at all reasonable times.

12. Inspection of Books and Records

Members of a company will have no general right under the Companies Act to inspect or obtain copies of the register of members or corporate records of the company. They will, however, have such rights as may be set out in the company's articles of association.

13. Special Resolutions

The Companies Act provides that a resolution is a special resolution when it has been passed by a majority of at least two-thirds of such members as, being entitled to do so, vote in person or, where proxies are allowed, by proxy at a general meeting of which notice specifying the intention to propose the resolution as a special resolution has been duly given, except that a company may in its articles of association specify that the required majority shall be a number greater than two-thirds, and may additionally so provide that such majority (being not less than two-thirds) may differ as between matters required to be approved by a special resolution. Written resolutions signed by all the members entitled to vote for the time being of the company may take effect as special resolutions if this is authorised by the articles of association of the company.

14. Subsidiary Owning Shares in Parent

The Companies Act does not prohibit a Cayman Islands company acquiring and holding shares in its parent company provided its objects so permit. The directors of any subsidiary making such acquisition must discharge their duties of care and to act in good faith, for a proper purpose and in the interests of the subsidiary.

15. Mergers and Consolidations

The Companies Act permits mergers and consolidations between Cayman Islands companies and between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (a) "merger" means the merging of two or more constituent companies and the vesting of their undertaking, property and liabilities in one of such companies as the surviving company, and (b) "consolidation" means the combination of two or more constituent companies into a consolidated company and the vesting of the undertaking, property and liabilities of such companies to the consolidated company. In order to effect such a merger or

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consolidation, the directors of each constituent company must approve a written plan of merger or consolidation, which must then be authorised by (a) a special resolution of each constituent company and (b) such other authorisation, if any, as may be specified in such constituent company's articles of association. The written plan of merger or consolidation must be filed with the Registrar of Companies of the Cayman Islands together with a declaration as to the solvency of the consolidated or surviving company, a list of the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette. Dissenting shareholders have the right to be paid the fair value of their shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) if they follow the required procedures, subject to certain exceptions. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

16. Reconstructions

There are statutory provisions which facilitate reconstructions and amalgamations approved by a majority in number representing 75% in value of shareholders or creditors, depending on the circumstances, as are present at a meeting called for such purpose and thereafter sanctioned by the Grand Court of the Cayman Islands. Whilst a dissenting shareholder would have the right to express to the Grand Court his or her view that the transaction for which approval is sought would not provide the shareholders with a fair value for their shares, the Grand Court is unlikely to disapprove the transaction on that ground alone in the absence of evidence of fraud or bad faith on behalf of management and if the transaction were approved and consummated the dissenting shareholder would have no rights comparable to the appraisal rights (i.e. the right to receive payment in cash for the judicially determined value of his or her shares) ordinarily available, for example, to dissenting shareholders of United States corporations.

17. Take-overs

Where an offer is made by a company for the shares of another company and, within four months of the offer, the holders of not less than 90% of the shares which are the subject of the offer accept, the offeror may at any time within two months after the expiration of the said four months, by notice require the dissenting shareholders to transfer their shares on the terms of the offer. A dissenting shareholder may apply to the Grand Court of the Cayman Islands within one month of the notice objecting to the transfer. The burden is on the dissenting shareholder to show that the Grand Court should exercise its discretion, which it will be unlikely to do unless there is evidence of fraud or bad faith or collusion as between the offeror and the holders of the shares who have accepted the offer as a means of unfairly forcing out minority shareholders.

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18. Indemnification

Cayman Islands law does not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy (e.g. for purporting to provide indemnification against the consequences of committing a crime).

19. Liquidation

A company may be placed in liquidation compulsorily by an order of the court, or voluntarily (a) by a special resolution of its members if the company is solvent, or (b) by an ordinary resolution of its members if the company is insolvent. The liquidator's duties are to collect the assets of the company (including the amount (if any) due from the contributories (shareholders)), settle the list of creditors and discharge the company's liability to them, rateably if insufficient assets exist to discharge the liabilities in full, and to settle the list of contributories and divide the surplus assets (if any) amongst them in accordance with the rights attaching to the shares.

20. Stamp Duty on Transfers

No stamp duty is payable in the Cayman Islands on transfers of shares of Cayman Islands companies except those which hold interests in land in the Cayman Islands.

21. Taxation

Pursuant to section 6 of the Tax Concessions Act (2018 Revision) of the Cayman Islands, the Company may obtain an undertaking from the Financial Secretary of the Cayman Islands:

- (a) that no law which is enacted in the Cayman Islands imposing any tax to be levied on profits, income, gains or appreciations shall apply to the Company or its operations; and
- (b) in addition, that no tax to be levied on profits, income, gains or appreciations or which is in the nature of estate duty or inheritance tax shall be payable:
 - (i) on or in respect of the shares, debentures or other obligations of the Company;
or
 - (ii) by way of the withholding in whole or in part of any relevant payment as defined in section 6(3) of the Tax Concessions Act (2018 Revision).

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The Cayman Islands currently levy no taxes on individuals or corporations based upon profits, income, gains or appreciations and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to the Company levied by the Government of the Cayman Islands save certain stamp duties which may be applicable, from time to time, on certain instruments executed in or brought within the jurisdiction of the Cayman Islands. The Cayman Islands are not party to any double tax treaties that are applicable to any payments made by or to the Company.

22. Exchange Control

There are no exchange control regulations or currency restrictions in the Cayman Islands.

23. General

Travers Thorp Alberga, the Company's legal adviser on Cayman Islands law, have sent to the Company a letter of advice summarising aspects of Cayman Islands company law. This letter, together with a copy of the Companies Act, is available for inspection as referred to in the section headed "Documents Delivered to the Registrar of Companies in Hong Kong and on Display" in Appendix V. Any person wishing to have a detailed summary of Cayman Islands company law or advice on the differences between it and the laws of any jurisdiction with which he or she is more familiar is recommended to seek independent legal advice.

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A. FURTHER INFORMATION ABOUT OUR GROUP

1. Incorporation of our Company

Our Company was incorporated in the Cayman Islands under the Cayman Companies Act as an exempted company with limited liability on November 1, 2018. We have established a principal place of business in Hong Kong at 5/F, Manulife Place 348, Kwun Tong Road, Kowloon, Hong Kong and have been registered as a non-Hong Kong company under Part 16 of the Companies Ordinance on February 23, 2021 under the same address. Ms. CHAN Sze Ting has been appointed as our authorised representative under the Companies Ordinance for the acceptance of service of process and notices on our behalf in Hong Kong.

As we were incorporated in the Cayman Islands, our operations are subject to the relevant laws of the Cayman Islands and our constitution which comprises the Memorandum and the Articles. A summary of certain provisions of our constitution and relevant aspects of the Cayman Companies Act is set forth in Appendix III to this document.

2. Changes in our share capital

As at November 1, 2018, being the date of incorporation of the Company, our authorized share capital was US\$50,000 divided into 500,000,000 Shares with a par value of US\$0.0001 each.

The following sets forth the changes in the share capital of our Company during the two years immediately preceding the date of this document:

- (a) On November 15, 2022, the Company entered into share surrender agreements with VP EIP US and VP EIP NUS, pursuant to which VP EIP US surrendered for no consideration of 2,800,000 non-voting Shares, VP EIP NUS surrendered for no consideration of 7,859,500 non-voting Shares. The surrendered Shares were canceled accordingly on November 16, 2022.

Save as disclosed above, there has been no alteration in our share capital within two years immediately preceding the date of this document.

3. Changes in the share capital of our subsidiaries

A summary of the information on our subsidiaries is set forth in the Accountants' Report, the text of which is set forth in Appendix I to this document.

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The following alterations in the share capital of our subsidiaries have taken place within two years immediately preceding the date of this document:

VISEN Shanghai

On July 20, 2023, the registered share capital of VISEN Shanghai increased from US\$75 million to US\$80 million.

On October 11, 2023, the registered share capital of VISEN Shanghai increased from US\$80 million to US\$95 million.

On July 4, 2024, the registered share capital of VISEN Shanghai increased from US\$95 million to US\$113 million.

VISEN HK

On July 17, 2023, VISEN HK issued 20,000,000 shares to the Company for a consideration of US\$20 million.

On December 21, 2023, VISEN HK issued 6,000,000 shares to the Company for a consideration of US\$6 million.

On July 8, 2024, VISEN HK issued 18,000,000 shares to the Company for a consideration of US\$18 million.

Save as disclosed above, there has been no alteration in the share capital of our subsidiaries that took place within two years preceding the date of this document.

4. Resolutions passed by our Shareholders

Pursuant to the written resolutions passed by our Shareholders on [●], 2024, the following resolutions, among others, were duly passed:

- (a) the Memorandum and Articles of Association were approved and adopted, and will come into effect upon [REDACTED];
- (b) conditional on (1) the [REDACTED] Committee granting the [REDACTED] of, and permission to [REDACTED] in, the Shares in [REDACTED] and to be [REDACTED] as mentioned in this document; and (2) the obligations of the [REDACTED] under the [REDACTED] becoming unconditional and the [REDACTED] not being terminated in accordance with the terms therein or otherwise:
 - (i) the [REDACTED] and the [REDACTED] were approved and our Directors were authorized to effect the same, and to allot and issue the [REDACTED] pursuant to the [REDACTED] and the [REDACTED];

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- (ii) the grant of the [REDACTED] by our Company to the [REDACTED] to allot and issue up to [REDACTED]% of the [REDACTED] initially available under the [REDACTED] to cover, among other things, the [REDACTED] in the [REDACTED] was approved; and
 - (iii) the proposed [REDACTED] was approved, and our Directors were authorized to implement such [REDACTED].
- (c) a general unconditional mandate was granted to our Directors to allot, issue and deal with Shares, and to make or grant [REDACTED], agreements, or options which might require such Shares to be allotted and issued or dealt with at any time subject to the requirement that the aggregate nominal value of the Shares so allotted and issued or agreed conditionally or unconditionally to be allotted and issued, shall not exceed 20% of the aggregate nominal value of the share capital of our Company in issue immediately following completion of the [REDACTED].

This mandate does not cover Shares to be allotted, issued, or dealt with under a rights issue or scrip dividend scheme or similar arrangements, or a specific authority granted by our Shareholders or upon the exercise of the [REDACTED]. This general mandate to issue Shares will remain in effect until:

- (i) the conclusion of the next annual general meeting of our Company;
- (ii) the expiration of the period within which the next annual general meeting of our Company is required to be held under the applicable laws or the Articles of Association; or
- (iii) it is varied or revoked by an ordinary resolution of our Shareholders at a general meeting of our Company;

whichever is the earliest;

- (d) a general unconditional mandate was granted to our Directors to exercise all powers of our Company to repurchase Shares with an aggregate nominal value of not more than 10% of the aggregate nominal value of the share capital of our Company in issue immediately following completion of the [REDACTED] (excluding Shares which may be allotted and issued upon the exercise of the [REDACTED]).

This mandate only relates to repurchase made on the Stock Exchange or on any other stock exchange on which the Shares may be [REDACTED] (and which is recognized by the SFC and the Stock Exchange for this purpose) and made in accordance with all applicable laws and regulations and the requirements of the Listing Rules. This general mandate to repurchase Shares will remain in effect until:

- (i) the conclusion of the next annual general meeting of our Company;

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- (ii) the expiration of the period within which the next annual general meeting of our Company is required to be held under any applicable laws or the Articles of Association; or
- (iii) it is varied or revoked by an ordinary resolution of our Shareholders at a general meeting of our Company;

whichever is the earliest; and

- (e) the general unconditional mandate as mentioned in paragraph (c) above would be extended by the addition to the aggregate nominal value of the Shares which may be allotted and issued or agreed to be allotted and issued by our Directors pursuant to such general mandate of an amount representing the aggregate nominal value of the Shares purchased by our Company pursuant to the mandate to repurchase Shares referred to in paragraph (d) above (up to 10% of the aggregate nominal value of the Shares in issue immediately following completion of the [REDACTED], excluding any Shares which may fall to be allotted and issued pursuant to the exercise of the [REDACTED]).

5. Restrictions on Repurchase

This section sets out information required by the Stock Exchange to be included in this document concerning the repurchase by us of our own Shares.

(a) Provisions of the Listing Rules

The Listing Rules permit companies with a primary listing on the Stock Exchange to repurchase their own Shares on the Stock Exchange subject to certain restrictions, the most important of which are summarized below:

(i) Shareholders' Approval

All proposed repurchase of Shares (which must be fully paid up in the case of shares) by a company with a primary listing on the Stock Exchange must be approved in advance by an ordinary resolution of the shareholders, either by way of general mandate or by specific approval of a particular transaction.

(ii) Source of Funds

Repurchases must be funded out of funds legally available for the purpose in accordance with the constitutive documents of a listed company, the laws of the jurisdiction in which the listed company is incorporated or otherwise established. A listed company may not repurchase its own securities on the Stock Exchange for a consideration other than cash or for settlement otherwise than in accordance with the trading rules of the Stock Exchange from time to time. Subject to the foregoing, any repurchases by a listed company may be made out of the funds which would

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otherwise be available for dividend or distribution or out of the proceeds of a new issue of shares made for the purpose of the repurchase. Any amount of premium payable on the purchase over the par value of the shares to be repurchased must be out of the funds which would otherwise be available for dividend or distribution or from sums standing to the credit of our share premium account.

(iii) Trading Restrictions

The total number of shares which a listed company may repurchase on the Stock Exchange is the number of shares representing up to a maximum of 10% of the aggregate number of shares in issue.

A company may not make a new issue or announce a proposed new issue of shares for a period of 30 days after any repurchase (other than an issue of securities pursuant to an exercise of warrants, share options or similar instruments requiring the listed company to issue securities which were outstanding prior to such repurchase) without the prior approval of the Stock Exchange.

In addition, a listed company is prohibited from repurchasing its shares on the Stock Exchange if the purchase price is 5% or more than the average closing market price for the five preceding trading days on which its shares were traded on the Stock Exchange.

The Listing Rules also prohibit a listed company from repurchasing its securities which are in the hands of the public falling below the relevant prescribed minimum percentage as required by the Stock Exchange.

A company is required to procure that the broker appointed by it to effect a repurchase of securities discloses to the Stock Exchange such information with respect to the repurchase made on behalf of the listed company as the Stock Exchange may require.

A listed company may not make any repurchase of shares after inside information has come to its knowledge until the information is made publicly available. In particular, during the period of one month immediately preceding the earlier of: (i) the date of the board meeting (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of a listed company's results for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules); and (ii) the deadline for a listed company to announce its results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules) and ending on the date of the results announcement, the listed company may not repurchase its shares on the Stock Exchange other than in exceptional circumstances.

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(iv) Status of Repurchased Shares

All repurchased securities (whether effected on the Stock Exchange or otherwise) will be automatically delisted and the certificates for those securities must be cancelled and destroyed.

(v) Reporting Requirements

Certain information relating to repurchases of shares on the Stock Exchange or otherwise must be reported to the Stock Exchange not later than 30 minutes before the earlier of the commencement of the morning trading session or any pre-opening session on the following business day on which the listed company makes a purchase of its shares. The report must state the total number of shares purchased by the listed company the previous day, the purchase price per share or the highest and lowest prices paid for such purchases. In addition, a listed company's annual report is required to disclose details regarding repurchases of shares made during the year, including the number of shares repurchased each month (whether on the Stock Exchange or otherwise), the purchase price per share or the highest and lowest price paid for all such purchases, where relevant, and the aggregate price paid.

(vi) Core Connected Persons

A listed company is prohibited from knowingly repurchasing its shares from a "core connected person," that is, a director, chief executive or substantial shareholder of the company or any of its subsidiaries or their close associates and a core connected person is prohibited from knowingly selling its shares to the company.

(b) Reasons for Repurchase

Our Directors believe that it is in the best interest of us and our Shareholders for our Directors to have general authority from the Shareholders to enable us to repurchase Shares in the market. Such repurchases may, depending on market conditions and funding arrangements at the time, lead to an enhancement of the net asset value per Share and/or [REDACTED] and will only be made where our Directors believe that such repurchases will benefit us and our Shareholders.

(c) Funding of Repurchases

In repurchasing securities, we may only apply funds legally available for such purpose in accordance with the Memorandum of Association and Articles of Association, the Companies Act or other applicable laws of Cayman Islands and the Listing Rules. On the basis of our current financial condition as disclosed in this document and taking into account our current working capital position, our Directors consider that, if the Repurchase Mandate were to be exercised in full, it might have a material adverse effect

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on our working capital and/or our gearing position as compared with the position disclosed in this document. However, our Directors do not propose to exercise the repurchase mandate to such an extent as would, in the circumstances, have a material adverse effect on our working capital requirements or the gearing levels which in the opinion of our Directors are from time to time appropriate for us.

(d) General

Exercise in full of the current repurchase mandate, on the basis of [REDACTED] Shares in issue after completion of the [REDACTED] (without taking into account of the Shares which may be allotted and issued pursuant to the exercise of the [REDACTED]), could accordingly result in up to approximately [REDACTED] Shares being repurchased by us during the period prior to:

- (i) the conclusion of our next annual general meeting;
- (ii) the expiration of the period within which the next annual general meeting of our Company is required by any applicable law or the Articles of Association to be held; or
- (iii) the date on which the repurchase mandate is varied or revoked by an ordinary resolution of our Shareholders in general meeting; whichever is the earliest.

None of our Directors nor, to the best of their knowledge having made all reasonable enquiries, any of their close associates (as defined in the Listing Rules) currently intends to sell any Shares to us or our subsidiaries. Our Directors have undertaken with the Stock Exchange that, so far as the same may be applicable, they will exercise the repurchase mandate in accordance with the Listing Rules, the Memorandum of Association and Articles of Association, the Companies Act or any other applicable laws of the Cayman Islands.

If, as a result of a repurchase of our Shares pursuant to the repurchase mandate, a Shareholder's proportionate interest in our voting rights is increased, such increase will be treated as an acquisition for the purpose of the Takeovers Code. Accordingly, a Shareholder or a group of Shareholders acting in concert could obtain or consolidate control of us and become obliged to make a mandatory offer in accordance with Rule 26 of the Takeovers Code. Save as aforesaid, our Directors are not aware of any consequences which would arise under the Takeovers Code as a consequence of any repurchases pursuant to the repurchase mandate.

No core connected person, as defined in the Listing Rules, has notified us that he/she or it has a present intention to sell his/her or its Shares to us, or has undertaken not to do so, if the repurchase mandate is exercised.

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B. FURTHER INFORMATION ABOUT OUR BUSINESS

1. Summary of material contracts


We have entered into the following contracts (not being contracts entered into in the ordinary course of business) within the two years preceding the date of this document that are or may be material:

- (1) the [REDACTED].

2. Intellectual Property Rights of Our Group

(a) Trademarks

As at the Latest Practicable Date, our Group has registered the following trademarks, which we consider to be or may be material to our business:

No.	Trademark	Owner	Class	Place of Registration	Expiry Date	Registration Number
1	VISEN	VISEN Shanghai	35	PRC	September 6, 2033	46448849
2	VISEN	VISEN Shanghai	35	PRC	April 13, 2032	50914244
3	VISEN	VISEN Shanghai	5	PRC	October 6, 2031	51329106
4	VISEN	VISEN Shanghai	10	PRC	February 6, 2032	58107493
5	维昇	VISEN Shanghai	10	PRC	September 13, 2033	63503436
6	维昇	VISEN Shanghai	5	PRC	October 27, 2032	54815389
7	维昇	VISEN Shanghai	35	PRC	January 6, 2033	54827259
8	维昇	VISEN Shanghai	35	PRC	May 20, 2032	54836276
9	维臻高	VISEN Shanghai	5	PRC	January 27, 2032	58118622
10	维昇笔	VISEN Shanghai	10	PRC	January 27, 2032	58120354
11	VISENPHM	VISEN Shanghai	35	PRC	August 6, 2029	35290153
12	VISENPHM	VISEN Shanghai	5	PRC	August 6, 2029	35301061
13	VISENMED	VISEN Shanghai	5	PRC	August 20, 2029	35440861
14	VISENMED	VISEN Shanghai	35	PRC	August 13, 2029	35444832
15		VISEN Shanghai	10	PRC	May 13, 2034	75054451
16	VISEN	VISEN HK	5, 10 & 35	HK	July 27, 2031	305701509
17	维臻高 (Series)	VISEN HK	5	HK	July 27, 2031	305701383
18	维昇 (Series)	VISEN HK	5, 10 & 35	HK	July 27, 2031	305701491

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As at the Latest Practicable Date, our Group has applied for the registration of the following trademarks, which we consider to be or may be material to our business:

No.	Trademark	Class	Registrant	Place of Registration	Registration No.	Application Date
1.		35	VISEN Shanghai	PRC	58099506	July 30, 2021
2.		35	VISEN Shanghai	PRC	58099518	July 30, 2021
3.		5	VISEN Shanghai	PRC	77141005	March 7, 2024

(b) Patents

The following table sets forth the details of the material granted patents and filed patent applications in connection with our drug candidates:

Patent Application/ Publication Number	Scope of Protection	Jurisdiction	Applicant	Application Date	Status	Expiration date	Rights of the Company
<i>Lonapegsomatropin</i>							
CN101980725B	Cycloheximide bridging agent	CN	ASCENDIS PHARMA AS	January 30, 2009	Granted	January 30, 2029	The Company was granted by the Applicant an exclusive, royalty-free licence (with the right to grant sub-licences) under this patent to develop, manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize licensed product in the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the excluded indications in the PRC, including Hong Kong, Macau and Taiwan.
CN102014965B	PEGylated recombinant human growth hormone compounds	CN	Ascendis Pharma Endocrinology Division	April 29, 2009	Granted	April 29, 2029	
CN102989001B	hGH prodrugs	CN	Ascendis Pharma Endocrinology Division	April 29, 2009	Granted	April 29, 2029	
HK1179899	hGH prodrugs	HK	Ascendis Pharma Endocrinology Division	April 29, 2009	Granted	April 29, 2029	
HK 18100073.0	Polymeric human growth hormone prodrug	HK	Ascendis Pharma Endocrinology Division	November 17, 2015	Granted	November 17, 2035	
HK 18103805.9	Long- Acting Growth Hormone Dosage Forms	HK	Ascendis Pharma Endocrinology Division	November 20, 2015	Granted	November 20, 2035	
CN113573698A (2020800183773)	Pharmaceutical formulation comprising long-acting growth hormone	CN	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S	March 3, 2020	Pending	-	
HK40054591A	Pharmaceutical formulation comprising long-acting growth hormone	HK	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S	November 26, 2021	Pending	-	
HK40061346A	Pharmaceutical formulation comprising long-acting growth hormone	HK	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S	March 30, 2022	Pending	-	
HK1152239A1	Growth Hormone (rhGH)	HK	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S	April 29, 2009	Granted	April 29, 2029	

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Patent Application/ Publication Number	Scope of Protection	Jurisdiction	Applicant	Application Date	Status	Expiration date	Rights of the Company
HK1244227A	Pharmaceutical formulation comprising a long-acting growth hormone	HK	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S	November 20, 2015	Pending	-	
HK1209445A1	Pharmaceutical formulation comprising a long-acting growth hormone (hGH)	HK	ASCENDIS PHARMA A/S	October 8, 2013	Granted	October 8, 2033	
<i>TransCon CNP (navepegritide)</i>							
CN101980725B	Cycloheximide bridging agent	CN	ASCENDIS PHARMA AS	January 30, 2009	Granted	January 30, 2029	The Company was granted by the Applicant an exclusive, royalty-free licence (with the right to grant sub-licences) under this patent to develop, manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize licensed product in the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the excluded indications in the PRC, including Hong Kong, Macau and Taiwan.
HK1152240	Cycloheximide bridging agent	HK	ASCENDIS PHARMA AS	January 30, 2009	Granted	January 30, 2029	
CN107405409B	CNP prodrug or pharmaceutically acceptable salts thereof	CN	Ascendis Pharma Growth Disorders	January 8, 2016	Granted	January 8, 2036	
HK1246666B	CNP prodrug or pharmaceutically acceptable salts thereof	HK	Ascendis Pharma Growth Disorders	January 8, 2016	Granted	January 8, 2036	
CN108472380B	Controlled-release CNP agonist	CN	Ascendis Pharma Growth Disorders	January 5, 2017	Granted	January 5, 2037	
CN 114306629 B (Divisional patent of the CN108472380B)	Controlled-release CNP agonist	CN	Ascendis Pharma Growth Disorders	January 5, 2017	Granted	January 5, 2037	
HK40069215A	Controlled-release CNP agonist	HK	ASCENDIS PHARMA GROWTH DISORDERS A/S	January 5, 2017	Granted	January 5, 2037	
MAEJ/007651	Controlled-release CNP agonist	Macau	ASCENDIS PHARMA GROWTH DISORDERS A/S	January 5, 2017	Granted	January 5, 2037	
HK1259384A	Controlled-release CNP agonist	HK	Ascendis Pharma Growth Disorders	January 5, 2017	Granted	January 5, 2037	
CN108472383B	Controlled-release CNP agonists with low NPR-C binding	CN	Ascendis Pharma Growth Disorders	January 5, 2017	Granted	January 5, 2037	
HK1257769B	Controlled-release CNP agonists with low NPR-C binding	HK	ASCENDIS PHARMA GROWTH DISORDERS A/S	January 4, 2019	Granted	January 4, 2039	
HK1262973A	Controlled-release CNP agonists with low NPR-C binding	HK	Ascendis Pharma Growth Disorders	January 5, 2017	Granted	January 5, 2037	
J/006504	Controlled-release CNP agonists with low NPR-C binding	Macau	Ascendis Pharma Growth Disorders	January 5, 2017	Granted	January 5, 2037	

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<u>Patent Application/ Publication Number</u>	<u>Scope of Protection</u>	<u>Jurisdiction</u>	<u>Applicant</u>	<u>Application Date</u>	<u>Status</u>	<u>Expiration date</u>	<u>Rights of the Company</u>
HK 17103600.7	Hyperbranched polymer conjugates via non-enzymatic cleavable linker	HK	ASCENDIS PHARMA	October 1, 2004	Granted	October 1, 2024	
HK 18100069.6	CNP prodrug	HK	Ascendis Pharma	January 8, 2016	Granted	January 8, 2036	
CN109843295B	CNP combination therapy	CN	Ascendis Pharma	September 28, 2017	Granted	September 28, 2037	
HK40008972A1	CNP combination therapy	HK	Ascendis Pharma	September 28, 2017	Granted	September 28, 2037	
TW202200194A	Dry pharmaceutical formulations of CNP conjugates	Taiwan	Ascendis Pharma	June 19, 2020	Pending	-	
CN113423384B (2020800134620)	Pharmaceutical formulation comprises a CNP conjugate	CN	ASCENDIS PHARMA	February 10, 2020	Granted	February 10, 2040	
HK40052552B	Dry pharmaceutical formulations of CNP conjugates	HK	ASCENDIS PHARMA	November 9, 2021	Granted	November 9, 2041	
CN 117281783 A (2023114269633) Divisional application of CN113423384B	Pharmaceutical formulation comprises a CNP conjugate	CN	ASCENDIS PHARMA	February 10, 2020	Pending	-	
CN115177720A	Controlled release CNP	CN	ASCENDIS PHARMA	January 5, 2017	Pending	-	
HK40074497A	Controlled release CNP	HK	ASCENDIS PHARMA	January 5, 2017	Pending	-	
HK40000047A	Controlled-release CNP agonist	HK	ASCENDIS PHARMA	January 5, 2017	Pending	-	
HK1262967A	Controlled-release CNP agonist	HK	ASCENDIS PHARMA	January 5, 2017	Pending	-	
HK1263063A	Controlled-release CNP agonist	HK	ASCENDIS PHARMA	January 5, 2017	Pending	-	
HK1262548A	CNP prodrugs	HK	ASCENDIS PHARMA	January 5, 2017	Pending	-	
HK1262549A	CNP prodrug	HK	ASCENDIS PHARMA	January 5, 2017	Pending	-	

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Patent Application/ Publication Number	Scope of Protection	Jurisdiction	Applicant	Application Date	Status	Expiration date	Rights of the Company
HK1240818A	CNP prodrugs	HK	ASCENDIS PHARMA GROWTH DISORDERS A/S	January 8, 2016	Pending	-	
J/007895	Dry Pharmaceutical formulations of CNP conjugates	Macau	ASCENDIS PHARMA GROWTH DISORDERS A/S	February 28, 2024	Pending		
Divisional application of CN117281783A CN118382462A	Effective doses of CNP conjugates	CN	ASCENDIS PHARMA GROWTH DISORDERS A/S	December 12, 2022	Pending		
<i>Palopegeteriparatide</i> CN101980725B	Cycloheximide bridging agent	CN	ASCENDIS PHARMA AS	January 30, 2009	Granted	January 30, 2029	The Company was granted by the Applicant an exclusive, royalty-free licence (with the right to grant sub-licences) under this patent to develop, manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize licensed product in the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the excluded indications in the PRC, including Hong Kong, Macau and Taiwan.
HK1152240	Cycloheximide bridging agent	HK	ASCENDIS PHARMA AS	January 30, 2009	Granted	January 30, 2029	
CN109069659B	PTH prodrugs	CN	Ascendis Pharma Bone Diseases	February 28, 2017	Granted	February 28, 2037	
CN115025239A (2022103105298)	PTH prodrugs	CN	Ascendis Pharma Bone Diseases	February 28, 2017	Pending	-	
Divisional application of the patent CN109069659B HK40072521	PTH prodrugs	HK	ASCENDIS PHARMA BONE DISEASES A/S	February 28, 2017	Pending	-	
HK40000751A1	PTH prodrugs	HK	Ascendis Pharma Bone Diseases	February 28, 2017	Granted	February 28, 2037	
J/006258	PTH prodrugs	Macau	Ascendis Pharma Bone Diseases	February 28, 2017	Pending	-	
CN109789221B	Pharmaceutical composition	CN	Ascendis Pharma Bone Diseases	September 28, 2017	Granted	September 28, 2037	
HK40007777A	Pharmaceutical composition	HK	Ascendis Pharma Bone Diseases	September 28, 2017	Pending	-	
CN109789188B	PTH compounds with low peak-to-trough ratios	CN	Ascendis Pharma Bone Diseases	September 28, 2017	Granted	September 28, 2037	
CN 117257922 A (2023110527602)	PTH compounds with low peak-to-trough ratios	CN	Ascendis Pharma Bone Diseases	September 28, 2017	Pending	-	
Divisional application of the patent CN109789188B HK40007965A	PTH compounds with low peak-to-trough ratios	HK	Ascendis Pharma Bone Diseases	September 28, 2017	Pending	-	
CN109789189B (Just received Notice of Allowance)	Controlled release compounds	CN	Ascendis Pharma Bone Diseases	September 28, 2017	Granted	September 28, 2037	

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<u>Patent Application/ Publication Number</u>	<u>Scope of Protection</u>	<u>Jurisdiction</u>	<u>Applicant</u>	<u>Application Date</u>	<u>Status</u>	<u>Expiration date</u>	<u>Rights of the Company</u>
HK40007776A	Dosage regimen for a controlled-release PTH compound	HK	ASCENDIS PHARMA BONE DISEASES A/S	October 18, 2019	Granted	October 18, 2039	
HK40011848A	Controlled release compounds	HK	Ascendis Pharma Bone Diseases	September 28, 2017	Pending	-	
CN112334152A	Starting dose of PTH conjugates	CN	Ascendis Pharma Bone Diseases	May 17, 2019	Pending	-	
HK40046206A	Starting dose of PTH conjugates	HK	Ascendis Pharma Bone Diseases	May 17, 2019	Pending	-	
TW202200195A	Liquid formulation of PTH conjugate	Taiwan	Ascendis Pharma Bone Diseases	June 19, 2020	Pending	-	
CN116847870A	Treat mental health	CN	Ascendis Pharma Bone Diseases A/S	September 27, 2021	Pending	-	
HK40096950A	Treat mental health	HK	ASCENDIS PHARMA BONE DISEASES A/S	September 27, 2021	Pending	-	
CN116059321A	Pharmaceutical composition for controlling the PTH release	CN	Ascendis Pharma Bone Diseases A/S	September 28, 2017	Pending	-	
HK40091935A	Pharmaceutical composition defined by administration frequency	HK	ASCENDIS PHARMA BONE DISEASES A/S	September 28, 2017	Pending	-	
CN113423383A	Liquid pharmaceutical formulation	CN	Ascendis Pharma Bone Diseases A/S	February 10, 2020	Pending	-	
HK40052553A	Liquid pharmaceutical formulation	HK	ASCENDIS PHARMA BONE DISEASES A/S	November 9, 2021	Pending	-	
HK40062302A	Liquid pharmaceutical formulation	HK	ASCENDIS PHARMA BONE DISEASES A/S	February 10, 2020	Pending	-	
CN115003320A	Compound defined by regimen	CN	Ascendis Pharma Bone Diseases A/S	January 12, 2021	Pending	-	
HK1263064A	PTH prodrug	HK	ASCENDIS PHARMA BONE DISEASES A/S	February 28, 2017	Pending	-	
HK40046205A	Pharmaceutical formulation comprising long-acting growth hormone	HK	ASCENDIS PHARMA BONE DISEASES A/S	May 17, 2019	Pending	-	
MAEJ/006797	Pharmaceutical formulation comprising long-acting growth hormone	Macau	ASCENDIS PHARMA BONE DISEASES A/S	September 28, 2017	Granted	September 28, 2037	

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Patent Application/ Publication Number	Scope of Protection	Jurisdiction	Applicant	Application Date	Status	Expiration date	Rights of the Company
CN117838873A Divisional application of CN109789189A	Dosage regimen for a controlled-release PTH compound	CN	Ascendis Pharma Bone Diseases A/S	September 28, 2017	Pending		
CN118234506A	Long-acting PTH compound treatments	CN	Ascendis Pharma Bone Diseases A/S	September 21, 2022	Pending		
MAEJ/007897	Dosage regimen for a controlled-release PTH compound	Macau	Ascendis Pharma Bone Diseases A/S	September 28, 2017	Granted	September 28, 2037	
HK40105690A	CNP conjugates	HK	Ascendis Pharma Bone Diseases A/S	February 10, 2020	Pending		
HK40104816A	PTH compounds	HK	Ascendis Pharma Bone Diseases A/S	September 28, 2017	Pending		
<i>Auto-Injector</i> CN115591054A	Autoinjector	CN	Ascendis Pharma GmbH	May 23, 2018	Pending	-	The Company was granted by the Applicant an exclusive, royalty-free licence (with the right to grant sub-licences) under this patent to develop, manufacture, have made, use, sell, offer for sale, import, export or otherwise commercialize licensed product in the treatment and/or prevention of any disease, condition or disorder of any human indication, excluding the excluded indications in the PRC, including Hong Kong, Macau and Taiwan.
CN110769873B	Autoinjector	CN	Ascendis Pharma GmbH	May 23, 2018	Granted	May 23, 2038	
CN115154759A	Autoinjector	CN	Ascendis Pharma GmbH	June 29, 2018	Pending	-	
CN110809484B	Autoinjector	CN	Ascendis Pharma GmbH	June 29, 2018	Granted	June 29, 2038	
HK1262197A	Autoinjector	HK	ASCENDIS PHARMA A/S	December 29, 2016	Pending	-	
HK1262144	Autoinjector	HK	ASCENDIS PHARMA A/S	December 29, 2016	Pending	-	
HK1262199A	Autoinjector	HK	ASCENDIS PHARMA A/S	December 30, 2015	Pending	-	
HK1262201A	Autoinjector	HK	ASCENDIS PHARMA A/S	December 30, 2015	Pending	-	
TW202322862A	Autoinjector	Taiwan	ASCENDIS PHARMA A/S	September 29, 2022	Pending	-	

(c) Domain name

As at the Latest Practicable Date, our Group owned the following domain name, which we consider to be or may be material to our business:

www.visenpharma.com

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C. FURTHER INFORMATION ABOUT OUR DIRECTORS AND SUBSTANTIAL SHAREHOLDERS

1. Disclosure of interests

(a) Disclosure of interests of Directors and Chief Executive

Immediately following completion of the [REDACTED] (without taking into account any Shares which may be issued or allotted upon any exercise of the [REDACTED]), the interests or short positions of our Directors or chief executives in our Shares, underlying Shares and debentures of our Company or our associated corporations (within the meaning of Part XV of the SFO) which will be required to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests or short positions which they were taken or deemed to have under such provisions of the SFO) or which will be required, under Section 352 of the SFO, to be entered in the register referred to in that section, or which will be required, under the “Model Code for Securities Transactions by Directors of Listed Issuers” as set forth in Appendix C3 to the Listing Rules (the “Model Code”) to be notified to us, once our Shares are [REDACTED] will be as follows:

(i) Interest in our Company

Name of Director	Nature of interest	Number of Shares or underlying Shares	Percentage of shareholding interest (without taking into account any Shares which may be issued or allotted upon any exercise of the [REDACTED])	Percentage of shareholding interest upon the exercise of the [REDACTED]
Mr. LU An-bang	Beneficiary of a trust/Founder of a discretionary trust ⁽¹⁾	5,000,000	[REDACTED]%	[REDACTED]%

Note:

- (1) The VPP Trust is a discretionary trust established by Mr. Lu as the settlor, whose beneficiaries include, among others, Mr. Lu and his family members. The trustee of the VPP Trust is Tricor Equity Trustee Limited. Therefore, under the SFO, Mr. Lu is deemed to be interested in the Shares which are held by Tricor Equity Trustee Limited through VPP LU Limited.

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(b) Disclosure of interests of Substantial Shareholders

Save as disclosed in the section headed “Substantial Shareholders” in this document, our Directors or chief executives are not aware of any other person, not being a Director or chief executive of our Company, who has interests or short positions in our Shares or underlying Shares, which following the completion of the [REDACTED], would fall to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or 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.

Save as disclosed in this document, to the best knowledge of our Directors, immediately following the completion of the [REDACTED], no persons will, 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 any other members of our Company.

2. Particulars of Directors’ service contracts and appointment letters

(a) Executive Directors and non-executive Directors

Our executive Director entered into a service contract with our Company for a term of three years effective from the [REDACTED] and subject to termination in accordance with their respective terms. Each of these service contracts may be renewed in accordance with the Articles and the applicable laws and regulations.

Each of the non-executive Directors entered into a letter of appointment with our Company for a term of three years effective from the [REDACTED] and subject to termination in accordance with their respective terms. Each of these letters of appointment may be renewed in accordance with the Articles and the applicable laws and regulations.

(b) Independent non-executive Directors

Each of the independent non-executive Directors has signed a letter of appointment with our Company for a term of one year commencing from April 1, 2021 and such appointment shall be automatically renewed for one year at the end of the term. The letters of appointment are subject to termination in accordance with their respective terms.

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3. Remuneration of Directors

The aggregate amount of remuneration (including salaries, bonuses, allowances and benefits in kind, contributions to pension scheme, discretionary bonus and bonus based on performance) that was paid by our Group to our Directors for the years ended December 31, 2022 and 2023 and the four months ended April 30, 2024 was approximately RMB62.5 million (including share grant), RMB19.1 million (including share grant) and RMB18.2 million (including share grant), respectively. Please refer to Note 9 of the Accountants' Report in Appendix I to this document on the Directors' and chief executive's emoluments and employees' remuneration for the Track Record Period.

It is estimated that emoluments of approximately RMB35.0 million in aggregate will be paid to our Directors in respect of the financial year ending December 31, 2024 under arrangements in force at the date of this document.

The aggregate amount of remuneration (including salaries, allowances and benefits in kind, contributions to pension scheme, discretionary bonus and bonus based on performance) paid to our five highest paid individuals (including both employees and Directors) for the years ended December 31, 2022 and 2023 and the four months ended April 30, 2024 was approximately RMB97.3 million, RMB38.6 million and RMB26.0 million, respectively.

There has been no arrangement under which a Director has waived or agreed to waive any remuneration or benefits in kind for the Track Record Period.

4. Fees or commissions received

Save as disclosed in this document, none of the Directors or any of the persons whose names are listed in the paragraphs under "– F. Other Information – 8. Consent of Experts" below had received any commissions, discounts, agency fee, brokerage or other special terms in connection with the issue or sale of any capital of any member of our Group within the two years immediately preceding the date of this document.

5. Disclaimers

Save as disclosed in this document:

- (a) none of our Directors or chief executives has any interests and short positions in our Shares, underlying Shares and debentures of our Company or its associated corporation (within the meaning of Part XV of the SFO) which will have to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he is taken or deemed to have under such provisions of SFO) or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or will be required, pursuant to the Model Code to be notified to us and the Stock Exchange, in each case once our Shares are [REDACTED] on the Stock Exchange;

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- (b) so far as is known to any of our Directors or chief executives, no person has an interest or short position in our Shares and underlying Shares which would fall to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or is, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any other member of our Group;
- (c) none of our Directors nor any of the persons whose names are listed in the paragraphs under “– F. Other Information – 8. Consent of Experts” in this Appendix is interested in our promotion, or in any assets which have, within the two years immediately preceding the issue of this document, been acquired or disposed of by or leased to us, or are proposed to be acquired or disposed of by or leased to us;
- (d) save as disclosed in this document or in connection with the [REDACTED], none of our Directors nor any of the persons whose names are listed in the paragraphs under “– F. Other Information – 8. Consent of Experts” in this Appendix is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of our Group;
- (e) save in connection with the [REDACTED], none of our Directors nor any of the persons whose names are listed in the paragraphs under “– F. Other Information – 8. Consent of Experts” in this Appendix: (i) is interested legally or beneficially in any of our Shares or any share in any of our subsidiaries; or (ii) has any right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group;
- (f) none of our Directors or their respective associates (as defined under the Listing Rules) or any of our Shareholders (who to the knowledge of our Directors owns more than 5% of our issued share capital) has any interest in our five largest suppliers or customers; and
- (g) none of the Directors or any past Directors of any members of our Group has been paid any sum of money for the two years ended December 31, 2022 and 2023 and the four months ended April 30, 2024 (i) as an inducement to join or upon joining us or (ii) for loss of office as a Director of any member of our Group or of any other office in connection with the management of the affairs of any member of our Group.

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D. EQUITY INCENTIVE PLAN

The following is a summary of the principal terms of the Equity Incentive Plan approved and adopted by the Board on April 29, 2019, and as amended and restated by the Board on January 8, 2021 and March 10, 2021, respectively. The terms of the Equity Incentive Plan are not subject to the provisions of Chapter 17 of the Listing Rules. After [REDACTED], no further options or other type of awards would be granted pursuant to this Equity Incentive Plan.

The principal terms of the Equity Incentive Plan are as follows:

1. Purpose

The Equity Incentive Plan, through the granting of Share Awards (as defined below), is intended to help the Company and its affiliates to secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the Company and any affiliate and provide means by which the eligible recipients may benefit from increases in value of the Shares.

2. Duration

The Board may suspend or terminate the Equity Incentive Plan at any time. Unless terminated sooner by the Board, the Plan will automatically terminate on April 28, 2029. No Share Awards may be granted under the Equity Incentive Plan while it is suspended or after it is terminated.

3. Administration

The Board will administer the Plan. The Board may delegate administration of the Equity Incentive Plan to any committee or committees.

4. Share Award Agreement

Any terms and conditions of a Share Award (as defined below) grant shall be evidenced by a written agreement between the Company and the grantee (the “Share Award Agreement”).

5. Eligibility

Share Awards may be granted to employees and consultants of the Company or its affiliates.

6. Types of Awards

The Plan provides for the grant of the following types of share awards, (i) options and share appreciation rights (“SAR”); (ii) restricted share awards; (iii) restricted share unit awards (“RSU”), and (iv) other share awards, collectively, “Share Awards.”

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7. Options and SAR

- (a) **Term.** No Option or SAR will be exercisable after the expiration of ten (10) years from the date of its grant or such shorter period specified in the Share Award Agreement;
- (b) **Exercise price.** The exercise or strike price of each option or SAR granted to a US grantee will be not less than one hundred percent (100%) of the fair market value of the Shares subject to the Option or SAR on the date the Share Award is granted. The exercise or strike price of each option or SAR granted to a Participant that is not a U.S. Participant shall be determined by the Board and shall comply with applicable laws. In addition, no option or SAR may be granted with an exercise or strike price lower than the par value of the Shares, if any.
- (c) **Transferability.** The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board will determine.
- (d) **Vesting.** The total number of Shares subject to an option or SAR may vest and become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of performance goals or other criteria) as the Board may deem appropriate.
- (e) **Termination of continuous service without cause or the disability or death of grantee.** If a grantee's continuous service (as an employee, Director or consultant) terminates (other than for cause), or in the event of the grantee's disability or death, the grantee, or the grantee's estate or such other person entitled to exercise the option or grantee, may exercise the grantee's option or SAR within the applicable timeframe as set forth in the Equity Incentive Plan and the Share Award Agreement.
- (f) **Termination for cause.** Except as provided otherwise in a grantee's Share Award Agreement or other individual written agreement, if a grantee's continuous service is terminated for cause, the option or SAR will terminate and may not be exercised immediately upon such employee's termination of continuous service.

8. Restricted Share Awards

- (a) **Consideration.** A restricted share award may be awarded in consideration for cash, check or other form of legal consideration that may be acceptable to the Board in its sole discretion, and permissible under applicable law.
- (b) **Vesting.** Shares awarded under the Restricted Share Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

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- (c) **Termination of continuous service.** If a grantee's continuous service terminates, the Company may receive through a forfeiture condition or a repurchase right, any or all of the Shares held by the grantee as of the date of such termination under the terms of the Restricted Share Award Agreement.
- (d) **Transferability.** Rights to acquire Shares under the Restricted Share Award Agreement will be transferable by the grantee only upon such terms and conditions as are set forth in the Restricted Share Award Agreement, as the Board will determine in its sole discretion, so long as such Shares remain subject to the terms of the Restricted Share Award Agreement.

9. Restricted Share Unit Awards

- (a) **Consideration.** At the time of grant of an RSU, the Board will determine the consideration, if any, to be paid by the grantee upon delivery of each Share subject to the RSU. The consideration (if any) may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.
- (b) **Vesting.** The Board may impose such restrictions on or conditions to the vesting of the RSU as it, in its sole discretion, deems appropriate.
- (c) **Payment.** An RSU may be settled by the delivery of Shares, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the RSU Award Agreement.
- (d) **Termination of continuous service.** Except as otherwise provided in the applicable RSU Award Agreement, such portion of the RSU that has not vested will be forfeited upon the grantee's termination of continuous service.

10. Other Share Awards

- (a) the Board will have sole and complete authority to determine the persons to whom and the time or times at which such other Share Awards will be granted, the number of Shares (or the cash equivalent thereof) to be granted and all other terms and conditions of such other Share Awards.

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11. Establishment of the Employee Trust and Escrow and Mr. Lu’s Trust

Employee Trust and Escrow

On March 29, 2021, the Company (as the settlor) and Tricor Trust (Hong Kong) Limited (“Tricor HK”), an Independent Third Party, entered into (i) a trust deed for the administration of the Equity Incentive Plan for the establishment and operation of the PRC trust (the “PRC Employee Trust”); and (ii) a deed of settlement in relation to the escrow arrangement for the establishment and operation of the U.S. Employee Escrow. The settlor’s duties, which include ensuring adequate funding for the trusts and notifying the trustees of key events, are mainly administrative tasks undertaken to facilitate the effective management of the trusts for the benefit of the Company. Both the PRC Employee Trust and the U.S. Employee Escrow, managed by the trustee, an Independent Third Party, operate independently. All of the Shares held by the PRC Employee Trust and the U.S. Employee Escrow are non-voting Shares.

The PRC Employee Trust is established for the purpose of administering awards which may be granted to employees and consultants (each as defined thereunder) of PRC nationality. Pursuant to the PRC Employee Trust arrangement, Tricor HK has agreed to act as the trustee to hold through VP EIP NUS LIMITED certain Shares underlying the RSUs that have been or may be granted under the Equity Incentive Plan and to administer the vesting of the RSUs. The U.S. Employee Escrow is established for the purpose of administering awards which may be granted to employees and consultants (each as defined thereunder) of U.S. Nationality. Pursuant to the U.S. Employee Escrow arrangement, Tricor HK has agreed to act as the agent to hold through VP EIP US LIMITED certain Shares underlying the RSUs that have been granted under the Equity Incentive Plan and to administer the vesting of the RSUs.

On March 30, 2021, the Company issued and allotted to VP EIP NUS LIMITED and VP EIP US LIMITED 11,000,000 Shares and 4,000,000 Shares, respectively, for the operation of the Equity Incentive Plan. On November 15, 2022, the Company entered into share surrender agreements with VP EIP NUS LIMITED and VP EIP US LIMITED, pursuant to which VP EIP NUS LIMITED surrendered for no consideration of 7,859,500 Shares, VP EIP US LIMITED surrendered for no consideration of 2,800,000 Shares. The surrendered shares were canceled accordingly on November 16, 2022. As a result, VP EIP NUS LIMITED and VP EIP US LIMITED holds 3,140,500 and 1,200,000 non-voting Shares in the Company, respectively. All the Shares issued and allotted by the Company to VP EIP NUS LIMITED and VP EIP US LIMITED are non-voting Shares.

Mr. Lu’s Trust

On March 10, 2021, the Board approved the grant of RSUs representing 5,000,000 Shares to Mr. Lu An-bang (“Mr. Lu”) under the Equity Incentive Plan, and the relevant grant documents were entered into on March 15, 2021. Shares underlying the RSUs granted to Mr. Lu were issued and allotted to Mr. Lu on March 30, 2021.

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On March 29, 2021, Mr. Lu (as the settlor), established the VPP Trust with Tricor Equity Trustee Limited (“Tricor Trustee”), an Independent Third Party, acting as the trustee. On the same date, Mr. Lu transferred the 5,000,000 Shares underlying Mr. Lu’s RSUs to VPP LU Limited by way of gift. Tricor Trustee holds through VPP LU Limited the 5,000,000 Shares for the benefit of beneficiaries which include, among others, Mr. Lu and his family members. All the Shares held by VPP LU Limited are non-voting Shares.

12. Outstanding Grants

As of the Latest Practicable Date, there were outstanding RSUs representing 6,475,000 Shares that had been granted to 26 grantees under the Equity Incentive Plan, among which RSUs representing 5,000,000 Shares were granted to Mr. Lu and held by VPP LU Limited, and RSUs representing 1,475,000 Shares have been granted to other grantees of the Company and held by VP EIP NUS LIMITED and VP EIP US LIMITED. The details of the grants are disclosed in the table below. It is expected that the Company may further grant 2,865,500 RSUs representing 2,865,500 Shares prior to [REDACTED] through the remaining non-voting Shares held by VP EIP NUS LIMITED and VP EIP US LIMITED and none of the future grantees under the Equity Incentive Plan would be the Directors or connected persons of the Company. As such, at the time of [REDACTED], save as Mr. Lu, no Director or connected person of the Company will be a grantee under the Equity Incentive Plan. After [REDACTED], no further awards would be granted pursuant to this Equity Incentive Plan.

All the Shares underlying the awards granted under Equity Incentive Plan have been allotted and issued and are held by PRC Employee Trust, U.S. Employee Escrow and Mr. Lu’s Trust through their respective nominee entities as of the Latest Practicable Date. Accordingly, the vesting of RSUs granted under the Equity Incentive Plan will not cause any dilution effect on the shareholdings of our Shareholders nor any impact on the [REDACTED] arising from the vesting of RSUs.

The table below shows the details of Awards granted under the Equity Incentive Plan that are outstanding as of the Latest Practicable Date.

Grantee	Position/ Relationship	Number of Shares under outstanding Awards granted as of the date of this Document and immediately before the completion of [REDACTED]	Date of Grant	Vesting Period	Exercise price (US\$ per Share)	Consideration paid by the Grantee	Approximately percentage in the issued Shares immediately after completion of the [REDACTED] and assuming [REDACTED] is not exercised
Directors							
LU An-Bang (盧安邦)	Chief Executive Officer	5,000,000	March 15, 2021	Note 1	Nil	Nil	[REDACTED]
Subtotal		5,000,000					[REDACTED]

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Grantee	Position/ Relationship	Number of Shares under outstanding Awards granted as of the date of this Document and immediately before the completion of [REDACTED]	Date of Grant	Vesting Period	Exercise price (US\$ per Share)	Consideration paid by the Grantee	Approximately percentage in the issued Shares immediately after completion of the [REDACTED] and assuming [REDACTED] is not exercised
Senior management of our Company who are not Directors							
CHEN Jun (陳軍)	Chief Commercial Officer	1,000,000	August 30, 2021	Note 1	Nil	Nil	[REDACTED]
Subtotal		1,000,000					[REDACTED]
Other employees of our Group							
Du Nan (杜楠)	Clinical Science Director	40,000	March 15, 2021	Note 1	Nil	Nil	[REDACTED]
Li Ying (李穎)	Biostatistics Statistition Director	40,000	March 15, 2021	Note 1	Nil	Nil	[REDACTED]
Chen Rui (陳睿)	Vice president of Clinical Operation	30,000	March 15, 2021	Note 1	Nil	Nil	[REDACTED]
Zhu Huiling (朱慧玲)	Quality Director, GCP	20,000	March 15, 2021	Note 1	Nil	Nil	[REDACTED]
Wang Chao (王超)	Legal & Compliance Senior Director	20,000	March 15, 2021	Note 1	Nil	Nil	[REDACTED]
Zhang Xiaoxu (張曉旭)	Human Resource Director	10,000	March 15, 2021	Note 2	Nil	Nil	[REDACTED]
Shan Wei (單瑋)	Finance Director	7,500	March 15, 2021	Note 2	Nil	Nil	[REDACTED]
Hao Zhixin (郝誌新)	Real World Evidence (RWE) Associate Director	5,000	March 15, 2021	Note 2	Nil	Nil	[REDACTED]
Tian Yan (田妍)	Clinical Data Management Associate Director	5,000	March 15, 2021	Note 2	Nil	Nil	[REDACTED]
Wang Weifeng (王衛鋒)	Drug Supply Senior Manager	5,000	March 15, 2021	Note 2	Nil	Nil	[REDACTED]
Wu Zhenrong (吳貞蓉)	Clinical Operation Project Management Associate Director	5,000	March 15, 2021	Note 2	Nil	Nil	[REDACTED]
Wei Wenwen (衛雯雯)	Compensation and Benefits Manager	2,500	March 15, 2021	Note 2	Nil	Nil	[REDACTED]
Su Hang (蘇杭)	Project Manager of Clinical Operation	2,500	March 15, 2021	Note 2	Nil	Nil	[REDACTED]
Dong Xiaowei (董曉偉)	Project Manager of Clinical Operation	2,500	March 15, 2021	Note 2	Nil	Nil	[REDACTED]

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Grantee	Position/ Relationship	Number of Shares under outstanding Awards granted as of the date of this Document and immediately before the completion of [REDACTED]	Date of Grant	Vesting Period	Exercise price (US\$ per Share)	Consideration paid by the Grantee	Approximately percentage in the issued Shares immediately after completion of the [REDACTED] and assuming [REDACTED] is not exercised
Ye Yudie (葉雨蝶)	Accounting Supervisor	3,750	March 15, 2021	Note 2	Nil	Nil	[REDACTED]
Lu Yun (盧雲)	Admin Supervisor	3,750	March 15, 2021	Note 2	Nil	Nil	[REDACTED]
An Muxi (安慕溪)	Clinical Project Assistant	2,500	March 15, 2021	Note 2	Nil	Nil	[REDACTED]
Gu Qing (顧青)	Vice President of Medical Affairs	30,000	August 30, 2021	Note 1	Nil	Nil	[REDACTED]
Pan Haifeng (潘海風)	Vice President of Commercial Operations	50,000	August 30, 2021	Note 1	Nil	Nil	[REDACTED]
Wang Yan (王燕)	Senior Vice President of Clinical Development	50,000	March 17, 2022	Note 1	Nil	Nil	[REDACTED]
Ma Teng (馬騰)	Project Director, Engineering	20,000	March 17, 2022	Note 1	Nil	Nil	[REDACTED]
Guo Yi (鄒毅)	Vice President of Business Development	50,000	March 17, 2022	Note 1	Nil	Nil	[REDACTED]
Zhu Jing (朱靜)	CMC Senior Director	20,000	March 17, 2022	Note 1	Nil	Nil	[REDACTED]
Lin Baiyou (林柏佑)	Vice President of Taiwan Operation	50,000	March 17, 2022	Note 1	Nil	Nil	[REDACTED]
Subtotal		475,000					[REDACTED]
Total		6,475,000					[REDACTED]

Note:

- (1) The Awards shall vest over a period of four years, contingent upon the Company’s successful [REDACTED]. Additionally, as detailed in each Grantee’s notice of Award and respective Award agreements, the vesting of these Awards may be subject to several other objective conditions, including achievement of specified milestones, the Grantee’s continuous service with the Company or its affiliates, and the fulfillment of performance criteria. These performance criteria involve meeting key performance indicators that are established based on objective standards set by the human resources department of the Company for the individual Grantee.
- (2) The Awards shall vest over a period of four years, contingent upon the Company’s successful [REDACTED].

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E. [REDACTED] SHARE AWARD SCHEME

The following is a summary of the principal terms of the [REDACTED] Share Award Scheme conditionally adopted by the Shareholders’ resolutions dated November 16, 2022, effective from the [REDACTED]. The terms of the [REDACTED] Share Award Scheme are compliant with the provisions of Chapter 17 of the Listing Rules.

1. Purpose

The purpose of the [REDACTED] Share Award Scheme is to align the interests of eligible participants with those of our Group through ownership of Shares, dividends and other distributions paid on Shares and/or the increase in value of the Shares, and to encourage and retain eligible participants to make contributions to the long-term growth and profits of our Group. No performance target is attached to the [REDACTED] Share Award Scheme. The Board and the committee of the Board or person(s) to which the Board has delegated its authority shall have the power from time to time, as part of the terms and conditions of any Award (as defined below), to specify the performance targets that must be satisfied before the vesting of the Award pursuant to the terms of the [REDACTED] Share Award Scheme.

2. Eligible Participants

Any individual/entity, being an employee, service provider or any director or employee of any holding companies, fellow subsidiaries or associated companies of the Company (the “Related Entities”, each a “Related Entity”), who the Board or its delegate(s) considers, in its sole discretion, to have contributed or will contribute to our Group is eligible to receive an Award. However, no individual who is resident in a place where the grant, acceptance or vesting of an Award pursuant to the [REDACTED] Share Award Scheme is not permitted under the laws and regulations of such place or where, in the view of the Board, compliance with applicable laws and regulations in such place makes it necessary or expedient to exclude such individual, shall be entitled to participate in the [REDACTED] Share Award Scheme.

3. Awards

An Award gives a selected participant a conditional right, when the Shares vest, to obtain the Shares or, if in the absolute discretion of the Board or its delegate(s), it is not practicable for the selected participant to receive the Award in Shares, the cash equivalent from the sale of the Shares. An Award includes all cash income from dividends in respect of those Shares from the date the Award is granted (“Grant Date”) to the date the Award vests (“Vesting Date”). For the avoidance of doubt, the Board at its discretion may from time to time determine that any dividends declared and paid by our Company in relation to the Shares be paid to the selected participant even though the Shares have not yet vested.

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4. Grant of Award

The Board or the committee of the Board or person(s) to which the Board has delegated its authority may, from time to time, at their absolute discretion, grant an Award to a selected participant (in the case of the Board's delegate(s), to any selected participant other than a Director or an officer of our Company) by way of an award letter ("Award Letter"). The Award Letter will specify the Grant Date, the number of Shares underlying the Award, the vesting criteria and conditions, the Vesting Date and such other details as the Board or its delegate(s) may consider necessary.

Each grant of an Award to any selected participant who is a Director, chief executive or substantial shareholder of the Company, or any of their respective associates, shall be subject to the prior approval of the independent non-executive Directors (excluding any independent non-executive Director who is a proposed recipient of the grant of an Award). Our Company will comply with the relevant requirements under Chapter 14A and Chapter 17 of the Listing Rules for any grant of shares to connected persons and Director, chief executive or substantial shareholder or any of their respective associates of our Company.

The Board and its delegate(s) may not grant any Shares to any selected participant in certain circumstances, including the following:

- (i) where any applicable approval from any applicable regulatory authorities has not been granted;
- (ii) where any member of our Group will be required under applicable securities laws, rules or regulations to issue a document or other [REDACTED] documents in respect of such Award or the [REDACTED] Share Award Scheme, unless the Board determines otherwise;
- (iii) where such Award would result in a breach by any member of our Group or its directors of any applicable securities laws, rules or regulations in any jurisdiction;
- (iv) where the Company or any eligible participant is in possession of unpublished inside information in relation to our Company or where [REDACTED] by Directors are prohibited under any code or requirement of the Listing Rules and all applicable laws, rules or regulations, from time to time;
- (v) during the period of one month immediately preceding the earlier of (i) the date of the meeting of the Board (as such date is first notified by the Company to the Stock Exchange in accordance with the Listing Rules) for approving the Company's results of any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules); and (ii) the deadline for the Company to announce its results for any year or half-year under the Listing Rules (whether or not required under the Listing Rules), and ending on the date of the results announcement. No Award may be granted during any period of delay in publishing a results announcement.

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5. Maximum number of Shares available for subscription

The total number of Shares which may be issued upon vesting of all Awards to be granted under the [REDACTED] Share Award Scheme and any grants under any other share option scheme and/or share award scheme involving issuance of new Shares adopted and to be adopted by the Company from time to time (the “Share Schemes (New Shares)”) after the [REDACTED] in compliance with Chapter 17 of the Listing Rules is [REDACTED] (the “Scheme Mandate Limit”). Awards and options lapsed/forfeited in accordance with the rules of the [REDACTED] Share Award Scheme or the terms of any Share Schemes (New Shares) will not be regarded as utilized for the purpose of calculating the Scheme Mandate Limit. The Scheme Mandate Limit represents approximately [REDACTED] of the total issued shares of the Company upon completion of the [REDACTED] (assuming the [REDACTED] is not exercised and no Shares are issued under the [REDACTED] Share Award Scheme).

The total number of Shares which may be issued in respect of all Awards to be granted to all service providers under the [REDACTED] Share Award Scheme shall not exceed 3% of the Scheme Mandate Limit (the “Service Provider Sublimit”).

The Company may seek approval by its Shareholders in general meeting for refreshment of the Scheme Mandate Limit and the Service Provider Sublimit pursuant to the relevant terms of the [REDACTED] Share Award Scheme and in accordance with relevant Listing Rules. The total number of Shares which may be issued in respect of all options and awards to be granted under the [REDACTED] Share Award Scheme and Share Schemes (New Shares) as refreshed shall not exceed 10% of the relevant class of Shares in issue as at the date of approval of the refreshed scheme mandate. Options and awards previously granted under this [REDACTED] Share Award Scheme and any other Share Schemes (New Shares) of the Company (including those outstanding, cancelled or lapsed in accordance with its terms or exercised), shall not be counted for the purpose of calculating the limit as refreshed.

The Company may seek separate approval by its Shareholders in general meeting for granting Awards beyond the Scheme Mandate Limit, provided that the Awards in excess of the Scheme Mandate Limit are granted only to selected employee specifically identified by the Company before such approval is sought. The Company must send a circular to the Shareholders in accordance with the relevant requirements under the Listing Rules.

The maximum number of the shares which may be awarded to a selected participant under the [REDACTED] Share Award Scheme and any other Share Scheme (New Shares) in any 12-month period shall not exceed 1% of the issued share capital of the Company in issue (the “Individual Limit”). If any grant of Award to an individual selected participant would result in the Shares issued and to be issued in respect of all options and awards granted to such selected participant in the 12-month period up to and including the date of such grant representing in aggregate exceeding the Individual Limit, such grant must be separately approved by Shareholders in general meeting with such selected participant and his close associates (or associates if the selected participant is a connected person) abstaining from voting. In such case, the Company shall send a circular to the Shareholders in accordance with the relevant requirements under the Listing Rules.

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If the Company conducts a share consolidation or subdivision, the maximum number of Shares that may be issued in respect of all Awards to be granted under the [REDACTED] Share Award Scheme, as a percentage of the total number of issued shares at the date immediately before and after such consolidation or subdivision shall be the same, rounded to the nearest whole share.

6. Scheme Mandate

To the extent that the Scheme Mandate Limit is subsequently increased by way of alteration of the [REDACTED] Share Award Scheme and our Company is required to issue and allot new shares to satisfy any Awards in excess of any amount previously approved by our Shareholders (as the case may be), our Company shall at a general meeting propose, and the Shareholders shall consider and, if thought fit, pass an ordinary resolution approving a mandate specifying:

- (i) the maximum number of new Shares that may be issued for this purpose; and
- (ii) that the Board has the power to issue, allot, procure the transfer of and otherwise deal with the Shares in connection with the [REDACTED] Share Award Scheme;

the mandate will remain in effect during the period from the passing of the ordinary resolution granting the mandate until the variation or revocation of such mandate by an ordinary resolution of the Shareholders in a general meeting.

7. Rights attached to the Award

Save that the Board at its discretion may from time to time determine that any dividends declared and paid by our Company in relation to the Shares be paid to the selected participants even though the Shares have not yet vested, the selected participant only has a contingent interest in the Shares underlying an Award unless and until such Shares are actually transferred to the selected participant, nor does he/she have any rights to any cash or non-cash income until the Shares and related income vest.

8. Rights attached to the Shares

Any Shares transferred to a selected participant in respect of any Awards will be subject to all the provisions of the Memorandum and Articles of Association and will form a single class with the fully paid Shares in issue on the relevant date.

The Shares underlying the Awards granted, when allotted and issued, shall rank pari passu among themselves and with the other Shares in issue.

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9. Assignment of Awards

Any Shares granted under the [REDACTED] Share Award Scheme but not yet vested are personal to the selected participants to whom they are granted and cannot be assigned or transferred. A selected participant shall not in any way sell, transfer, charge, mortgage, encumber or create any interest in favor of any other person over or in relation to any Award, or enter into any agreement to do so. Subject to the approval by the Board and the Stock Exchange, and compliance with Listing Rules, applicable laws and regulations, an Award may be transferred to a vehicle (such as a trust or a private company) for the benefit of the selected participant and any family member of such selected participant (e.g., for estate planning or tax planning purposes) that would continue to meet the purpose of the [REDACTED] Share Award Scheme.

10. Vesting of Awards

The Board or its delegate(s) may from time to time while the [REDACTED] Share Award Scheme is in force and subject to all applicable laws, determine such vesting criteria and conditions or periods for the Award to be vested.

The vesting period for any Award shall not be less than 12 months, provided that a shorter vesting period may apply to the following:

- (a) grants of "make-whole" Award to new joinders to replace the share awards they forfeited when leaving the previous employer;
- (b) grants to a participant whose employment is terminated due to death or occurrence of any change in control event, in which the vesting of Awards may accelerate;
- (c) grants with performance-based vesting conditions in lieu of time-based vesting criteria;
- (d) grants that are made in batches during a year for administrative and compliance reasons; and
- (e) grants with a mixed or accelerated vesting schedule such as where the awards may vest evenly over a period of 12 months.

If there is an event of change in control of our Company by way of a merger, a privatization of our Company by way of a scheme or by way of an offer, the Board or the committee of the Board or person(s) to which the Board has delegated its authority shall at their sole discretion determine whether the vesting dates of any Awards will be accelerated to an earlier date.

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If necessary to comply with applicable laws, any selected participants who holds the Shares under an Award shall dispose of such Shares: (1) within six (6) months after the termination of employment by reason of retirement, death, permanent physical or mental disablement; or (2) within three (3) months after termination of employment by reason other than retirement, death, permanent physical or mental disablement or by reason of the circumstances as described in section 12 paragraph 3.

11. Adjustment upon occurrence of relevant event

Upon the occurrence of any alteration in the share capital of the Company arising from any capitalisation issue, reduction, sub-division or consolidation of share capital of the Company, any rights issue of any share capital of the Company by way of capitalisation of profits or reserves or in connection with an open offer to the Shareholders (except where Shares are issued as consideration or part consideration in a transaction), the number of awarded Shares may be adjusted in a manner as determined by the Board. The adjustment must give the selected participant the same proportion of the awarded Shares, rounded to the nearest whole share, as that to which he was previously entitled prior to such adjustments, but no such adjustments may be made to the extent that a Share would be issued at less than its nominal value (if any). In respect of any such adjustments, other than any made on a capitalization issue, an independent financial adviser or the Company's auditor shall confirm to the Board in writing that the adjustments proposed satisfy the requirements set out in Rule 17.03(13) of the Listing Rules. All fractional shares (if any) arising out of the consolidation or sub-division in respect of the Shares of a selected participant shall be deemed as returned shares ("Returned Shares") and shall not be transferred to the relevant selected participant on the relevant Vesting Date.

12. Retirement, death or permanent physical or mental disability of an eligible participant

If a selected participant ceases to be an eligible participant by reason of retirement of the selected participant, any outstanding Shares and related income not yet vested shall be immediately forfeited, unless the Board or its delegate(s) determines otherwise at their absolute discretion.

If a selected participant ceases to be an eligible participant by reason of (i) death of the selected participant; (ii) termination of the selected participant's employment or contractual engagement with our Group or the Related Entities by reason of his/her permanent physical or mental disablement; or (iii) termination of the selected participant's employment or contractual engagement with our Group by reason of redundancy, any outstanding Shares and related income not yet vested shall be immediately forfeited, unless the Board or its delegate(s) determines otherwise at their absolute discretion.

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If a selected participant, being an employee whose employment is terminated by our Group or a Related Entity by reason of the employer terminating the contract of employment without notice or payment in lieu of notice, or the selected participant having been convicted of any criminal offense involving his or her integrity or honesty, or the selected participant having made any misstatement(s) in the Company's financial statements, any outstanding Shares and related income not yet vested shall be immediately forfeited, unless the Board or its delegate(s) determines otherwise at their absolute discretion.

13. Grant of Shares under the [REDACTED] Share Award Scheme

As of the date of this document, no Shares have been granted or agreed to be granted under the [REDACTED] Share Award Scheme.

Application has been made to the [REDACTED] Committee for the [REDACTED] of, and permission to [REDACTED] in, the Shares which may be issued pursuant to the [REDACTED] Share Award Scheme.

14. Duration and termination

The [REDACTED] Share Award Scheme shall be valid and effective for ten years from the [REDACTED] (the "Award Period") (after which no Awards will be granted), and thereafter for so long as there are any non-vested Shares granted prior to the expiration of the [REDACTED] Share Award Scheme, in order to give effect to the vesting of such Shares or otherwise as may be required in accordance with the rules of the [REDACTED] Share Award Scheme. Subject to the foregoing, the Board may at any time resolve to terminate the operation of this [REDACTED] Share Award Scheme prior to the expiry of the Award Period and in such event no further Awards will be offered or granted, but the provisions of this [REDACTED] Share Award Scheme shall remain in full force to the extent necessary to give effect to any subsisting rights of any selected participants under the [REDACTED] Share Award Scheme. Awards complying with the provisions of Chapter 17 of the Listing Rules which are granted during the life of this [REDACTED] Share Award Scheme and in respect of which Shares are not yet issued prior to the termination of the operation of this [REDACTED] Share Award Scheme shall continue to be valid in accordance with their terms of issue after the termination of this [REDACTED] Share Award Scheme.

15. Administration by trustee

Without prejudice to the Board's general power of administration, to the extent not prohibited by applicable laws and regulations, the Board or the committee of the Board or persons to which the Board has delegated its authority may from time to time appoint one or more trustees in respect of granting administration or vesting of any Shares under the [REDACTED] Share Award Scheme.

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Subject to the rules of the [REDACTED] Share Award Scheme:

- (i) our Company shall, as soon as reasonably practicable and no later than 30 business days from the Grant Date, for the purposes of satisfying the grant of awards, issue and allot Shares to the trustee and/or transfer to the trust the necessary funds and instruct the trustee to acquire Shares through on-market transactions at the prevailing market price; and
- (ii) our Company shall instruct the trustee whether or not to apply any Returned Shares to satisfy any grant of Awards made, and if the Returned Shares, as specified by our Company, are not sufficient to satisfy the Awards granted, our Company shall as soon as reasonably practicable and no later than 30 business days from the Grant Date, for purposes of satisfying the Awards granted, issue and allot further Shares to the trustee and/or transfer to the trust the necessary funds and instruct the trustee to acquire further Shares through on-market transactions at the prevailing market price.

Where the trustee has received instructions from our Company to acquire shares through on-market transactions, the trustee shall acquire such number of Shares as instructed by our Company on-market at the prevailing market price as soon as reasonably practicable after receiving the necessary funds from our Company. The trustee shall only be obliged to transfer Shares granted (and the related income derived from such Shares) to selected participants on vesting to the extent that Shares granted (and the related income derived from such Shares) are comprised in the trust.

F. OTHER INFORMATION

1. Estate duty

Our Directors have been advised that no material liability for estate duty is likely to fall on any member of our Group.

2. Litigation and claims

As of the Latest Practicable Date, save as disclosed in this document, we are not aware of any other litigation or arbitration proceedings of material importance pending or threatened against us or any of our Directors that could have a material adverse effect on our financial condition or operating results.

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3. Joint Sponsors

The Joint Sponsors have made an application on our behalf to the [REDACTED] for the [REDACTED] of, and permission to [REDACTED] in, our Shares in issue and to be issued as mentioned in this document (including any Share which may be issued pursuant to the [REDACTED]).

The Joint Sponsors satisfy the independence criteria applicable to sponsors set forth in Rule 3A.07 of the Listing Rules. The Joint Sponsors will receive an aggregate fee of US\$1,000,000 for acting as the sponsor for the [REDACTED].

4. Compliance adviser

Our Company has appointed Somerley Capital Limited to act as the compliance adviser upon [REDACTED] in compliance with Rule 3A.19 of the Listing Rules.

5. Preliminary expenses

We have not incurred any material preliminary expenses in relation to the incorporation of our Company.

6. Promoter

We have no promoter for the purpose of the Listing Rules. Save as disclosed in this document, within the two years immediately preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given nor are any proposed to be paid, allotted or given to any promoters in connection with the [REDACTED] and the related transactions described in this document.

7. Qualification of experts

The following sets forth the qualifications of the experts who have given opinion or advice contained in this document:

<u>Name</u>	<u>Qualifications</u>
Morgan Stanley Asia Limited	A licensed corporation to conduct Type 1 (dealing in securities), Type 4 (advising on securities), Type 5 (advising on futures contracts), Type 6 (advising on corporate finance) and Type 9 (asset management) regulated activities under the SFO

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<u>Name</u>	<u>Qualifications</u>
Jefferies Hong Kong Limited	A licensed corporation to conduct Type 1 (dealing in securities), Type 4 (advising on securities) and Type 6 (advising on corporate finance) regulated activities under the SFO
Ernst & Young	Certified Public Accountants Registered Public Interest Entity Auditor
Frost & Sullivan International Limited	Industry Consultant
Travers Thorp Alberga	Legal adviser as to Cayman Islands laws
JunHe LLP	Legal adviser as to PRC laws

8. Consent of experts

Each of the experts named in paragraph 7 above has given and has not withdrawn its written consent to the issue of this document with the inclusion of its report, letter or opinion (as the case may be) and the references to its name or summary of report, letter or opinion included in this document in the form and context in which they respectively appear.

None of the experts named in paragraph 7 above has any shareholder interests in any member of our Group or the right (other than the penal provisions) of sections 44A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance insofar as applicable.

9. Binding effect

This document shall have the effect, if an application is made in pursuance of this document, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance insofar as applicable.

10. Registration procedures

The principal register of members of our Company will be maintained in the Cayman Islands by our [REDACTED] and a branch register of members of our Company will be maintained in Hong Kong by our [REDACTED]. Save where our Directors otherwise agree, all transfers and other documents of title to Shares must be lodged for registration with, and registered by, our [REDACTED] and may not be lodged in the Cayman Islands.

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11. Miscellaneous

Save as disclosed in this document:

- (a) within the two years immediately preceding the date of this document:
 - (i) no share or loan capital of our Company or any of our subsidiaries has been issued or agreed to be issued or is proposed to be fully or partly paid either for cash or a consideration other than cash;
 - (ii) no share or loan capital of our Company or any of our subsidiaries is under option or is agreed conditionally or unconditionally to be put under option;
 - (iii) no founders or management or deferred shares of our Company or any of our subsidiaries have been issued or agreed to be issued;
 - (iv) no commissions, discounts, brokerages or other special terms have been granted or agreed to be granted in connection with the issue or sale of any share or loan capital of our Company or any of our subsidiaries; and
 - (v) no commission has been paid or is payable for subscription, agreeing to subscribe, procuring subscription or agreeing to procure subscription of our Share or any share in any of our subsidiaries.
- (b) Save as disclosed in this document, we had not issued any debentures nor did it have any outstanding debentures or any convertible debt securities.
- (c) Directors confirm that:
 - (i) there has been no material adverse change in our financial or trading position or prospects of our Group since April 30, 2024 (being the date to which the latest audited consolidated financial statements of our Group were prepared); and
 - (ii) there is no arrangement under which future dividends are waived or agreed to be waived; and
 - (iii) there has not been any interruption in the business of our Group which may have or has had a significant effect on the financial position of our Group in the 12 months preceding the date of this document.

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- (d) Our principal register of members will be maintained by [REDACTED], in the Cayman Islands and our Hong Kong register of members will be maintained by [REDACTED], in Hong Kong. Unless the Directors otherwise agree, all transfer and other documents of title of Shares must be lodged for registration with and registered by our [REDACTED] and may not be lodged in the Cayman Islands.
- (e) All necessary arrangements have been made to enable our Shares to be admitted into [REDACTED] for clearing and settlement.
- (f) No company within our Group is presently [REDACTED] on any stock exchange or traded on any trading system.

12. Bilingual document

The English and Chinese language versions of this document are being published separately, in reliance upon the exemption provided by section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG AND ON DISPLAY

1. DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES

The documents attached to the copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were (i) the written consents referred to in the section headed “Appendix IV – F. Other Information – 8. Consent of Experts” to this document, and (ii) copies of each of the material contracts referred to in the section headed “Appendix IV – B. Further Information About Our Business – 1. Summary of Material Contracts” to this document.

2. DOCUMENTS ON DISPLAY

Copies of the following documents will be on display on the website of the Stock Exchange at www.hkexnews.hk and our website at www.visenpharma.com during a period of 14 days from the date of this document:

- (a) our Memorandum and Articles of Association;
- (b) the Cayman Companies Act;
- (c) the Accountants’ Report and the report on the unaudited [REDACTED] financial information of our Group prepared by Ernst & Young, the texts of which are set out in Appendices I and II to this document;
- (d) the audited consolidated financial information of our Company for the two financial years ended December 31, 2022 and 2023 and four months ended April 30, 2024;
- (e) the legal opinions issued by JunHe LLP, our PRC Legal Adviser, in respect of certain aspects of the Group and the property interests of our Group;
- (f) the letter of advice prepared by Travers Thorp Alberga, our legal adviser on Cayman Islands law, summarizing certain aspects of the Cayman Companies Act referred to in Appendix III to this document;
- (g) the industry report prepared by Frost & Sullivan International Limited referred to in the section headed “Industry Overview” in this document;
- (h) the material contracts referred to under the section headed “Appendix IV – Statutory and General Information – B. Further Information about Our Business – 1. Summary of Material Contracts” to this document;

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- (i) the service contracts and the letters of appointment with our Directors referred to in “Statutory and General Information – C. Further Information about our Directors and Substantial Shareholders – 2. Particulars of Directors’ Service Contracts and Appointment Letters” in Appendix IV to this document;
- (j) the written consents referred to under the paragraph headed “Statutory and General Information – 8. Consent of Experts” in Appendix IV to this document; and
- (k) the terms of the Equity Incentive Plan and [REDACTED] Share Award Scheme.