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OVERVIEW

We are a clinical-stage pharmaceutical company headquartered in Guangzhou, China. We are committed to the development and commercialization of modified new drugs based on previously approved APIs, by applying alternative formulations and drug-delivery technologies featuring dissolving microneedle drug delivery and nasal inhalation drug delivery. Committed to advancing formulation technologies, we aim to reduce the need for conventional injections, enhance drug administration convenience, and provide therapeutic options to address clinical needs. We do not engage in the discovery or development of new API.

Our dissolving microneedle drug formulations are designed to provide a minimally invasive transdermal delivery approach, aiming to alleviate patients’ fear and discomfort associated with injections. Our nasal inhalation drug formulations are developed based on the intended nasal delivery approach, which may enable drug transport to the CNS via the nose-to-brain delivery pathway to enable drugs to bypass the blood-brain barrier (BBB) and reach the central nervous system (CNS). This approach is designed to provide timely relief for patients symptom.

Drawing on our extensive expertise in drug formulation technologies and robust in-house research and development (R&D) capabilities, we have established two core platforms with proprietary technologies: dissolving microneedle drug formulation technology platform and nasal inhalation drug formulation technology platform. These platforms serve as the foundation for us to continuously develop a competitive pipeline of product candidates aimed at addressing limitations of traditional routes of administration and supporting patient compliance.

Our product candidates developed using our formulation technology platforms are designed to provide minimally invasive and more patient-friendly treatment options by improving the delivery, release, and absorption pathways of APIs. This is intended to reduce pain, simplify administration, and support improved patient adherence. These advantages also strengthen the commercial potential and differentiation of our product pipeline.

One of our Core Products, DHMP, is the first dissolving microneedle drug patch approved for clinical trials in China. As of the Latest Practicable Date, DHMP has completed the conduct of clinical studies for Phase IIa clinical trial for the pediatric indication, and Phase IIa is expected to be completed by the third quarter of 2026 with the issuance of the clinical study report. DHMP has also entered Phase II clinical trial for the adult indication, representing an important step forward in platform validation. Our other Core Product, XJN010, is intended for the on-demand treatment of “Off” episodes in Parkinson’s disease. It is the first nasal inhalation formulation approved to enter clinical trials in China in this therapeutic area, as confirmed by Frost & Sullivan. As of the Latest Practicable Date, XJN010 has also completed the conduct of clinical studies for Phase II clinical trial and Phase II is expected to be completed by the third quarter of 2026 with the issuance of the clinical study report.

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OUR PIPELINE OF PRODUCT CANDIDATES

Our pipeline follows a framework that aligns patient need, formulation feasibility, and commercial attractiveness. The following chart illustrates our pipeline and summarizes the development status of our product candidates, including both clinical- and preclinical-stage programs, as of the Latest Practicable Date, together with their anticipated milestones.

Pipeline product	Target	Therapeutic regimen	Indication	Preclinical research	IND preparation	Clinical Phase I	Clinical Phase II	Clinical Phase III	Key regulatory authority	Key regulatory and/or clinical milestones achieved	Next regulatory/clinical milestone	Sponsor(s) for clinical trials	Commercial rights
Disolving microneedle drug formulation technology platform	★ Desmethylsodium hydrochloride microneedle patch	α ₂ -adrenergic receptor	Preoperative sedation for children 2-6 years old						NMPA	IND approval granted in April 2024; Phase I commenced in February 2025; Entered Phase IIa in August 2025; Completed conduct of clinical studies for Phase IIa in June 2026	Q3 2026 – Complete Phase IIa by issuing clinical study report	Company	Global
			Preoperative sedation for adults						NMPA	Phase II approval granted in September 2025; Phase II commenced in the first quarter of 2026	Q4 2026 – Complete Phase II		
			Glucose control for adult type 2 diabetes						FDA	IND granted in February 2026 ⁶	Q4 2026 – Initiate Phase I		
	XJN 1102	Mono	Long term weight management for overweight or obese adults						NMPA		Q4 2026 – Submit IND Application	Company ⁹	Global
									FDA		Q4 2026 – Submit IND Application		
Nasal inhalation drug formulation technology platform	★ XJN 0107	Mono	For the on-demand treatment of “Off” episodes in adult patients with Parkinson’s disease ⁷						NMPA	IND approval granted in August 2024; Phase I commenced in March 2025, completed in June 2025; Entered Phase II in August 2025; Completed conduct of clinical studies for Phase II in April 2026	Q3 2026 – Complete Phase II by issuing clinical study report	Company	Global
									FDA	IND approval for direct Phase II entry granted in February 2026 ⁶	Q3 2026 – Initiate Phase II		
									NMPA	IND approval granted in January 2026; Phase I initiated in April 2026	Q1 2027 – Complete Phase I		
	★ XJN 026	Mono	For the acute treatment of migraine attacks with or without aura						FDA		Q4 2026 – Submit IND Application	Company ⁹	Global
			For the acute treatment of nausea and vomiting caused by radiotherapy, chemotherapy, or surgery						NMPA		Q4 2026 – Submit IND Application		

★ Core Product ★ key product

Notes:

1. The Company submitted a pre-IND communication to the FDA in June 2025, requesting that the FDA consider allowing XJN010 to enter Phase II clinical trials in the U.S. directly, without a separate U.S. Phase I clinical trial, having regard to (i) the product characteristics, (ii) the non-clinical results for XJN010, (iii) the results of the Phase I clinical trial conducted in China, (iv) the established safety and efficacy data for the API in XJN010 (i.e., levodopa) in Parkinson’s disease, and (v) the Phase II clinical trial protocol. Following its consideration of the Company’s pre-IND request, the FDA issued a written response in September 2025

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indicating that a U.S. Phase I clinical trial may be waived and that the Company may proceed directly to a Phase II clinical trial, subject to the FDA’s formal review. In October 2025, the Company submitted a formal IND application. The FDA approved the IND application in February 2026, allowing XJN010 to proceed directly to a Phase II clinical trial in the U.S. The clinical trial data submitted from the Chinese Mainland to the FDA includes particulars on the pharmacokinetics and safety of the drug, and contains no any personal information, sensitive information or material data. As affirmed by our PRC Legal Advisor, the submission of clinical trial data from the Chinese Mainland to the FDA complies with applicable PRC data privacy laws and regulations in material aspects.

2. For the on-demand treatment of “Off” episodes in adult patients with Parkinson’s disease who are receiving dopa decarboxylase inhibitor/levodopa therapy.

3. In the IND approval granted for the pediatric indication, the NMPA explicitly instructed the Company to refer to the Technical Guidelines for Clinical Trials of Improved Chemical Drugs for Children (Trial) (兒童用化學藥品改良型新藥臨床試驗技術指導原則(試行)), the Technical Guidance Principles for Extrapolating Adult Medication Data to Pediatric Populations (成人用藥數據外推至兒科人群的技术指導原則), and ICH E11(R1). Specifically, the NMPA’s IND approval stated that the Company should “obtain sufficient safety, PK, and PD research data in adults” and gain a thorough understanding of the preparation’s delivery performance before initiating studies in children. Accordingly, the Phase I clinical trial for the pediatric indication was conducted in healthy adults.

Upon completion of the Phase I trial in adults, a formal meeting was held with the NMPA in July 2025, where we presented the adult Phase I trial data. Based on this data, the NMPA reached an agreement with us on the rationality, risk-benefit profile, and safety of the proposed dosage regarding the pediatric clinical development plan. After this meeting and the relevant correspondence between us and the NMPA, the NMPA made no further objections to the Phase IIa clinical trial protocol proposed by us.

According to Frost & Sullivan, the above-mentioned approach of supporting pediatric development based on adult Phase I clinical trial data is a common practice in the industry. According to the Notice on “Guiding Principles for Quantitative Methodology of Extrapolating Adult Drug Data to Pediatric Populations (Trial)” issued by NMPA, extrapolation strategies may be adopted to apply adult clinical trial data to pediatric development (particularly in pharmacokinetics and safety aspects), provided that sufficient similarities exist between pediatric and adult populations regarding disease, drug pharmacology, and expected therapeutic responses. This practice not only maximizes the utilization of adult data and reduces risks to pediatric subjects, but also accelerates the progress of pediatric clinical trials.

4. In our June 2025 clinical trial application for the adult indication, we explicitly submitted that (1) the adult and pediatric indications were identical in pharmaceutical development and non-clinical research materials; (2) the completed Phase I clinical trial in healthy adults conducted under the pediatric indication was planned to be used to support the adult Phase II clinical trial application, serving as the safety basis. The NMPA accepted the adult indication application in July 2025 and approved it in September 2025 without requiring a separate adult Phase I clinical trial. We subsequently completed NMPA registration for the adult Phase II clinical trial, and no objections had been received as of the Latest Practicable Date. The Phase II clinical trial for the adult indication commenced in March 2026.

5. As all pipeline products are self-developed, the Company holds global commercialization rights in respect of such products. The Company currently intends to prioritize China and the U.S. as the initial target jurisdictions for the Core Products.

6. We submitted IND on January 15, 2026, and FDA did not place the IND on clinical hold during the 30-day review period. FDA subsequently informed us on February 18, 2026 by email that the study may proceed.

7. The API for XJN010 is levodopa. The API for key product XJN026, and other products XJN1102 and XJN2503, are not disclosed in this Document due to confidentiality and commercial sensitivity reasons, as these product candidates are still at an early stage of development and have not yet entered clinical trials. Our patent portfolio relating to our product candidates is summarized on pages 319.1 to 321.4 and Appendix VI-9 to VI-16.

8. In China, all pipeline product candidates are being developed under the NMPA regulatory framework for Class 2 modified new drugs (2類: 境內外均未上市的改良型新藥). Class 2 modified new drugs refer to products developed based on known active ingredients, with optimization of, among others, the dosage form, formulation, manufacturing process, route of administration and/or indication, and which are intended to provide clinically meaningful advantages. In the U.S., all pipeline product candidates are being developed under the FDA regulatory pathway under Section 505(b)(2) of the U.S. Federal Food, Drug, and Cosmetic Act. The 505(b)(2) pathway is applicable to modified drug products developed with reference to one or more previously approved drugs, where the proposed product involves modifications such as dosage form, route of administration, formulation and/or indication.

9. For XJN026, IND approval was granted by the NMPA in January 2026, but no U.S. IND application had been submitted as of the Latest Practicable Date. Accordingly, the sponsor disclosure relating to the U.S. refers to the planned U.S. IND application, for which the Company is expected to act as the sole sponsor. For XJN1102 and XJN2503, no IND application had been submitted for either candidate as of the Latest Practicable Date, as both candidates were still at the preclinical stage. Accordingly, the sponsor disclosure refers to the planned IND applications, for which the Company is expected to act as the sole sponsor.

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Our product pipeline covers therapeutic areas including preoperative sedation, diabetes, weight management, and central nervous system disorders. Using our dissolving microneedle drug formulation and nasal inhalation drug formulation technology platforms, we will continue to develop and introduce modified new drugs to the market.

Our management team brings multidisciplinary experience across the life cycle of modified new drugs, including candidate selection, pharmaceutical research and development, product manufacturing, and regulatory affairs. The team brings together diverse senior professionals, covering project initiation, innovative formulation R&D, GMP facility construction and operation, and communication with regulatory agencies in China, the U.S., and other regions. This enables us to build full process capabilities from project selection and efficient execution to large scale operation.

Our R&D team covers key functions including formulation research and development, quality control and analytical research, manufacturing control, and regulatory affairs. To accelerate the translation of modified new drugs from research to market, we have established the dissolving microneedle drug formulation and nasal inhalation drug formulation technical platforms, aiming to shorten the time from conception to clinical application. Supported by systematic and standardized R&D and quality management frameworks, we have built efficient and compliant R&D and manufacturing processes to ensure the quality, compliance, and controllability of clinical samples and future commercial products. In addition, through systematic patent protection, we build solid technological barriers.

OUR COMPETITIVE STRENGTHS

Technology platforms that support the continuous development of multiple pipeline products

Dissolving microneedle drug formulation technology platform

Globally, transdermal drug delivery products based on microneedle drug formulation technology remain at the clinical trial stage, with no products approved for commercial use yet according to Frost & Sullivan as of the Latest Practicable Date. During this critical window of opportunity, our drug formulations developed based on the dissolving microneedle drug formulation technology platform are in a relatively advanced stage of research and development globally and possess strong potential for early market entry, as confirmed by Frost & Sullivan.

Our DHMP for preoperative sedation in pediatric patients completed Phase I and entered Phase IIa clinical trial in China in August 2025. As of the Latest Practicable Date, conduct of clinical studies for the Phase IIa clinical trial has been completed, and Phase IIa is expected to be completed by the third quarter of 2026. It is currently the first and only dissolving microneedle drug patch under clinical development in China, as confirmed by Frost & Sullivan. In addition, we are advancing product candidates and have established a clear pipeline in other therapeutic areas, such as endocrinology. Both of our major microneedle product pipelines are developed based on the same dissolving microneedle drug formulation technology platform, demonstrating the maturity, reliability, and broad applicability of our platform technology. Collectively, these advancements signify that we have established an integrated system encompassing technology R&D, product translation, and industrial-scale manufacturing that meets international standards.

Within our dissolving microneedle drug formulation technology platform, we have integrated multiple technological features relating to drug delivery efficiency and dosing precision, establishing a high technological barrier in the field of microneedle transdermal drug delivery. Our effective skin penetration technology precisely control the mechanical rigidity and toughness of microneedles through formulation component optimization, ensuring effective penetration of the skin's stratum corneum and providing a critical foundation for subsequent transdermal drug delivery. Our effective targeted delivery technology and effective transdermal absorption technology act together to support transdermal delivery. The former achieves effective drug enrichment in the microneedles' active loading region, enabling targeted deposition at the intended skin site, while the latter employs permeation-enhancing excipient compositions to substantially improve transdermal absorption efficiency. This technology is applicable to a wide range of drug types, including small-molecule chemical drugs, peptides, and biological macromolecules such as proteins, demonstrating exceptional technological versatility and platform scalability. In addition, our precise and controllable drug loading technology and precise continuous infusion technology provide quality assurance for the platform. The precise and controllable drug loading technology enables accurate dosage customization through formulation optimization and process innovation, meeting the needs of personalized drug administration. The precise continuous infusion technology has enabled successful pilot scale sample production across multiple batches, laying a solid foundation for the design of our commercial production line.

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At the same time, we have developed a formulation-device integrated solution, combining our dissolving microneedle drug formulation technology with specialized delivery devices to achieve full-process integration, from skin penetration and drug delivery to absorption. This approach substantially enhances the overall efficiency and stability of microneedle transdermal drug delivery.

Nasal inhalation drug formulation technology platform

Our nasal inhalation drug formulation technology platform positions us in a therapeutic area that we believe is relatively underexplored. While traditional nasal drug products primarily target local effects or systemic absorption, our platform is designed to support intranasal CNS delivery and is intended to facilitate drug transport to the brain, including potentially via pathways associated with the olfactory and/or trigeminal nerves, which may enable bypass of the BBB. This approach is intended to address the therapeutic needs of CNS drugs by enabling rapid onset of action, enhancing drug exposure in brain, and reducing gastrointestinal side effects, avoiding the limitations associated with traditional routes of administration. By providing a non-invasive approach to CNS drug delivery, our platform provides a clinically meaningful alternative to oral, injectable, or pulmonary inhalation formulations.

Currently, the use of nasal drug delivery formulations for the treatment of CNS diseases is developing rapidly in China and has become a key area of R&D. However, only a limited number of such products have been launched, including diazepam nasal spray, which is indicated for the treatment of epilepsy, and sumatriptan nasal spray, which is indicated for migraine. According to Frost & Sullivan, no marketed nasal drug delivery formulations are available for specific indications such as the treatment of “Off” episodes in Parkinson’s disease. As a result, there remains a clinical need.

Our nasal inhalation drug formulation for the treatment of “Off” episodes in Parkinson’s disease has completed Phase I clinical trial in China in June 2025 and commenced Phase II clinical trial in China in August 2025, making it the first product in China to have entered Phase II clinical development in this therapeutic area. As of the Latest Practicable Date, conduct of clinical studies for Phase II clinical trial has been completed, and Phase II is expected to be completed by the third quarter of 2026. In addition, we have established well-defined pipeline layouts for indications that require rapid symptom relief, such as migraine, and nausea and vomiting caused by chemotherapy, radiotherapy or surgery. These two product pipelines are currently in the Investigational New Drug (IND) application stage and preclinical research stage, both progressing ahead of the industry.

All three of our major nasal inhalation product pipelines are developed based on the same nasal inhalation drug formulation technology platform, demonstrating its reliability, reproducibility, and scalability in research and industrial application. Our product pipelines are currently the only ones of their kind in China according to Frost & Sullivan and remain competitively positioned in global development, reflecting the technological leadership and innovation strength of our platform, as confirmed by Frost & Sullivan.

Within our nasal inhalation drug formulation technology platform, we have integrated a number of core technologies, establishing a high technological barrier. Our precision olfactory-region drug delivery technology is designed to facilitate drug deposition in the olfactory region through integrated formulation and device control, which may provide a foundation for nose-to-brain drug delivery approaches. We are currently developing an olfactory-targeted spray device to work synergistically with the formulation to support delivery precision and consistent performance. Our effective mucosal absorption and intracerebral transport technology utilizes permeation-enhancing excipient compositions designed to improve drug absorption efficiency across the olfactory mucosa and potentially facilitate transport towards the brain. This technology is intended to be applicable to a wide range of drug types, including small-molecule chemical drugs, peptides, and biological macromolecules such as proteins, demonstrating strong technical versatility and platform scalability.

The therapeutic potential of this technology platform spans multiple CNS indications where factors such as speed of onset, ease of administration, and improved drug exposure in brain are important considerations for treatment. Key areas of application include:

- Neurodegenerative diseases — such as Parkinson’s disease, where bypassing gastrointestinal metabolism and achieving targeted CNS delivery can significantly enhance drug efficacy. Nasal inhalation drug delivery also provides a needle-free, swallow-free alternative, particularly beneficial for patients who experience dysphagia or difficulty swallowing, which is common in advanced stages of neurodegenerative conditions.
- CNS related acute diseases and symptoms — such as migraines, nausea and vomiting, where rapid onset of action is essential and non-injectable formulations improve patient convenience.

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By combining formulation expertise and biological insight, our technology platform lays the foundation for a new generation of CNS drug formulations. These formulations not only act more rapidly, but may also reduce the impact of food on drug absorption. As we continue to expand our pipeline, we believe this technology will unlock significant opportunities across both high-value specialty indications and broader public health needs.

Our Core Product, DHMP, is the first dissolving microneedle drug patch approved for clinical trials in China, and the only one in China to have advanced to Phase II clinical trial, as confirmed by Frost & Sullivan

With years of accumulated expertise, we have gained unique insights into microneedle drug formulations and built strong execution capabilities. Our Core Product, DHMP, capitalizes on the advantages of microneedle transdermal drug delivery, including convenience of administration and avoidance of issues associated with traditional injections such as needle phobia and needle injuries. Built upon our technology system relating to delivery efficiency, the product possesses competitive advantages in the following aspects:

Technological leadership

DHMP demonstrates rapid drug absorption following application, achieving a time to reach peak plasma concentration (T_{max}) of approximately 15 minutes. This enables the product to effectively meet clinical needs for rapid sedation, while its microneedle based drug delivery with provides patients with a comfortable therapeutic experience.

Proven safety profile based on Phase I clinical trial

In the Phase I clinical study, healthy subjects administered with low-, medium-, and high-dose DHMP demonstrated good safety and tolerability. No drug-related serious adverse events were reported. Local skin irritation assessments indicated that no significant irritation reactions occurred across any of the dose groups.

Promising Market Prospects

The preoperative sedation market is advancing from traditional adjunctive medications toward more sophisticated perioperative management solutions. With increasing emphasis on precision, safety, and convenience, modified new drugs are gaining broader clinical acceptance. Their potential for rapid action and ease of administration positions them to drive meaningful penetration into the sedation market.

A major growth opportunity lies in expanding clinical usage beyond traditional surgery settings. Preoperative sedation is now widely adopted in dental procedures, orthopedic day surgeries, imaging examinations (MRI/CT), endoscopy, and interventional diagnostics, reflecting strong demand across high-frequency medical scenarios. Outpatient and minimally invasive procedures continue to rise, creating fertile ground for modified new drugs that support convenient and efficient clinical workflows.

The pediatric sector is emerging as a strategic entry point for market expansion. Children commonly experience preoperative anxiety and poor acceptance to injections, highlighting the value of minimally invasive, rapid-acting, and user-friendly formulations. Policy initiatives promoting child-friendly healthcare environments and pediatric-focused drug development are expected to further accelerate the adoption of modified new drugs that improve compliance and perioperative comfort.

In summary, growing comfort-focused care demand, broadening application scenarios, and policy support for pediatric innovation collectively create promising market prospects. Modified new drugs are poised to penetrate mainstream clinical practice and unlock new usage settings, supporting the evolution of a more standardized, compliance-driven, and patient-centered preoperative sedation ecosystem.

Our Core Product XJN010, is the first and only investigational product addressing the “Off” episodes in Parkinson’s disease approved for clinical trials in China, as confirmed by Frost & Sullivan

Another Core Product, XJN010, is designed to capitalize on the potential advantages of nasal delivery for CNS-targeted therapies, including avoidance of first-pass metabolism, rapid onset of action, and the potential ability to bypass the BBB to achieve higher drug exposure in brain. Combined with our precise olfactory-region delivery technology and effective intracerebral transport technology, the product possesses competitive advantages in the following aspects:

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Technological Leadership

Following nasal administration, XJN010 demonstrates rapid drug absorption, achieving a time to reach peak plasma concentration (T_{max}) of less than 1 hour. This rapid pharmacokinetic profile may enable the product to alleviate “Off” episodes in patients with Parkinson’s disease in a timely manner, addressing the clinical need for fast-acting symptom relief.

Proven safety profile based on Phase I clinical trials

In the Phase I clinical study, healthy subjects who received a single administration of the XJN010 nasal spray demonstrated good overall safety and tolerability. No serious adverse reactions (SARs) or serious adverse events (SAEs) were observed, and there were no deaths or withdrawals related to adverse events (AEs). All reported adverse events were mild (CTCAE Grade 1) and had fully recovered or resolved during the trial period.

Promising market prospects

With the accelerating ageing of the population, the number of Parkinson’s disease patients experiencing “Off” episodes in China is expected to increase from 1.42 million in 2021 to 2.35 million by 2030, while the corresponding market size is projected to expand significantly from US\$0.31 billion in 2021 to approximately US\$0.85 billion by 2030. Globally, the Parkinson’s disease “Off” episode market is also undergoing rapid expansion, having grown from US\$5.72 billion in 2021 to US\$8.10 billion in 2025, and is expected to reach US\$13.02 billion by 2030, according to Frost & Sullivan. With increasing clinical demand for treatment options that offer faster onset of action, greater ease of administration, and improved safety, XJN010 is well positioned to meet these needs and demonstrates significant market potential.

A pipeline based on selected indications and alternative formulation technologies

Our pipelines are strategically diversified across therapeutic areas, with each product candidate selected through rigorous clinical, scientific, and commercial evaluation. This targeted approach maximizes development success rates and ensures strong alignment with clinical needs and market demand. Rather than a collection of technologies, our pipelines reflect a high-certainty model that apply advanced engineering to address real clinical challenges.

We prioritize indications where traditional formulations present significant clinical limitations, such as invasive administration, poor patient compliance, or suboptimal drug exposure. Our drug formulation technologies are specifically designed to overcome these challenges, enabling more effective, safer, and more patient-friendly therapeutic options. Our indication selection strategy is highly consistent and aligned as follows:

- Clearly defined clinical scenarios: Focused on specific clinical conditions where existing routes of administration present evident deficiencies, such as preoperative sedation, “Off” episodes in Parkinson’s disease, and acute migraine attacks.
- Patient-oriented drug administration: Our focus goes beyond improving therapeutic efficacy. We also aim to address the underlying challenge of comfort and ease in drug administration, reducing patient discomfort and enhancing treatment adherence to improve the overall medication experience. Our approach is designed to meet continuing clinical needs.
- Significant commercial value: Each of our product candidates is designed to deliver clinical benefits and patient value within its respective application scenario, thereby demonstrating potential for market pricing power and adoption by both healthcare professionals and patients.
- High level of certainty: We select well-established APIs whose safety and efficacy have been previously validated through large-scale clinical use, and enhance them through our alternative formulation technologies to create therapeutic products. This approach provides three key advantages: significantly reducing R&D risks and enhancing the probability of success, accelerating the regulatory approval process and shortening time-to-market, and strengthening commercial value to ensure market acceptance.

Overall, the breadth and depth of our pipeline reflect our ability to translate drug delivery technologies into therapeutic solutions that respond to real-world clinical challenges. Our products offer meaningful benefits to patients and healthcare providers.

A management team with extensive industry expertise and market insight

Our Company is led by an experienced management team with extensive expertise in drug formulation R&D, manufacturing, and commercialization, enabling the solid execution of our strategic initiatives.

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Dr. Wu Chuanbin (吳傳斌), Founder, Chairman of the Board, Executive Director, and Chief Executive Officer (CEO)

Dr. Wu is the founder of our Company and serves as the Chairman of the Board, an executive Director and our chief executive officer. Dr. Wu has over 30 years of experience in the biopharmaceutical industry. For further biographical details of Dr. Wu, please refer to the paragraph headed “Directors and Senior Management — Board of Directors — Executive Directors — Dr. Wu Chuanbin” in this document.

Dr. Tang Yu (湯宇), Chief Technology Officer (CTO)

Dr. Tang is specialized in the field of innovative pharmaceutical formulation development, with over 10 years of experience in managing R&D teams, and has successfully established multiple drug delivery technology platforms. For further biographical details of Dr. Tang, please refer to the paragraph headed “Directors and Senior Management — Senior Management — Dr. Tang Yu” in this document.

Ms. Yang Beibei (楊蓓蓓), Executive Director and Director of The Microneedle Formulation R&D Center

Ms. Yang is the director of the microneedle formulation R&D Center of our Company and a key R&D expert in our team who oversees the entire development cycle of microneedle products of our Group, including formulation design, design optimisation, quality research, etc. Ms. Yang is the project leader of DHMP. For further biographical details of Ms. Yang, please refer to the paragraph headed “Directors and Senior Management — Board of Directors — Ms. Yang Beibei” in this document.

OUR STRATEGIES

We are a clinical stage pharmaceutical company dedicated to developing modified new drugs. Guided by our goal to become a global technology leader in modified new drugs, and under the leadership of our CEO, Dr. Wu Chuanbin, together with our experienced R&D team, we have established a growing global footprint. To advance our long-term vision and strengthen our value proposition to patients, healthcare providers, and shareholders, we will pursue the following core strategies based on our competitive advantages:

Strategically accelerate the global clinical development and regulatory approval of our Core Products, enhance delivery capabilities, and expedite global commercialization

Accelerate the clinical development of Core Products

We intend to continue adhering to our global clinical development strategy and multi-indication development approach. By leveraging efficient regulatory pathways in different countries and regions and capitalizing on the advantages of global patient populations, we aim to further enhance the efficiency of our clinical trials while fully realizing the global value of our Core Products.

To accelerate the clinical development and regulatory approval of our Core Products and advance their global commercialization, we are executing a global clinical development strategy with parallel clinical trials in China and overseas. We seek to utilize the comparative strengths and resources of different countries and regions to optimize clinical trial protocols and operations, thereby expediting global regulatory approval processes. We plan to maintain close communication and cooperation with leading clinical institutions and principal investigators both in China and abroad, while leveraging China’s large patient population to ensure efficient patient enrollment and compliance with the regulatory requirements of different jurisdictions. Our objective is to bring our Core Products to market as quickly as possible to address continuing clinical needs.

Clinical development and registration of Core Product DHMP

We conducted a multi-center, randomized, double-blind, placebo-controlled Phase IIa clinical trial in China for preoperative sedation for children of 2–6 years old. As of the Latest Practicable Date, conduct of clinical studies for the Phase IIa clinical trial has been completed, and preparation of the clinical study report is ongoing. We plan to initiate a Phase III clinical trial in the second half of 2026. After the completion of Phase III clinical trial, we will submit a New Drug Application (NDA) to the National Medical Products Administration (NMPA) for marketing approval.

For preoperative sedation in adults, we have received the Notification of Approval for Drug Clinical Trial in September 2025 for Phase II trial.

At the same time, following pre-IND communication with the U.S. FDA, we submitted an IND application in January 2026 for the adult indication and obtained FDA clearance to proceed with Phase I clinical trial in February 2026. We plan to commence a Phase I clinical trial in the U.S. in Q4 2026.

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We plan to allocate approximately HK\$[REDACTED] million (or approximately [REDACTED]%) of the net [REDACTED] from the [REDACTED] to fund our clinical development and regulatory submissions of our Core Product DHMP. For details, please refer to the section headed “Future Plans and Use of [REDACTED] — Use of [REDACTED]” in this Document.

Clinical development and registration of Core Product XJN010

We conducted a multi-center, randomized, double-blind, placebo-controlled Phase II clinical trial in China for the treatment of “Off” episodes in patients with Parkinson’s disease. As of the Latest Practicable Date, conduct of clinical studies for the Phase II clinical trial has been completed, and preparation of the clinical study report is ongoing. We plan to initiate a Phase III clinical trial in 2027. After the completion of Phase III clinical trial, we will submit NDA to the NMPA.

In addition, we have submitted an IND application to the FDA in October 2025 and received FDA approval in February 2026 for directly entering Phase II clinical trial in the U.S. We plan to initiate clinical studies in the U.S. in the third quarter of 2026.

We plan to allocate approximately HK\$[REDACTED] million (or approximately [REDACTED]%) of the net [REDACTED] from the [REDACTED] to fund our clinical development and regulatory submissions of our Core Product XJN010. For details, please refer to the section headed “Future Plans and Use of [REDACTED] — Use of [REDACTED]” in this Document.

Enhance the delivery capabilities of our Core Products and accelerate the global commercialization

To support the future clinical and commercial supply of our Core Products and other modified new drugs, we have commenced the establishment of two industrial bases for our core technology platforms: the Microneedle Formulation Industrial Base and the Nasal Inhalation Formulation Industrial Base. Both sites are being constructed in strict compliance with regulatory standards of major jurisdictions, including China and the U.S., with the aim of building a stable and compliant global supply chain to ensure the continuous and reliable supply of high-quality pharmaceutical products to patients worldwide. The dual-site configuration enhances supply security, technology transfer efficiency, and business continuity for worldwide commercialization. For further details of these industrial bases, including their planned production lines, designed annual production capacity and utilisation rates, see “Business — Testing and Manufacturing Capacity — Our production facilities”.

Our Core Products and key products are currently at clinical development stages and have not been commercialized yet. The Core Products include the world’s first dissolving drug microneedle patch for preoperative sedation to enter Phase II clinical trial, and the first nasal inhalation drug formulation for the on-demand “Off” treatment of Parkinson’s disease patients already receiving dopa decarboxylase inhibitor/levodopa therapy to enter Phase II clinical trial. For the conduction of clinical trials, we adhere to rigorous standards in selecting principal investigators (PIs), comprehensively considering their professional qualifications, academic achievements, industry recognition, and past research experience in the relevant field. We believe that the academic influence and industry reputation of the PIs not only ensure the smooth execution and high-quality management of clinical trials but also help enhance the products’ acceptance by regulators and the academic community, laying the foundation for future market access.

On the commercialization path, we plan to establish an internal marketing team responsible for developing commercialization strategies, conducting academic promotion, and identifying potential partners. Considering the significant costs of building our own sales team, we have determined not to do so. Instead, we plan to partner with pharmaceutical companies in key markets such as China and the U.S. that possess strong commercialization capabilities and established distribution networks in our focused therapeutic areas. Through this strategic cooperation, we can leverage our partners’ comprehensive sales networks and market resources to more efficiently penetrate pharmacies, clinics, and hospitals, thereby capturing market potential, maximizing the commercial value of our Core Products, and achieving mutual benefit.

We plan to allocate approximately HK\$[REDACTED] million (or approximately [REDACTED]%) of the net [REDACTED] from the [REDACTED] to fund the expansion of our production capacity and support the commercialization of our pipeline products upon regulatory approval and sales authorization. For details, please refer to the section headed “Future Plans and Use of [REDACTED] — Use of [REDACTED]” in this Document.

Advance continuous innovation to unlock the full potential of our core technology platforms, engage strategic partners, and expand our product pipeline

To drive continuous advancement of our core technology platforms, unlock their full potential, strengthen our strategic collaboration ecosystem, and expand our product pipeline, we plan to establish a dual-engine growth model that combines internal innovation and external collaboration. Through

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in-house R&D, we will continue to build core technological capabilities, while open partnerships will enable us to integrate high-quality global resources. These two tracks will reinforce each other to strengthen our long-term competitiveness and support sustainable growth.

We plan to make full use of the hardware infrastructure and regulatory advantages of our Microneedle Formulation Industrial Base to gradually establish a large-molecule drug microneedle formulation manufacturing platform that meets GMP standards applicable to major global markets, including China and the U.S. The platform will feature multi-category adaptability, covering microneedle formulations for peptide drugs, protein drugs, and vaccines, thereby providing core manufacturing capacity to support pipeline expansion. Centering on this manufacturing platform, we aim to continuously expand our self-developed pipeline, deepen our technological and product reserves in large-molecule drug microneedle applications, and build an open and collaborative global ecosystem. Through these efforts, we intend to establish a microneedle drug formulation manufacturing hub representing China’s innovation in biopharmaceuticals. We do not plan to allocate any net [REDACTED] from the [REDACTED] to support our execution of this strategy.

Enhance brand recognition and industry influence for our core technology platforms

To strengthen the market recognition and industry influence of our core technology platforms, we plan to systematically enhance our brand awareness and industry presence through a comprehensive and multi-dimensional strategy, as outlined below.

We plan to strengthen our technological capabilities and intellectual property (IP) protection framework by focusing on the advantages of our core technologies. Through continuous technological iteration and optimization, we aim to strengthen our competitiveness while building a comprehensive IP protection system. By strategically securing patents, we aim to establish robust technological barriers that reinforce the uniqueness and defensibility of our platforms.

We plan to enhance academic and professional endorsement by actively publishing research findings related to our core technologies in leading domestic and international academic journals. By consistently producing high-quality scientific publications, we aim to demonstrate our R&D strength. In addition, we will regularly participate in top-tier industry conferences in China and overseas to share technological progress and strengthen professional recognition of our platforms.

We plan to broaden our strategic collaborations within the industry and further integrate high-quality resources by establishing strategic partnerships with leading domestic and international pharmaceutical companies to jointly advance technology translation and product co-development. Through these collaborations, we aim to validate the value of our technology platforms via the endorsement of leading enterprises while also attracting strategic investments from global industry leaders to expand our network and extend the reach of our technology platforms.

We also intend to take an active role in shaping industry standards in specialized areas such as microneedle drug formulations and nasal inhalation drug formulations. By contributing our technological expertise and practical experience to the formulation of such standards, we aim to solidify the position of our core technology platforms as industry benchmarks. We do not plan to allocate any net [REDACTED] from the [REDACTED] to support our execution of this strategy.

Build and sustain a globally diverse talent base by consistently attracting, retaining, and motivating top talent

Our talent strategy is built on “technological vision, growth opportunities, shared success, and cultural alignment”, with the goal of establishing a global and interdisciplinary team that is creative, high caliber, cohesive, positive, and capable of driving continuous innovation and supporting our global commercialization efforts. We also aim to deepen our institutional knowledge by attracting and retaining top tier scientific, engineering, clinical, regulatory, and commercial talent who can contribute to the evolution and optimization of our platform technologies. We recognize that organizational efficiency and human capital are critical to our long-term success. Accordingly, we are committed to aligning the long-term interests of our people with those of the company through incentive and talent programs, while fostering a dynamic and mission driven work environment that supports professional growth and innovation. In parallel, we will continue to refine our internal systems, ranging from operational workflows and standard operating procedures to project management frameworks, to enhance R&D efficiency and cross functional collaboration, thereby ensuring the successful execution of our talent strategy. Save for the net [REDACTED] allocated for establishing local sales, operation and after-sales team under the strategy headed “Enhance the delivery capabilities of our Core Products and accelerate the global commercialization”, we do not plan to allocate additional net [REDACTED] from the [REDACTED] to support our execution of this strategy.

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OUR TECHNOLOGY PLATFORMS

Our Core Products and major pipeline assets are built upon our two core platforms : dissolving microneedle drug formulation technology platform and nasal inhalation drug formulation technology platform, each addressing significant medical needs with broad therapeutic applications. Using these two technology platforms, we have established a well-balanced R&D pipeline. Our product candidates were selected through a rigorous and systematic evaluation process that considers clinical pain points, application prospects, market potential, and technical feasibility. This selection process integrates our longstanding expertise and accumulated experience in drug formulation technologies, maximizing the potential for successful development and commercialization of our product candidates.

Dissolving microneedle drug formulation technology platform

Building on more than a decade of dedicated research and technical development, we have independently established a microneedle drug formulation technology platform based on dissolving microneedle technology. This technology platform provides a solid foundation for our innovative dissolving microneedle drug formulations and forms a key part of our formulation capabilities.

Guided by the scientific principles of precise transdermal delivery and supported by our innovations, we have developed a core technology platform with independent intellectual property rights, comprising effective skin penetration, effective targeted delivery, and effective transdermal absorption technologies, together with precise and controllable drug loading and precise continuous infusion technologies. These technologies are designed to improve microneedle penetration performance, targeting accuracy, transdermal drug absorption, as well as accurate dose control and stable, continuous drug loading. Together, they provide technical support for the research, development, and industrialization of dissolving microneedle drug formulations for small molecules, peptides, and biological macromolecules. We hold full intellectual property rights to all the technologies we have developed within this technology platform and have secured comprehensive protection through a portfolio of core patents both domestically and internationally, making it difficult for competitors to replicate, thereby safeguarding our technological leadership and competitive advantage. This technology platform provides us with the following technological advantages and capabilities:

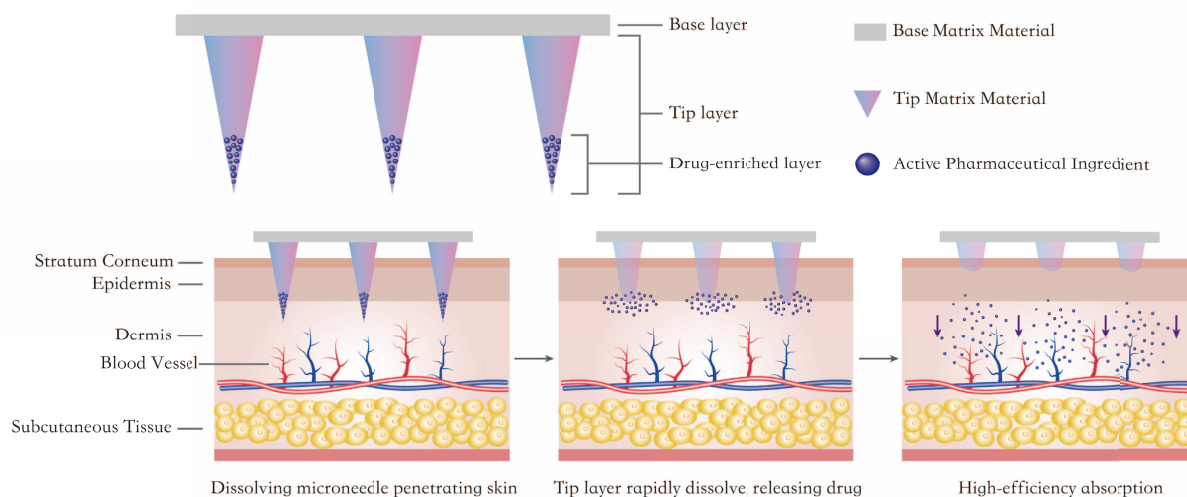


Illustration of dissolving microneedles drug delivery process

Effective skin penetration technology

Successful penetration of the skin’s stratum corneum is a fundamental prerequisite for effective transdermal drug delivery through dissolving microneedles, while the rate of microneedle dissolution and drug release within the skin is an equally critical parameter. Drawing on years of accumulated expertise, we have overcome the mechanical performance limitations of microneedle systems and developed a technology that precisely regulates the mechanical strength of microneedles through systematic formulation screening.

Our technology platform can adjust the mechanical strength of microneedles to ensure sufficient strength for efficient skin penetration while maintaining rapid dissolution within the skin. This design enables optimized drug delivery efficiency. By employing strength-enhancing agents and optimizing their interactions with the microneedle matrix, we have established a flexible and highly adaptable

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formulation system capable of meeting the specific requirements of different drugs and clinical applications. This capability supports the development of customized microneedle transdermal drug delivery solutions and accelerates the advancement of our product pipeline.

Effective targeted delivery technology

Efficient delivery of drug to the targeted skin layer is a core determinant of the effectiveness of dissolving microneedle drug delivery. Through process optimization, we accurately concentrate the drug at the microneedle tips, and flexibly adjust the distribution depth of the drug within the microneedle according to the therapeutic needs of different skin layers.

In addition, based on our technology platform-based design philosophy, we have independently developed a microneedle-specific drug delivery device with independent intellectual property rights. Working synergistically with the dissolving microneedle drug formulations, this device significantly enhances positional accuracy, dose uniformity, and operational reliability during the administration process.

Effective transdermal absorption technology

Efficient absorption of drugs delivered to the targeted skin layer is a decisive factor in determining the therapeutic efficacy of dissolving microneedle drug formulations. The delivery method integrates microchannel formation and permeation enhancement, where physical microchannels created by microneedle penetration are combined with effective permeation-enhancing excipient compositions. This approach significantly improves drug permeation rate, absorption efficiency, and bioavailability. This technology is applicable not only to various small-molecule drugs, but also effectively promotes the absorption of proteins, peptides, and biological macromolecules, offering broad carrier compatibility and strong potential for therapeutic indication expansion.

Precise and controllable drug loading technology

Accurate regulation of drug loading capacity is a key aspect of our dissolving microneedle drug formulation technology platform. For large-molecule drugs such as GLP-1 and GIP receptor agonists, multi-dosage specifications are essential to accommodate variations in patient condition, body weight, and treatment stage. To address this clinical need, we have developed a precise and controllable drug loading technology system, which enables flexible adjustment of drug content within individual microneedle units through formulation optimization, microneedle structural design, and process innovation. This system allows precise alignment with a full range of dosage requirements, from low-dose to high-dose drug formulations, providing robust technological support for large-molecule drug therapies and personalized treatment regimens.

Precise continuous infusion technology

Precise continuous infusion technology serves as a core foundation for achieving high-quality and large-scale production of dissolving microneedle drug formulations. We are progressing as planned with the step-by-step establishment of microneedle formulation production lines that comply with GMP standards of both China and the U.S.. Each production line is designed with an annual capacity of approximately 3 million patches, to support the clinical and commercial needs of our Core Products and key products.

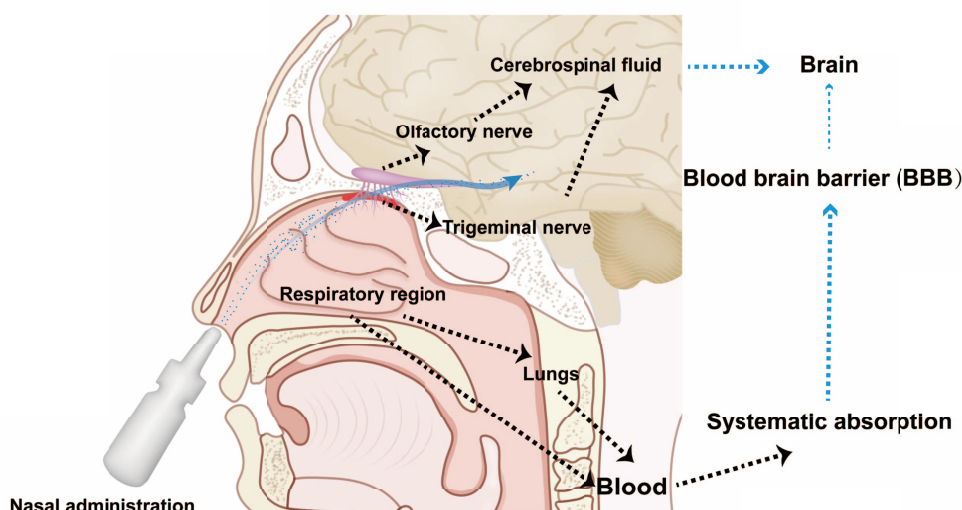
We are developing a portfolio of product candidates under this platform. Leading the pipeline is our Core Product DHMP. We are also developing another product, XJN1102, a glucagon-like peptide-1 (GLP-1) microneedle patch.

Nasal inhalation drug formulation technology platform

We have dedicated years to advancing core technologies and industrial translation in the field of nasal inhalation drug formulations. Guided by the scientific principles of olfactory-targeted drug delivery and supported by our permeation enhancement technologies, we have successfully established a technology system with independent intellectual property rights, comprising precise olfactory-region administration and effective intracerebral transport technology. This system is designed to improve drug deposition in the olfactory region and enhances absorption across the olfactory mucosa, which may enhance drug exposure in brain and providing technical support for the development of nasal inhalation drug formulations intended for CNS diseases. Building upon this technology platform, we have developed the following core technologies and capabilities:

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Precision olfactory-region drug delivery technology



Nose-to-brain delivery route

Effective intranasal CNS drug delivery requires accurate drug deposition in the olfactory region. To address this, we have developed a precision olfactory-region drug delivery technology system, which enables targeted control over key parameters such as plume angle, droplet size, and spray area through the tuning of formulation properties. This system is designed to facilitate targeted drug deposition in the olfactory region, thereby supporting rapid absorption and therapeutic effect in the intended area of action.

Nasal sprays are defined by the FDA as drug-device combination products, and the nasal spray device itself is a key factor influencing intranasal delivery. However, core technologies in this field have long been monopolized by foreign companies. To break this technological barrier, we are developing an olfactory-targeted spray device, which, when integrated with our formulation design, is expected to support precise drug delivery to the olfactory region. This device will support potential pipeline products within our nasal inhalation drug formulation technology platform. In addition, we plan to establish a joint patent pool covering both formulations and devices to build a strong technological barrier.

Effective mucosal absorption and intracerebral transport technology

Drug absorption in the olfactory region is a critical determinant of intranasal drug delivery efficiency. To ensure efficient absorption following nasal administration, we screened multiple permeation-enhancing excipients and successfully incorporated the most effective enhancer into our nasal inhalation drug formulation technology platform. Innovatively, we applied this absorption enhancer to a nasal drug delivery strategy for Parkinson's disease and have filed intellectual property protection for this application. In our Core Product XJN010, the addition of this enhancer is intended to improve absorption across the olfactory mucosa and the intranasal CNS delivery approach. In preclinical studies, this approach was associated with findings consistent with enhanced delivery from the nasal cavity to brain tissues and increased brain exposure in the relevant study.

Our nasal inhalation drug formulation technology platform supports a broad range of molecules, including small molecules as well as larger biological compounds such as peptides and proteins, demonstrating versatility and scalability, and providing a potential pathway for developing treatments for CNS diseases and disorders via the intranasal route.

Preclinical and scientific basis of nose-to-brain delivery pathway

Our nasal inhalation drug formulation technology platform is designed to support CNS-targeted nasal delivery and may facilitate drug transport via the nose-to-brain pathway. The scientific rationale for this approach is based on formulation design, together with preclinical observations (including animal pharmacokinetic, tissue distribution and imaging studies for certain product candidates, including XJN010), which were consistent with the possibility of transport from the nasal cavity to brain tissues. However, these findings do not establish in humans that direct nose-to-brain transport is the primary mechanism of delivery.

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OUR PIPELINE PRODUCTS

DHMP — our Core Product for preoperative sedation

Overview

DHMP is a self-developed product which as confirmed by Frost & Sullivan is the first dissolving microneedle transdermal drug patch approved for clinical trials in China. Developed for preoperative sedation in both pediatric and adult patients, it delivers dexmedetomidine hydrochloride via dissolving microneedle drug delivery system, offering a potentially safe, effective, and patient-friendly method of drug administration.

Sedation is an important component of preoperative and diagnostic care. In practice, the anesthesiologist prescribes an individualized preoperative sedation plan based on the patient’s physical status, underlying illness, and surgical needs. Appropriate use of sedatives alleviates fear and anxiety, so patients enter the operating room calm and emotionally stable, which facilitates smoother anesthesia induction and supports surgical efficiency and safety. Despite its importance, commonly used methods present significant challenges. Intravenous (IV) remains the standard, yet they can be painful and intimidating, particularly for children and for patients with needle anxiety. Establishing IV access is uncomfortable and time-consuming and often requires additional staff when patients resist or become anxious. Although oral sedatives or nasal spray alternatives may help alleviate injection-related anxiety, they still present limitations such as delayed onset of action and individual variability. These constraints not only increase the complexity of preoperative sedation procedures and contribute to surgical delays, but also impose additional psychological stress on both patients and medical staff.

DHMP is designed to address certain practical limitations of existing sedation methods. It is designed to support rapid transdermal delivery without the need for IV injection or active patient cooperation, providing advantages in pediatric care and in adults who may experience preoperative anxiety or difficulty with IV access. Its easy-to-apply format simplifies the sedation process, enhances patient comfort, and reduces the burden on clinical staff. By combining reliability with patient-centered design, the microneedle transdermal drug patch creates a minimally invasive easy-to-apply alternative for preoperative sedation.

Phase I clinical trials demonstrated favorable safety, tolerability, and preliminary pharmacokinetic profiles. For the adult indication, Phase II clinical trial is ongoing in China to evaluate clinical efficacy, dose optimization, and patient acceptability in the target patient population, and is expected to be completed by the fourth quarter of 2026. For the pediatric indication, conduct of clinical studies for the Phase IIa clinical trial in China has been completed as of the Latest Practicable Date, and Phase IIa is expected to be completed by the third quarter of 2026. DHMP is positioned to become the first microneedle based dexmedetomidine hydrochloride product to be approved in China, with regulatory approval anticipated in 2028 for both adult and pediatric use. This would mark an important milestone in the development of alternative administration options for preoperative sedation.

Mechanism of action

DHMP is a dissolving microneedle patch developed for the transdermal delivery of dexmedetomidine hydrochloride. Dexmedetomidine hydrochloride is a well-established sedative used in both adults and children for preoperative care and diagnostic procedures. It provides safe and reliable sedation without significant respiratory depression. These attributes make dexmedetomidine hydrochloride an ideal active ingredient for a microneedle drug formulation, combining proven clinical value with a safety profile that aligns with the needs of a patient-friendly sedation product.

DHMP is designed to translate these clinical advantages into practice through a precisely engineered dissolving microneedle system designed for rapid, efficient, and minimally invasive delivery. Each patch consists of two layers: a base layer made from polymers approved for transdermal administration, providing reliable support; and a microneedle tip layer composed of dexmedetomidine hydrochloride, a structural matrix made from biocompatible materials approved for injectable use. The structural matrix provides mechanical strength, allowing the microneedles to maintain structural integrity during skin insertion even at high drug-loading levels. The tip-loading design of the patch concentrates dexmedetomidine hydrochloride at the microneedle tips. Upon application, the microneedles are designed to cross the stratum corneum and deliver the drug into the superficial dermis, where it is intended to be absorbed into systemic circulation.

Through its combination of precisely engineered delivery technology and stable preparation technology, DHMP is designed to address the limitations of dissolving microneedles, including limitations in needle-tip mechanical strength needle-tip drug enrichment and drug delivery uniformly. It delivers pharmacokinetic profiles that are comparable to subcutaneous injection while avoiding the need for a traditional needle-based administration procedure. Combined with the well-established clinical benefits of dexmedetomidine hydrochloride, DHMP offers an alternative mode of administration that is

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minimally invasive and operationally convenient. It is intended to provide a rapid and practical option for preoperative sedation that does not require IV access or active cooperation. This is advantageous for children undergoing surgery or diagnostic procedures, and equally valuable for adults with preoperative anxiety or difficulties with conventional sedation methods.

Market opportunities and competition

According to Frost & Sullivan, preoperative sedation is expanding from traditional surgical settings to a wider range of clinical procedures, including dental treatment, orthopedic day surgeries, medical imaging (e.g., MRI/CT), endoscopy, and interventional diagnostics. As outpatient minimally invasive procedures and day medical services increase, the need for sedation to support patient cooperation during procedures is also increasing. Its cross-department and cross-age-group applicability gives preoperative sedation broad clinical utility within perioperative management systems.

For details of the market size and growth outlook of the global, China and U.S. sedative drug markets, see “Industry Overview — Preoperative Sedation Market.”

Currently commonly used preoperative sedatives still face challenges related to onset time, dosage control, duration of action, and side effect management. Injectable forms require professional administration, while oral sedatives often have delayed onset of action and variable absorption, making them less suitable for clinical scenarios that require fast onset and quick recovery within short preoperative windows. Additionally, some drugs carry risks such as postoperative sedation residue and respiratory depression. Against this backdrop, hospitals and outpatient centers are increasingly seeking solutions that support safety and workflow efficiency, particularly through innovative drug formulations and drug delivery systems. Products that offer differentiated profiles, such as minimally invasive administration, faster onset, simplified operation, and improved tolerability, are well positioned to unlock incremental value and expand utilization across additional clinical settings and patient groups.

Our DHMP is designed to address this need. As a dissolving microneedle patch designed for the transdermal delivery of dexmedetomidine hydrochloride, it provides an alternative to traditional hospital-based IV administration and opens new opportunities in outpatient, pediatric, and pre-surgical care. With no microneedle-based dexmedetomidine hydrochloride products currently on the market in China according to Frost & Sullivan, our product may be one of the earlier entrants in this segment. Subject to regulatory approval, it is being developed for the management of preoperative anxiety in adult and pediatric populations, for moderate sedation during invasive diagnostic procedures such as endoscopy, imaging, and dental interventions, and for adjunctive treatment of mild to moderate post-operative pain. Looking forward, its potential applications may extend into chronic pain management and sleep disorders, subject to further research and clinical development.

From a commercialization perspective, we aim to promote a comfortable, patient-friendly sedation approach. The strategy targets China’s rapidly growing day surgery, outpatient diagnostic, and pediatric markets. In line with national initiatives that prioritize children, we seek to deliver compassionate, patient-centered healthcare services that embody empathy and human warmth, better addressing the needs of child-friendly hospitals, such as the development of “no-cry operating rooms”. Professional promotion will focus on in-hospital channels such as anesthesiologists, pain management specialists, endoscopy centers, and pediatricians. The long-term goal is to position our DHMP as a standard, convenient solution for sedation and analgesia in perioperative care and invasive procedures, with the aim of supporting broader use in clinical practice.

Competitive advantages

Dexmedetomidine hydrochloride is widely used because of its favorable safety profile and minimal respiratory depression. Although alternative formulations, including nasal sprays and oral therapies, have been explored, the majority of current approved formulations remain IV injections, which require invasive access and skilled personnel. Our DHMP introduces a new approach: a dissolving microneedle patch delivering a proven sedative through microneedle technology platform. According to Frost & Sullivan, DHMP is the first and only microneedle-based dexmedetomidine hydrochloride product to enter Phase II clinical trials in China, and may therefore be among the earlier entrants in this segment. This innovation is designed to address certain limitations of existing delivery routes while offering potential benefits for patients, clinicians, and healthcare systems.

Minimally invasive, easy-to-administer format

Our DHMP is a microneedle patch that can be applied quickly and easily, without the need for IV access or specialized equipment. This format simplifies clinical workflows, reduces procedural burdens, and enhances patient experience. It is particularly advantageous for children, elderly patients, and adults who experience anxiety or difficulty cooperating with traditional sedation methods.

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Rapid onset and consistent absorption

By penetrating the stratum corneum and delivering dexmedetomidine hydrochloride into the superficial dermis, our DHMP is designed to enable systemic absorption through the capillary network. In our clinical pharmacokinetic study, DHMP reached maximum plasma concentration (T_{max}) within 0.08 to 0.25 hours across tested dose groups, compared with approximately 0.33 hours for dexmedetomidine IV injection at the 68 µg dose level, indicating a broadly similar absorption profile in our study. In our clinical pharmacodynamic study using the Ramsay sedation score, except for the 34 µg dose group, the microneedle patch groups achieved a median score of ≥ 3 within 10 minutes. In particular, both the 68 µg DHMP group and the same-dose dexmedetomidine IV injection group achieved a median Ramsay sedation score of 3.0 at 10 minutes after administration. Accordingly, at the 68 µg dose level, DHMP demonstrated a sedation onset broadly comparable to IV injection in our study. Sedation in the microneedle patch groups generally declined to a mean score of < 3 after approximately 1.25 hours, whereas the IV injection group maintained a mean score of ≥ 3 from 10 minutes up to 2 hours. Accordingly, the microneedle patch demonstrated a shorter duration of sedation, which may be preferable in certain short procedures or diagnostic settings.

Based on our Phase I clinical study, DHMP showed sedation onset within approximately 10 to 15 minutes, depending on the dose group. We believe such onset time may be clinically suitable for preoperative sedation. While depending on the dose group, DHMP may have a longer onset time than intravenously administered dexmedetomidine, Frost & Sullivan is of the view that an onset time of ≤ 30 minutes would be clinically suitable for preoperative sedation. In addition, in clinical practice, chloral hydrate, a widely used central sedative, is commonly administered approximately 20 minutes before a procedure, with reported onset generally within 15 to 30 minutes and peak effect at around 30 minutes. This reflects a commonly accepted effective time window of approximately 10 to 30 minutes for preoperative sedation. The observed 10 to 15-minute onset time of DHMP falls within such time window and therefore suggests that DHMP may be compatible with routine preoperative sedation workflow, although its clinical suitability will need to be further evaluated in later-stage clinical trials.

Broader applicability and clinical flexibility

DHMP expands the use of dexmedetomidine hydrochloride beyond hospital-based IV administration into outpatient, pediatric, and diagnostic settings. Its minimally invasive format may increase acceptance among patients who might otherwise resist injections. This broader applicability provides greater flexibility for clinicians, making sedation feasible in a wider range of settings.

Differentiation in a crowded market

Traditional injectable dexmedetomidine hydrochloride products in China are increasingly commoditized due to centralized procurement programs that drive price competition and erode margins. Our DHMP, by contrast, competes in value rather than price. Its minimally invasive format and operational efficiency differentiate it from existing products and may reduce its exposure to direct price-based competition.

Limitations

DHMP is subject to certain limitations and uncertainties. As of the Latest Practicable Date, conduct of clinical studies for Phase IIa clinical trial for the pediatric indication has been completed, and preparation of the clinical study report is ongoing. Phase II clinical trial for the adult indication is still ongoing. Further clinical trials are required before any marketing authorization may be obtained. Given the novelty of the delivery approach, the effectiveness and clinical benefit of DHMP remain uncertain, and there is no assurance that it will demonstrate favorable safety and efficacy outcomes in later-stage clinical trials or obtain regulatory approval in any jurisdiction. In addition, unlike IV administration, use of a microneedle patch may be associated with local skin reactions at the application site. The microneedle patch may also be unsuitable for patients with extensive skin damage at the intended application site or systemic dermatological diseases, and such patients may be unable to use the microneedle patch.

Clinical trial sponsor(s)

We are the sole sponsor of the clinical trials for DHMP. As the sponsor, we are responsible for, among other things, the overall initiation, management and financing of the relevant clinical trials, and for ensuring compliance with applicable regulatory and ethical requirements.

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Summary of clinical trial results

In pediatric patients

We commenced preclinical studies of our DHMP since May 2022. We submitted the IND application to the NMPA in February 2024 and received the Notification of Approval for Drug Clinical Trial (藥物臨床試驗批准通知書) in April 2024 to conduct Phase I clinical trial in China for the indication of preoperative sedation in pediatric patients of 2 to 6 years old. We successfully completed the relevant clinical trial studies in March 2025 and received the formal report in May 2025. The results demonstrated that transdermal administration of the product achieved rapid onset of sedation within 15 minutes, with no adverse events of Grade 2 or above reported, indicating a favorable safety profile and low skin irritation. After the completion of Phase I clinical trial, we submitted the trial results and the Phase IIa clinical trial protocol to the NMPA in May 2025. In July 2025, Phase IIa clinical trial in pediatric patients aged 2 to 6 years has been approved by the NMPA. We commenced such Phase IIa clinical trial in August 2025, and as of the Latest Practicable Date, conduct of clinical studies for the Phase IIa clinical trial has been completed, and preparation of the clinical study report is ongoing. We expect to complete the Phase III clinical study and submit the NDA in 2028. As of the Latest Practicable Date, we have not received any questions or objections from the NMPA regarding our clinical development plan for DHMP for preoperative sedation in pediatric patients.

Below is a summary of these clinical trials in reverse chronological order.

Phase IIa Clinical Trial

- Trial design

The Phase IIa clinical trial of DHMP in children employed a randomized, double-blind, placebo-controlled, multicenter clinical trial design. The trial consisted of three stages. Stage 1 enrolled 16 large-weight children for safety, pharmacokinetics, and efficacy evaluation. Stage 2 further validated the proposed dose extrapolated from Stage 1, with 24 large-weight children to be enrolled for safety, pharmacokinetics, and efficacy evaluation. Stage 3 enrolled 24 small-weight children, who were administered different doses of DHMP or placebo patches for safety, pharmacokinetics, and efficacy evaluation.

Endpoints

Primary endpoints: (1) changes in physical examination, vital signs, blood oxygen saturation, 12/18-lead electrocardiogram, and other laboratory tests before and after medication; (2) occurrence of adverse events (AEs) and severe adverse events (SAEs) during the study period.

Secondary endpoints: (1) Population pharmaceutical characteristics: Population pharmacokinetic (PopPK) parameters. (2) Efficacy: (i) Proportion of subjects who successfully separated from their parents and achieved a Ramsay score ≥ 3 within 45 minutes after administration; (ii) the completion rate of the examination; Examination completion is defined as the completion of the examination after successful sedation within 45 minutes of administration, or successful initiation of anesthesia induction after parent-child separation. Successful sedation is defined as a Ramsay score ≥ 3 and successful parent-child separation within 45 minutes of administration. Otherwise, sedation failure is considered. The following parameters will be examined: (a) the proportion of subjects who achieved a Ramsay score ≥ 3 within 45 minutes after administration, (b) the time to first achieve a Ramsay score ≥ 3 within 45 minutes after administration, (c) the proportion of subjects who successfully separated from their parents within 45 minutes after administration, (d) the time from administration to the first successful separation from their parents, (e) the time to recovery from anesthesia. (3) Safety: Evaluation of changes in skin at the administration site before and after administration.

- Trial status

As the Latest Practicable Date, conduct of clinical studies for Phase IIa clinical trial has been completed. Preparation of the clinical study report is ongoing, and we expect to issue the clinical study report in the third quarter of 2026.

Phase I Clinical Trial

Although the IND approval was issued for pediatric use, in accordance with internationally accepted ethical principles and regulatory guidance including the ICH E11(R1) guideline on clinical investigation of medicinal products in the pediatric population, first-in-human and early Phase I studies are generally conducted in healthy adult volunteers to evaluate safety, tolerability, and pharmacokinetics while minimizing risk to vulnerable populations. Accordingly, the Phase I clinical trial for DHMP in pediatric use was conducted in healthy adults. Following the completion of the Phase I clinical trial in healthy adults, we held a formal communication meeting with the NMPA in July 2025 to discuss our subsequent clinical development plan for the pediatric indication. Based on the data obtained from the

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adult Phase I trial, we reached an agreement with the NMPA on the rationality of the development plan, concluding that the potential benefits outweighed the risks, and that the proposed dosage for children was safe. As of the Latest Practicable Date, the NMPA has no objection for the Company to commence the Phase II clinical trial.

For details of Phase I Clinical Trial conducted in healthy adults, please refer to the paragraph headed “In adult patients — Phase I Clinical Trial” in this document.

In adult patients

In April 2024, we received the Notification of Approval for Drug Clinical Trial from the NMPA to conduct Phase I clinical trial in China for the indication of preoperative sedation in pediatric patients aged 2 to 6 years. As discussed above in the paragraph headed “In pediatric patients — Phase I Clinical Trial”, in accordance with internationally accepted ethical principles and regulatory guidance, the Phase I clinical trial for DHMP in pediatric use was conducted in healthy adults. Data obtained from such Phase I clinical trial was also used to support the subsequent progression to Phase II clinical trial in adult patients. In our clinical trial application for the adult indication submitted in June 2025, we explained in the application materials that the adult and pediatric indication applications were identical in terms of pharmaceutical development and non-clinical research materials and that we were using the completed Phase I clinical study conducted in healthy adult subjects under the pediatric indication to support the adult indication Phase II clinical trial application. We cited such Phase I clinical results as the safety basis for the adult Phase II clinical trial. The NMPA accepted the adult indication clinical trial application in July 2025 and subsequently approved the application in September 2025, without requiring a separate Phase I clinical trial to be conducted for the adult indication. We thereafter completed the required NMPA registration for the Phase II clinical trial for the adult indication, and no objection had been received as of the Latest Practicable Date. The adult indication Phase II clinical trial commenced in March 2026.

Below is a summary of these clinical trials in reverse chronological order.

Phase I Clinical Trial

- Trial design

The trial employed a single-center, open-label, randomization within the queue, crossover design to evaluate the safety, pharmacokinetic, and pharmacodynamic characteristics of DHMP in healthy adult subjects in China. The trial planned to enroll 36 subjects, and 36 subjects were actually enrolled. In Cohort 1 and Cohort 2, subjects received a single dose on days 1, 3, and 5, with exit testing on day 6. In Cohort 3, subjects received a single dose on days 1 and 3, with exit testing on day 4. A 2-day washout period was included in the study period.

- Trial status

The trial was commenced in February 2025 and completed in March 2025. As confirmed by Frost & Sullivan, the short duration of Phase I clinical trial is in line with industry norm. Of the 36 subjects enrolled, 35 subjects completed the trial and one subject discontinued the trial for personal reasons unrelated to the trial, study treatment or any adverse event.

- Pharmacokinetics, pharmacodynamics and other analytical conclusions

After administration of 34 µg, 68 µg, and 118 µg of the microneedle patch, the mean peak concentration ($C_{\max}$) was 147.63 ± 39.803 pg/mL, 451.3 ± 96.85 pg/mL, and 485.2 ± 187.16 pg/mL, respectively, with median time to peak concentration ($T_{\max}$) of 0.250 h, 0.080 h, and 0.080 h, respectively. In the intravenous injection group, the mean peak concentration ($C_{\max}$) was 1315.3 ± 243.08 pg/mL, and the median time to peak concentration ($T_{\max}$) was 0.330 h.

The elimination half-life of each microneedle patch group was approximately 2.281 h, similar to that of the intravenous injection reference group. DHMP was absorbed rapidly and did not exhibit significant sustained-release characteristics.

DHMP has a rapid onset of action after administration. Both the 68 µg and 118 µg dose groups took effect within 0.25 hours after administration and remained effective until 1.25 hours after administration.

Based on our Phase I clinical study, the DHMP demonstrated rapid systemic absorption. In the PK analysis, the observed median $T_{\max}$ for DHMP across the studied groups was generally approximately 0.08 to 0.25 hours, as compared to approximately 0.33 hours for the intravenous injection group. These data suggest that DHMP is capable of achieving systemic exposure within a relatively short period following administration.

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As of the Latest Practicable Date, we are not aware of any other relevant dissolving microneedle formulations of dexmedetomidine that would permit a meaningful comparison with DHMP.

We have also referred to publicly available clinical trial data for the marketed dexmedetomidine hydrochloride nasal spray product Aibeimei® (艾倍美®), according to which the reported onset time of clinically effective sedation was 23 minutes and the reported median $T_{\max}$ was 30 minutes, whereas in our Phase I clinical study, the DHMP showed an onset time of 15 minutes and a $T_{\max}$ of 15 minutes. Such comparison is not based on a head-to-head clinical study, and the data were derived from different studies and therefore may not be directly comparable.

- **Safety**

No severe adverse events (SAEs) or severe adverse reactions (SARs) were observed. All reported adverse events (AEs) and adverse reactions (ARs) were mild (CTCAE grade 1) and all were recovered/resolved. The reported AEs and ARs primarily consisted of minor fluctuations in vital signs, such as heart rate and blood pressure; temporary variations in laboratory parameters including blood uric acid, triglycerides, bilirubin, and routine urinalysis findings; and occasional instances of mild dizziness and nausea. These events are consistent with the established safety profile for dexmedetomidine hydrochloride, and no new or unexpected safety signals were identified.

Summary of preclinical studies

DHMP is a Class 2.2 modified new drug. The API is dexmedetomidine hydrochloride, the mechanisms of action, binding targets, and safety profile of which have been fully established. Our preclinical studies investigated toxicity, skin irritation, and allergy-related safety of DHMP in rats and Bama miniature pigs. Sedative effects were evaluated in rats, and pharmacokinetic characteristics and tissue distribution were assessed in Bama miniature pigs. The results show that the DHMP have low safety risk, no skin irritation or allergic reactions, and sedative effects comparable to dexmedetomidine hydrochloride injection. Currently, the above-mentioned preclinical studies have been completed under GLP conditions.

Material Communications and Next Steps

As of the Latest Practicable Date, we have not received any questions or objections from the NMPA regarding our clinical development plan for DHMP for the indication of preoperative sedation in pediatric patients.

Using the same pharmaceutical and nonclinical data submitted for the pediatric indication, in combination with adult Phase II clinical trial protocol, we submitted an IND application in July 2025 for phase II clinical trial for preoperative sedation in adults. Approval for phase II clinical trial was granted by the NMPA for the adult indication in September 2025. We commenced the adult indication Phase II clinical trial in March 2026 and expect to complete it in the fourth quarter of 2026.

In July 2025, we submitted a pre-IND application to the FDA for the indication of preoperative sedation in adults via the 505b(2) route. In September 2025, we received a written response from the FDA acknowledging the preclinical data we provided and finding no significant deficiencies. We held a pre-IND meeting with the FDA in September 2025 and received written meeting minutes in October 2025, which confirmed the overall development plan for the Phase I clinical trial in the U.S. We submitted an IND application on 15 January 2026 and the IND became effective from 15 February 2026 since no clinical hold was imposed by the FDA during the 30-day review period. We plan to commence a Phase I clinical trial in the U.S. in Q4 2026.

Upon commercialization, we plan to conduct post-marketing clinical studies to expand potential indications in response to market demand.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET THE DEXMEDETOMIDINE HYDROCHLORIDE MICRONEEDLE PATCH SUCCESSFULLY.

XJN010 — our Core Product, a nasal inhalation drug formulation for the treatment of “Off” episodes in Parkinson’s disease

Overview

Our Core Product, XJN010, is a self-developed, clinical-stage nasal inhalation drug formulation developed for the on-demand treatment of “Off” episodes in patients with Parkinson’s disease who are already receiving a levodopa-based regimen. Levodopa-based regimens are considered a primary treatment approach for managing motor symptoms in Parkinson’s disease, and levodopa is often administered in combination with a dopa decarboxylase inhibitor. XJN010 differs from conventional formulations primarily in its formulation and delivery route, namely intranasal administration via the nose-to-brain pathway, rather than in the active pharmaceutical ingredient itself. “Off” episodes are

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marked by a temporary loss of effectiveness of Parkinson’s medication, resulting in the sudden re-emergence of motor symptoms such as stiffness, tremors, and slowness of movement, often requiring rapid intervention to restore mobility.

By applying our nasal inhalation drug formulation platform technologies, XJN010 is designed to support nasal delivery for CNS-targeted therapy and may facilitate transport of the drug via the nose-to-brain pathway, with potential advantages such as avoidance of first-pass metabolism, rapid onset, and high drug exposure in brain. The nasal inhalation route may enable bypass of the blood-brain barrier (BBB), a major obstacle in CNS drug delivery, and may reduce the delays and variability associated with conventional oral and pulmonary administration. The approach is intended to provide a fast-acting, patient-friendly rescue therapy to support symptom management during “Off” episodes, especially those with unpredictable symptoms or difficulty taking oral or pulmonary inhalation medications.

We have completed a series of preclinical studies on XJN010. In August 2024, we received IND approval from the NMPA. According to the IND approval notice, we are permitted to carry out clinical trials for XJN010 in China, and after completion of Phase II clinical trials and prior to commencement of Phase III clinical trials, we should communicate with the NMPA regarding the existing clinical data and the Phase III clinical trial protocol. We subsequently completed our Phase I clinical trial in June 2025. These studies demonstrated rapid absorption of the API following administration and showed a favorable safety and tolerability profile. Through our nasal inhalation drug formulation platform technologies, XJN010 is designed to support faster absorption and enhanced delivery.

In August 2025, we commenced Phase II clinical trials to evaluate clinical efficacy, dose optimization, and patient compliance in target patient populations, and the NMPA has had no objection for our commencement of this Phase II study. As of the Latest Practicable Date, conduct of clinical studies for the Phase II clinical trial has been completed, and Phase II is expected to be completed by the third quarter of 2026 with the issuance of the clinical study report. Subject to clinical development progress and regulatory communications, we currently expect the Phase III clinical trial to be completed in 2027, after which we plan to submit an NDA to the NMPA.

To advance the product’s global development, in June 2025, we submitted a pre-IND application to the FDA for a Phase I clinical trial. In September 2025, we received a written response from the FDA, which agreed to exempt us from the Phase I clinical trial in the U.S. and allow us to proceed directly to the Phase II clinical trial. We submitted an IND application in October 2025 and received approval in February 2026 for directly entering Phase II clinical trial in the U.S. We plan to initiate the Phase II clinical trial in the third quarter of 2026.

Mechanism of action

XJN010 is a liquid suspension nasal inhalation drug formulation being developed as a rapid-acting, non-invasive therapy for the on-demand treatment of “Off” episodes in Parkinson’s disease. Currently, there is no approved prescription therapy in China specifically indicated for the management of “Off” episodes in Parkinson’s disease, and treatment options in this therapeutic area remain limited.

Conventional oral formulations exhibit notable pharmacokinetic and clinical constraints. Due to extensive first-pass metabolism, a large proportion of the API is metabolized in the periphery before reaching the CNS. As a result, over 95% of the administered dose is metabolized in peripheral tissues, leaving less than 1% available to cross the BBB to exert therapeutic effects in the CNS. The high systemic exposure to dopamine also causes a range of adverse effects, including cardiovascular complications such as arrhythmias, hypotension, and gastrointestinal disturbances such as nausea and vomiting. Pulmonary inhaled delivery has been explored to overcome some of these drawbacks by bypassing the gastrointestinal tract and enabling faster absorption. However, its effectiveness is limited by the need for adequate inspiratory capacity and coordination, which can be compromised during “Off” episodes. Inconsistent lung deposition, continued peripheral conversion, and comorbid respiratory conditions in patients can lead to inconsistent therapeutic efficacy and increased systemic side effects.

To address these limitations, XJN010 employs our nasal inhalation drug formulation platform technologies that are designed to support nasal delivery and may facilitate transport of the API via the nose-to-brain, potentially bypassing the gastrointestinal tract and the BBB. The olfactory epithelium, located in the upper nasal cavity, provides anatomical connections to the CNS via olfactory nerve and trigeminal nerve. By targeting this narrow and highly specific region, XJN010 is intended to support rapid onset of action, enhance delivery efficiency.

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For XJN010, preclinical pharmacokinetic, tissue distribution and imaging studies in animals provided support for the scientific rationale of its intended nose-to-brain delivery approach, including observations of rapid absorption and findings consistent with the possibility of transport from the nasal cavity to brain tissues. However, such findings do not establish the primary delivery pathway in humans. See “Summary of preclinical studies” for XJN010 for further information.

XJN010 is formulated as a liquid suspension for nasal inhalation. To enhance absorption, the formulation incorporates penetration enhancers to improve olfactory mucosal permeability. Preclinical studies demonstrated rapid absorption, with peak concentrations ($C_{\max}$) reached within minutes of administration. The peak concentrations ($C_{\max}$) also increased significantly, significantly exceeding that of the oral formulation at the same dose.

XJN010 is a stable formulation optimized for viscosity and chemical stability. It contains the API along with carefully selected excipients that support consistent drug delivery and storage stability under non-refrigerated conditions. In addition, the formulation has demonstrated enhanced drug absorption in preclinical nasal administration studies.

XJN010 is designed to address the key challenge of delivering sufficient drug quantities to the small (about 3–5% of the nasal surface area) and anatomically constrained olfactory region, thereby supporting improved delivery efficiency and promoting inter-patient consistency.

By combining a stabilized drug suspension with clinically validated penetration enhancers and targeted delivery technology, XJN010 is designed to provide a rapid-acting, efficient, and patient-friendly therapeutic alternative. The product supports effective administration without requiring swallowing or pulmonary inhalation capability, making it particularly suitable for patients with Parkinson’s disease experiencing “Off” episodes or for those facing challenges with the conventional routes of administration.

Market opportunities and competition

According to Frost & Sullivan, the patient population and market size for Parkinson’s disease “Off” episodes have been growing in the global, China and U.S. markets and are expected to continue to expand. For details, see “Industry Overview — NASAL SPRAY FORMULATION MARKET — Parkinson’s disease Market — Global Market”.

This rising prevalence has driven significant growth in healthcare spending on Parkinson’s disease. According to Frost & Sullivan, China’s “Off” episodes Parkinson’s disease market is forecasted to grow significantly from USD 0.31 billion in 2021 to USD 0.85 billion by 2030. This corresponds to a high CAGR of 9.41% from 2021 to 2025, accelerating to 13.36% from 2026 to 2030. With a growing emphasis on motor complication management and patient quality of life, the “Off” episodes Parkinson’s segment is emerging as a key driver of neurological pharmaceutical innovation in China. For the U.S., according to Frost & Sullivan, the “Off” episodes Parkinson’s disease patient population is expected to double over the next decade, rising from 0.25 million in 2021 to 0.44 million in 2030. The CAGR remains robust, reaching 7.45% during 2021 to 2025 and slightly moderating to 5.14% from 2026 to 2030. This sustained expansion is fueled by the aging baby boomer population, earlier diagnoses, and the progression of existing cases. As disease burden intensifies, this trend underscores the growing importance of long-term neurological care capacity and improved access to advanced treatment modalities in the U.S. healthcare system. The U.S. “Off” episodes Parkinson’s disease market is projected to nearly triple in value, rising from USD1.09 billion in 2021 to USD2.58 billion in 2030. With a CAGR of 10.00% during 2021 to 2025 and peaking at 9.84% during 2026 to 2030, the market demonstrates robust momentum, driven by both increasing patient volume and evolving clinical treatment needs. The introduction of advanced therapies, expanded insurance coverage, and heightened focus on managing motor and non-motor complications further bolster demand. As the patient burden grows, pharmaceutical innovation and accessible long-term care will remain critical for sustaining market growth.

According to Frost & Sullivan, as of the Latest Practicable Date, XJN010 is the only candidate targeting the “Off” episodes of Parkinson’s Disease.

Our product XJN010 is differentiated by its innovative nasal inhalation drug formulation. This approach is designed to bypass the BBB and achieve faster and more reliable symptom relief, offering significant value for patients with Parkinson’s disease experiencing “Off” episodes, as well as for those with respiratory conditions or swallowing difficulties. As the demand from patients and healthcare providers for treatment options that are efficient, convenient, and capable of improving quality of life continues to grow, modified new drugs designed to meet these needs are expected to garner significant attention.

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Competitive advantages

Our XJN010 product for the treatment of “Off” episodes in Parkinson’s disease is built on our innovative nasal inhalation drug formulation technology platform. It offers a unique combination of clinical relevance, technological innovation, and practical usability, designed to meet the evolving needs of patients and healthcare systems both domestically and globally.

Targeted solution for a widespread and growing need

Parkinson’s disease affects millions of people globally, with prevalence increasing steadily due to aging populations. “Off” episodes characterized by the re-emergence of disabling motor symptoms remain a significant challenge in disease management. Current options for rapid symptom relief are limited, especially for patients who experience difficulty swallowing or using pulmonary inhalation devices. XJN010 is designed to address this unmet need with a fast-acting, non-invasive alternative intended to support relief of motor symptoms during “Off” episodes.

As there are currently no medications specifically approved for treating Parkinson’s disease “Off” episodes as an independent indication, management generally relies on existing Parkinson’s disease therapies, which are predominantly oral formulations (including levodopa-based products). Accordingly, the reference product used in our pharmacokinetic assessment of XJN010 in the Phase I clinical trial was an oral drug. In healthy subjects, following a single intranasal dose of 40 mg XJN010, the median plasma T_{max} was 0.98 hour. In comparison, following single-dose oral administration of the reference product, the median T_{max} was 1.23 hours, and following a high-fat meal with a single oral dose of the reference product, the median T_{max} was 2.49 hours. This suggests that XJN010 may achieve peak exposure more quickly and with less susceptibility to food-related delays than oral therapy, which may be beneficial when rapid symptom relief is desired.

Innovative nasal inhalation drug formulation technology platform

Our XJN010 product is enabled by a fully integrated and innovative nasal inhalation drug formulation technology platform designed to address the limitations of conventional CNS-targeted drug delivery through nasal inhalation. It incorporates:

- Precision olfactory-region delivery, achieved through tailored formulation that allows control over plume angle, droplet size, and spray area, supporting targeted and reproducible deposition to the small and anatomically constrained olfactory region.
- Effective intracerebral transport, supported by a penetration enhancer that improves uptake across the olfactory mucosa, facilitating effective delivery of the drug to its site of action.

This combined formulation strategy is intended to support fast and consistent therapeutic effects and an improved patient experience.

Limitations

XJN010 is subject to certain limitations and uncertainties. As of the Latest Practicable Date, conduct of clinical studies for Phase II clinical trial has been completed, and preparation of the clinical study report is ongoing. Further clinical trials are required before any marketing authorization may be obtained in any jurisdiction. Phase I studies are primarily designed to evaluate safety, tolerability and pharmacokinetics rather than efficacy. Accordingly, although the Phase I clinical trial results demonstrated a favorable safety and tolerability profile, the efficacy of XJN010 in the target patient population remains subject to evaluation based on the results of Phase II and any subsequent clinical trials. In particular, XJN010 utilizes an alternative formulation designed for nasal administration which may enable the already approved API to be delivered via an intended nose-to-brain pathway, which differs from conventional delivery routes used in routine Parkinson’s disease therapy. Given the novelty of this delivery approach, the effectiveness, onset characteristics and overall clinical benefit of XJN010 remain uncertain and will need to be evaluated through analysis of the Phase II clinical trial results and subsequent clinical trials. There is no assurance that XJN010 will demonstrate favorable safety and efficacy outcomes in later-stage clinical trials or obtain regulatory approval in any jurisdiction. In addition, as a nasal spray, XJN010 may be unsuitable for certain patient groups and clinical circumstances. In particular, it may not be suitable for patients with severe rhinitis, nasal cavity injury, or abnormal nasal anatomy/physiological structure, as these conditions may affect administration, tolerability and/or absorption.

Clinical trial sponsor(s)

We are the sole sponsor of the clinical trials for XJN010. As the sponsor, we are responsible for, among other things, the overall initiation, management and financing of the relevant clinical trials, and for ensuring compliance with applicable regulatory and ethical requirements.

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Summary of clinical trial results

We commenced preclinical studies of our XJN010 nasal spray since September 2022. The Phase I clinical trial was commenced in March 2025 and successfully completed in June 2025. The results demonstrated that XJN010 exhibited rapid absorption and a favorable safety and tolerability profile following administration. In August 2025, we commenced Phase II clinical trial in China to assess the efficacy of XJN010, and as of the Latest Practicable Date, conduct of clinical studies for the Phase II clinical trial has been completed, and preparation of the clinical study report is ongoing. We expect to complete Phase III clinical trial in 2027, with an NDA submission to the NMPA planned for 2028.

Below is a summary of these clinical trials in reverse chronological order.

Phase II Clinical Trial

- Trial design

This trial uses a multicenter, randomized, double-blind, placebo-controlled design to test the efficacy of XJN010 in the on-demand treatment of “Off” episodes in Parkinson’s disease patients already receiving levodopa treatment with dopa decarboxylase inhibitor.

We planned to enroll 84 patients and randomly assign them in a 1:1:1 ratio to the 20 mg, 40 mg, and 80 mg dose groups. Within each group, patients were randomly assigned in a 3:1 ratio to receive either XJN010 or a placebo nasal spray. Treatment lasted for 2 weeks, with the nasal spray administered as needed, up to a maximum of 5 times daily.

Primary endpoint: the average change in UPDRS-III score within 60 minutes (average of change in UPDRS-III score at 15 minutes, 30 minutes, and 60 minutes after treatment) compared with pre-treatment UPDRS-III score.

Secondary endpoints: the mean change from pre-dose in the UPDRS-III score at 15 minutes, 30 minutes and 60 minutes after each treatment on D1, D7 and D14; the mean change from pre-dose in the WOQ-9 score at 5 minutes and 10 minutes after each treatment on D1, D7 and D14; the proportion of patients who, within 60 minutes after treatment on D1, D7 and D14, achieved a transition from the “OFF” state to the “ON” state and maintained the “ON” state; the change from baseline in the average daily duration of the “OFF” state on D7 and D14; the change from baseline in the PGI-C assessment on D7 and D14; the change from baseline in the PDQ-39 score on D7 and D14; safety, including the incidence and severity of adverse events, including local irritation reactions (with severity graded according to NCI CTCAE v6.0), as well as vital signs, physical examinations, clinical laboratory tests and auxiliary examination results; and pharmacokinetic parameters, including T_{max} , T_{0-4h} , C_{max} and AUC_{0-4h} .

- Trial status

As of the Latest Practicable Date, conduct of clinical studies for Phase II clinical trial has been completed. Preparation of the clinical study report is ongoing, and we expect to issue the clinical study report in the third quarter of 2026.

Phase I Clinical Trial

- Trial design

This trial consists of two studies. Study 1 is a relative bioavailability study, and Study 2 is a single-dose study. Study 1 employs a randomized, open-label, single-dose design with three administration routes (reference tablet under fasting conditions, reference tablet under fed conditions, and XJN010 nasal spray), a three-period, double 3×3 Latin square design. Study 2 is a single-dose study with a randomized, open-label, parallel-group design.

- Trial status

The trial was commenced in March 2025 and completed in June 2025.

- Pharmacokinetics

Results

Following a single nasal administration of 20 mg, 40 mg, and 80 mg of XJN010 nasal spray to healthy subjects, the median time to peak concentration (T_{max}) ranged from 0.73 to 0.98 h. C_{max} increased with increasing dose, with mean values of 357, 1016, and 1193 ng/mL, respectively. The 40 mg and 80 mg doses showed little difference in C_{max} . Exposure (AUC_{0-t} and $AUC_{0-\infty}$) increased with increasing dose, with mean AUC_{0-t} values of 692, 1,827, and 2,381 h*ng/mL, and mean $AUC_{0-\infty}$ values of 859, 2,030, and 2,443 h*ng/mL, respectively. Apparent volume of distribution ($V_{z/F}$) and half-life

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($t_{1/2}$) differed among dose groups, while the 40 mg and 80 mg dose groups showed little difference from each other, both were lower than the 20 mg dose group. Clearance (CL/F) remained relatively consistent across dose groups.

Conclusion

After nasal administration of 40 mg XJN010, the bioavailability relative to the reference oral tablets under fasting conditions and under fed conditions was 118% and 98.3%, respectively. Within the dose range of 20 mg to 80 mg, XJN010 was rapidly absorbed *in vivo* after nasal administration, and the exposure level of XJN010 increased with increasing dose.

- Safety

Results

The overall safety profile of healthy subjects receiving a single nasal administration of XJN010 nasal spray (20–80 mg) was good. No treatment emergent severe adverse events (TESAEs) or treatment related severe adverse events (TRSAEs) were observed, and there were no deaths or premature withdrawals from the trial due to adverse events (AEs). All reported AEs were mild (CTCAE grade 1) and all recovered/resolved.

Conclusion

The subjects in each dose group had good safety and tolerability. All reported AEs were mild (CTCAE grade 1) and had recovered/resolved. No severe adverse events (SAEs) occurred.

In simple terms, our Phase I trial was designed to assess how quickly XJN010 is absorbed after nasal administration, how high the blood drug levels rise, how long the drug stays in the body, and the safety and tolerability. The results showed that the API in XJN010 was absorbed into the bloodstream within a relatively short period of time after nasal administration and reached peak blood levels in less than one hour across the tested dose groups. Clearance was generally consistent across dose groups. XJN010 was also generally well tolerated in this study, with all reported adverse events being mild (CTCAE Grade 1), recovered/resolved, and no severe adverse events observed.

In addition, published literature, including Levodopa Dose Equivalency in Parkinson’s Disease: Updated Systematic Review and Proposals (Dafsari et al., Movement Disorders 38(7):p1236-1252, July 2023.), which cited Preclinical and clinical assessment of inhaled levodopa for OFF episodes in Parkinson’s disease (Freed et al., Sci Transl Med. 2016 Oct 12;8(360):360ra136.), suggests that levodopa plasma concentrations above 400 ng/mL may be associated with meaningful improvement of OFF periods in Parkinson’s disease patients. In our Phase I study, following a single 40 mg dose of XJN010 nasal spray, the API in XJN010 reached a peak blood concentration above this referenced level, within a relatively short period of time, and remained above that level for a period of time in the study. Our Phase I trial was not designed to evaluate disease control or clinical efficacy in Parkinson’s disease patients, and we do not have efficacy data from this Phase I trial. However, based on the published literature and our pharmacokinetic data, these findings may support further clinical evaluation of XJN010 in Parkinson’s disease “Off” episodes. These observations are provided as pharmacokinetic reference only and do not constitute clinical efficacy evidence in Parkinson’s disease patients.

Summary of preclinical studies

XJN010 nasal spray is a Class 2.2 modified new drug intended for the on-demand treatment of “Off” episodes in Parkinson’s disease patients. The API in XJN010 is levodopa, for which the mechanisms of action, binding targets, and safety profile are well established. Nonclinical safety information of the API, including genotoxicity, carcinogenicity, reproductive and developmental toxicity is available from existing formulations with the same API. Our nonclinical studies investigated toxicity, nasal irritation, respiratory function effects, CNS effects, efficacy, pharmacokinetic behavior and tissue distribution characteristics in animals.

Preclinical pharmacology studies showed activity of XJN010 in an animal model of Parkinson’s disease-related motor symptoms. In safety pharmacology and toxicology studies, XJN010 was generally well tolerated, with no material abnormal findings attributable to XJN010 in evaluated CNS, cardiovascular or respiratory parameters, and no significant local irritation or allergic reactions observed under the tested conditions.

These findings are preclinical in nature and do not constitute clinical efficacy evidence in Parkinson’s disease patients. While they may support further clinical evaluation of XJN010, there can be no assurance that such preclinical observations will translate into clinical benefit in humans. The above studies were conducted under GLP experimental conditions.

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In preclinical animal studies, intranasal administration of XJN010 was associated with earlier brain tissue exposure and higher peak levels and overall exposure in brain tissue in the relevant study, as compared to oral reference. Preclinical pharmacokinetic studies in rats further showed rapid absorption after intranasal administration and distribution to tissues at and around the administration site as well as brain tissue, with earlier brain tissue exposure than observed with oral administration in the relevant study. Imaging/tracer observations after nasal administration were also consistent with the possibility of transport from the nasal cavity to brain tissues. These findings support the scientific rationale for further clinical evaluation of XJN010’s intended nose-to-brain delivery approach. However, these findings are preclinical in nature, do not establish the primary delivery pathway in humans, and may not be predictive of human pharmacokinetics, brain exposure or clinical efficacy.

Direct confirmation in living human patients of the precise transport pathway(s) by which intranasally administered drug reaches brain tissues is inherently limited. Such confirmation would generally require invasive and/or impractical methods, such as direct sampling of brain tissue and/or region-specific intracranial fluids, which are not ethically or clinically appropriate in routine clinical trials for our target indications. Accordingly, our assessment is based on formulation design, preclinical data and published scientific literature, each of which has limitations.

Material Communications and Next Steps

In May 2024, we submitted an IND application to the NMPA for XJN010 in China. In August 2024, we received the Notification of Approval for Drug Clinical Trial from the NMPA. As disclosed in the Summary and the overview of XJN010 in this section, the notification provides that, after completion of Phase II clinical trials and prior to commencement of Phase III clinical trials, we should communicate with the NMPA regarding the existing clinical data and the Phase III clinical trial protocol. As of the Latest Practicable Date, we have completed conduct of clinical studies for our Phase II clinical trial in China and had not received any material questions or objections from the NMPA regarding our Phase I and Phase II clinical development plans for XJN010.

To advance the product’s global development, in June 2025, we submitted a pre-IND application to the FDA using our Phase I clinical data obtained in China and Phase II clinical trial design for the U.S. In September 2025, we received a written response from the FDA indicating that our nonclinical and clinical data appeared sufficient to support the proposed Phase II clinical trial. Accordingly, we submitted a formal IND application in October 2025, and received IND approval from the FDA in February 2026 to enter Phase II clinical trial in the U.S. directly. The FDA did not impose any condition in order to proceed directly into the Phase II clinical trial. We plan to initiate the Phase II clinical trial in the third quarter of 2026.

Following commercialization, we plan to conduct post-marketing clinical studies to expand its indications to the broader treatment of Parkinson’s disease.

Classification of XJN010

XJN010 comprises a drug component and a nasal spray delivery component. We have not obtained a standalone formal classification ruling from the relevant regulatory authorities in China or the U.S. expressly determining the classification of XJN010.

In China, based on our actual IND filing path and the relevant application materials, XJN010 was filed as a drug, and the relevant application materials did not indicate XJN010 to be a drug-device combination product. In addition, according to published property determination results of the NMPA, esketamine nasal spray, as a reference product for nasal spray products, was determined not to be a drug-device combination product and should be filed as a drug. Based on our actual filing situation and the published property determination results relating to nasal spray products, we do not consider XJN010 to be a drug-device combination product in China.

In the U.S., based on the applicable FDA framework and our actual IND filing path, XJN010 has been treated as a combination product. In our IND submission to the FDA, the combination product field in the application form was marked “Yes”, with “Combination Product Type 2” selected, and the FDA accepted and approved the clinical trial application on that basis. We also note that, under the FDA’s combination product framework, Type 2 refers to a prefilled drug delivery device/system, where the drug is filled into or otherwise combined with the device and the sole purpose of the device is to deliver the drug, and nasal spray is listed as a common example. “Combination Product Type 2” is not a standalone Class I, II or III medical device classification. As of the Latest Practicable Date, the FDA has not assigned XJN010 a standalone medical device class.

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In addition, there has been no determination by the NMPA or FDA that the primary therapeutic effect or primary mode of action of XJN010 is medical device-based or mechanical/physical rather than pharmacological. To the extent XJN010 is treated as a combination product in the U.S., we currently understand its principal therapeutic effect to be attributable to the pharmacological action of levodopa, with the nasal spray device serving as the delivery tool.

Based on the foregoing, we have disclosed XJN010 as a drug product for the purposes of Chapter 18A and Chapter 2.3 of the Guide for New Listing Applicants.

XJN010 Nasal Spray Device

For our ongoing clinical trials and planned initial commercial launch, we utilize standardized, pharmaceutical-grade devices procured from third-party medical device manufacturers. These delivery systems are common in the industry for the administration of medications to the nasal cavity and serves as a representative example of the spray device suitable for XJN010. Such devices are typically composed of a medicinal high-density polyethylene (HDPE) bottle, a medicinal spray pump, and a medicinal actuator.

During the Track Record Period and up to the Latest Practicable Date, we procured the delivery device for XJN010 from our principal supplier, a third-party medical device manufacturer. We have also entered into contractual arrangement with another third-party medical device manufacturer, as an alternative supplier, although such alternative supplier had not yet supplied devices for XJN010 as of the Latest Practicable Date. Accordingly, although one manufacturer was our principal supplier during the relevant period, we had put in place an alternative supply arrangement to reduce single-source supply risk. The principal terms of our agreements with third-party medical device manufacturers generally include provisions relating to product name, model, specifications, quantity, unit price and total contract amount, as well as packaging, delivery, acceptance, quality requirements and inspection standards, payment terms, confidentiality, liability for breach and dispute resolution. In certain cases, the contract price may be adjusted subject to changes in raw material prices and agreement between the parties. We enter into such agreements in the ordinary course of business and on normal commercial terms. Save for the contracted quantities under the relevant purchase contracts, the agreements do not provide for any ongoing minimum purchase targets or long-term purchase commitments. In addition, our principal supplier has completed the relevant filing/registration for the nasal spray device with the NMPA and the FDA. Accordingly, for the regulatory application of XJN010, we are only required to provide the relevant filing/registration information of the nasal spray device to the NMPA or the FDA, and are not required to separately obtain regulatory filing, licence or approval for the nasal spray device.

While we are in the process of self-developing a delivery device to potentially enhance patient experience and provide further product differentiation in the future, our core development and commercialization plan for XJN010 does not depend on the completion of this device project. According to our current development plan, the self-development of our delivery device is expected to proceed in phases, including preliminary research, prototype design and iterative optimization, material research, patent application, registration testing, registration application and registration. We currently expect to carry out conceptual design, feasibility verification and multiple rounds of prototype optimization during 2024 to 2026. During 2024 and 2025, we completed preparatory work, including preparation of model drug solution and relevant excipients, procurement and analysis of the reference device, and spray performance research and data collection, and completed conceptual design, feasibility verification and prototype optimisation work for multiple prototype versions. During 2026, we expect to continue prototype optimisation, including optimisation of a further prototype version and corresponding spray performance research and data collection, and determine the final version of the self-developed delivery device based on testing results. This will be followed by material-related research and further device optimization during 2026 to 2027, patent filing and registration testing during 2027 to 2029, and registration application and registration procedures during 2029 to 2030. As of the Latest Practicable Date, our planned commercial production of XJN010 does not rely on self-developed delivery devices, and we currently expect to continue procuring delivery devices from qualified third-party medical device manufacturers for the foreseeable future.

To ensure sufficient supply of delivery devices for the R&D and future commercialisation of XJN010, we have adopted a number of measures. In particular, we procure standardized device models that are interchangeable among multiple qualified suppliers, maintain cooperation with one principal supplier and have contracted with another third-party medical device manufacturer as an alternative supplier, and enter into contractual arrangements covering product specifications, quality requirements, delivery and acceptance standards. By utilizing commercially available devices for the initial launch, we rely on delivery systems that have already demonstrated reliability in clinical settings, thus providing a clear and established regulatory pathway for the product's market entry. In addition, we are advancing the planned self-development of delivery devices as a supplementary long-term measure to

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enhance our supply chain resilience and operational flexibility. Based on the foregoing, our Directors are of the view that we have adopted reasonable measures to support a stable and sufficient supply of delivery devices for the R&D and planned commercialisation of XJN010.

Collaboration and Clinical Manufacturing

We have engaged Jewin Pharmaceutical (Shandong) Co., Ltd. (“**Jewin**”), a specialized contract manufacturing organization (CMO), pursuant to an entrusted pharmaceutical technology development agreement dated 1 August 2023, which became effective on the same date, to carry out process transfer, sample batch manufacturing for IND application, product batch manufacturing for clinical trials, testing, preparation of production and quality documents, storage and handling of relevant materials, and related GMP inspection and registration support work for XJN010. For this purpose, “process transfer” mainly refers to the technical transfer and implementation work required for Jewin to carry out sample batch and clinical trial batch manufacturing of XJN010, including receipt and review of technical materials, personnel training, confirmation of production process and process parameters, confirmation or transfer of analytical methods, preparation of production and quality documents, and trial and registration batch production. “Registration support work” mainly refers to manufacturing related and quality related support for the IND application and regulatory review, including preparation and provision of production records, testing data, quality documents, GMP inspection related materials and other CMC related documents, and cooperation in registration related site inspection and verification work. As confirmed by Frost & Sullivan, the current service scope under the Jewin Agreement aligns with the standard services provided by contract manufacturing organizations.

Under the terms of the agreement, we act as the sole sponsor for clinical trials, the sole applicant for drug registration and the marketing authorization holder, and remain responsible for the overall development of XJN010, regulatory registration, product lifecycle management and the provision of the relevant technical materials, quality standards and certain materials required for production. We retain absolute control over all substantive aspects of the R&D process, including trial design, clinical strategy and regulatory interactions, and we also retain responsibility for product quality and safety and have audit and on-site supervision rights over Jewin’s production, testing, warehousing and quality management activities. As between us and Jewin, we are responsible for product quality issues attributable to the materials, formulation, process or technical materials provided or determined by us. Jewin is responsible for product quality issues attributable to its failure to comply with the agreed production process, GMP requirements, quality standards or its production, testing, storage or quality management obligations. Where the cause of a product quality issue cannot be determined, the parties may submit samples for third-party testing or identification and allocate responsibility based on the results. Payment is made in instalments based on agreed project milestones, with certain additional out-of-scope expenses to be separately agreed and settled. Such out-of-scope expenses refer to expenses not included in Jewin’s quotation, mainly including supplier audit fees, site inspection fees and production costs for three batches of products for supplemental application. Based on the currently identified out-of-scope items, the maximum amount payable to Jewin is expected to be approximately RMB540,000. The agreement remains effective until a final conclusion is reached in China on the product’s clinical trial application and may be terminated by mutual agreement, for material breach not remedied within the agreed period after notice, automatically upon registration failure, or in other specified circumstances, including where Jewin no longer has the necessary qualifications to continue performing the project. Upon termination or expiry, Jewin must return to us all production technical materials provided by us to Jewin, and all technical materials generated by Jewin in relation to XJN010. We hold 100% of the intellectual property, disposal rights and future commercial interests associated with XJN010. Jewin acts solely as our service provider, is not a co-sponsor of the clinical trials of XJN010, does not possess any independent rights to XJN010 or its subsequent development, and may not subcontract its obligations without our prior written consent.

The entrusted pharmaceutical technology development agreement is in nature an entrusted development and technical service contract. According to the relevant PRC laws and regulations, the ownership and control of technical results and related rights under such entrusted development or technical service contracts are determined by the contractual agreement between the parties. According to the agreement, all intellectual property rights, technical materials and results arising from the research, development and manufacturing of XJN010 belong exclusively to the Company, and Jewin acts solely as a commissioned service provider without any ownership or independent rights in respect of XJN010 or its subsequent development.

In addition, under the PRC pharmaceutical regulatory framework, a marketing authorization holder (“**MAH**”) bears primary responsibility for the entire life cycle of a drug. Accordingly, as the sole sponsor and intended MAH of XJN010, the Company retains full control and independent rights over its research and development, commercialisation, and IP.

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Our Directors are of the view that we have full control over, and independent rights in, the research and development, planned commercialisation, and intellectual property rights of XJN010. The basis for this view is that, under the relevant entrusted development and clinical trial agreements, the intellectual property rights arising from the agreed entrusted matters, work and research projects are exclusively owned by us, including the rights to apply for patents, use and transfer technological results and exclusively own the relevant technical secrets. In addition, we have the right to use the technological results generated in performing the relevant agreements for regulatory filings, registration and subsequent improvement, and any new technological results and patents with substantive and inventive technical advancement arising therefrom are also exclusively owned by us. Our Directors are also of the view that the signed entrusted agreements relate only to the agreed entrusted development and research matters and do not impose any directional restriction, and that we retain control over all substantive aspects of the relevant research and development process, including experimental design, clinical strategy and regulatory interactions.

As affirmed by our PRC Legal Advisor, the Company has full control over, and independent rights to, the R&D, commercialisation and IP of XJN010. Based on the independent due diligence works conducted by the Sole Sponsor, and upon consideration of the view of the PRC Legal Advisor, the Sole Sponsor is of the view that the Company has full control and independent rights over the research and development, planned commercialisation, and intellectual property rights of XJN010. Accordingly, the Directors and the Sole Sponsor are of the view that the Jewin Agreement does not adversely affect the Company's satisfaction of the eligibility criteria under Chapter 18A of the Listing Rules and Chapter 2.3 of the Guide.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET XJN010 SUCCESSFULLY.

XJN026 — our key product, a vasoconstrictor intranasal inhalation formulation, for the acute treatment of migraine attacks

Overview

XJN026 is a self-developed vasoconstrictor nasal inhalation formulation, it is currently in preclinical development, intended for the acute treatment of migraine attacks with or without aura in adults and pediatric patients aged 6 to 17 years. Administered intranasally, the product is designed to enable rapid and efficient drug absorption. Compared with the oral reference formulation, the product demonstrated rapid absorption in preclinical studies, with a systemic T_{max} of approximately 2 to 5 minutes. Absorption was not affected by food intake in these studies, supporting reliable pharmacokinetic performance. With its rapid absorption and peak plasma concentration observed in nonclinical models, XJN026 has the potential to provide a fast-acting option for managing migraine symptoms.

We have submitted an IND application to the NMPA in October 2025 and received IND approval in January 2026. We initiated Phase I clinical trial in China in April 2026.

Mechanism of Action

XJN026 is a Class 2.2 modified new drug intended for the acute treatment of migraine. It is a nasal inhalation formulation containing a solution of a vasoconstrictor. Its active ingredient has been used clinically for more than 20 years. The product is developed using our nasal inhalation drug formulation platform technologies and is designed to facilitate rapid drug delivery via the nasal route, bypass the gastrointestinal tract, and reduce reliance on oral absorption.

Market opportunities and competition

Migraine is a recurrent neurovascular disorder characterized by unilateral or bilateral throbbing moderate-to-severe headache, with attack duration usually ranging from 4 to 72 hours. The disease has a significant impact on the quality of life and social functioning of patients and is one of the leading causes of disability worldwide.

According to Frost & Sullivan, the number of migraine patients and the market for migraine therapies have increased and are expected to continue to grow in the global, China and U.S. markets. For details of the relevant patient population, market size and growth projections, see “Industry Overview — Migraine Market”.

Migraine treatment primarily focuses on rapid relief of acute attacks and preventive therapy for patients with frequent or severe episodes. Acute management typically involves NSAIDs and triptans, emphasizing early intervention and avoidance of medication overuse. Preventive strategies include traditional medications such as beta-blockers, antidepressants, and antiepileptics, as well as newer CGRP-targeted therapies aimed at reducing attack frequency and severity. Special populations, including pregnant women and children, require tailored treatment plans prioritizing safety. Overall,

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effective migraine management relies on individualized approaches to improve patient outcomes and quality of life. Currently, four nasal spray formulations for migraine treatment have been approved for market release: Pfizer's Zavzpret, GSK's IMITREX nasal spray, Bausch Health's Migranal nasal spray, and Upsher-Smith's Tosymra. However, there is still room for improvement in its overall clinical efficacy. The majority of clinical pipelines for migraine nasal sprays under development focus on CGRP receptor antagonist nasal sprays.

Competitive advantages

According to Frost & Sullivan, in the future, the migraine treatment market will exhibit multidimensional development trends: First, acute attack management will evolve toward rapid onset, non-invasive, and high-compliance approaches. Novel delivery methods such as nasal sprays and buccal absorption formulations are gaining attention for their potential to provide swift symptom relief and enhance patient adherence, while also catering to populations unable to take oral medications or experiencing sudden symptom onset. Second, long-term preventive treatment will emphasize personalized combination therapies and comprehensive intervention strategies to enhance treatment stability and quality of life.

Compared with the oral reference formulation, XJN026 demonstrated rapid absorption in preclinical studies, with a systemic $T_{\max}$ of approximately 2 to 5 minutes. Absorption was not affected by food intake in these studies, supporting reliable pharmacokinetic performance. With its rapid absorption and peak plasma concentration observed in preclinical models, XJN026 may have the potential to be further developed as a non-invasive formulation for managing migraine symptoms, subject to confirmation in future clinical trials.

As of the Latest Practicable Date, we initiated Phase I clinical trial of XJN026 in China, but no clinical results from the trial are available yet. According to Frost & Sullivan, there is no relevant peer clinical data that would permit a meaningful like-for-like comparison with XJN026 at this stage. Accordingly, we are not in a position to substantiate the potential competitive advantages of XJN026 by reference to clinical data or to provide a comparison of its clinical data with that of peer products.

Summary of preclinical study

Given that the mechanism of action, binding targets, and safety profile of the API used in XJN026 are well established, our evaluation focused on toxicity, nasal irritation, effects on respiratory function and the central nervous system, and the *in vivo* pharmacokinetics and tissue distribution of XJN026 in the context of a nasal spray formulation.

Pharmacokinetic results showed that after intranasal administration of XJN026 nasal spray in rats, the drug achieved adequate exposure in the nasal cavity, was rapidly absorbed into the systemic circulation, and quickly distributed to tissues associated with the administration site (nasal mucosa) as well as to highly perfused tissues (liver, kidney, and lung). The plasma $T_{\max}$ ranged from 2 to 5 minutes, demonstrating rapid peak attainment compared with oral tablets ($T_{\max}$ ranged from 1 to 1.5 hours). Toxicological results indicated that XJN026 nasal spray was well tolerated at doses 30 to 70 times the proposed clinical dose, with no histopathological changes observed in any organs or tissues examined. Local irritation studies demonstrated that XJN026 nasal spray did not show risk of hypersensitivity and showed good local tolerability.

In conclusion, the preclinical studies of XJN026 nasal spray showed rapid systemic absorption and favourable preclinical tolerability. However, as no clinical trials of XJN026 had been conducted as of the Latest Practicable Date, its clinical efficacy, safety and competitive advantages remain to be confirmed in future clinical trials. All of the above studies were conducted under GLP-compliant conditions.

Limitations

XJN026 is subject to certain limitations and uncertainties. As of the Latest Practicable Date, we initiated Phase I clinical trial of XJN026 in China, but no clinical results from the trial are available yet. Although XJN026 contains an active ingredient with a well-established mechanism of action and clinical safety profile in its approved forms, XJN026 utilizes an intranasal route of delivery and a nasal inhalation formulation platform, which differs from conventional delivery routes used in routine migraine therapy. Given the novelty of this delivery approach, the safety, tolerability, pharmacokinetics, effectiveness, onset characteristics and overall clinical benefit of XJN026 remain uncertain and will need to be evaluated through clinical trials. There is no assurance that XJN026 will achieve the intended clinical profile, demonstrate favorable safety and efficacy outcomes in clinical trials or obtain regulatory approval in any jurisdiction.

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Material communications and next steps

In August 2024, we initiated regulatory communication with the NMPA regarding the clinical advantages of XJN026 nasal spray for the treatment of migraine. In December 2024, we received a positive written response from the NMPA for the treatment of acute pain, achieving analgesia in a shorter timeframe holds significant clinical value. In October 2025, we submitted an IND application to the NMPA, and received IND approval in January 2026. We initiated Phase I clinical trial in China in April 2026. As of the Latest Practicable Date, we have obtained approval of the clinical trial protocol and ethics approval.

At the same time, we are also actively preparing for the submission of IND to the FDA. We plan to submit the IND application in the fourth quarter of 2026.

Phase I clinical trial

- Trial design

This trial comprises two stages, with Stage II to be conducted based on the results of Stage I. We plan to enroll a total of 46 healthy male and female participants aged 18 to 45 years old, including 30 participants in Stage I and 16 participants in Stage II.

Stage I is a safety and tolerability study employing a randomized, double-blind, placebo-controlled, single- and multiple-ascending-dose (SAD/MAD) design. A total of 30 participants will be enrolled in three dose cohorts, with 10 participants in each cohort. Within each cohort, participants will be randomly assigned in an 8:2 ratio to receive XJN026 nasal spray or placebo, with a male-to-female ratio of 1:1. Participants in the low-dose cohort will receive a single administration. Participants in the medium- and high-dose cohorts will receive a single administration on Day 1, followed by three administrations on Day 2 at two-hour intervals.

Stage I primary endpoints: safety and tolerability, as assessed by vital signs, physical examinations, 12-lead electrocardiograms, clinical laboratory tests, adverse events and nasal examinations.

Stage II is a relative bioavailability study employing a randomized, open-label, single-dose, four-sequence, four-period, four-way crossover design. A total of 16 participants will be enrolled, with a male-to-female ratio of 1:1. Using stratified block randomization, participants will be randomly assigned in a 1:1:1:1 ratio to one of four treatment sequences. During the four treatment periods, each participant will receive a single administration of each of the following: XJN026 nasal spray (Dose 1), XJN026 nasal spray (Dose 2), the reference drug (5 mg) and the reference drug (10 mg).

Stage II primary endpoints: the relative bioavailability of XJN026 nasal spray compared with the reference drug, as assessed by C_{max} , AUC_{0-t} and AUC_{0-∞}.

- Trial status

As of the Latest Practicable Date, the Phase I clinical trial protocol has been approved and ethics approval has been obtained. Participant enrollment has not yet commenced.

Clinical trial sponsor(s)

We are the sole sponsor of the clinical trials in China and are expected to act as the sole sponsor of the planned U.S. IND application and clinical trials. As the sole sponsor, we are or will be responsible for, among other things, the overall initiation, management and financing of the relevant clinical development activities, and for ensuring compliance with applicable regulatory and ethical requirements.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET XJN026 SUCCESSFULLY.

XJN1102 — our other product, a GLP-1 microneedle patch, for the treatment of type II diabetes and weight management in overweight or obese adults

Overview

XJN1102, is a self-developed innovative dissolving microneedle transdermal drug patch developed for the treatment of type 2 diabetes and long-term weight management in overweight or obese adults. The product utilizes a glucagon-like peptide-1 (GLP-1) receptor agonist with proven efficacy in improving glycemic control and reducing body weight as its active pharmaceutical ingredient (API).

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Built on our dissolving microneedle drug formulation platform technologies, XJN1102 is designed to address certain limitations of existing GLP-1 delivery methods. Current therapies rely primarily on subcutaneous injections, which can cause discomfort, injection-site reactions, and low treatment adherence. Our microneedle patch provides a minimally invasive and patient-friendly alternative that simplifies administration and may improve acceptance, particularly for patients requiring long-term therapy.

The XJN1102 microneedle patch features a drug-concentrated microneedle tip structure, which enables precise dosing, rapid penetration through the stratum corneum, and consistent systemic absorption via the dermal microcirculation. This formulation is designed to support pharmacokinetic performance comparable to injectable GLP-1 therapies while avoiding the need for traditional injections. As of the Latest Practicable Date, XJN1102 was at the preclinical stage and no IND application had been submitted in China or the United States.

Mechanism of action

XJN1102 uses dissolving microneedles to deliver a GLP-1 receptor agonist through the skin in a minimally invasive manner. The microneedle tips are formulated from fully synthetic GLP-1 receptor agonist combined with water-soluble polymer materials, supporting stability and rapid dissolution.

Preclinical studies indicated that its bioavailability was over 50%. Preclinical studies have also shown that, upon application, the microneedles dissolve within 15 minutes, releasing the GLP-1 receptor agonist and reaching peak plasma concentration in about eight hours, which is approximately three times faster than subcutaneous injection. The product demonstrates good stability at room temperature, which can reduce storage and transportation requirements for future commercialization. Furthermore, preclinical animal studies indicate that our dissolving microneedle drug formulation technology addresses the low delivery efficiency observed in conventional transdermal systems for peptides. The microneedles can penetrate the stratum corneum and dissolve in situ, allowing the released peptide drug to be rapidly absorbed systemically. Together, these findings establish XJN1102 as a differentiated product with strong technical and formulation-based barriers to entry, and highlight its potential to provide a convenient, reliable, and patient-friendly alternative to injectable GLP-1 therapies.

Market opportunities and competition

According to Frost & Sullivan, the patient population and treatment market for diabetes, particularly type 2 diabetes, have been growing in the global, China and U.S. markets and are expected to continue to expand. GLP-1 receptor agonists are an established therapeutic class in these markets. However, currently available products remain injectable products, constrained by injection pain, needle phobia, low patient compliance, and cold-chain storage requirements. XJN1102, a dissolving microneedle patch, is designed to offer a minimally invasive and convenient alternative that is designed to address these limitations. By combining the proven efficacy of the GLP-1 receptor agonist with our innovative dissolving microneedle drug formulation technology platform, XJN1102 is well positioned to capture significant share in China’s rapidly expanding weight-management market.

Development plan

XJN1102 is designed with a staged indication expansion strategy to maximize clinical and commercial impact. We plan to submit IND applications to the NMPA and the FDA in the fourth quarter of 2026 for the treatment of type 2 diabetes in adults. Subject to regulatory clearance, we expect to complete a Phase I clinical trial in China by the end of 2027 and a Phase I clinical trial in the U.S. in the first quarter of 2028. We currently plan to submit NDA applications in China and the United States in 2030. These development timelines are based on our current development plan and may be subject to change. In the fourth quarter of 2026, we also intend to submit additional IND applications to the NMPA and the FDA for the weight management indication in overweight or obese adults.

Clinical trial sponsor(s)

As no IND application had been submitted for XJN1102 as of the Latest Practicable Date, we are expected to act as the sole sponsor of the planned IND applications and clinical trials in China and the U.S. As the sole sponsor, we will be responsible for, among other things, the overall initiation, management and financing of the relevant clinical development activities, and for ensuring compliance with applicable regulatory and ethical requirements.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET XJN1102 SUCCESSFULLY.

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XJN2503 — our other product, a 5-HT₃ receptor antagonist nasal inhalation formulation, for the treatment of nausea and vomiting

XJN2503 is a self-developed 5-HT₃ receptor antagonist nasal inhalation formulation developed for the rapid relief and prevention of nausea and vomiting associated with chemotherapy, radiotherapy, and postoperative recovery. The product is intended for both adults and pediatric patients aged four years and above, addressing one of the most common and distressing adverse effects in cancer treatment and surgical care.

Intranasal delivery provides advantages over existing oral and injectable options. Radiotherapy patients who experience vomiting often have difficulty swallowing, while chemotherapy patients may be unable to take oral medications or intolerant to injectable formulations. Unlike IV or subcutaneous administration, XJN2503 does not require needle-based delivery and is intended to offer a more convenient and potentially more tolerable option for patients.

Once administered, the drug is rapidly absorbed, having the potential to achieve a faster onset of action compared with oral formulations of the same API, such as tablets or oral films that typically require 1.3 to 2 hours to reach peak plasma concentration. The potential ability to achieve peak levels more quickly makes XJN2503 suitable for situations requiring timely management of nausea and vomiting in patients.

XJN2503 is also designed to address an unmet need in pediatric patients by offering a rapid-onset therapy where no suitable alternatives currently exist. Furthermore, the formulation is designed for self-administration, enabling patients to continue antiemetic therapy at home following outpatient or day-care chemotherapy, providing a convenient option for ongoing management.

The commercial potential is substantial. Chemotherapy-induced nausea and vomiting remain a common adverse event in oncology, as confirmed by Frost & Sullivan. According to Frost & Sullivan, in China, chemotherapy-induced vomiting patients increased from 1.83 million in 2021 to 2.10 million in 2025, representing a CAGR of 3.58%. It is projected to further increase to 2.19 million in 2026 and 2.54 million in 2030. Current antiemetic options often fail to provide adequate delayed-phase control. This highlights both the urgency of clinical need and the scale of the market opportunity, positioning XJN2503 in a high-growth market with strong, persistent clinical need.

The program is currently in preclinical development, with an IND application to the NMPA planned for submission in the fourth quarter of 2026.

Clinical trial sponsor(s)

As no IND application had been submitted for XJN2503 as of the Latest Practicable Date, we are expected to act as the sole sponsor of the planned IND applications and clinical trials in China and the U.S. As the sole sponsor, we will be responsible for, among other things, the overall initiation, management and financing of the relevant clinical development activities, and for ensuring compliance with applicable regulatory and ethical requirements.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET XJN2503 SUCCESSFULLY.

OUR BUSINESS MODEL

Internal R&D-driven innovation

We are a research-driven biopharmaceutical company focused on the development of innovative, non-invasive drug formulations intended to enhance therapeutic performance, patient compliance, and clinical practicality. Our pipeline is primarily advanced through internal R&D resources and capabilities, allowing us to retain full control over the development process.

Our product candidates originate from internally initiated modified new drugs, selected through a rigorous evaluation process that considers clinical value, technical feasibility, and commercial potential. For each project, our management team defines clear development objectives, allocates appropriate resources, and forms dedicated R&D teams responsible for designing and implementing development plans, conducting preclinical and clinical studies, and preparing regulatory submissions.

We are currently advancing two Core Products, DHMP and XJN010, both of which are the first of their kind to receive approval for clinical trials in China. This highlights our innovation advantage and commitment to addressing continuing clinical needs. In addition, our diversified portfolio spans multiple therapeutic areas, including adult and pediatric anesthesiology, CNS diseases and disorders, and metabolic diseases, covering a broad range of drug types from small molecules to biologics such as peptides and proteins. This diversification not only mitigates development risks but also broadens our market opportunities.

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R&D team and capabilities

Our in-house R&D team comprises professionals specialized in Pharmacy, Pharmaceuticals, Pharmaceutical Engineering, Microbiology, Chemistry, Medicine, and related disciplines, supported by leadership with experience in multinational pharmaceutical companies, academic institutions, and regulatory agencies.

Our R&D team is organized across functions covering formulation development, quality research, manufacturing control, regulatory affairs, and policy compliance. The team works in close coordination to efficiently advance projects from concept through clinical development. As of the Latest Practicable Date, we have a total of 122 R&D personnel, of whom 46 R&D personnel responsible for the development of our Core Products, 25 R&D personnel responsible for the development of our other product candidates, and 51 R&D personnel responsible for our CRO Services. The table below sets forth the number and composition of the core R&D personnel responsible for the Core Products:

Function	Number of personnel
Formulation and process development	15
Non-clinical studies	2
Clinical studies	2
Analytical research	15
Quality management	5
Regulatory submissions	1
Project management	6
Total	46

As of the Latest Practicable Date, 30 members of our R&D team, representing 24.6% of the total R&D team, and 20 members of our core R&D personnel responsible for the Core Products, representing 43.5% of the core R&D personnel responsible for the Core Products, hold a master’s degree or above. All the key employees involved in the development of the Core Products remained employed by us during the Track Record Period and as of the Latest Practicable Date.

As confirmed by Frost & Sullivan, our Company’s R&D progress is aligned with industry peers, after having considered the following factors:

- *R&D investment intensity* — during the years ended December 31, 2024 and 2025 and the five months ended May 31, 2025 and 2026, the Company’s R&D expense to revenue ratios were 33.5%, 69.2%, 48.6% and 114.5%, respectively, which is not uncommon for innovative pharmaceutical companies in an expansion phase within the industry to have R&D expense-to-revenue ratios exceeding 100%, representing a high-investment scenario within the normal range;
- *R&D expenses growth rate* — the R&D expense growth rate of our Company of approximately 132.9% from 2024 to 2025 is consistent with innovative pharmaceutical enterprises in expansion phase, exceeding most industry peers and remaining within a reasonable range of the high-growth bracket;
- *Cost structure* — the R&D cost structure of our Company aligns with industry norms. The R&D expenses for our two Core Products increased from approximately RMB11.9 million during the year ended December 31, 2024 to approximately RMB26.3 million during the year ended December 31, 2025, and increased from approximately RMB5.3 million during the five months ended May 31, 2025 to approximately RMB14.8 million during the five months ended May 31, 2026 which was driven by higher experiment and testing expenses and staff costs following the completion of Phase I and commencement of Phase II clinical trials, and such cost structure is consistent with the biopharmaceutical practice where clinical trial and personnel costs typically represent the majority of development spending;
- *Products pipeline* — our Company’s products pipeline, built around two core products, one of which is based on microneedle transdermal technology and the other on intranasal brain-delivery technology, and both having entered Phase II clinical trials, is consistent with the industry practice of early-stage innovative pharmaceutical companies to diversify risks and focus on differentiated technology platforms; and
- *Clinical investment* — our Company’s clinical investment strategy is consistent with industry practice. Our R&D expenses increased significantly during the Track Record Period when the R&D of our two Core Products advanced from Phase I to Phase II clinical trials, and the

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majority of our R&D spendings are concentrated on clinical trial-related costs and personnel expenses, which aligns with the typical capital allocation model of innovative pharmaceutical companies during clinical development.

As further confirmed by Frost & Sullivan, our Company has sufficient R&D capability, after having considered (i) our Company’s R&D progress in inhalation and microneedle drug formulation platforms is consistent with industry benchmarks for biopharmaceuticals advancing programs through early-stage clinical development; (ii) as at the Latest Practicable Date, our Company’s R&D team consisted of 122 professionals, of whom 30 (approximately 24.6%) hold a master’s degree or above; (iii) our Company’s R&D spending is primarily allocated to our two Core Products, which is aligned with industry practice where biopharmaceutical firms concentrate resources on lead candidates. Specifically, R&D expenses attributable to our two Core Products increased from approximately RMB11.9 million during the year ended December 31, 2024 to RMB26.3 million during the year ended December 31, 2025, and increased from approximately RMB5.3 million during the five months ended May 31, 2025 to RMB14.8 million during the five months ended May 31, 2026 representing 72.5%, 69.0%, 51.0% and 77.9% of our total R&D expenses, respectively. This increase coincided with the transition of both Core Products from Phase I to Phase II clinical trials, a pattern consistent with rising development costs as programs advance. R&D expenses for our two Core Products during the Track Record Period predominantly composed of clinical and non-clinical development expenses and personnel costs, which together accounted for the majority of our R&D expenses, a cost structure typical for clinical-stage biotech companies; and (iv) our two Core Products obtained IND approval in PRC during the year ended December 31, 2024 and subsequently commenced Phase II clinical trials during the year ended December 31, 2025, specifically we commenced Phase II clinical trials for both the pediatric indication of DHMP and XJN010 in August 2025. No publicly disclosed clinical project terminations have been identified.

Core R&D functions

Our fully integrated R&D process includes:

- Formulation design and optimization: Based on dissolving microneedle formulation platform technology and nasal inhalation formulation platform technology, product development objectives are defined to match specific indications and clinical needs. Dosage forms are designed accordingly, followed by further optimization of formulations and manufacturing processes by integrating product quality requirements, scalability and commercialization considerations, and preclinical study results.
- Preclinical evaluation: pharmacokinetics, pharmacodynamics, and safety assessments using validated models and methods, and use these results to guide clinical development strategy.
- Clinical development: We work with professional clinical research organizations to lead core strategy development and clinical protocol design, and to manage communications with regulatory authorities. Our partners provide specialized clinical operations and execution support, ensuring that clinical trials are conducted efficiently and in compliance with international standards.
- Analytical science and quality control: We have established a comprehensive analytical platform covering analytical method development, product testing, and stability studies. Guided by the Quality by Design (QbD) principle, we maintain rigorous control over product quality, providing reliable assurance for both clinical development and manufacturing.

Early-stage research

We have a dedicated team responsible for evaluating and prioritizing product candidates to be developed. Prior to initiating R&D activities, we conduct detailed analyses, including assessments of technological feasibility, the competitive landscape, and disease prevalence. Our management reviews these assessments and determines whether to advance the product candidate into subsequent stages of R&D.

Preclinical development

For each product candidate that progresses beyond the discovery stage, we form a dedicated product development team with direct responsibility for preclinical R&D activities. This team is supported by experts from our two drug formulation technology platforms and other R&D functions, including process development and quality research.

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Clinical development

We are committed to the systematic and efficient advancement of our clinical development programs, with a focus on evaluating the safety, efficacy, pharmacokinetics, and patient usability of our innovative drug formulation products. All trials are conducted in compliance with Good Clinical Practice (GCP) and the relevant regulatory requirements in China.

Our clinical programs are designed to evaluate the safety and therapeutic potential of our non-invasive drug formulations compared to conventional routes such as oral or injectable administration. Protocol design is guided by preclinical data, regulatory expectations, disease characteristics, and target patient populations.

Trial sites

Our clinical trials are conducted with qualified hospitals and principal investigators across multiple provinces in China. Trial site selection is based on institutional experience with relevant indications or delivery methods, access to suitable patient populations, compliance with GCP, and operational efficiency. These trial sites provide access to diverse patient populations and clinical expertise, establishing a strong foundation for the conduct of multi-center trials.

Regulatory interactions

Our regulatory team engages directly with the NMPA to support the clinical development of our pipeline products. We maintain active dialogue with the regulators to ensure that our clinical plans are fully aligned with regulatory expectations for innovative formulation-based drug products in China.

We believe that the continued execution of our clinical development strategy will enable us to introduce innovative drug formulations featuring new delivery routes. These patient-centric, non-invasive formulations are intended to offer potential advantages in areas such as efficacy, convenience, and patient compliance compared to existing treatment modalities.

R&D infrastructure

Our R&D operations are based at our dedicated facility located in Guangzhou which houses formulation laboratories, analytical equipment, and pilot-scale production capabilities to support both preclinical and clinical development. The facility is equipped with cleanroom spaces, stability chambers, and controlled-environment storage to meet the quality requirements for clinical-grade product development. We continue to expand our in-house infrastructure to support long-term pipeline growth and process scalability.

Collaboration with CROs

During the Track Record Period, we have engaged third party CROs for certain R&D services in relation to our Core Products. In contrast with our CRO Services which are primarily CMC related pharmaceutical studies services, we engage third party CROs to provide (i) non-clinical services, such as animal toxicology, pharmacokinetics, and pharmacodynamic services, and (ii) clinical trial services for our Core Products. The services purchased from our CROs partners therefore fall outside of the scope of the CRO Services we provided. Our CRO suppliers are responsible for the management of the overall clinical trial process. Where required, our CRO suppliers will assist with identifying and screening suitable third parties such as hospitals and clinical trial sites, and the CROs will engage such hospitals and clinical trial sites to perform specific services under the clinical trial process. The third parties engaged by our CRO suppliers to carry out certain stages or services of the clinical trial will designate a team of professionals to monitor and conduct trials based on the scope of work as agreed between these third parties and our CRO suppliers. Among others, (i) principal investigators are key individuals responsible for the comprehensive planning, organization, and implementation of the clinical trials, ensuring the project process in accordance with the protocol and timeline; (ii) consultants usually provide high-level strategic advice on regulatory pathways, trial design and data analyses; (iii) physicians are responsible for the execution of specific experiments, day-to-day patient visits, and documentation of the data; and (iv) medical experts, who are the participants of the meeting organized by the Center for Drug Evaluation of NMPA, are primarily responsible for evaluating the trial design, the efficacy and safety of the treatment.

We select our CROs partners by reviewing a number of factors, including their quality standard, regulatory compliance, technical expertise, geographic proximity, track record and reputation in the industry, reliability in meeting development timelines, and the competitiveness of financial terms offered by them. For details of the salient terms of the agreements entered into with CROs, please refer to the section headed “— Key Contractual Terms with Our Suppliers” of this Document.

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The following table sets forth the number of CROs engaged and the amount of expenses incurred thereon for the years and periods indicated:

	Number of CROs engaged	Expenses incurred RMB'000
Year ended December 31, 2024	2	5,116
Year ended December 31, 2025	8	15,899
Five months ended May 31, 2026	4	9,548

R&D expenses

For the years ended December 31, 2024 and 2025 and the five months ended May 31, 2025 and 2026, our R&D expenses were approximately RMB16.4 million, RMB38.2, RMB10.4 million and RMB19.0 million respectively.

A substantial share of our R&D expenses was allocated to advancing our two Core Products, DHMP and XJN010. The following table sets forth a breakdown of our research and development expenses attributable to each of the Core Products for the years and periods indicated:

	Year ended December 31,		Five months ended 31 May	
	2024	2025	2025	2026
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Research and development expenses attributable to each of the Core Products				
— DHMP	5,616	11,500	2,336	9,256
— XJN010	6,283	14,845	2,966	5,519
Total	11,899	26,345	5,302	14,775

Our R&D expenses incurred for our two Core Products were approximately RMB11.9 million, RMB26.3 million, RMB5.3 million and RMB14.8 million for the years ended December 31, 2024 and 2025 and the five months ended May 31, 2025 and 2026, respectively, accounting for 72.5%, 69.0%, 51.0% and 77.9% of our total research and development expenses, and 30.7%, 29.9%, 24.2% and 39.5% of our total operating expenses (i.e. selling and distribution expenses, administrative expenses, research and development expenses) during the same periods, respectively. The increase in R&D expenses was primarily due to the increase in experiment and testing fees and staff cost as a result of the completion of phase I clinical trials and the conducting of phase II clinical trials for our two Core Products.

Notwithstanding our R&D expenses incurred for our two Core Products as a percentage of our total research and development expenses decreased slightly from approximately 72.5% for the year ended December 31, 2024 to approximately 69% for the year ended December 31, 2025, and that the aggregate of our selling and distribution expenses, and administrative expenses exceeded our R&D expenses for the years ended December 31, 2024 and 2025, we remain primarily engaged in R&D for the purpose of developing our Core Product and have continued such R&D during the 12 months prior to [REDACTED].

Particularly, (i) our R&D expenses incurred for our two Core Products increased by approximately 121.4% for the year ended December 31, 2025 to approximately RMB26.3 million, and remains substantially higher than our other R&D expenses of approximately RMB11.9 million for the year ended December 31, 2025; (ii) the slight decrease in the R&D expenses incurred for our two Core Products as a percentage of our total R&D expenses was attributable to the substantial increase in R&D expenses incurred for our key product, XJN026, at the pre-IND approval stage during the year ended December 31, 2025, leading to an increase in our R&D expenses incurred for our key product of approximately 227% for the year ended December 31, 2025 and offsetting the percentage increase of our R&D expenses incurred for our two Core Products; (iii) the aggregate of our selling and distribution expenses and administrative expenses exceeded our R&D expenses for the year ended December 31, 2025 primarily due to non-recurring expenses incurred under our selling and distribution expenses and administrative expenses during the year ended December 31, 2025, including share-based compensation expenses of approximately RMB9.1 million as a result of the awards granted under the Pre-[REDACTED] Equity Incentive Scheme during the year ended December 31, 2025 and [REDACTED] expenses of approximately RMB[REDACTED] million. For illustrative purpose, by excluding share-based compensation expenses and [REDACTED] expenses, the aggregate of our selling and distribution expenses and administrative expenses for the years ended December 31, 2025

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would amount to approximately RMB31.4 million which remains less than our R&D expenses of approximately RMB34.9 million (after excluding share-based compensation expenses under our R&D expenses); (iv) we have continued to develop our two Core Products and have achieved regulatory milestones during the year ended December 31, 2025, including but not limited to the commencement of Phase II clinical trials in PRC for the pediatric indication of our DHMP, obtaining approval from NMPA to initiate Phase II clinical trials in PRC for the adult indication of our DHMP, and commencement of Phase II clinical trials in PRC for XJN010; and (v) our R&D expenses incurred for our two Core Products for the five months ended May 31, 2026 as a percentage of our total research and development expenses and our total operating expenses as compared with the five months ended May 31, 2025, have increased from approximately 51.0% to 77.9% and from 24.2% to 39.5%, respectively. For detailed discussion of our R&D expenses, selling and distribution expenses and administrative expenses, please refer to the section headed “Financial Information — Description of Certain Selected Items of Consolidated Statements of Profit or Loss and Other Comprehensive Income” and “Financial Information — Period-to-Period Comparison of Results of Operations”.

Scientific and industrial recognition

Our sustained commitment to scientific innovation has been recognized by industry awards and regulatory designations, underscoring the quality and impact of our research.

Commercialization strategy

We have established a clear commercialization strategy designed to translate our innovative R&D outcomes into sustainable market success. We will develop effective commercialization pathways based on the pharmaceutical market landscape and healthcare reimbursement policies in China and other countries. Before initiating development, we conduct systematic evaluations of clinical pain points, technical feasibility, and commercial potential, to ensure that our pipeline is designed to address existing clinical needs while offering compelling market opportunities.

Our commercialization approach is guided by three core principles:

Targeting high-value clinical segments

We strategically focus on therapeutic areas where conventional formulations present notable limitations, particularly within the “elderly and pediatric” populations (“一老一小”). Even before the introduction of the national policy highlighting the “elderly and pediatric” healthcare segments, we had already recognized their market potential and initiated the development of our two Core Products: one for pediatric preoperative sedation, and the other for Parkinson’s disease. By addressing these critical needs, our products aim to address large market segments where existing solutions remain limited.

Driving differentiation through platform technologies

Our pipeline is built on our platform technologies, including dissolving microneedle drug formulation platform and nasal inhalation drug formulation platform technologies. These platform technologies are intended to support safety, patient compliance, and broader therapeutic applicability. By building a patent pool around our innovative platform technologies and drug formulations, we aim to establish strong technological barriers, safeguarding our competitive edge and supporting long-term commercial scalability.

Building a diversified product portfolio to mitigate risks and capture market opportunities

Our diversified portfolio of new drug formulation candidates spans multiple therapeutic areas, including but not limited to adult and pediatric indications, CNS diseases and disorders, and metabolic diseases, and encompasses a wide range of drug types, from small molecules to peptides and proteins. This diversification not only helps mitigate development risks, but also expands our potential market reach. Our in-house expertise in innovative drug formulation, device integration, and clinical development further strengthens our ability to bring differentiated products to market.

Looking ahead, we intend to advance commercialization through a combination of in-house market development and strategic partnerships. For our Core Products with significant potential in China, we plan to build an internal marketing team responsible for commercialization strategy, scientific promotion, and identifying potential partners, while also leveraging pharmaceutical companies with strong commercialization capabilities and established distribution networks to maximize the commercial value of our core products. For products with broader international potential, we will actively pursue out-licensing, co-development, or regional commercialization partnerships, thereby accelerate global market entry while managing investment risks.

Building on our differentiated technology platforms and R&D pipeline driven by patient needs, together with a commercialization strategy that combines in-house marketing and strategic partnerships, we seek to continuously strengthen our leadership position in innovative drug formulation technologies.

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According to a report by Frost & Sullivan, the aging population and increasing burden of chronic diseases are creating urgent demand for safer, more convenient therapies. Future priorities include developing precision platforms and targeted formulations for traditionally difficult-to-treat areas such as brain disorders and cancer; providing efficient and painless delivery solutions for biologics to enhance patient compliance; and enabling personalized dosing through flexible dosage form design. Ultimately, modified new drugs will move beyond serving merely as “delivery tools” and become core drivers in addressing critical clinical needs and shaping future treatment approaches.

Leveraging experiences from other business

During the Track Record Period, in addition to focusing on the R&D of our pipeline products, we have also carried out Contract Research Organization (CRO) services and Marketing Authorization Holder (MAH) business relating to high-end drug formulations in parallel. We believe that the conduct of such business activities not only helps supplement our cash flow to support the R&D of our innovative drug formulations pipeline, but also enables us to accumulate valuable experience in both R&D and commercialization. These experiences support the development and future commercialization of our Core Products.

Establishment of Technology Platforms

We are deeply engaged in the R&D and industrialization of modified new drugs. Leveraging our dissolving microneedle drug formulation technology platform and nasal inhalation drug formulation technology platform, we have established a comprehensive R&D system, and have received several government recognitions, including Guangzhou Enterprise R&D Institution, Guangdong Doctoral Workstation, Guangdong Drug Microneedle Engineering Technology Research Center, and Guangzhou Postdoctoral Innovation Practice Base.

Looking forward, while our pipeline remains primarily developed through internal resources, we remain open to strategic partnerships that align with our long-term vision. We may selectively consider collaboration in areas such as clinical development, regulatory strategy, and commercialization, particularly in regions where local expertise or infrastructure can provide added value.

TESTING AND MANUFACTURING CAPACITY

Our production facility

We have a non-commercial production facility in Guangzhou which has been providing supplies for pilot experiments, Phase I and Phase II clinical trials in relation to DHMP.

As the non-commercial production facility is mainly a pre-commercial production system designed and built for the purpose of clinical trials, it is not equipped with a full-scale production system and thus is not suitable for mass commercial production. To prepare for the anticipated commercialization of our Core Products, key product and other pipeline products, we have commenced the establishment of two commercial industrial bases, namely the Microneedle Formulation Industrial Base and the Nasal Inhalation Formulation Industrial Base.

The construction of our commercial production facilities is strategically planned, synchronized with both our clinical development milestones and market commercialization requirements. These industrial bases will be established in full compliance with the GMP regulations of key global markets, including China, and the U.S. to ensure readiness for the anticipated commercialization of our modified new drugs.

As of the Latest Practicable Date, both the Microneedle Formulation Industrial Base and the Nasal Inhalation Formulation Industrial Base are still under construction and had not commenced operation. Accordingly, their utilisation rates were nil.

The table below sets forth certain details of our Guangzhou non-commercial production facility and industrial bases as of the Latest Practicable Date:

Facility	Nature of materials or products manufactured /to be manufactured	Total GFA (sq.m.)	Designed annual production capacity (pilot production/commercial production)	Number of production lines	Utilization rate
Guangzhou non-commercial production facility ^{Note 1}	pilot-scale batches/clinical trial materials for microneedle drug products, in particular DHMP	165.9	approximately 0.45 million patches (pilot production)	1	Not applicable

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Facility	Nature of materials or products manufactured /to be manufactured	Total GFA (sq.m.)	Designed annual production capacity (pilot production/commercial production)	Number of production lines	Utilization rate
Microneedle Formulation Industrial Base ^{Note 2}	clinical trial samples and commercial products of microneedle drug formulations, including DHMP, XJN1102, and other microneedle pipeline candidates	2,855.2	approximately 3 million patches for Line 1; approximately 3 million patches for Line 2 (commercial production)	2	Nil
Nasal Inhalation Formulation Industrial Base ^{Note 3}	clinical and commercial products of nasal inhalation drug formulations, including XJN010 and other nasal inhalation pipeline candidates	4,686.4	approximately 5 million bottles (commercial production)	1	Nil

Notes:

- Our Guangzhou non-commercial production facility is not utilized as a manufacturing facility. It primarily produces pilot scale batches or clinical trial materials for our microneedle drug products, in particular DHMP, on an as needed basis. Due to the limitation in size of our Guangzhou non-commercial production facility, it is not suitable and will not be converted to a commercial manufacturing facility, accordingly, commercial manufacturing GMP is not applicable. Since production at our Guangzhou non-commercial production facility is on an as needed basis, utilisation rate is not applicable.
- Our Microneedle Formulation Industrial Base is located in the Lianyungang Economic and Technological Development Zone, Lianyungang, PRC, and will be utilized as a commercial manufacturing facility. It is designed to be GMP-compliant and solely produces clinical trial samples and commercial products of microneedle drug formulations.
- Our Nasal Inhalation Formulation Industrial Base is located in the Jinwan District of Zhuhai City, PRC, and will be utilized as a commercial manufacturing facility. It is designed to be GMP-compliant and solely produces clinical and commercial products of nasal inhalation drug formations.

The Microneedle Formulation Industrial Base is designed to support future clinical sample supply and commercialization needs for our Core Products and other products. Our first microneedle drug formulation production line is expected to be completed in the third quarter of 2026 and will be used for the manufacture of Phase III clinical trial samples and future commercial products of DHMP. The designed annual production capacity of this line is approximately 3 million patches. To meet the clinical and commercial needs of XJN1102, we plan to establish a second microneedle drug formulation production line that is expected to be completed in the fourth quarter of 2026. The designed annual production capacity of this line is approximately 3 million patches.

The Microneedle Formulation Industrial Base has been designed with sufficient space and supporting infrastructure to meet our long-term research and production needs. Adequate workshop areas have been reserved to support the R&D, pilot-scale and commercial-scale manufacturing of microneedle drug formulation products. Located within a well-equipped industrial park, the facility is designed to accommodate the production of microneedle drug formulations for both chemical and biological drug types. All environmental protection and emission standards applicable to the facility are expected to comply with national and local regulatory requirements.

The Nasal Inhalation Formulation Industrial Base is intended to serve as our core production base for multiple nasal inhalation products for both clinical and commercial purposes. Its nasal inhalation formulation production line is expected to be completed in the third quarter of 2027. The designed annual production capacity of this production line is approximately 5 million bottles.

After the commercial production facilities are put into use and meet the demands of our clinical development and commercial production plans, the operation of our non-commercial production facility in Guangzhou will be utilized for our production needs during the R&D phase of our future modified new drugs.

Our Manufacturing Team and Collaboration with CMOs

We are in the process of systematically establishing a comprehensive manufacturing and quality control team. As of May 31, 2026, our management team for manufacturing and quality control consisted of six key personnel, with two of them responsible for quality assurance. The management

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team possesses over 10 years of expertise in drug development, manufacturing, quality control, and compliance with GMP regulations, and has a profound understanding of the laws and regulations pertinent to pharmaceuticals.

During the Track Record Period, we have engaged certain qualified third parties as CMOs to provide manufacture services for our pre-clinical and clinical trials for XJN010 and XJN026. We select our CMO partners by reviewing a number of factors, including their quality standard, regulatory compliance, technical expertise, production capacity, geographic proximity, track record and reputation in the industry, reliability in meeting delivery timelines, and the financial terms offered by them. We have established procedures to closely monitor and communicate with our CMO partners to ensure their practices meet our internal standards and comply with regulatory guidelines. These include holding regular meetings for project review and technical discussion, constantly exchanging ideas and technical know-how, and timely reviewing all relevant documents and records such as manufacturing batch records and quality control records. Additionally, all intellectual properties generated from the collaboration shall be solely and exclusively owned by us.

The following table sets forth the number of CMOs engaged for manufacturing services for our pre-clinical and clinical trials for our pipeline products and the amount of expenses incurred thereon for the years and periods indicated:

	Number of CMOs engaged	Expenses incurred
		<i>RMB'000</i>
Year ended December 31, 2024	1	75
Year ended December 31, 2025	2	434
Five months ended May 31, 2026	Nil	Nil

For details of the salient terms of the agreements entered into with the CMOs, please refer to the section headed “— Key Contractual Terms with Our Suppliers” of this Document.

COMMERCIALIZATION, SALES AND MARKETING

None of our Core Products or key product has been approved or in commercial stage, including DHMP, a dissolving microneedle patch for pediatric preoperative sedation, advanced to a Phase II clinical trial, and XJN010, a clinical-stage nasal inhalation drug formulation developed for the on-demand treatment of “Off” episodes in patients with Parkinson’s disease who are already receiving a dopa decarboxylase inhibitor/levodopa regimen.

In advancing these clinical trials, we adopt stringent standards when selecting PIs, taking consideration of the candidates’ professional qualifications, academic achievements, industry recognition, and prior research experience. We firmly believe that the academic influence and industry reputation of our chosen PIs are critical not only for ensuring the smooth execution and high-quality management of the clinical trials but also for enhancing the credibility and acceptance of our pipeline products in the scientific community, which is essential for our future market access.

We will build an in-house team responsible for developing our commercialization strategies, executing academic promotion campaigns, and identifying potential business partners. In parallel, we will partner with leading Contract Sales Organizations (CSOs) that possess robust commercialization capabilities and well-established distribution networks within our focused therapeutic areas in both China and the United States. This approach allows us to leverage specialized expertise while avoiding the significant investment required to build and maintain a dedicated in-house sales team to carry out the actual sales and marketing work. Through strategic cooperation, we aim to leverage our business partners’ extensive sales networks and market resources to efficiently penetrate key retail and healthcare endpoints, including pharmacies, clinics, and hospitals. This approach will enable us to capture market potential, maximize the commercial value of our core product candidates, and achieve mutually beneficial outcomes for all stakeholders.

OUR OTHER BUSINESSES

During the Track Record Period, we generated revenue from (i) the provision of CRO Services, and (ii) our MAH Business. During the Track Record Period, we were also involved in the production, sales and marketing of cosmetics but we ceased such operations on September 1, 2025. For the two years ended December 31, 2024 and 2025 and the five months ended May 31, 2025 and 2026, income generated from our cosmetics business amounted to approximately RMB1.8 million, RMB0.3 million, RMB0.2 million and nil, respectively. Our cosmetics business ceased operation on September 1, 2025 to better utilize our resources, focusing on the development and commercialization of our two Core Products.

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Our CRO Services

Leveraging on our technology platforms, we provide pre-clinical CMC pharmaceutical studies CRO Services on a fee-for-service model.

Our CRO Services and fee models — Pre-clinical CMC Pharmaceutical Studies Services

Our pre-clinical CMC pharmaceutical studies services primarily includes (i) R&D for new drugs IND application, (ii) R&D for new drugs NDA, and (iii) R&D for generic drugs product registration application. Where our customers require non-clinical services (such as toxicology studies) or clinical trial services (such as bioequivalence studies), we may, in accordance with the relevant project agreements, be engaged to coordinate with other qualified third parties. Our CRO Services have been conducted using our R&D premises and relevant equipment, and do not involve the use of any patents of our Group.

The following table illustrates details of different stages, from engagement to delivery, of our pre-clinical CMC pharmaceutical studies services:

<i>Project enquiry and evaluation</i>	:	Our customers engage us and provide us with the initial plans, including details of the new drug for IND application, such as the proposed drug formulations, or the generic drugs for production registration application.
<i>R&D Plan formulation and execution</i>	:	Based on our customers’ initial proposals, our designated project team will formulate a R&D plan for our customers with reference to, among others, the proposed drug formulation, research data of comparable drugs, patent status of the relevant formulation or technical features of the proposed drug, the applicable national and international quality and regulatory standards.
		We will then carry out an array of services in accordance with the R&D plan, including but not limited to, (a) conducting R&D on the drug product such as formulation screening, dosage-form selection, manufacturing process development; (b) small scale and pilot-scale laboratory testing; (c) quality studies; and (d) stability studies, ensuring that the drug is compliant with the applicable quality and regulatory standard and specifications for clinical trials or product registration (as the case may be).
<i>Regulatory submissions</i>	:	Where required, we will assist our customers in preparing regulatory submission documents for their IND application, NDA application or generic drug registration application, such as compiling CMC research data, pre-clinical data and provide follow-up supplementary research services or other on-site support.

Our pre-clinical CMC pharmaceutical studies services are provided on a fee-for-service model. Under this model, our customers submit to us their requirements of services and we provide them with a payment schedule. The payment schedule sets out the fees for services we provide at the respective stage of services or milestone events as set out in the contract or work order. In determining the pricing of our pre-clinical pharmaceutical studies services, we take into account factors such as the complexity and technicality of the project, costs of our services such as labor costs and material costs, development cycle, and fee level of comparable services offered by our competitors.

During the Track Record Period, our revenue was mainly generated from our CRO Services. For the years ended December 31, 2024 and 2025 and the five months ended May 31, 2025 and 2026, revenue generated from the provision of CRO Services amounted to approximately RMB46.3 million, RMB41.9 million, RMB15.5 million and RMB12.4 million, respectively. Since initiating the R&D of our two Core Products, we have progressively scaled down our CRO Services and intend to further limit the onboarding of new projects each year, with a view to cease the provision of CRO Services upon the full discharge of its contractual obligations.

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Our MAH Business

We acquired the listing rights of Propofol Injectable Emulsion and Esomeprazole Magnesium Delayed-Release Capsules from two different Independent Third Parties in December 2022. Both Propofol Injectable Emulsion and Esomeprazole Magnesium Delayed-Release Capsules are generic drugs and neither is related to our core technology platform.

During the Track Record Period, we allocated a small internal team primarily responsible for managing contractual arrangements and ensuring regulatory compliance for the MAH Business. Our MAH Business has been conducted using our office premises, rather than R&D premises or equipment, and we do not hold material assets and/or patents for our MAH Business.

Esomeprazole Magnesium Delayed-Release Capsules

During the Track Record Period and up to the Latest Practicable Date, we entered into a distribution agreement with one distributor, an Independent Third Party, and granted it an exclusive license to import, purchase, market, distribute, use, offer for sale, and sell Esomeprazole Magnesium Delayed-Release Capsules (the “**Product**”) in the U.S. as part of our MAH Business. Our Directors are of the view that collaborating with the distributor who has sales networks and end-customer resources is a good option for the Company as it has no intention of establishing a direct sales team in the U.S. for this business. For details of the key contractual terms with our MAH Business customer, please refer to the section headed “Business — Our Customers — Key Contractual Terms with Our Customers” in this Document.

Propofol Injectable Emulsion

During the Track Record Period, we also supply Propofol Injectable Emulsion manufactured by our contract manufacturer, to certain Independent Third Party customers in PRC, who place purchase orders with us and would resell to third parties. We have entered into distributorship agreements for the sale of Propofol Injectable Emulsion in PRC with these customers. Our Directors confirm that we have ceased to accept any purchase orders since January 2024 after having considered various factors, among others, (i) the 10mL formulation of our Propofol Injectable Emulsion was less commonly adopted in clinical practice in PRC, whereas the 20mL formulation offered by our competitors had become the predominant market standard; (ii) our Propofol Injectable Emulsion lacked pricing competitiveness, and any further price reductions would have adversely impacted our profit margins; and (iii) we intend to consolidate our resources for the R&D of our two Core Products.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any disputes with any of the customers of our MAH Business concerning the settlement of trade receivables. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any potential misuse of our name or identity by any of such customers that could adversely affect our reputation, business operations, or financial contributions, and we had not experienced any material product returns, complaints, or claims from such customers.

Our aggregate sales under our MAH Business in the years ended December 31, 2024 and 2025 and the five months ended May 31, 2026 amounted to approximately RMB2.7 million, RMB13.4 million and RMB4.2 million, respectively.

We may evaluate potential divestment opportunities for our MAH Business should suitable options arise, as it has not been a strategic priority for us.

OUR CUSTOMERS

Our customers during the Track Record Period primarily included CMOs. The aggregate sales to our five largest customers during the year ended December 31, 2024 and 2025, and the five months ended May 31, 2026 amounted to approximately RMB18.6 million, RMB28.5 million and RMB11.4 million, respectively, and accounted for approximately 37.9%, 51.5% and 68.8% of our total revenue for the respective year/period. Revenue from our single largest customer during the year ended December 31, 2024 and 2025, and the five months ended May 31, 2026 amounted to approximately RMB7.8 million, RMB13.4 million and RMB4.2 million, respectively, and accounted for approximately 15.9%, 24.2% and 25.1% of our total revenue for the respective year/period.

The following table sets forth the details of our five largest customers during the Track Record Period in the years/period indicated.

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For the year ended December 31, 2024

Customer	Principal business	Registered capital of customer <i>RMB'000</i>	Products/ services provided	Commencement of business relationship	Credit terms and payment method	Revenue derived from the customer	
						<i>RMB'000</i>	%
Customer A ⁽¹⁾	Medical research and experimental development	20,000	CRO Services	2023	10 working days after fulfilment of milestone; bank transfer	7,809	15.9
Customer B ⁽¹⁾	Manufacturing and sales of Class I and Class II medical devices, pharmaceutical production	50,000	CRO Services	2021	10 working days after fulfilment of milestone; bank transfer	2,849	5.8
Customer C ⁽¹⁾	Pharmaceutical manufacturing and wholesale	60,000	CRO Services	2022	10 working days after fulfilment of milestone; bank transfer	2,722	5.6
Customer D ⁽²⁾	Manufacturing and sales of pharmaceutical products	1,664,218	CRO Services	2015	10 - 20 working days after fulfilment of milestone; bank transfer	2,606	5.3
Customer E ⁽¹⁾	Pharmaceutical manufacturing and wholesale, medical research and experimental development	109,980	CRO Services	2023	10 working days after fulfilment of milestone; bank transfer	2,594	5.3
Top five customers in aggregate						18,580	37.9
All other customers						30,446	62.1
Total revenue						49,026	100

Notes:

- Customer A, Customer B, Customer C and Customer E are private companies established in the PRC with limited liability.
- Customer D is a public company established in the PRC and listed on the Shenzhen Stock Exchange, and is a subsidiary of a large public company engaged in pharmaceutical manufacturing, wholesale and distribution businesses, a company listed on the Main Board of the Stock Exchange.

For the year ended December 31, 2025

Customer	Principal business	Registered capital of customer <i>RMB'000</i>	Products/ services provided	Commencement of business relationship	Credit terms and payment method	Revenue derived from the customer	
						<i>RMB'000</i>	%
Customer F ⁽¹⁾	Manufacturing and marketing of generic injectables and ophthalmic products	Not applicable	MAH drug sales	2023	30 days; bank transfer	13,382	24.2
Customer G ⁽²⁾	Investment activities with self-owned funds, medical research and experimental development	5,000	CRO Services	2024	10 working days after fulfilment of milestone; bank transfer	4,557	8.2
Customer B	Manufacturing and sales of Class I and Class II medical devices, pharmaceutical production	50,000	CRO Services	2021	10 working days after fulfilment of milestone; bank transfer	3,858	7.0
Customer H ⁽²⁾	Pharmaceutical manufacturing and wholesale, medical research and experimental development	20,000	CRO Services	2024	15 working days after fulfilment of milestone; bank transfer	3,351	6.1
Customer D	Manufacturing and sales of pharmaceutical products	1,664,218	CRO Services	2015	10 - 20 working days after fulfilment of milestone; bank transfer	3,304	6.0
Top five customers in aggregate						28,452	51.5
All other customers						26,786	48.5
Total revenue						55,238	100

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Notes:

- Customer F is a private company incorporated in the United States with limited liability.
- Customer G and Customer H are private companies established in the PRC with limited liability.

For the five months ended May 31, 2026

Customer	Principal business	Registered capital of customer	Products/ services provided	Commencement of business relationship	Credit terms and payment method	Revenue derived from the customer	
		<i>RMB'000</i>				<i>RMB'000</i>	%
Customer F . . .	Manufacturing and marketing of generic injectables and ophthalmic products	Not applicable	MAH drug sales	2023	30 days; bank transfer	4,165	25.1
Customer I ⁽¹⁾ . . .	Research and development, production and sales of pharmaceutical products	41,060	CRO Services	2012	10 working days after fulfilment of milestone; bank transfer	2,990	18.1
Customer H . . .	Pharmaceutical manufacturing and wholesale, medical research and experimental development	20,000	CRO Services	2024	15 working days after fulfilment of milestone; bank transfer	1,668	10.1
Customer J ⁽¹⁾ . . .	Research and development, production and sales of pharmaceutical products	80,000	CRO Services	2024	10 working days after fulfilment of milestone; bank transfer	1,646	9.9
Customer G . . .	Investment activities with self-owned funds, medical research and experimental development	5,000	CRO Services	2024	10 working days after fulfilment of milestone; bank transfer	933	5.6
Top five customers in aggregate						11,402	68.8
All other customers						5,165	31.2
Total revenue						16,567	100.0

Notes:

- Customer I and J are private companies established in the PRC with limited liability.

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

Key Contractual Terms with Our Customers

During the Track Record Period, we entered into one distribution agreement with our MAH Business customer for the distribution of esomeprazole magnesium delayed-release capsules in the U.S. and service agreements with our CRO Services customers for the provision of CRO Services.

The key contractual terms under our esomeprazole magnesium delayed-release capsules distribution agreement are as follows: (i) the distributor is restricted to sales of the product within the U.S. only; (ii) the distributor shall be solely responsible for establishing its selling prices for the product throughout the U.S.; (iii) the distributor submits purchase orders for its requirements with three months prior notice; (iv) we manufacture (through contract manufacturer) and supply the product to the distributor on a mutually exclusive basis at a fixed price; (v) both parties share the net profits based on a predetermined percentage; and (vi) unless terminated for cause, the term is for a period of seven years and renewed automatically thereafter annually unless either party terminates. The distributor has thirty days from later of distributor's receipt of the Product or the distributor's receipt of certificate of analysis, to inspect such product to determine whether the product conforms to specifications and free of defect. The distributor may notify us of any defects but acceptance of the shipment constitutes waiver of any claims by the distributor. The distributor may return the product for latent defect having a shelf life for less than six months. If we disagree with the distributor that the product meets the specifications within fifteen days of the distributor's notice, the matter may be submitted to an independent testing laboratory. If it is determined that the product does not meet the specifications, we shall replace the product at our expense.

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Our CRO Services agreements with our customers have primarily adopted the standardized technology service contract form issued by the Ministry of Science and Technology of the PRC. The table below summarises the key contractual terms under our CRO Services agreements:

- Technical objectives** Sets out the basic information of the project, including the subject and nature of CRO Services to be provided under the service agreement. We primarily provide CMC pharmaceutical studies of the following areas:
- (a) R&D for new drugs IND application: we provide full range of R&D for our customers' new drugs IND application, including API quality studies and internal control standard setting, formulation development, analytical method development and validation, stability studies and the compilation of the complete documentation;
 - (b) R&D for new drugs NDA: we provide full range pharmaceutical research to support NDA submissions, which includes process validation, commercial-scale stability studies, and the compilation of the complete documentation;
 - (c) R&D for generic drug registration and application: we provide comprehensive pharmaceutical research to support Abbreviated New Drug Application (**ANDAs**) submissions, which includes research and analysis on the reference drug or formulation, API quality analyses and internal control standard setting, development of formulation and process, quality studies, stability studies and the compliance of the complete documentation;

where required, we may provide non-clinical studies and clinical studies services in relation to the aforesaid areas. Such non-clinical studies and clinical studies services will be provided by third-party CROs engaged by us on behalf of our customers, or directly by our customers where we will assist in identifying and selecting suitable CROs for our customers.

- Obligations of parties** Sets out the respective obligations of the parties to the service agreement:
- (i) obligations of our customers primarily include:
 - (a) payment obligations in accordance with the payment terms of the service agreement;
 - (b) handling of administrative procedures in relation to the relevant IND application;
 - (c) provision of project background information;
 - (d) procurement of materials for pilot-scale and commercial-scale production;
 - (e) quality inspection on the final products;
 - (ii) obligations of our Company primarily include:
 - (a) developing and executing detailed pharmaceutical research protocols and plans;
 - (b) finishing laboratory-scale studies, pilot-scale studies, quality studies, etc.;
 - (c) compiling the research reports for each stage involved;
 - (d) assisting the Client in preparing the pharmaceutical documentation required for regulatory submissions;

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Project closing	Sets out the milestone event for closing of the project: <ul style="list-style-type: none"> (i) for CRO Services in relation to R&D for new drugs IND application, the project is generally completed upon the customer obtaining NMPA’s approval for clinical trial; (ii) for CRO Services in relation to new drugs NDA or generic drugs registration application, the project is generally completed upon the receipt of the drug registration certificate issued by the NMPA by the customer
Project plan and schedule	We set out the detailed R&D plan and timetable for the project, and identify the key milestones
Payment terms	We primarily provide our services on a fee-for-service model, with payment tied to specific stages or milestone events as set out in the R&D plan
Intellectual property	We warrant to our customers that the products we deliver do not infringe the intellectual property rights and other legal rights of third parties. Each party retains ownership of its respective background intellectual properties. Our customers retain ownership of all products or technical inventions developed or conceived during the performance of the agreement.
Liability	Each party is liable for their respective breaches under the service agreement. If, due to our technical defects or gross negligence, the research data provided by us is inaccurate or incomplete, and such deficiencies directly result in the pharmaceutical documentation being rejected by the relevant regulatory authority, we shall bear the corresponding liabilities in accordance with the service agreement.

PRICING STRATEGY

When our Core Products and other pipeline products progress to commercialization, we will adopt a value and patient-centric framework when we determine the respective prices of our products, designed to ensure market sustainability and long-term corporate viability. The pricing of our pipeline products will primarily be determined by a number of factors, including (i) intrinsic value of our products, such as production costs, differential technology features and associated therapeutic benefits; (ii) assessment of market referents, such as competitor drug prices, market trends, and fluctuations in supply and demand; and (iii) payer dynamics, such as affordability of patients, health economic considerations and variations in regional healthcare policies and reimbursement systems. We intend to develop detailed pricing strategies as these pipeline products approach commercialization.

To secure market share against existing and future branded and generic competitors, we will pursue inclusion of our Core Products and other pipeline products in the National Reimbursement Drug List (NRDL) and other reimbursement programs through formal negotiations with relevant authorities. However, NRDL inclusion is subject to evaluation and determination by governmental authorities, and we anticipate facing fierce competition for successful placement. Concurrently, we will explore the integration of our products into medical benefit plans included in local policy-based commercial health insurances, corporate supplementary medical benefits, or patient assistance programs in the PRC, to ensure continued accessibility and commercial sustainability, particularly in the event of intense competition or before NRDL inclusion. As of the Latest Practicable Date, no pricing guidance or centralized procurement requirements had been imposed by the PRC government on our pipeline products.

For our CRO business and MAH business during the Track Record Period, our products were priced on a cost-plus basis, determined based on our costs and commercial considerations of competitive market prices.

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OUR SUPPLIERS

During the Track Record Period, our suppliers primarily included (i) suppliers of raw materials and consumables for our drug development, (ii) suppliers of utilities, such as water and electricity, for our R&D, as well as production, and (iii) CROs, who provide third-party contracting services for certain non-clinical research and clinical implementation requiring specific qualifications or resources, such as procedures and studies that must be conducted in compliance with the GLP.

The aggregate purchases from our five largest suppliers during the year ended December 31, 2024 and 2025 and the five months ended May 31, 2026 amounted to approximately RMB14.2 million, RMB35.3 million and RMB17.2 million, respectively, and accounted for approximately 42.6%, 45.0% and 65.4% of our total purchases for the respective year/period. The purchases from our single largest supplier during the year ended December 31, 2024 and 2025 and the five months ended May 31, 2026 amounted to approximately RMB4.5 million, RMB12.5 million and RMB5.9 million, respectively, and accounted for approximately 13.5%, 15.9% and 22.6% of our total purchases for the respective year/period.

The following table sets forth details of our five largest suppliers in each year during the Track Record Period.

For the year ended December 31, 2024

Supplier	Principal business	Registered capital of supplier	Products/services purchased	Commencement of business relationship	Credit terms and payment method	Purchase amount	
		RMB'000				RMB'000	%
Supplier A ⁽¹⁾	Medical research and experimental development, technical services, inspection and testing services, etc.	20,000	R&D services	2023	5 days; bank transfer	4,498	13.5
Supplier B ⁽¹⁾	Non-residential real estate leasing, property management	60,000	Leasing of premises	2020	monthly; bank transfer	3,722	11.2
Supplier C ⁽²⁾	Pharmaceutical manufacturing, pharmaceutical sales and related activities	293,527	Contract manufacturing	2023	30 days; bank transfer	2,208	6.7
Supplier D ⁽¹⁾	Manufacturing, repair, and sales of equipment and instruments, etc.	10,000	Equipment procurement	2021	(for small-value consumables) 7 days; (for large-value equipment) 15 days for prepayment of 30% and 7 days for the balance of 70%; bank transfer	2,038	6.1
Supplier E ⁽¹⁾	Pharmaceutical clinical trial services	12,235	R&D services	2023	5–10 working days after fulfillment of milestone; bank transfer	1,684	5.1
Top five suppliers in aggregate						14,150	42.6
All other suppliers						19,067	57.4
Total purchases						33,217	100

Note:

- Supplier A, Supplier B, Supplier D and Supplier E are private companies established in the PRC with limited liability.
- Supplier C is a private company established in the PRC with limited liability and is a subsidiary of a large pharmaceutical services company listed on the Shanghai Stock Exchange.

For the year ended December 31, 2025

Supplier	Principal business	Registered capital of supplier	Products/services purchased	Commencement of business relationship	Credit terms and payment method	Purchase amount	
		RMB'000				RMB'000	%
Supplier C	Pharmaceutical manufacturing, pharmaceutical sales and related activities	293,527	Contract manufacturing	2023	30 days; bank transfer	12,488	15.9

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Supplier	Principal business	Registered capital of supplier	Products/services purchased	Commencement of business relationship	Credit terms and payment method	Purchase amount	
		<i>RMB'000</i>				<i>RMB'000</i>	%
Supplier F ⁽¹⁾	Medical research and experimental development	42,580	R&D services	2025	7 days upon receipt of invoices; bank transfer	7,070	9.0
Supplier G ⁽¹⁾	Construction and engineering activities, installation, modification, and maintenance of special equipment, etc.	80,000	Renovation and remodeling	2025	7–10 days upon receipt of invoices; bank transfer	6,220	7.9
Supplier H ⁽²⁾	Medical research and experimental development	385,556	R&D services	2022	5 days upon confirmation of monthly settlement statement; bank transfer	5,888	7.5
Supplier I ⁽³⁾	Financial consultancy	2,000	Consultancy services	2023	15 days after receipt of transaction payment or completion of closing; bank transfer	3,663	4.7
Top five suppliers in aggregate						35,329	45.0
All other suppliers						43,225	55.0
Total purchases						78,554	100

Note:

- Supplier F and Supplier G are private companies established in the PRC with limited liability.
- Supplier H is a public company established in the PRC and listed on the Shenzhen Stock Exchange.
- Supplier I comprises of two private companies established in the PRC with limited liability with the same ultimate beneficial owner.

For the five months ended May 31, 2026

Supplier	Principal business	Registered capital of supplier	Products/services purchased	Commencement of business relationship	Credit terms and payment method	Purchase amount	
		<i>RMB'000</i>				<i>RMB'000</i>	%
Supplier H	Medical research and experimental development	385,556	R&D services	2022	7 working days after fulfilment of milestone; bank transfer	5,943	22.6
Supplier C	Pharmaceutical manufacturing, pharmaceutical sales and related activities	293,527	Contract manufacturing	2023	30 days; bank transfer	3,820	14.6
Supplier F	Medical research and experimental development	42,580	R&D services	2025	7 working days after fulfilment of milestone; bank transfer	2,997	11.4
Supplier J ⁽¹⁾	Import and export of various commodities and technologies	11,000	Procurement of equipment	2025	7 working days after fulfilment of milestone; bank transfer	2,795	10.7
Supplier B	Non-residential real estate leasing, property management	60,000	Leasing of premises	2020	Monthly; bank transfer	1,614	6.2
Top five suppliers in aggregate						17,169	65.4
All other suppliers						9,078	34.6
Total purchases						26,247	100.0

Notes:

- Suppliers J is a private company established in the PRC with limited liability.

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

Key Contractual Terms with Our Suppliers

During the Track Record Period, we have procured raw materials and consumables for the production of our pipeline products and our contract manufacturing services. We have established procurement management procedures and material management procedures. Specifically, we look for suitable potential suppliers based on factors such as supply stability, product quality, product pricing, and our past experience. We further review the qualifications and certifications of potential suppliers and consider product pricing and their ability to provide technical support when needed to determine candidate suppliers and backup suppliers. Finally, we negotiate with candidate suppliers to confirm the order price. We inspect the corresponding products upon receipt to verify quantity and quality, and record relevant data. We maintain a list of qualified suppliers and update it periodically. During the Track Record Period and up to the Latest Practicable Date, we did not experience any significant fluctuations in raw material prices or delays that had a material impact on our results of operations or financial position.

During the Track Record Period, we primarily entered into services agreements with our CRO suppliers, contract manufacturing agreements with our CMO suppliers, equipment or material procurement agreements, and lease agreements for the lease of our Group’s leased premises.

Our CRO procurement agreements with our suppliers have primarily adopted the standardized technology service contract form issued by the Ministry of Science and Technology of the PRC. The table below summarises the key contractual terms under our CRO procurement agreements:

Technical objectives	Sets out the basic information of the project, including <ul style="list-style-type: none"> (i) the subject and nature of CRO services to be procured under the service agreement. We primarily procure non-clinical and clinical studies CRO services in the areas of (a) non-clinical studies such as animal toxicology, pharmacokinetics, and pharmacodynamic studies services, and (b) clinical studies such as clinical trial services; (ii) the specific national and industry standards, and quality standards that are required for the specific project
Obligations of parties	Sets out the respective obligations of the parties to the service agreement: <ul style="list-style-type: none"> (i) obligations of our suppliers primarily include: <ul style="list-style-type: none"> (a) jointly formulate the clinical trial plan and protocols with our Company (such clinical trial plan and protocols are devised based on the initial proposals provided by our Company, including but not limited to, enrollment strategies, eligibility and exclusion criteria etc., and are subject to our final approval); (b) preparation and submission of the clinical trial application to the ethics committee (such application subject to the review and submission approval of our Company); (c) selection or engagement of third party clinical agencies;

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- (d) management and execution of the clinical trial in accordance with the clinical trial plan among others, deliver progress reports to our Company, handling and securing trial data collected in accordance with the relevant protocols and regulations, duly report to our Company and the ethics committee in respect of adverse events or incidents, and assisting our Company in handling any claims in relation to the same;
 - (ii) obligations of our Company primarily include:
 - (a) payment obligations in accordance with the payment terms of the service agreement;
 - (b) provision of the requisite technical data, documents, research reports to the CRO supplier;
 - (c) provision and delivery of drug samples of proper quality and specifications to the CRO supplier and/or external clinical trial agencies engaged by the CRO supplier;
 - (d) provision of adequate insurance or indemnity in respect of adverse or side effects caused by our drugs during clinical trial
 - Project closing** The project typically completes upon the delivery of the respective clinical trial research report to our Company and our inspection of the same
 - Project plan and schedule** Sets out the detailed clinical trial plan and timetable, including all technical specifications, protocols, national and industry standards, and quality standards that have to be met by our CRO suppliers during different stages of the clinical trial.
 - Payment terms** Payment under the service agreement is typically tied to specific stages of the clinical trial as set out in the payment schedule of the agreement.
 - Intellectual property** We retain ownership of all products or technical inventions developed or conceived during the performance of the agreement.
 - Liability** Each party is liable for their respective breaches under the service agreement.
- Each party is also subject to additional liquidated damages for their respective breaches, the amount of which represents certain percentage of the total contract sum determined on case-by-case basis.

During the Track Record Period, we have entered into supply agreements with CMOs for the manufacturing and production of our MAH Business products and for the manufacturing and production of clinical trial products and IND registration batches of our Core Products.

The key contractual terms under our master supply agreement with CMO for the manufacturing and production of esomeprazole magnesium delayed-release capsules are as follows: (i) we are the holder of the FDA approved abbreviated new drug application (ANDA) of the product and we own all intellectual property associated with the product; (ii) the products manufactured under the master supply agreement shall be distributed in the U.S. and we have the exclusive distribution rights of the product in the U.S.; (iii) the CMO has the exclusive rights to supply the product to us and is prohibited from distributing, or supplying the product to other distributors for the distribution, in the U.S.; (iv) the product supplied by the CMO shall comply with the product quality specifications; (v) the quantity of product to be supplied is determined by the written purchase orders placed by us from time to time, products shall be delivered within ninety (90) days of the placement of the purchase order and all delivered products shall have an expiration period of at least twenty-one (21) months from the date of delivery; (vi) the price per quantity as specified in the master supply agreement shall be inclusive of all

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costs, including but not limited to raw materials, packaging, delivery costs etc.; (vii) we have the right to terminate any purchase order with sixty (60) days notice prior to delivery; (viii) we shall settle payment within thirty (30) days upon delivery of the products to the designated U.S. port; and (ix) where the product is recalled by the FDA by reason of our breaches under the master supply agreement, we shall be responsible for all costs incurred in connection with the recall, whereas where the product is recalled by the FDA by reason of the CMO’s breaches under the master supply agreement, the CMO shall be responsible for all costs incurred in connection with the recall.

The key contractual terms under our supply agreements with CMOs for the manufacturing and production of clinical trial products and IND registration batches of our Core Products are as follows: (i) we act as the sole applicant for drug registration and the MAH. We retain control over the R&D process and we hold 100% of the intellectual property, disposal rights, and future commercial interests associated with our Core Product. The role of the CMOs is limited to providing manufacturing of the subject products or materials in accordance with the provided specifications, and technical support as a service provider, and they do not possess any independent rights to our Core Product or its subsequent development.

During the Track Record Period, we have entered into certain material or equipment procurement agreements with our suppliers. The key contractual terms under such procurement agreements are as follows: (i) the agreement specifies the subject model, order quantity and price; (ii) the agreement sets out the relevant national, industry and quality standards or specifications of the product that have to be met by our suppliers; (iii) the agreement sets out the delivery period of the order, for small value consumables, the deliver period will be shorter, whereas for large value equipment, our suppliers will have a longer delivery period, we are also typically entitled to a fixed post-delivery warranty period; (iv) we shall make payments in accordance with the payment schedule as set out in the procurement agreements.

During the Track Record Period, we have entered into lease agreements in respect of our leased premises. The key contractual terms under such lease agreements are as follows: (i) the lease agreement sets out details of the leased premises including location, size and permitted uses of the premises; (ii) we typically enter into a fixed term lease arrangement; (iii) we shall pay rent and other utilities and management fees monthly; (iv) we are entitled to transfer the lease or sub-lease to our related entities; and (v) we are subject to obligations and restrictions set out in the lease agreements, such as the obligation to maintain proper insurance in respect of occupiers and properties in the leased premises, obligations to comply with the relevant regulations in respect of construction, renovation or maintenance within the leased premises etc.

INVENTORY

As of the Latest Practicable Date, our inventory mainly consists of raw materials, testing materials, and consumables required for R&D. We procure these materials and consumables based on the relevant research plans. We closely monitor inventory levels and delivery schedules to reduce the risk of material shortages.

We have implemented an inventory management process that controls each stage of warehousing. The business department and warehouse management department conduct a comprehensive inventory of stock annually, while the finance department carries out random stock checks half-yearly. Leveraging management software enables the digitalised management of inventory across the entire warehouse. A deviation report is required to be filed if a difference occurs between the book value and the count value of the materials or the consumables, to record the stock gain or loss, and help identify the reason for the deviation and determine whether such materials or consumables can be cleared for use or rejected.

Throughout the Track Record Period and up to the Latest Practicable Date, we did not encounter any material inventory shortages. Going forward, we aim to further optimise inventory levels by analysing historical sales data to develop effective purchasing and production plans enhancing inventory management and aligning purchasing and production volumes with anticipated customer demand.

QUALITY CONTROL

Our quality control team

We endeavor to ensure the quality of our operation through a comprehensive quality management system in accordance with the regulations of the NMPA and the FDA and other applicable regulations, including GMP/cGMP and the standards of the Chinese and American Pharmacopoeias. We have implemented a multi-tiered, product risk-oriented quality management framework comprising the following key components: (i) the quality manual, which defines quality policies, objectives, and risk management principles, aligning all quality activities with regulatory requirement; (ii) the master file,

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which covers quality standards for raw materials, intermediates, and finished products, ensuring technical rigor at every production stage; (iii) the standard operating procedures, governing manufacturing, inspection, storage, and transportation processes, as to guarantee operational consistency and traceability; (iv) the report system, which utilises batch records, stability reports, and annual quality reviews to continuously monitor product quality trends and proactively address potential risks; and (v) the integrated control mechanisms which ensure manufacturing stability through validated processes and continuous verification, maintain rigorous supplier qualification audits for raw materials, packaging and logistics, enabling end-to-end traceability of smallest saleable units, and driving continuous quality management system improvement via systematic internal audits and management reviews.

As of the Latest Practicable Date, we have established a management team of quality control and management consisting of five members, with most members possessing bachelor’s or higher degrees and each member possesses a minimum of three years of hands-on experience in quality management and control of aseptic manufacturing. Our quality management system covers material control system, quality assurance, quality control, manufacturing, equipment and facilities system, and packaging and labeling control system. They are responsible for the key stages of drug development, including R&D, pilot experiments, and supplies production in Phase I, II, and III clinical trials. This includes discovery, preclinical research, clinical trials, pilot production, procurement, supply chain, process development, production, warehousing, delivery, and recalls. Moving forward, building upon our existing quality management system, we are committed to establishing a comprehensive, integrated R&D-to-commercial-manufacturing quality management system in accordance with the applicable laws and regulations. Qualified suppliers will be selected according to stringent criteria, and our production and quality management teams will be expanded as planned to accommodate future commercial manufacturing quality system development needs. There were no material claims or complaints relating to product quality during the Track Record Period and up to the Latest Practicable Date.

CYBERSECURITY AND DATA PRIVACY

Our Company consistently regards information security and data management as a cornerstone of its operations. We have established a comprehensive management system, ensuring that our management requirements are deeply integrated with business practices.

In terms of organisational management for information security and customer information protection, our Company has implemented a safety responsibility system that involves all employees. We require all staff to strictly comply with the information security management system and related safety measures. We enter into employee confidentiality agreements with all our employees, which provide that, among other things, our employees are legally obligated not to misuse the confidential information while in office, to surrender all confidential information in possession while resigning, and to retain their confidential obligations after they cease employment, and such information security requirements are incorporated into employees’ performance assessments.

We have adopted multi-layered and comprehensive technical measures to establish a robust security network. At the infrastructure security level, we have deployed firewalls, access security control, internet usage behavior control, data flow management, etc. to continually enhance our network perimeter protection capabilities, effectively defending against various external attack threats. In terms of enterprise domain control, we have built a comprehensive protection system in the field of data security across multiple core dimensions, including document encryption, access control, external transmission and offline protection, endpoint security, and auditing. Additionally, we have implemented physical isolation between our R&D network and office network, ensuring independent protection for laboratory-specific terminals and core data.

In terms of transmission security, we have employed a combination of encryption technologies and document encryption mechanisms to comprehensively safeguard the security and integrity of data during transmission. For data backup and disaster recovery, we have established a data backup mechanism to ensure the integrity, continuity, and recoverability of our business data.

The Group as the clinical trial sponsor, can only access the trial data without downloading or further processing such data. The Investigator is responsible for collecting clinical trial data required for the clinical trial protocol, assigning subject identification numbers, and anonymizing the names of trial subjects. The clinical trial data include subjects’ physical examinations, vital signs, blood routine tests, urine routine tests, blood biochemistry tests, coagulation function tests, electrocardiograms; medication data during the treatment period; subjects’ concurrent medication status; efficacy indicators; and doctors’ evaluations. The trial data does not include any personal information of trial subjects.

The Group has established a data security management system and conduct data privacy and compliance training for employees on an annual basis.

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During the Track Record Period and up to the Latest Practicable Date, in order to obtain clinical trial approval for XJN010 from the FDA, we submitted application materials to the FDA, which include data relating to the pharmacokinetics and safety of the drug. In addition, we also, as the marketing authorization holder, submitted other application materials to the FDA for the purposes of filing change applications and annual reports under the Abbreviated New Drug Applications (ANDAs). The data in both cases do not contain any personal information, sensitive information or material data. As affirmed by our PRC Legal Advisor, the submission of clinical trial data from the Chinese Mainland to the FDA complies with applicable PRC data privacy laws and regulations in material aspects.

During the Track Record Period and up to the Latest Practicable Date, we have not collected or processed medical information or personal data from individuals in the U.S., accordingly, as confirmed by our U.S. legal advisors, we have not conducted data processing activities that would be subject to material regulation under applicable U.S. data privacy or data security laws.

In the Directors’ view, with the support of the opinions of the relevant legal advisors, the Group (1) has not experienced any material data leakage, and (2) has, in all material respects, complied with all applicable laws and regulations regarding data privacy and security within the PRC and the U.S. during the Track Record Period and up to the Latest Practicable Date.

During the Track Record Period and up to the Latest Practicable Date, we did not encounter any breaches of confidential client information or any other incidents related to client information that could adversely affect our business, financial condition, or operational results. Our PRC Legal Advisor has confirmed that, during the Track Record Period and up to the Latest Practicable Date, we have not been subject to any material penalties concerning data privacy and data transfer.

INTELLECTUAL PROPERTY RIGHTS

As a company focused on the research, development and commercialization of modified new drugs, we consider intellectual property to be fundamental to our business. We actively seek patent protection for our platform technologies and pipeline products and, where appropriate, file additional patent applications covering manufacturing processes and methods of use (including methods of medical use). Our intellectual property strategy is designed to support the development and commercialization of our pipeline products and to protect key aspects of our technologies. As of the Latest Practicable Date, we had developed a portfolio of patent applications and patents covering various aspects of our platforms and pipeline products.

As of the Latest Practicable Date, we held 41 patents exclusively. As of the same date, we also had 13 invention patent applications pending in China, three invention patent applications pending in the U.S., and two PCT applications open for entry into the national phase. Among these, six granted patents and one pending patent application in China, three pending patent applications in the U.S., and two PCT applications open for entry into the national phase materially cover, or are directed to, the core technical features, manufacturing processes, pharmaceutical formulations or medical indications of our pipeline products and are considered our material patents and patent applications. All material patents and patent applications as of the Latest Practicable Date were owned exclusively by our Company or its subsidiaries. As of the Latest Practicable Date, we held four granted patents and five pending patent applications in connection with our Core Products and the key product, including two granted patents and one pending application for DHMP, one granted patent and two pending applications for XJN010, and one granted patent and two pending applications for XJN026.

The following table sets out details of our material patents and patent applications as of the Latest Practicable Date. We hereby disclose that the API for XJN010 is levodopa. The APIs for certain other product candidates are not disclosed in this Document due to confidentiality and commercial sensitivity, as these product candidates are still at an early stage of development and have not yet entered clinical trials.

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Product Candidate	Patent/ Application Number	Type of Patent	Name of Patent/Application	Inventors	Jurisdiction ¹	Status	Application Date	Expiration Date	Grant Date	Applicant/ Patentee	Acquisition Way	Protection Scope
DHMP	ZL202411676053.5	Invention	Dexmedetomidine microneedle patch and its preparation method and application (右美托咪定微針貼劑及其製備方法和應用)	Yang Beibei; Tang Yu; Yang Jingyin; Liao Langkun; Yang Dan; Liu Hualiang; Wu Chuanbin	PRC	Granted	21 November 2024	21 November 2044	28 Nov 2025	Company	Original	Dexmedetomidine microneedle patch, its preparation method and its use in treating insomnia
DHMP	ZL202210847168.0	Invention	Dexmedetomidine hydrochloride soluble microneedle and preparation method thereof (一種鹽酸右美托咪定可溶性微針及其製備方法)	Chen Hangping; Yang Beibei; Liao Langkun; Feng Disang; Wang Yalong; Zhao Zhiming	PRC	Granted	19 July 2022	19 July 2042	18 Mar 2025	Novken Research	Original	Dexmedetomidine hydrochloride soluble microneedle and preparation method thereof
DHMP	US19/303,705	Invention	Dexmedetomidine microneedle patch, preparation method and application thereof	Yang Beibei; Tang Yu; Yang Jingyin; Liao Langkun; Yang Dan; Liu Hualiang; Wu Chuanbin	US	Pending	19 August 2025	N/A	N/A	Company	Original	Dexmedetomidine microneedle patch, its preparation method and its use in treating insomnia
XIN010	ZL202311494072.1	Invention	Levodopa nasal spray, and preparation method and use thereof (一種左旋多巴鼻噴霧劑及其製備方法及應用)	Yue Xiao; Zhang Xuejuan; Wang Yalong; Lifeng; Tang Yu; Chen Hangping	PRC	Granted	9 November 2023	9 November 2043	22 Nov 2024	Company	Original	Levodopa nasal spray, its preparation method and its use in treating Parkinson's disease
XIN010	US19/127,903 ²	Invention	Levodopa nasal spray, and preparation method and use thereof	Yue Xiao; Zhang Xuejuan; Tang Yu; Liu Hualiang; Liang Xuxia; Wu Chuanbin	US	Pending	6 November 2024	N/A	N/A	Company	Original	Levodopa nasal spray, its preparation method and its use in treating Parkinson's disease
XIN010	PCT/CN2024/130102 ³	Invention	Levodopa nasal spray, and preparation method and use thereof (一種左旋多巴鼻噴霧劑及其製備方法及應用)	Yue Xiao; Zhang Xuejuan; Tang Yu; Liu Hualiang; Liang Xuxia; Wu Chuanbin	PCT	Pending	6 November 2024	N/A	N/A	Company	Original	Pharmaceutical composition comprising Levodopa and/or benserazide and/or carbidopa, its preparation method and its use in treating Parkinson's disease

- 1 It is noted that the patent application marked as “PCT” in the Jurisdiction column denote an international application filed under the Patent Cooperation Treaty. Such a PCT application is in the international phase and does not itself constitute a granted patent in any jurisdiction. It will require entry into the national/regional phase in designated countries or regions to obtain patent protection.
- 2 The prolonged application of the patent is due to a combination of common factors in global patent prosecution, including backlogs at USPTO, the technical complexity of the inventions requiring thorough assessment, and the Company's strategic management of the prosecution process to align with its commercial objectives. This application is actively progressing within the normal procedural timelines, and the Company is diligently engaging with the USPTO to advance them.
- 3 This application is a PCT application. It is important to clarify that the international phase under the Patent Cooperation Treaty does not involve substantive examination or grant. Substantive examination occurs only upon, and independently within, each national or regional phase entry (e.g., in China or the US). Therefore, the timeline for the international phase is not indicative of a “prolonged application” but rather reflects the standard 30/31-month decision period for entering target markets, which the Company utilizes for strategic global portfolio planning.

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Product Candidate	Patent/ Application Number	Type of Patent	Name of Patent/Application	Inventors	Jurisdiction ¹	Status	Application Date	Expiration Date	Grant Date	Applicant/ Patentee	Acquisition Way	Protection Scope
XIN026	ZL202210541760.8	Invention	Rizatriptan nasal spray and preparation method thereof (利扎曲普坦鼻噴霧劑及其製備方法)	Zhang Xuejun; Wang Guanlin; Wu Chuanbin; Wu Jinlong; Huang Ying; Yue Xiao; Xia Xiao; Guo Haihua	PRC	Granted	17 May 2022	17 May 2042	03 Feb 2023	Company	Assigned ⁴	Rizatriptan nasal spray and preparation method thereof
XIN026	CN202411697980.5 ⁵	Invention	A drug solution composition, a preparation method thereof, a nasal spray and application thereof (一種藥物溶液組合物及其製備方法、鼻噴霧劑和應用)	Yue Xiao; Zhang Xuejun; Tang Yu; Liang Er; Wang Guanlin; Yang Beibei; Wu Chuanbin	PRC	Pending	25 November 2024	N/A	N/A	Company	Original	Pharmaceutical composition comprising Rizatriptan, its preparation method, nasal spray and use in treating migraine
XIN026	PCT/CN2025/100381	Invention	A pharmaceutical solution composition, its preparation method, nasal spray, and its application (一種藥物溶液組合物及其製備方法、鼻噴霧劑和應用)	Yue Xiao; Zhang Xuejun; Tang Yu; Liang Er; Wang Guanlin; Yang Beibei; Wu Chuanbin	PCT	Pending	11 June 2025	N/A	N/A	Company	Original	Pharmaceutical composition comprising Rizatriptan, its preparation method, nasal spray and use in treating migraine
XIN102	ZL202210028787.7	Invention	Semaglutide dissolving soluble microneedle patch and preparation method thereof (司美格魯肽可溶性微針貼片及其製備方法)	Wu Chuanbin; Chen Hangping; Li Feng; Feng Disang; Yang Beibei; Zhao Zhiming	PRC	Granted	11 January 2022	11 January 2042	01 Aug 2023	Company	Original	Semaglutide soluble microneedle patch and preparation method thereof
XIN102	ZL202210162729.3	Invention	Semaglutide soluble microneedle composition and preparation method thereof (一種司美格魯肽可溶性微針組合物及其製備方法)	Wu Chuanbin; Chen Hangping; Li Feng; Feng Disang; Yang Beibei; Zhao Zhiming	PRC	Granted	22 February 2022	22 February 2042	19 Sep 2023	Company	Original	Semaglutide soluble microneedle composition and preparation method thereof
XIN102	US18/772,038 ⁶	Invention	Semaglutide soluble microneedle composition and preparation method thereof	Wu Chuanbin; Tang Yu; Yang Beibei; Liu Hualiang	US	Pending	17 March 2022	N/A	N/A	Company	Original	Semaglutide soluble microneedle composition and preparation method thereof

We also held patents and patent applications in respect of our technology platforms. The following table sets out details of these patents and patent applications as of the Latest Practicable Date.

- 4 Assigned from Jinan University.
- 5 The prolonged application of the patent is due to a combination of common factors in global patent prosecution, including backlogs at CNIPA, the technical complexity of the inventions requiring thorough assessment, and the Company's strategic management of the prosecution process to align with its commercial objectives. This application is actively progressing within the normal procedural timelines, and the Company is diligently engaging with the CNIPA to advance them.
- 6 The prolonged application of the patent is due to a combination of common factors in global patent prosecution, including backlogs at USPTO, the technical complexity of the inventions requiring thorough assessment, and the Company's strategic management of the prosecution process to align with its commercial objectives. This application is actively progressing within the normal procedural timelines, and the Company is diligently engaging with the USPTO to advance them.

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Patent/ Application Number	Type of Patent	Name of Patent/Application	Inventors	Jurisdiction	Status	Application Date	Expiration Date	Grant Date	Applicant/ Patentee	Acquisition Way	Protection Scope
ZL201710393418.7 . . .	Invention	Thymopentin soluble microneedle and preparation method thereof (胸腺五肽可溶性微針及其製備方法)	Wu Chuanbin; Lin Shiqi; Quan Guilan; Pan Xin; Cai bingzhen; Hou Yuanlin; Yang Peipei	PRC	Granted	27 May 2017	27 May 2037	07 Jan 2020	Company	Assigned ¹	Thymopentin soluble microneedle and preparation method thereof
ZL201811022455.8 . . .	Invention	Fast-separating soluble microneedle and a preparation method thereof (快速分離型可溶性微針及其製備方法)	Wu Chuanbin; Hou Yuanlin; Quan Guilan; Yang Beibei; Pan Xin	PRC	Granted	03 Sep 2018	03 Sep 2038	01 Apr 2022	Company	Assigned ²	Fast-separating soluble microneedle and a preparation method thereof
ZL201911223281.6 . . .	Invention	Microneedle patch for improving skin hypertrophic scars and preparation method thereof (改善皮膚增生性癰痕的微針貼片及其製備方法)	Wen Xinguo; Zhang Minmin; Chen Hangping; Yang Sichao; Ren Chunyan	PRC	Granted	03 Dec 2019	03 Dec 2039	29 Oct 2021	Company	Assigned ³	Microneedle patch for improving skin hypertrophic scars and preparation method thereof
ZL201911236031.6 . . .	Invention	Microneedle patch for improving skin acne and preparation method thereof (改善皮膚痤瘡的微針貼片及其製備方法)	Wen Xinguo; Zhang Minmin; Xiao Zijie; Chen Hangping; Yang Sichao; Ren Chunyan	PRC	Granted	05 Dec 2019	05 Dec 2039	08 Feb 2022	Company	Assigned ⁴	Microneedle patch for improving skin acne and preparation method thereof
ZL201911342239.6 . . .	Invention	Microneedle patch for losing weight and preparation method thereof (用於減肥的微針貼片及其製備方法)	Zhang Minmin; Xiao Zijie; Chen Hangping; Chen Yesheng; Ren Chunyan	PRC	Granted	23 Dec 2019	23 Dec 2039	04 Oct 2022	Company	Assigned ⁵	Microneedle patch for losing weight
ZL202211255974.5 . . .	Invention	Rivastigmine nasal spray and its preparation method (卡巴拉汀鼻噴霧劑及其製備方法)	Huang Zhengwei; Zhang Xuejuan; Wang Guanlin; Wu Chuanbin; Wu Jinlong; Huang Ying; Yue Xiao; Xia Xiao; Guo Hahua	PRC	Granted	13 Oct 2022	13 Oct 2042	11 Aug 2023	Company	Assigned ⁶	Rivastigmine nasal spray and its preparation method

- 1 Assigned from Sun Yat-sen University.
- 2 Assigned from Sun Yat-sen University.
- 3 Assigned from 廣州新濟微娜娜生物科技有限公司.
- 4 Assigned from 廣州新濟微娜娜生物科技有限公司.
- 5 Assigned from 廣州新濟微娜娜生物科技有限公司.
- 6 Assigned from Jinan University.

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Patent/ Application Number	Type of Patent	Name of Patent/Application	Inventors	Jurisdiction	Status	Application Date	Expiration Date	Grant Date	Applicant/ Patentee	Acquisition Way	Protection Scope
ZL202310406063.6 . . .	Invention	An abaparatide soluble microneedle patch and its preparation method (一種阿巴帕肽可溶性微針貼片及其製備方法)	Chen Hangping; Yang Beibei; Xie Chenguang; Zhang Shuai; Wang Yalong; Zhao Zhiming	PRC	Granted	14 Apr 2023	14 Apr 2043	18 Oct 2024	Novaken Research	Original	Abaparatide soluble microneedle patch and its preparation method
CN202311035778.1 . . .	Invention	A minodronic acid soluble microneedle patch and its preparation method (一種米諾龍酸可溶性微針貼片及其製備方法)	Yang Beibei; Wang Yalong; Xie Chenguang; Chen Hangping; Zhang Shuai; Zhao Zhiming; Li Feng	PRC	Pending	16 Aug 2023	N/A	N/A	Company	Original	Minodronic acid soluble microneedle patch and its preparation method
CN202311820595.0 . . .	Invention	A hand-held microneedle drug delivery device (一種手持式微針給藥裝置)	Chen Hangping; Xie Chenguang; Zhao Zhiming; Wang Yalong; Tang Yu; Yang Beibei; Feng Dsang; Li Feng	PRC	Pending	26 Dec 2023	N/A	N/A	Company; Novaken Research	Original	Hand-held microneedle drug delivery device
ZL202411901165.6 . . .	Invention	Rizatriptan microneedle patch and its preparation method and use (利扎曲普坦微針貼劑及其製備方法和應用)	Yang Beibei; Yang Jingxin; Tang Yu; Tang Wenjing; Yue Xiao; Wu Chuanbin	PRC	Granted	20 Dec 2024	20 Dec 2044	04 Nov 2025	Company	Original	Rizatriptan microneedle patch and its preparation method and use in treating migraine
ZL202311494348.6 . . .	Invention	A nasal spray acting on central nervous system and its preparation method and use (一種作用於中樞神經系統的鼻噴霧劑及其製備方法及應用)	Zhang Xuejuan; Yue Xiao; Wang Yalong; Wang Guanlin; Liang En; Tang Yu; Chen Hangping	PRC	Granted	09 Nov 2023	09 Nov 2043	11 Jul 2025	Company	Original	Central nervous system nasal spray and its preparation method

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We intend to seek patent protection in overseas jurisdictions into which we expand, where appropriate and in a timely manner.

The scope and extent of protection afforded by a patent vary on a claim-by-claim and jurisdiction-by-jurisdiction basis and depend on a number of factors, including the type of patent, the scope of its claims, the availability of any patent term extensions or adjustments, the availability of legal remedies in the relevant jurisdiction, and the validity and enforceability of the patent. For further details, see “Risk Factors — Risks Relating to Intellectual Property Rights”.

A freedom-to-operate searches and analyses (“**FTO Analysis**”) has been conducted in China and the U.S. in relation to our Core Products. Based on the FTO analysis, our Directors are of the view that there are no valid and enforceable patents of any third party in China and the U.S. in respect of our Core Products and we have not infringed any valid and enforceable patents or other IP rights of any third parties.

We also own a number of registered trademarks and pending trademark application. As of the Latest Practicable Date, we had 35 registered trademarks in China and 12 registered trademarks in Hong Kong. We intend to seek additional trademark protection where appropriate and in a timely manner.

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any material proceedings, nor had we received notice of any material claims, relating to alleged infringement of intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent and that may have a material adverse impact on us.

COMPETITION

The biopharmaceutical industries are defined by fast-paced technological innovation, intense market competition and a strong focus on proprietary drugs development. While we believe our pipeline of clinical and preclinical stage proprietary assets, R&D capability, technology platforms and an experienced management team provide us with competitive advantages, we still face potential competition from, among others, major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, and public and private research institutions. Any pipeline product that we successfully develop and commercialise will face competition from both existing drugs and future novel drugs. Please also refer to the paragraph headed “Risk Factors — Risks Relating to Manufacturing and Commercialisation of our Pipeline Products — We may face intense competition if competing drugs are more effective, have fewer side effects, are better marketed and cost less than our drugs or pipeline product, or receive regulatory approval or enter the market ahead of ours, or if our drugs or pipeline product are not approved. We may also face rapid technological advancements and changes which may possibly allow our competitors to develop therapies that are similar, more advanced, or more effective than ours, which may diminish our market share, hinder the successful commercialisation of our pipeline product and adversely impact our financial condition and business prospects” in this document for further details.

We focus on utilising our industry experience and established R&D capabilities for the internal discovery and development of differentiated therapeutic products primarily for chronic diseases, particularly metabolic disorders. We face intense competition from existing products and product candidates under development in the market. Please refer to the section titled “Industry Overview” in this Document for further details on the competitive landscape of the various markets in which we compete. We also face uncertainties in clinical trial development, which are subject to numerous factors, including satisfactory safety and efficacy results from clinical trials, successful patient enrollment, and the performance by CROs and other parties involved in clinical trial development, and other factors. Please refer to the paragraph headed “Risk Factors — Risks Relating to the Development, Clinical Trials and Regulatory Approval of our Pipeline Products” in this document for further details.

EMPLOYEES

The following table sets forth a breakdown of our employees by function as of Latest Practicable Date, all of whom were based in China:

Function	Number	% of Total
R&D	122	70.1
Production, manufacturing and supply chain.	26	14.9
Administrative	26	14.9
Total	174	100

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We enter into individual employment contracts with our employees covering salaries, bonuses, employee benefits, confidentiality obligations, work product assignment clauses, and grounds for termination. We also execute separate confidentiality with our senior management and certain key members of our R&D team.

To maintain our workforce’s quality, knowledge, and skill levels, we provide regular and specialised training tailored to departmental needs. We are committed to ensuring safe working conditions throughout our operations and that employees are treated with due care and respect.

Employee remuneration comprises salaries, performance appraisal, housing provident funds, social insurance premiums, and other welfare payments. Furthermore, we provide various incentives and benefits, including bonuses and equity incentive plan, particularly to key employees. We have made contributions to employees’ social insurance premiums (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing provident funds in accordance with applicable laws and regulations.

Certain of our practices have not been in full compliance with the mandatory contributions for social insurance and housing provident funds under the PRC law. For a more detailed discussion of the related risks, please refer to “Risk Factors — Risks Relating to Doing Business in Jurisdictions Where We Operate — We may be subject to additional social insurance fund, housing provident fund contributions and late fees or fines imposed by relevant regulatory authorities.” in this Document. During the Track Record Period and up to the Latest Practicable Date, we had not received any administrative penalties, claims or notices from government authorities regarding inadequate contributions. According to our PRC legal counsel, under the premise that there are no significant changes to current PRC policies and regulations or to the enforcement and supervision requirements of local governments and that there are no material employee complaints, litigation or arbitration proceedings the likelihood of being imposed material administrative penalties or centralized collection in connection with shortfalls in our contributions to social insurance and housing provident fund is remote, provided that we make any outstanding contributions and late fees, if required, within the stipulated timeframe.

During the Track Record Period and up to the Latest Practicable Date, no labour union was established among our employees. We maintain a positive working relationship with our employees. During the Track Record Period and up to the Latest Practicable Date, we experienced no strikes, protests or other significant labour conflicts that could materially affect our business or reputation.

INSURANCE

We hold insurance policies in compliance with PRC laws and regulations, and aligned with our operational requirements and industry standards. We maintain product liability insurance for the products we sell, accident insurance and vehicle insurance for employees, as well as insurance for adverse events in clinical trials. While we consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm, it may, however, be insufficient to cover all claims for product liability, damage to our assets, facilities and equipment or employee injuries. For further details, please refer to the paragraph headed “Risk Factors — Risks Relating to Doing Business in Jurisdictions Where We Operate — We have limited insurance coverage, and any claims beyond our insurance coverage may result in us incurring substantial costs and a diversion of resources” in this document. During the Track Record Period and up to the Latest Practicable Date, we had not made, nor been the subject of, any material insurance claims.

PROPERTIES AND FACILITIES

As of the Latest Practicable Date, we had 9 leased properties in China with a total aggregate gross floor area of approximately 21,251.48 sq.m. We believe our current facilities are sufficient to meet our near-term needs, and additional space can be obtained on commercially reasonable terms to meet our future needs. We do not anticipate undue difficulty in renewing our leases upon their expiration. As of the Latest Practicable Date, we did not have any self-owned properties.

The following table sets forth a summary of the leased properties as of the Latest Practicable Date:

Location	Usage	Address	Gross Floor Area (sq.m)	Lease Term
Lianyungang, Jiangsu Province	Factory	1st, 2nd & 8th Floors, Workshop Building 15, No. 82 Jingqiao Road, Lianyungang Economic and Technological Development Area	8,637.42	November 1, 2024 to October 31, 2031

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Location	Usage	Address	Gross Floor Area (sq.m)	Lease Term
Zhuhai, Guangdong Province	Manufacturing, R&D, office, and warehousing	Units 101 & 201, Building 5, Gechuang Jinjin Health Port, No. 111 Yaoguan Road, Sanzuo Town, Jinwan District, Zhuhai City	4,686.39	August 1, 2025 to July 31, 2030
Guangzhou, Guangdong Province	Office	Room 105, Building No. 1, Xingye Avenue East No. 1078, Hualong Town, Panyu District, Guangzhou, PRC	130.82	May 22, 2020 to May 21, 2030
Guangzhou, Guangdong Province	Industrial warehouse facilities	Room 107, Building No. 1, Xingye Avenue East No. 1078, Hualong Town, Panyu District, Guangzhou, PRC	65.41	July 22, 2022 to May 21, 2030
Guangzhou, Guangdong Province	Office	Rooms 401, 501, 601, Lift 2, Building No. 1, Xingye Avenue East No. 1078, Hualong Town, Panyu District, Guangzhou, PRC	2,739.42	May 22, 2020 to May 21, 2030
Guangzhou, Guangdong Province	Industrial warehouse facilities	Rooms 701, 801, Lift 2, Building No. 1, Xingye Avenue East No. 1078, Hualong Town, Panyu District, Guangzhou, PRC	1,826.28	July 22, 2022 to May 21, 2030
Guangzhou, Guangdong Province	Office	9th Floor, Building No. 1, Xingye Avenue East No. 1078, Hualong Town, Panyu District, Guangzhou, PRC	913.14	May 22, 2020 to May 21, 2030
Guangzhou, Guangdong Province	Office, R&D, warehousing, manufacturing and commercial uses	2nd and 3rd Floors plus 65.41 square meters of apportioned area on 1st Floor, Block A2, Building No. 1, Xingye Avenue East No. 1078, Hualong Town, Panyu District, Guangzhou, PRC	1,891.69	October 22, 2025 to May 21, 2030
Guangzhou, Guangdong Province	Office	Unit 301-3, Room 301, No. 245 Science Avenue, Huangpu District, Guangzhou, PRC	360.91	April 1, 2026 to March 31, 2027

We expect to renew and extend these leases before their respective expirations, or seek other premises based on business needs. For our other leases, we expect to initiate renewal discussions with the landlords and do not expect any material obstacles for successful extension. If we were unable to renew such leases, our Directors believe we can find alternative offices within a short time as there are plenty of comparable supplies in the market, and we will incur immaterial moving expenses for our operations. For risks related to lessors and other aspects of our leased properties, please refer to the paragraph headed “Risk Factors — Risks Relating to Doing Business in Jurisdictions Where We Operate — We are subject to risks associated with our leased properties” in this Document.

ENVIRONMENTAL, SOCIAL, HEALTH AND SAFETY MATTERS

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 customers, suppliers, and the broader community that our operations may impact.

Governance on ESG Matters

The Board actively promotes the implementation of ESG principles and integrates them into the Company’s governance framework. The Board is the highest decision-making authority within our Company on ESG-related matters and is responsible for setting the overall ESG goals and strategies, under which we will establish the Strategy & ESG Committee of the Board at [REDACTED], responsible for monitoring and guiding functions to guarantee the effective execution of ESG policies. Under the Strategy & ESG Committee, an ESG working group will be established to promote the implementation and execution of ESG issues, monitor the implementation status of ESG issues.

We adhere to relevant environmental regulations, ensuring our emissions consistently meet national standards. We actively pursue a greener business model by optimizing resource allocation, improving energy efficiency, and supporting China’s “carbon peaking and carbon neutrality goals (雙碳目標).” For this endeavor, We have implemented energy-saving measures, and enforced a waste sorting and recycling system to increase resource efficiency. We aim to achieve a sustainable balance between our business growth and our environmental responsibilities, continuously enhancing our long-term, green development.

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Potential Impact of ESG-Related Risks

As a biopharmaceutical company, we face a variety of environmental, health or safety-related risks associated with our operations over the short-, medium- and long-term. For example, our operations involve the use of hazardous materials, including chemicals, and may produce hazardous waste products to the environment. If we fail to process the hazardous materials in compliance with relevant laws and regulations, cause injury to persons involved or contaminate the environment, we could incur significant costs associated with administrative, civil or criminal fines and penalties, lose our permit/certificate or be ordered to make substantial alterations to our business operations. See the section titled “Risk Factors” for more details on the potential impact of such risks.

In light of the nature of our business, and to the best knowledge of our Directors, climate change is not expected to have any significant impact on our operations. In the event of extreme weather conditions, we will proactively respond to relevant local government policies and develop contingency plans. Should acute physical risks arise, such as direct damage to assets or indirect impacts from supply chain disruptions due to extreme weather events, we will implement appropriate contingency and disaster preparedness plans, and we believe we possess the capability to manage the climate crisis effectively. During the Track Record Period and up to the Latest Practicable Date, we have not encountered any material impact as a result of environmental, social, or climate-related issues.

Improper use of pharmaceuticals, particularly when administered beyond the intended uses specified in the drug label or package insert, may expose patients to unpredictable safety and efficacy risks, potentially leading to medical disputes and legal litigation. Concurrently, excessively high drug pricing may directly undermine healthcare accessibility, increase patients’ financial burdens, and exacerbate inequities in the distribution of medical resources. For specific internal control measures aimed at mitigating these risks, please refer to the section titled “Risk Factors.”

Metrics and Targets

We monitor the following metrics to assess and manage the environmental and climate-related risks arising from our business and manufacturing operations:

Resource consumption and pollutant disposals

- Electricity and water consumption. We have monitored our electricity consumption levels and implemented measures to improve energy efficiency during the Track Record Period. For the years ended December 31, 2024 and 2025, and five months ended May 31, 2026 our electricity consumption levels were approximately 878.33MWh, 929.84 MWh and 390.20MWh, respectively. We have monitored our water consumption levels and implemented measures to promote water conservation during the Track Record Period. For the years ended December 31, 2024 and 2025 and five months ended May 31, 2026, our water consumption levels were approximately 4,354 m³, 5,077 m³ and 1,939 m³, respectively.
- Hazardous solid waste discharge. The solid waste we produce is mainly divided into hazardous waste and non-hazardous waste. We have environment and safety administrators who monitor and manage the whole process of hazardous solid waste management, from generation to disposal. We have also contracted with a qualified third-party waste disposal company for the disposal of hazardous solid material and waste. For the years ended December 31, 2024, and 2025 and five months ended May 31, 2026, we transferred approximately 18.11 tons, 22.13 tons, and 12.17 tons of hazardous solid waste for disposal. To optimise storage and cost efficiency, we will transfer hazardous solid waste to the disposal company once we accumulate three tons.

Our Strategy & ESG Committee will set out targets for each material key performance indicator at the beginning of each financial year. The relevant targets for the material key performance indicators will be reviewed annually to ensure their continued suitability for our needs. When setting targets for environment-related KPIs, we considered our respective consumption or emission levels during the Track Record Period, while also taking into account our future business expansion comprehensively and prudently. We will continue to adopt environmental conservation measures to limit resource consumption and emissions. Moving forward, we will make continuous efforts in working towards the target of reducing our electricity and water consumption. Referencing the emission reduction targets outlined in ESG reports from industry peers and our company’s current resource consumption patterns, we have established relevant ESG objectives aligned with our current business direction. In 2025, our water and electricity consumption per thousand RMB of R&D expenditure stood at 0.13 m³/thousand RMB and 0.02 MWh/thousand RMB respectively, representing year-on-year reductions of 54.5% and 49.9%. Considering our future plans for commercial production of products, we will explore adopting resource consumption metrics based on product output or operating revenue as new ESG indicators aligned with our business direction. Until the industrialization process is fully implemented, we will continue to use R&D expenditure as our ESG target indicator. Using 2025 as the base year, our goal is

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to reduce electricity consumption, water usage, and emissions of hazardous solid waste per unit of R&D expenditure by 3% by 2030. Based on this target, our projected electricity consumption for 2026 and 2027 is approximately 2,800 and 3,630 MWh, respectively; our projected water consumption for 2026 and 2027 is approximately 15,290 and 19,820 m³, respectively; and the target volumes of hazardous solid waste transferred for disposal in 2026 and 2027 are approximately 70 and 90 tons, respectively. We will continue to dispose the hazardous wastes in compliance with relevant laws and regulations. Accordingly, we will actively implement a range of environmental protection measures to reduce resource consumption and emissions. In terms of resource consumption, we will (i) install energy-efficient equipment in our offices and manufacturing processes; (ii) provide training for employees to promote energy-saving practices and environmental awareness, encouraging behaviours such as switching off equipment when not in use. Regarding waste generation and greenhouse gas emissions, we will (i) keep regularly monitoring and evaluating the sources of hazardous solid waste, ensuring strict compliance with internal policies and legal requirements; and (ii) adopt more environmentally friendly production processes and facilities whenever feasible.

As our products gradually enter the commercialization phase, we anticipate that certain ESG-related metrics — particularly those related to the environmental dimension — will show a reasonable upward trend during the initial stages of business expansion. On the environmental front, driven by the inherent demands of large-scale production, logistics, and warehousing operations during the commercialization phase, total energy consumption, greenhouse gas emissions, and waste generation will increase. On the social front, the commercialization process will drive growth in the total number of employees, the scale of the supply chain, and the reach of patients. Correspondingly, we will continue to refine and enhance our management practices regarding investments in product quality and safety, as well as the coverage of ESG audits across our supply chain. As our products are commercialized in the future, our ESG goals may be adjusted based on the progress of commercialization, such as focusing on energy consumption and emissions intensity per unit of output or revenue. Following commercialization, we will actively strengthen our green operations and social responsibility practices to ensure that ESG management performance improves in tandem with business growth, thereby achieving sustainable commercial success.

Employee Rights and Benefits

We have adopted a people-oriented and talent-driven approach, emphasising the development of employee welfare systems and the optimization of compensation structures. We are committed to safeguarding employees’ basic rights and enhancing their job satisfaction and sense of belonging. We strictly abide by the relevant laws and regulations related to PRC labor law.

Training and Development

Our Company offers internal and external training to help employees enhance their work-related skills. To promote skill development and career advancement, Our Company implements three major training programmes: (i) the “Novaken Genius/Young Genius (新濟天才/青年天才)” programme, which aims at training high-potential key employees; (ii) Master’s and Doctoral Program that encourages outstanding employees to pursue graduate degrees while remaining employed; and (iii) the employee personal cultivation improvement programme. Our Company conducts programme participant selection every one to two years. Selected employees may receive funding support for talent development and participate in project-based training. Our Company systematically aligns our training framework with performance evaluations, career progression pathways, and long-term incentive structures to cultivate talent and drive sustainable organisational growth.

Workplace Safety

We have endeavored to provide a safe work environment by implementing company-wide self-protection policies for employees to either work remotely or on-site with protective masks and sanitisation. We have implemented and upheld a comprehensive set of rules, standard operating procedures, and measures to ensure the health and safety of our employees. We ensure that our employees continually acknowledge their understanding of safety protocols as needed. We have established strict internal management policies for hazardous chemicals, designed to comprehensively prevent and mitigate risks of accidental contamination, biochemical hazards, and personal injury within our facilities. We ensure employee safety and compliant hazardous chemical handling through measures including standard operating procedures, safety training, and regulated use of personal protective equipment. For chemical management, we maintain hazardous waste disposal protocols and operate a comprehensive life cycle registration, segregated storage, and tracking system for hazardous chemicals. Continuous safety training and oversight ensure systematic safety safeguards throughout the R&D process.

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We define the safety management responsibilities of each department. Meanwhile, we have established a “three-tier education” training system for occupational health to enhance occupational disease. We have established health check-ups and medical benefits for employees, along with comprehensive occupational disease monitoring mechanism. We have developed a scientifically sound and comprehensive emergency response plan and conduct regular drills to enhance employees’ capabilities in handling situations such as fires, leaks, and equipment failures. By implementing the measures as mentioned above, we are dedicated to maintaining a safe and healthy working environment for all staff. During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any significant workplace accident or fatality.

Workplace Diversity

We are committed to fostering an open and inclusive workplace that promotes equality. We hire employees based on their merits, and it is our corporate policy to provide equal opportunities regardless of gender, age, race, religion, or any other social or personal characteristics. As of the Latest Practicable Date, we had 174 employees, of whom 112 were female. Additionally, 111 of our employees are aged over 30 or above, and 8 are aged 50 or above. Our workforce reflects a diverse range of experiences and professional backgrounds. We adhere to a fair and transparent employee management system and strive to enhance gender and age diversity within our workforce.

LEGAL PROCEEDINGS AND COMPLIANCE

Social Insurance and Housing Provident Fund

During the Track Record Period and up to the Latest Practicable Date, we had made contributions to social insurance and the housing provident fund for our employees. However, we did not make full contributions to social insurance and housing provident fund for certain employees.

The potential maximum penalty with respect to fines that we may be exposed to due to shortfall of social insurance contributions during the Track Record Period and up to the Latest Practicable Date would be approximately RMB22.1 million. In addition, in the case that if the relevant authority makes an application to relevant courts for enforcement, the amount of maximum potential enforcement due to shortfall of housing provident fund contributions during the Track Record Period would be approximately RMB0.4 million.

Pursuant to the applicable regulations, if the relevant social insurance authorities determine that our contributions are insufficient, they may order us to settle the outstanding balance within a prescribed period, together with a late payment surcharge of 0.05% per day of the unpaid amount. Failure to comply within the specified timeframe could result in fines ranging from one to three times the total outstanding balance. In addition, if we fail to pay the housing provident fund within the prescribed time limit, we could be subject to compulsory enforcement from the courts if the payment is not made within the time limit prescribed by the competent authorities. Pursuant to the Notice on Implementing Several Measures to Further Support and Serve the Development of the Private Economy (《關於實施進一步支援和服務民營經濟發展若干措施的通知》) issued by the State Administration of Taxation on November 16, 2018, tax collection authorities shall not, on their own initiative, organize any centralized collection of payment arrears from previous years owed by payers, including private enterprises.

The Interpretation II of the Supreme People’s Court of Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》) (“**New Judicial Interpretation**”) was enacted by the Supreme People’s Court on 31 July 2025 and implemented on 1 September 2025. Pursuant to the Article 19(1) of the New Judicial Interpretation, if an employer and an employee agree or the employee commits that social insurance contributions are not required to be paid, the People’s Court shall deem such agreement or commitment invalid, and where an employer fails to pay social insurance contributions, and the employee requests to terminate the labor contract and claims economic compensation from the employer in accordance with the PRC Labor Contract Law, the People’s Court shall support such claims. During the Track Record Period and up to the Latest Practicable Date, the Group and the relevant employees have never signed any agreement which stipulates that no payment of social insurance would be required to be made by the Group. Therefore, the New Judicial Interpretation will not influence the assessment of the Group’s compliance with the contribution requirements.

Our PRC Legal Advisor, on behalf of us, has conducted telephone consultations with the competent authorities in the domiciles of the Company and its subsidiaries in December 2025, via publicly available telephone lines, and further conducted on-site interviews with the competent tax office and the competent housing provident fund management center in the domicile of the Company in April 2026. These government authorities have jurisdiction over the social insurance contribution and

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housing provident fund contribution matters. These government authorities confirm that they generally do not conduct blanket retroactive collection against enterprises. Generally no penalties apply if enterprises proactively cooperate with rectification.

Under the Reform Plan for the National and Local Tax Collection and Administration Systems (《國稅地稅徵管體制改革方案》) and the Administrative Measures of Guangdong Province on the Collection of Social Insurance Premiums by Tax Authorities (《廣東省社會保險費稅務徵收實施辦法》), the tax authorities are responsible for the collection, inspection and recovery of social insurance premiums. Under the Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》), a housing provident fund management center administers the deposit, withdrawal and use of housing provident fund within its area. On this basis, our PRC Legal Advisor is of the view that the tax authorities and the housing provident fund management centers consulted are the competent authorities to provide the relevant confirmations or assurances on behalf of the respective government authorities.

The Group has adopted the rectification plan for the insufficient payment of social insurance and housing fund, and will actively cooperate with the competent authorities to complete the supplementary payments upon their request. The Group has established regular review and monitoring procedures to track the reporting and contribution status of social insurance and housing fund, and timely monitor the regulatory developments. The Group’s employee Handbook has explicitly stipulated the requirements for making statutory contributions to social insurance and housing fund. The Group will strengthen legal and compliance training for the management team and enhance internal control policies to better manage such contributions, maintain ongoing communication with the relevant authorities to understand their requirements and interpretations of applicable laws and regulations, and make timely contributions in accordance with their specific guidance.

In particular, we aim to progressively adjust the social insurance and housing provident fund contribution bases to comply with applicable regulatory requirements. These adjustments involve various aspects of the Company’s internal management and operations, and the adjusted contribution bases will also require additional contributions from our employees. We have therefore commenced internal assessments and are communicating with our employees to seek their understanding and cooperation. We will implement these adjustments in a phased and orderly manner. Given that the social insurance contribution base is generally subject to annual adjustment during a prescribed window determined by the local authorities, we intend to apply for an adjustment of the social insurance contribution base, effective from the next available adjustment window following the [REDACTED], and expect to substantially complete such adjustment within 3 years following the [REDACTED]. Similarly, as the housing provident fund contribution base is subject to annual adjustment during a prescribed window determined by the relevant local housing provident fund management centers, we aim to apply for a corresponding adjustment of the housing provident fund contribution base, effective from the next available adjustment window following the [REDACTED].

During the Track Record Period and up to the Latest Practicable Date, based on (i) the credit reports of our Group companies, (ii) the public search results showing that we have not been subject to any penalties from the relevant authorities on the relevant websites of competent government authorities, (iii) the centralized collection of historical shortfalls for social insurance, have been strictly prohibited by the competent authority and (iv) the feedback obtained from the on-site interviews conducted by our PRC Legal Advisor with the competent authorities regarding housing provident fund policies and implementation indicating that they will not actively carry out a large-scale recovery of housing provident fund contributions from the enterprise. We had not received any administrative penalties, claims or notices from government authorities regarding inadequate contributions. We have confirmed to comply promptly with any requirement from the competent authorities to make outstanding contributions and late payments in the future, if any. Our PRC Legal Advisor are therefore of the view that under the premise that there are no significant changes to current PRC policies and regulations or to the enforcement and supervision requirements of local governments and that there are no material employee complaints, litigation or arbitration proceedings, the likelihood that we would be subject to material administrative penalties or centralized collection due to our failure to provide full social insurance and housing provident fund contributions is remote.

Based on the foregoing above, our Directors and our PRC Legal Advisor are of the view that the non-compliance incidents would not have any material adverse impact on the Group’s business, financial condition or results of operations.

Lease Properties

The potential maximum penalty that we may be subject to for failing to file and obtain the property leasing filing certificate and the ownership certificate from the lessor for one leased property is RMB10,000.

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The legal department of the Group has issued a notice on the review requirements for lease agreements. The notice clearly stipulates that all lease agreements to be signed shall be submitted to the legal department for review, together with the lessor’s valid identity document and the real estate ownership certificate. The legal department shall verify whether the lease agreement clearly stipulates the arrangements for handling lease registration and filing, and put forward review opinions.

As the Directors’ and the PRC Legal Advisors’ views, the non-compliance would not have a material adverse impact on the Group’s business, financial condition or results of operations.

During the Track Record Period and up to the Latest Practicable Date, we were not a party to, any actual or pending legal, arbitral or administrative proceeding, which, in our opinion, is likely to have a material and adverse effect on our business, financial conditions or results of operation. Further, during the Track Record Period and up to the Latest Practicable Date, we did not commit any material non-compliance of the laws and regulations which individually or in the aggregate, in the opinion of our Directors, would have a material and adverse effect on our business, financial condition or results of operations.

Our PRC Legal Advisor is of the opinion that our business was in compliance with the applicable laws and regulations of the PRC in all material aspects during the Track Record Period and up to the Latest Practicable Date. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business. We are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business, and we intend to maintain this culture through the strict implementation of our risk management and internal control policies. Please refer to the paragraph headed “— Risk Management and Internal Control” in this section for further details.

LICENSES AND PERMITS

As confirmed by our PRC legal advisors and U.S. legal advisors, during the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from the relevant government authorities that are material for our business operations in the PRC and the U.S..

The following table sets forth the details of our key licenses and permits in the PRC and U.S.:

Licences/permit	Grant date	Expiry date	Granting authority
Drug Manufacturing Certificate — 20220018	October 9, 2022	October 8, 2027	Guangdong Provincial Drug Administration
Drug Registration Certificate — H20051843	December 20, 2024	December 19, 2029	National Medical Products Administration
FDA Marketing Authorisation — A213859	December 2022	—	United States Food and Drug Administration
FDA Marketing Authorisation — A214395	December 2022	—	United States Food and Drug Administration
Drug Registration Certificate — H20253396	February 20, 2025	February 19, 2030	National Medical Products Administration
Drug Registration Certificate — H20253397	February 20, 2025	February 19, 2030	National Medical Products Administration
Approval notice for drug clinical trial (Dexmedetomidine Hydrochloride Microneedle Patch) — CXHL2500652	September 19, 2025	—	National Medical Products Administration
Approval notice for drug clinical trial (Dexmedetomidine Hydrochloride Microneedle Patch) — CXHL2500651	September 19, 2025	—	National Medical Products Administration
Approval notice for drug clinical trial (XJN010) — CXHL2400526	August 6, 2024	—	National Medical Products Administration
Approval notice for drug clinical trial (XJN026) — CXHL2501187	January 4, 2026	—	National Medical Products Administration
FDA correspondence relating to XJN010 confirming that Phase II clinical trials may proceed	February, 2026	—	United States Food and Drug Administration
FDA correspondence relating to Dexmedetomidine Hydrochloride Microneedle Patch confirming that clinical studies may proceed	February, 2026	—	United States Food and Drug Administration

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RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We are subject to various risks during our operations. Please refer to the paragraph headed “Risk Factors — Risks Relating to Doing Business in Jurisdictions Where We Operate” in this document. We are also exposed to various financial risks, in particular, credit, interest rate, liquidity and capital management that arise in the normal course of our business. Please refer to the paragraph headed “Financial Information — Financial Risk Disclosure” in this document for a discussion of these financial risks. We have adopted a series of risk management policies that set out a risk management framework to identify, assess, evaluate, and monitor key risks associated with our strategic objectives on an ongoing basis. Risks identified by management will be analysed based on likelihood and impact and will be properly followed up, mitigated and rectified by our Company and reported to our Directors. Our Audit Committee, and ultimately the Board, supervise the implementation of our risk management policies.

To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [REDACTED], we have adopted or will continue to adopt, among other things, the following risk management measures:

- establish an Audit Committee to review and supervise our financial reporting process and internal control system;
- adopt various policies to ensure compliance with the Listing Rules, including but not limited to aspects related to risk management, connected transactions and information disclosure;
- provide anti-corruption and anti-bribery compliance training periodically to our senior management and employees to enhance their knowledge and compliance with applicable laws and regulations; and
- attend training sessions by our Directors and senior management in respect of the relevant requirements of the Listing Rules and duties of directors of companies listed in Hong Kong.

We consider that our Directors and senior management team have the requisite knowledge and expertise to ensure effective corporate governance, particularly in areas of risk management and internal control.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. We have engaged an internal control consultant (the “**Internal Control Consultant**”) to perform certain agreed-upon procedures (the “**Internal Control Review**”) in connection with the internal control of our Company and our principal subsidiaries in certain aspects, including entity-level controls, financial reporting and disclosure controls, human resources and payroll management, general controls of IT system, contract management, tangible and intangible asset management, and other procedures of our operations. The Internal Control Consultant performed a follow-up review with regard to those actions taken by us and there are no material findings identified in the process of the follow up Review. As of the Latest Practicable Date, there were no material outstanding issues relating to our Company’s internal control.

Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- adopt various measures and procedures regarding each aspect of our business operation, such as quality control, risk management, intellectual property management, data compliance and occupational health and safety;
- establish an internal control compliance committee, chaired by Dr. Wu, consisting of the compliance officer, financial officer, legal officer, and human resources officer of our Company, thereby forming a cross-departmental collaborative compliance management system;
- establish the Audit Committee which (i) makes recommendations to our Directors on the appointment removal of external auditors, and (ii) reviews the financial statements and renders advice to respect of financial reporting as well as overseas internal control procedures of our Company;
- maintain strict confidentiality and data protection policies regarding the collection, analysis, storage and transmission of our R&D data. We only collect personal information necessary for handling complaints, such as name, contact details, and medication usage. Both electronic and paper records are encrypted and stored;
- engage Guotai Junan Capital Limited as our Compliance Advisor to provide advice to our Directors and management team in respect of its financial results for the first full financial year after the [REDACTED] regarding matters relating to the Listing Rules. We must

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consult with and, if necessary, seek advice from our Compliance Advisor where we propose to use the [REDACTED] of the [REDACTED] in a manner different from our plan that sets forth in “Future Plans and Use of [REDACTED]” in this document after [REDACTED]. Our Compliance Advisor will also provide support and advice regarding the requirements of relevant regulatory authorities in a timely fashion;

- require all of our employees to abide by our anti-bribery and anti-corruption compliance requirements and applicable laws and regulations to eliminate bribery and corruption risks. We strictly prohibit bribery or other improper payments in our business operation and maintain strict anti-corruption policies among our employees, and we will closely monitor our employees’ compliance with anti-bribery and anti-corruption policies. In addition, we have established a whistleblowing reporting system to ensure that our employees are able to report concerns of any action, situation or circumstance that appears to be in violation of our code of conduct, anti-corruption policy or any applicable laws, regulations or our other internal policies through multiple channels, including public, confidential, or anonymous submissions;
- together with our legal advisers, periodically review our compliance status with all relevant laws and regulations after the [REDACTED]; and
- plan to provide various and continuing training to update our Directors, senior management, and relevant employees on the latest applicable laws and regulations from time to time with a view to proactively identify any concerns and issues relating to any potential non-compliance.

We plan to provide our Directors, senior management, and relevant employees with continuous training programs and updates regarding the relevant applicable laws and regulations regularly and update our internal control policies in due course.

Anti-bribery

We maintain a zero-tolerance policy which strictly prohibit, among other things, bribery or other improper payments in our business operations, illegally encroaching on or impairing the legitimate interests of our Company, misappropriating the funds of the customers, working as a part-time employee at companies which compete or have cooperation with our Company. We also keep accurate books and records which reflect transactions and asset dispositions in reasonable detail. Requests for false invoices or payment of unusual, excessive or inadequately described expenses should be rejected and promptly reported. Misleading, incomplete or false entries in our books and records are never acceptable.

We have adopted, and will continue to adopt, comprehensive internal control measures for anti-corruption and anti-bribery by (i) providing regular anti-corruption and anti-bribery compliance training for senior management and employees, including regular compliance training and (if necessary) other ad hoc compliance training sessions, to enhance their knowledge and compliance with applicable law and regulations; (ii) monitoring books, records and accounts to identify any false, misleading or undisclosed entries; (iii) establishing whistle-blowing mechanisms and encouraging all employees, suppliers, customers and other third parties to report suspicious activities and violations of the policies.

AWARDS AND RECOGNITION

The table below sets forth a summary of the major awards and recognition that our company had received as of the Latest Practicable Date:

Award or Recognition	Year Granted	Granting Authority
2015 Guangzhou Enterprise R&D Institution* (廣州市企業研究開發機構 (2015年度))	2016	Guangzhou Municipal Science and Technology Innovation Commission* (廣州市科技創新委員會)
2018 China’s Fastest-Growing Innovative Pharmaceutical Enterprise* (2018年度中國最具成長力科技創新型醫藥企業)	2018	Pharmaceutical Preparations Professional Committee of Chinese Pharmaceutical Association, China Pharmaceutical Industry Information Center* (中國藥學會藥物製劑專業委員會、中國醫藥工業信息中心)

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Award or Recognition	Year Granted	Granting Authority
High and New Technology Enterprise* (國家高新技術企業)	2019	Department of Science and Technology of Guangdong Province, Department of Finance of Guangdong Province, Guangzhou Provincial Taxation Bureau of the State Administration of Taxation (廣東省科學技術廳、廣東省財政廳、國家稅務總局廣東省稅務局)
Guangdong Provincial Postdoctoral Workstation* (廣東省博士工作站)	2022	Department of Human Resources and Social Security of Guangdong Province* (廣東省人力資源和社會保障廳)
2023 Guangdong Provincial Intellectual Property Demonstration Enterprise* (2023年廣東省知識產權示範企業)	2023	Guangdong IP Protection Association (廣東省知識產權保護協會)
2024 Industry-Attention Award for Advanced Formulations* (2024年度行業關注度高端製劑獎)	2024	China Biomass Industrial Chain Innovation and Transformation Alliance (中國生物醫藥產業鏈創新轉化聯合體)
National “Little Giant” Enterprise for Specialised, Innovative, and High-Tech firms* (國家級專精特新“小巨人”企業) . . .	2024	Ministry of Industry and Information Technology of the PRC (中華人民共和國工業和信息化部)
Guangzhou Postdoctoral Innovation Practice Base* (廣州市博士後創新實踐基地)	2025	Guangzhou Municipal Human Resources and Social Security Bureau (廣州市人力資源和社會保障局)
Guangdong Provincial Engineering Research Center for Medical Microneedles* (廣東省藥物微針工程技術研究中心)	2025	Department of Science and Technology of Guangdong Province (廣東省科學技術廳)