OVERVIEW

We are a China-based vaccine company dedicated to the research, development, manufacturing and commercialization of innovative vaccines and traditional vaccines adopting new technical methods. In formulating our pipeline, we closely track global trends in infectious disease incidence and vaccine R&D, with a strategic focus on high-end vaccines, aiming to replace traditional vaccines and imported vaccines in China and establish our presence in international markets. As of the Latest Practicable Date, our pipeline included two Core Products, the quadrivalent subunit influenza vaccine and lyophilized human rabies vaccine candidate, along with 11 other vaccine candidates.

China's human vaccine market holds great potential. According to Frost & Sullivan, the market (excluding COVID-19 vaccines) expanded significantly from RMB53.5 billion in 2019 to RMB120.5 billion in 2023, at a CAGR of 22.5%. It is expected to further grow to RMB343.1 billion in 2032, at a CAGR of 12.3% from 2023 to 2032. The projected rapid growth of the human vaccine market in China is driven by increasing availability of high-quality vaccines due to technological evolvement, growing public awareness of the need for vaccination, policy support of preventive healthcare and enhanced affordability of commercially available vaccines.

We are well positioned to capitalize on the expanding human vaccine market in China. Our pipeline encompasses both innovative vaccines that are capable of meeting domestic demand and global standards and traditional vaccines that already have established track records and wide market acceptance but adopting new technical methods, allowing us to pursue scientific innovation in vaccine R&D while setting a clear path to commercial success. In particular, our quadrivalent subunit influenza vaccine represents a significant technological advancement from the traditional split-virion vaccines, offering comprehensive protection with high antigen purity and low risks of adverse reactions. It was approved by the NMPA for individuals aged three and above under the brand name Huierkangxin (慧爾康欣) in May 2023 and remained the first and only approved quadrivalent subunit influenza vaccine in China as of the Latest Practicable Date. Employing our in-house manufacturing facilities and sales and marketing team, we commenced commercialization of this vaccine after receiving approval and generated revenue of RMB217.2 million in the nine months ended September 30, 2024. We also submitted an NDA for the use of the quadrivalent subunit influenza vaccine in children aged 6 to 35 months, which was accepted by the NMPA in June 2024. Our lyophilized human rabies vaccine candidate is developed from human diploid cells, which are recommended as one of the safest cell culture substrates for the production of viral vaccines by the WHO, and poises to be a favorable alternative to mainstream Vero cell–based rabies vaccines due to its potentially stronger safety profile. As of the Latest Practicable Date, we had completed the Phase I clinical trial of our lyophilized human rabies vaccine candidate and expect to initiate a Phase III clinical trial in the second or third quarter of 2025. We are also developing 11 other vaccine candidates covering various disease areas with significant needs for vaccination.

The following chart summarizes our pipeline as of the Latest Practicable Date.

Product	Indication	R&D	Preclinical	IND Approval	Clinical			NDA Approval	Expected Near-term Milestone
					Phase I	Phase II	Phase III		
Quadrivalent subunit influenza vaccine*	Influenza (3 years and above)	Self-developed							Completion of post-approval safety study in Q4 2025
	Influenza (6 to 35 months)	Self-developed							NDA approval in 2025
Adjuvanted quadrivalent subunit influenza vaccine	Influenza (65 years and above)	Self-developed							Commencement of Phase I clinical trial in Q2 or Q3 2025
Trivalent subunit influenza vaccine	Influenza (3 years and above)	Self-developed							NDA approval in 2025
	Influenza (6 to 35 months)	Self-developed							NDA approval in 2025
Adjuvanted trivalent subunit influenza vaccine	Influenza (65 years and above)	Self-developed							Commencement of Phase I clinical trial in Q2 or Q3 2025
Lyophilized human rabies vaccine (human diploid cell)*	Rabies	Self-developed							Commencement of Phase III clinical trial in Q2 or Q3 2025
PPSV23	Invasive pneumococcal diseases	Acquired†							Commencement of Phase III clinical trial in Q4 2025 or Q1 2026
Recombinant zoster vaccine (CHO cell)	Herpes zoster	Self-developed							Commencement of Phase I clinical trial in Q1 2025
Recombinant RSV vaccine (CHO cell)	RSV LRTI	Self-developed‡							IND applications in Q2 or Q3 2025
mRNA RSV vaccine	RSV LRTI	Self-developed‡							Pre-IND application in Q3 or Q4 2025
mRNA monkeypox vaccine	Monkeypox	Self-developed							Pre-IND application in Q4 2025
PCV24	Invasive pneumococcal diseases	Self-developed							Pre-IND application in Q1 2026
Live attenuated varicella vaccine	Varicella	Self-developed							Pre-IND application in Q1 2026
Tetanus toxoid adsorbed vaccine	Tetanus	Self-developed							Pre-IND application in Q4 2025

* Core Product

† We contracted to acquire this asset before the clinical stage. We were and will continue to be responsible for clinical development. See "—Our Product and Product Candidates—Our Other Product Candidates—PPSV23" and "—Our Technology Transfer Arrangements—PPSV23 Technology Transfer Agreements."

‡ Self-developed with licensed antigen sequence

Clinical trial phase not required

LRTI: lower respiratory tract infection; PPSV: pneumococcal polysaccharide vaccine; PCV: pneumococcal conjugate vaccine; RSV: respiratory syncytial virus

Our comprehensive pipeline is supported by sophisticated platform technologies and in-house GMP-compliant commercial-scale manufacturing facilities, enabling us to advance in vaccine innovation and production. Our vaccine development support platforms, alongside our proprietary technology platforms, facilitate discovery and development of novel vaccine candidates across various disease areas, while our manufacturing facilities provide robust support for the commercialization of our quadrivalent subunit influenza vaccine and future products. Our manufacturing infrastructure comprises one operational facility and two additional facilities nearing completion. Our first manufacturing facility in Taizhou, Jiangsu, has a GFA of over 48,000 square meters and the currently operational influenza vaccine production line has a designed capacity of 4.0 million doses annually. Since its launch in 2023, our quadrivalent subunit influenza vaccine had achieved a 100.0% product qualification and lot release approval rate as of the Latest Practicable Date. We believe that our self-owned manufacturing capability, coupled with our strong R&D capability, will allow us to procure a stable supply of vaccines for both clinical and commercial purposes.

We are led by a experienced management team with successful track records. Mr. An Youcai, our founder and general manager, has more than 35 years of managerial experience, and is an industry veteran with over 15 years of experience in the biotechnology and pharmaceutical industries. The broader management team is composed of individuals with extensive and diverse experience in the development, manufacturing and commercialization of biological products in leading biopharmaceutical companies worldwide. Since our establishment, we have attracted substantial support from shareholders, including notable biotech investors such as GTJA Investment Group, Yingke PE, Highlight Capital and Addor Capital, as well as backing from local governments. We believe that the strong leadership from our seasoned management team, coupled with persistent investor support, is instrumental to advancing our future development and ensuring sustained growth.

OUR STRENGTHS

Upgraded traditional vaccines as potential blockbuster core products to address unmet demand for quality vaccines

Quadrivalent subunit influenza vaccine, our first and approved Core Product

Our quadrivalent subunit influenza vaccine (for individuals aged three and above) was the first and only approved quadrivalent subunit influenza vaccine in China as of the Latest Practicable Date. This product is a significant upgrade from the traditional split-virion vaccines, offering comprehensive protection, high antigen purity and low risks of adverse reactions. Our NDA for its use in children aged 6 to 35 months was accepted by the NMPA in June 2024. We are also developing an adjuvanted version of the vaccine aimed at providing enhanced protection for the elderly with relatively weak immune systems.

China's influenza vaccine market is large but remains significantly underpenetrated. According to the China CDC, the overall influenza vaccination rate in China was 3.8% in the 2022–2023 flu season, which dwarfed in comparison to developed markets such as the U.S., where the vaccination rate was 49.3% in all people aged six months and older for the same flu season, according to the U.S. CDC. With the diminishing impact of the COVID-19 pandemic and the recurrence of influenza outbreaks, the demand for annual flu vaccination is poised to grow. This growing demand is further propelled by an aging population, which is expected to lead to higher vaccination uptake. As a newly introduced category in this market, subunit influenza vaccines, marked for their favorable safety and efficacy, are especially well positioned to capture more market share, particularly toward the high end.

We believe our quadrivalent subunit influenza vaccine has the following advantages.

- *Enhanced safety profile*. Subunit influenza vaccines are designed to offer a robust safety profile due to their precise manufacturing process, which removes internal viral proteins and retains only high-purity hemagglutinin (HA) and neuraminidase (NA) antigen components. This approach aims to reduce the risk of adverse reactions. In our Phase III clinical trial, the overall incidence of vaccination-related adverse events (AEs) induced by our quadrivalent subunit influenza vaccine in participants aged 18 to 64 years was lower than that caused by the control quadrivalent split-virion vaccine (6.29% and 10.86%, respectively) and the difference was statistically significant (P = 0.031). These findings underscore the enhanced safety of our vaccine for certain target groups, making it an ideal choice for vaccinees with heightened safety awareness.

- *Robust immune response*. Our quadrivalent subunit influenza vaccine is able to elicit strong immune responses. In our Phase III clinical trial, in the total population of participants aged three years and above, our vaccine achieved seroprotection rates (the proportions of participants with an antibody titer of ≥1:40 post-vaccination) of 96.56%, 97.98%, 89.41% and 95.88% for the H1N1, H3N2, BV and BY virus strains, respectively, all above the widely used European Union standard of 70.0%. In the same group of participants, our vaccine also elicited significantly higher geometric mean titers (GMTs) of neutralizing antibodies against all four virus strains compared to the control quadrivalent split-virion influenza vaccine. GMT refers to the average level of antibodies in participants after vaccination and is a commonly used endpoint for primary vaccination efficacy evaluation. Higher GMT values generally indicate stronger immune responses. These results highlight the vaccine's potential for more effective immunization, offering greater protection against influenza viruses.

- *Clear commercialization and market expansion strategy in China and globally*. We began commercialization of our quadrivalent subunit influenza vaccine in 2023 and successfully completed a full influenza season which honed the capabilities of our manufacturing and sales and marketing teams. Currently, the commercialization of our vaccine is also supported by a robust network of third-party marketing service providers. Our quadrivalent subunit influenza vaccine has completed the market entry process in 30 provinces and been chosen by over 1,100 district- and county-level CDCs in local selections. With respect to overseas markets, we have completed registration in Macau and initiated the process in the Philippines. We will continue expanding into jurisdictions that have large vaccine markets and flu seasons timed differently from China's, such as Uruguay. This strategic expansion is poised to contribute to sustained sales growth, reinforcing our market presence both domestically and abroad.

Lyophilized human rabies vaccine (human diploid cell), our second Core Product

The human rabies vaccine market in China increased significantly from RMB3.8 billion in 2019 to RMB8.9 billion in 2023 and is expected to further increase to RMB12.5 billion in 2032. Rabies vaccines produced from human diploid cells are poised to serve as a favorable alternative to traditional rabies vaccines currently available in the China market due to their superior safety profile. As of the Latest Practicable Date, there were 23 marketed human rabies vaccines in China, with only two cultured from human diploid cells, underscoring significant growth potential.

We believe our lyophilized human rabies vaccine candidate has the following advantages.

- *Superior safety profile*. Rabies vaccines developed based on human diploid cells stand as the "gold standard" recommended by the WHO, showcasing superior safety profiles. A meta-analysis of 27 clinical studies involving 18,630 participants revealed that rabies vaccines developed based on human diploid cells had a significantly lower overall adverse reaction incidence compared to primary chicken embryo cell rabies vaccines and lower rates of fatigue and local pain/fever compared to vaccines developed based on Vero cells, evidencing their safety potential. In addition, our vaccine candidate is developed from 8^{th} generation human diploid cells, which are less prone to genetic mutation compared to the commonly used 10^{th}-30^{th} generation cells, ensuring better cell vitality, higher virus production efficiency and enhanced safety. Furthermore, our advanced purification technologies could reduce residual bovine serum albumin (which may cause allergic reactions in certain population) well below the Chinese Pharmacopoeia standards, the regulatory benchmark for rabies vaccines in China.

- *Convenient administration with pre-filled diluent syringe*. Our rabies vaccine candidate leverages a combination of lyophilized formulation and pre-filled syringe diluents, providing a more convenient vaccination experience without compromising the efficacy of the active ingredients. Pre-filled syringe diluents simplify the vaccination process and lower contamination risks by eliminating the need for manual extraction and preparation, which is required for traditional vial-and-syringe methods.

- *Flexible vaccination schedules providing more options for vaccinees*. We are developing our rabies vaccine candidate under the Essen regimen (five doses), Zagreb regimen (four doses) and a simplified four-dose regimen, each offering distinct advantages. The four-dose regimens are particularly appreciated for their convenience and cost-effectiveness, potentially enhancing adherence to the vaccination schedule, while the five-dose regimen is widely adopted due to its established track record. All regimens are designed to ensure effective immunological protection, giving vaccinees and healthcare providers the flexibility to select the most suitable regimen based on individual needs or clinical circumstances. This adaptability strengthens our competitive standing in county-level tenders.

Market-driven strategy building a diverse vaccine pipeline

Driven by market demand, we have developed a comprehensive vaccine pipeline through years of research and development, focusing on innovative vaccines and traditional vaccines adopting new technical methods that align with global trends in infectious disease incidence and vaccine R&D. In addressing unmet public health needs, we are exploring indications with significant commercial potential. In addition to our Core Products, we are actively developing 11 additional vaccines to address substantial unmet market demand.

Pneumococcal Vaccines

China's pneumococcal vaccine market is poised for significant expansion, marked by a substantial market size and robust growth potential. According to Frost & Sullivan, China's pneumococcal vaccine market reached RMB9.2 billion in 2023 in terms of production value and is expected to increase to RMB19.0 billion in 2032, at a CAGR of 8.4% from 2023 to 2032. This expansion is mainly driven by the public's enhanced awareness of preventative healthcare measures and an increasing elderly population with heightened susceptibility to pneumococcal diseases. Additionally, the expected expansion of serotype coverage and increase in the number of domestically developed vaccines also heighten the demand for pneumococcal vaccines in China.

We are developing a 23-valent pneumococcal polysaccharide vaccine (PPSV23) candidate indicated for individuals aged two years and above. PPSV23 products are the primary type of pneumococcal vaccine for adults in China, recognized for their efficacy across diverse age groups and authorized for use in all adults aged 50 and above and anyone aged two years or above with certain medical conditions that can lead to an increased risk for pneumococcal disease. In addition, we are also developing a 24-valent pneumococcal conjugate vaccine (PCV24) candidate that could potentially offer protection for a wider demographic, especially for infants below the two-year age limit, the elderly and the immunocompromized population.

- *PPSV23*. Our PPSV23 candidate is designed to provide extensive protection against pneumococcal infections caused by 23 of the most prevalent and invasive serotypes. Our Phase I clinical trial demonstrated that the PPSV23 candidate generated robust immunogenic responses in participants aged two years and above, suggesting significant vaccine efficacy. In the same trial, the incidence of vaccination-related AEs was lower in the PPSV23 group compared to the control group. In addition, we undertook significant process improvement, which includes the use of ion-exchange chromatography instead of ethanol precipitation, thereby eliminating harmful substances like ethanol and phenol and enhancing product safety. Our production process employs a closed-system design that facilitates automation and sterile operation, thereby minimizing contamination risks and ensuring product safety. This design also improves operational efficiencies by reducing the time and costs associated with cleaning and validating manufacturing facilities.

- *PCV24*. In preclinical studies conducted in animals, our PCV24 candidate demonstrated promising immunogenicity, generating good immune responses against all 24 serotypes. Specifically, the GMT levels of antibodies elicited by our PCV24 candidate were comparable to or, for certain serotypes, higher than those elicited by the marketed PCV20 vaccine in the same studies. We believe the PPSV23 and PCV24 candidates could form a synergetic product franchise for pneumococcal diseases, which underscores our commitment to capturing significant market opportunities while advancing vaccine technology. We plan to complete preclinical studies in 2025 and aim to submit a pre-IND application to the NMPA in the first quarter of 2026.

Trivalent Subunit Influenza Vaccine

In order to better adapt to the evolving virological landscape of influenza viruses and cater to diverse immunization needs of the vast market in China, we are also developing a trivalent subunit influenza vaccine in addition to our quadrivalent subunit influenza vaccine. Our trivalent subunit influenza vaccine candidate aims to provide protection against two influenza A viruses (H1N1 and H3N2 subtypes) and one influenza B virus (Victoria lineage), aligning with the coverage recommended by the WHO for the 2024-2025 northern hemisphere influenza season. In China, the influenza vaccine market includes trivalent and quadrivalent formulations, predominantly comprising split-virion vaccines. Introducing a trivalent subunit influenza vaccine will enhance our product portfolio by covering both approved valences and offer a cost-effective alternative, potentially broadening our market reach and increasing revenue by appealing to vaccinees that prioritize essential strain coverage.

Our trivalent influenza vaccine candidate leverages the established formulation of our approved quadrivalent subunit influenza vaccine, using the same bulk antigen with one influenza B virus subtype (Yamagata) omitted in the formulation. Leveraging the preclinical and clinical results of our quadrivalent subunit influenza vaccine, our NDAs for the trivalent subunit influenza vaccine candidate for individuals aged 3 years and above and for the 6 to 35 months age group were accepted by the NMPA in September 2024. As of the Latest Practicable Date, we were also developing an adjuvanted version of the vaccine candidate for individuals aged 65 years and above.

Recombinant Zoster Vaccine (CHO cell)

The zoster vaccine market in China has shown significant growth, reaching RMB2.6 billion in production value by 2020, following the approval of the first vaccine by the NMPA in 2019. The market is anticipated to further expand to RMB22.7 billion by 2032, primarily driven by an aging population more susceptible to herpes zoster infection, as well as technological advancements leading to safer and more effective vaccine options. In particular, Shingrix, a recombinant zoster vaccine approved by both the NMPA and the FDA, has demonstrated significantly better protective efficacy than earlier live attenuated vaccines in clinical trials.

Our recombinant zoster vaccine candidate features a proprietary glycoprotein E protein sequence, preserving advantageous antigenic epitopes and incorporating a self-developed dual-adjuvant system. It demonstrated good safety and immunogenicity profile in our preclinical studies. In particular, our recombinant zoster vaccine candidate induced superior cell-mediated immune responses in animal models (detected by ELISpot and ICS assays) compared to a marketed recombinant herpes zoster vaccine developed by an international pharmaceutical company, indicating a potentially stronger immunogenicity profile. We obtained an IND approval of our zoster vaccine candidate in August 2024 and plan to initiate a Phase I trial in the first quarter of 2025.

Respiratory Syncytial Virus (RSV) Vaccines

RSV is a common virus causing respiratory tract infections, with the potential of developing into severe cases like bronchiolitis or pneumonia, particularly among vulnerable populations such as the elderly and individuals with chronic illness. According to Frost & Sullivan, approximately 4.1 million new cases of RSV-induced acute lower respiratory tract infections were reported in China in 2023, with adult infection rates rising with age. Despite the prevalence of RSV, as of the Latest Practicable Date, no RSV vaccine had been approved by the NMPA. Current management of RSV infection in China relies on broad-spectrum antivirals and symptomatic treatment. Consequently, there is an urgent need for the development of an effective RSV vaccine.

We are developing two vaccine candidates designed to provide protection against RSV infections for a broad demographic: a recombinant RSV vaccine indicated for adults, including pregnant women, and an mRNA RSV vaccine indicated for individuals aged 60 and above.

- *Recombinant RSV vaccine (CHO cell).* As of the Latest Practicable Date, recombinant RSV vaccine was the only type of vaccine approved by the FDA for use in women between 32 and 36 weeks of pregnancy. Our recombinant RSV vaccine candidate is developed using a stabilized pre-F trimeric protein as the immunogen. In our preclinical studies, it showed expression levels and stability surpassing those of approved international vaccines according to their previously published results. We submitted a pre-IND application to the NMPA for our recombinant RSV vaccine candidate in December 2024. As of the Latest Practicable Date, we had produced three pilot-scale batches of bulk drug substance and drug product under GMP conditions and completed stability and safety tests for the vaccine candidate.

- *mRNA RSV vaccine.* mRNA vaccines have demonstrated the capacity to trigger strong cellular immune responses and long-lasting humoral immunity in clinical studies, making them a promising option for protecting elderly and immunocompromised individuals against severe lower respiratory tract infections caused by RSV. The safety of mRNA vaccines in this demographic has been affirmed by their extensive use during the COVID-19 pandemic. Both mRNA and recombinant RSV vaccines exhibit the ability to elicit robust and durable immune responses. We believe our mRNA RSV vaccine candidate could be complementary to our recombinant RSV vaccine candidate, and thereby broaden the coverage of at-risk population segments.

Other vaccine candidates

We are also developing an mRNA monkeypox vaccine, a live attenuated varicella vaccine, and a tetanus toxoid adsorbed vaccine. Our commitment is to advance full-spectrum, comprehensive vaccine development and leverage our proprietary technology to advance the development of innovative vaccines and upgrade of traditional vaccines.

Advanced R&D technology platforms supporting vaccine candidate development

We have established comprehensive vaccine development support platforms, enabling the discovery and development of new vaccines across various categories. These are complemented by our distinctive proprietary technology platforms, which further enhance our innovative capabilities. Our advanced manufacturing process development expertise supports the swift commercialization of our pipeline, ensuring the efficient production of safe and effective vaccines. To date, we have secured 32 patents related to these platforms, underscoring our commitment to technology innovation and excellence in the vaccine industry.

Our vaccine development support platforms include:

- *Genetic engineering and protein expression and purification platform*. Our genetic engineering and protein expression and purification platform supports the process development and pilot-scale GMP production of a variety of protein-based vaccine candidates, including the pneumococcal conjugate vaccine (utilizing a prokaryotic expression system, which enables rapid, high-volume production of its carrier protein, CRM197) and the recombinant zoster vaccine (utilizing a eukaryotic expression system, which allows more complicated post-translational modifications). This comprehensive platform extends to creation and selection of cell lines with stable protein expression, establishment of cell banks and process development of upstream fermentation and downstream purification, enabling us to efficiently advance vaccine development from discovery to GMP-compliant manufacturing.

- *mRNA vaccine research platform.* Our mRNA vaccine research platform enables the sophisticated design, synthesis and purification of mRNA molecules, ensuring production of drug substance with high quality, stability and productivity. It also supports the development and optimization of the encapsulation process to achieve safe and efficient cellular delivery of mRNA vaccines. Additionally, it includes the development of lyophilized formulations. Through the refinement of lyophilization techniques, lyophilized mRNA products developed through the platform can be stably stored at 2°C-8°C, thus improving logistical and deployment efficiency. Currently, the platform supports the development of our mRNA RSV vaccine candidate and mRNA monkeypox vaccine candidate.

- *Adjuvant development and production platform*. Our adjuvant development and production platform focuses on development of sophisticated adjuvant adsorption processes and studies on adjuvant-antigen interaction, utilizing advanced technologies to ensure adjuvant quality to meet regulatory standards. Our platform can achieve GMP pilot-scale production of self-developed MF59-like emulsion adjuvant, while also supports the development of adjuvants such as nanoscale aluminum-containing adjuvants and novel liposome adjuvants. Enabling tailored adjuvant formulations for different vaccines, the platform supports the development

of various vaccine candidates, such as our adjuvanted trivalent and quadrivalent subunit influenza vaccine candidates, recombinant zoster vaccine candidate, recombinant RSV vaccine candidate and tetanus toxoid adsorbed vaccine candidate.

Our proprietary vaccine technology platforms include:

- *Large-scale amplification platform*. Our large-scale amplification platform aims to enhance the yield of virus production while maintaining consistent quality. The platform can support high-throughput virus amplification in chicken embryo, managing 100,000 chicken embryos per batch. The platform also enables us to optimize cell factory process for rabies virus grown in human diploid cells, achieving optimal cell growth conditions and continuous passaging capability, with rabies virus titers reaching 10^8 CCID50/ml. Our large-scale amplification platform also includes a bioreactor scale-up system, designed with 26 parallel reactors, that could utilize either perfusion culture or fed-batch suspension culture to achieve sustained high-density cell growth.

- *Polysaccharide conjugation technology platform*. Our polysaccharide conjugation technology platform focuses on the conjugation and purification of polysaccharide-protein conjugates. Central to the conjugation process is the exploitation of polysaccharide-protein interactions to forge stable chemical bonds, thereby enhancing immunogenicity. Our research emphasizes the development of conjugation methodologies tailored to different pneumococcal serotypes to boost polysaccharide recovery and the quality of conjugate solutions. This platform supports the development of our PCV24 candidate.

- *Microbes and immunity research platform*. Our microbes and immunity research platform focuses on investigating the pathogenic mechanisms of microorganisms, including various bacteria and viruses, to develop corresponding vaccines. Building on traditional vaccine development principles, the platform introduces innovative R&D strategies that advance vaccine antigen design. It facilitates comprehensive studies of immune responses elicited by vaccines to assess and enhance their immunogenicity and effectiveness. The platform enables extensive R&D activities, including animal sample collection, virus and host cell culturing and the development of animal infection models for pathogens such as influenza, RSV, rabies and tetanus, allowing for thorough vaccine efficacy and preliminary safety evaluations. The platform is capable of monitoring both humoral and cellular immunity, evaluating immune persistence and establishing immunization protocols for our vaccine candidates.

Expanding manufacturing capacity ensuring sustained future vaccine supply

Vaccine manufacturing demands rigorous safety protocols and comprehensive quality management, requiring extensive expertise and specialized knowledge. Since 2019, we have been building our in-house manufacturing capabilities, employing a team of 249 vaccine manufacturing and 110 quality management professionals as of the Latest Practicable Date. Our leadership teams responsible for vaccine manufacturing and quality control bring years of experience in the vaccine industry and possess outstanding technical and managerial skills

crucial for ensuring seamless vaccine production and maintaining superior product quality, safety and control. Following the launch of our quadrivalent subunit influenza vaccine in 2023 and up to the Latest Practicable Date, we had achieved 100% product qualification and lot release approval rate. Our operations consistently passed inspections by regulatory agencies in 2023 and 2024, upholding a stable quality management system without major defects.

Our first manufacturing facility in Taizhou, Jiangsu, has a GFA of over 48,000 square meters and features the manufacturing, quality control and fill-finish facilities. Within such facility, the first influenza vaccine production line, which is currently operational, includes both drug substance and drug product facilities. The drug substance facility has the capacity to process 100,000 chicken embryos per batch and 20 to 30 million embryos annually. The drug product facility is responsible for the filling and packaging of influenza vaccines, and has the capacity to process 80,000 doses per batch and 4.0 million doses annually. A second influenza production line, which mirrors the capacities of the first, was undergoing process validation as of the Latest Practicable Date. Our first manufacturing facility also includes one rabies vaccine production line and one pneumococcal vaccine production line. Furthermore, our second and third manufacturing facilities are currently under construction. The second manufacturing facility, with a planned GFA of approximately 82,000 square meters and a designed annual capacity of 10.0 million doses, is intended for the commercial manufacturing of future influenza vaccines (including the trivalent subunit influenza vaccine and the adjuvanted quadrivalent and trivalent subunit influenza vaccines). The third manufacturing facility, with a planned GFA of approximately 27,000 square meters and a designed annual capacity of 20.0 million doses, is intended for the manufacturing of recombinant protein vaccines. We expect these projects to provide robust support for our future commercialization endeavors.

Our state-of-the-art separation and purification systems, including centrifugation, ultrafiltration and chromatography, are sourced from leading industry equipment suppliers. These systems are installed in GMP-compliant facilities, ensuring product safety, integrity of clinical data and regulatory compliance.

Market outreach led by academic promotion and supported by established sales network

Our market outreach strategy is anchored in academic promotion, educating vaccination institutions and vaccinees of the differentiated technical approaches and advantages of our products. For example, in 2024, we participated in four major national academic conferences and over 30 regional meetings, engaging with a wide group of participants across the country. We also participate in national vaccine-related research projects and collaborate with provincial CDCs in relevant studies to further enhance our academic influence. This specialized academic promotion strategy underscores our differentiated competitive strengths, helping us gain recognition among professionals and the general public through academic channels.

Leveraging the strong safety profile of our vaccine and vaccine candidates, our promotion strategies also place an emphasis on special populations, such as pregnant women and people with chronic diseases. By conducting relevant academic research, we support the utilization of our vaccines among these groups and influence the vaccination willingness of a broader population.

We have established a comprehensive sales and marketing system, laying a solid foundation for commercialization. As of the Latest Practicable Date, our sales and marketing team consisted of 52 experienced staff covering sales (with support from regional sales managers), marketing, medical affairs and operations. Our team is led by Deputy General Manager Mr. Zhao Guojun, who has over 40 years of experience in sales of bioproducts, having served in prominent vaccine companies like China National Biotec Group Co., Ltd. To build a specialized sales and marketing team capable of executing our academic promotion strategy, we conduct regular training on our products for the central marketing department and regional teams.

In addition to our own in-house sales and marketing team, we have engaged third-party marketing service providers to carry out promotional activities based on the strategies formulated by our in-house sales and marketing team. In line with our academic-driven marketing strategy, we have strengthened our training programs, organizing more than 30 sessions of online and offline training for third-party marketing service providers, followed by assessments on product-related knowledge. Currently, the commercialization of our quadrivalent subunit influenza vaccine is supported by a robust network of third-party marketing service providers in addition to our in-house sales and marketing team. Our quadrivalent subunit influenza vaccine has completed the market entry process in 30 provinces and been chosen by over 1,100 district- and county-level CDCs in local selections.

Experienced R&D management team, supported by reputable shareholders in industry

Our management team boasts extensive experience in the R&D of vaccines and other biological products and management of pharmaceutical companies, with an average of 23 years in the industry. This wealth of experience provides profound insights and expertise essential for leading our operations. Key team members include An Youcai (Chairman, General Manager), Li Runxiang (Chief Financial Officer), Zhang Yangyang (Board Secretary), Chen Ze (Deputy General Manager and Chief Scientist), Yelin Xiong (Deputy General Manager), Zhao Guojun (Deputy General Manager) and Wang Kai (Deputy General Manager).

Our R&D team complements this leadership with extensive expertise in the development, manufacturing and commercialization of biological products, amassed from leading biopharmaceutical companies worldwide. Deputy General Manager and Chief Scientist Dr. Chen Ze, alongside Deputy General Manager Dr. Yelin Xiong, each brings approximately 30 years of research experience in the global biotech industry. Under their guidance, the R&D team excels in directing our vaccine development, effectively designing and identifying optimal candidates and executing development plans that address market needs and drive our growth.

Since our inception, we have also received substantial support from shareholders, including renowned biotech investors such as GTJA Investment Group, Yingke PE, Highlight Capital and Addor Capital, as well as backing from local governments. We believe these investments signify strong recognition of our core value and growth potential, assuring continued support for our ongoing sustainable growth.

OUR STRATEGIES

Efficiently advance post-approval studies and clinical trials for our Core Products

Quadrivalent subunit influenza vaccine

- For individuals aged three and above: our quadrivalent subunit influenza vaccine was approved for use in individuals aged three and above in May 2023 and began commercialization in the third quarter of that year. According to the NDA approval, we are required to conduct a series of post-approval studies to continue monitoring the safety and efficacy of our vaccine in real world. Such continued studies include (i) a safety study in 3,000 participants aged three years and above, for which we had completed participant enrollment as of the Latest Practicable Date; (ii) a study to further explore immunization protocol in children aged 3-8 years, which we expect to begin in the first half of 2026; and (iii) a large-scale study to continue monitoring the vaccine's protective efficacy in a suitable age group. We expect to enroll 10,000 participants for the last study, which is expected to commence after the vaccine is approved for the 6-35 months age group.

- For individuals aged 6-35 months: we completed the Phase III clinical trial in participants aged 6-35 months and submitted an NDA for use in this age group, which was accepted by the NMPA in June 2024. Upon approval, we expect the NMPA will require post-approval studies of the vaccine in the 6-35 months age group similar to those required for individuals aged three years and above.

- For overseas markets: we completed registration in Macau in May 2024 and initiated the process in the Philippines in November 2024. We plan to initiate product registration in Thailand, Uruguay and Indonesia in 2025 and Canada, Singapore, Mexico and Hong Kong in 2026.

- For studies in special populations and co-administration with a marketed PPSV23: we will continue to push forward projects in collaboration with the NMPA, local CDCs and hospitals, including a large-scale active safety monitoring in population aged over three years following administration of our quadrivalent subunit influenza vaccine and evaluations of our vaccine in pregnant women and children with nephrotic syndrome. We will also quickly advance the study to evaluate the safety and immunogenicity of our quadrivalent subunit influenza vaccine in combination with a marketed PPSV23, aiming to provide reference data for the development of a combined immunization strategy for the two vaccines. These studies aim to enhance product use in special populations and improve vaccination willingness in healthy individuals, supporting our brand building strategy.

Lyophilized human rabies vaccine (human diploid cell)

Our IND applications for the lyophilized human rabies vaccine candidate for the Essen (five doses) regimen and for the Zagreb (four doses) and simplified four-dose regimens were approved in November 2022 and April 2023, respectively. We completed the Phase I clinical trial in October 2024 and plan to initiate a Phase III clinical trial in the second or third quarter of 2025.

Accelerate the development of other vaccine candidates to meet significant clinical needs and enrich our vaccine pipeline

We will continue to advance the preclinical and clinical development of our strategically selected vaccine candidates to expand our portfolio coverage, including:

- pneumococcal vaccines: we completed a Phase I clinical trial for the PPSV23 candidate in April 2023 and conducted additional studies for process improvement. We plan to initiate a Phase III clinical trial of the vaccine candidate in the fourth quarter of 2025 or the first quarter of 2026. For our PCV24 candidate, which was in the preclinical stage as of the Latest Practicable Date, we plan to complete preclinical studies in 2025 and aim to submit a pre-IND application to the NMPA in the first quarter of 2026.

- adjuvanted quadrivalent subunit influenza vaccine: we obtained the IND approval for adjuvanted quadrivalent subunit influenza vaccine for individuals aged 65 and above in July 2024 and expect to initiate a Phase I trial in the second or third quarter of 2025. Upon approval of this vaccine, our quadrivalent subunit influenza vaccine will achieve full age-range coverage.

- trivalent subunit influenza vaccines: our NDAs for the trivalent influenza vaccine candidate for individuals aged three and above and for those aged 6-35 months were accepted by the NMPA in September 2024. We expect to obtain approval for both age groups in 2025 and swiftly initiate commercial sales in the flu season, further strengthening our influenza vaccine product portfolio. For our adjuvanted trivalent subunit influenza vaccine candidate, we obtained an IND approval in October 2024 and plan to initiate a Phase I clinical trial in the second or third quarter of 2025.

- recombinant zoster vaccine (CHO cell): we obtained an IND approval for recombinant zoster vaccine candidate in August 2024 and plan to initiate a Phase I clinical trial in the first quarter of 2025.

- other vaccines: we will continue advancing the preclinical research of our RSV vaccine candidates, mRNA monkeypox vaccine candidate, live attenuated varicella vaccine candidate and tetanus toxoid adsorbed vaccine candidate, aiming to submit pre-IND applications in 2025 and 2026.

Continue to develop innovative technology platforms and enhance core technology competitiveness

Since the establishment of our Company, we have consistently focused on independent research and development activities to build our vaccine technology innovation capabilities. We will continue to develop and upgrade our technology platforms to support the research and development of existing vaccine candidates. Furthermore, the upgrading of our technology platforms, including our genetic engineering and protein expression and purification platform,

mRNA vaccine research platform, adjuvant development and production platform, large-scale amplification platform, polysaccharide conjugation technology platform and microbes and immunity research platform, will enable us to discover and develop new vaccine candidates with significant market demand that synergize with our existing pipeline.

Further strengthen manufacturing capacity and commercialization capabilities

We are committed to strengthening our manufacturing facilities in accordance with the clinical advancements of our vaccine candidates, ensuring a seamless transition from promising candidates to market-ready products. Our ongoing investment plan includes the construction of a second and a third manufacturing facility. The second manufacturing facility has a planned GFA of approximately 82,000 square meters and a designed annual capacity of 10.0 million doses. This site is dedicated to the commercial manufacturing of future influenza vaccines. The third manufacturing facility, with a planned GFA of approximately 27,000 square meters and a designed annual capacity of 20.0 million doses, is set for the commercial production of recombinant protein vaccines. Both facilities currently focus on designing integrated manufacturing equipment for respective vaccines, and essential infrastructure for quality assurance, warehousing, fire safety and office operations.

We aim to leverage our academic-driven marketing strategies to enhance the promotion and market penetration of our approved vaccine product, as well as those vaccine candidates nearing commercialization. By continuing to participate in key academic conferences and collaborating with research institutions, we intend to maintain and expand our influence among professionals and the general public. For this purpose, we plan to expand our internal sales and marketing team, focusing on increasing the number of regional sales managers among other measures, to more effectively target distinct customer groups.

Expand global business reach to maximize commercial value of vaccine candidates worldwide

We are strategically expanding our global business footprint to maximally utilize our production capacity throughout the year and address unmet market needs. Flu seasons in South America and certain Southeast Asian countries occur at different times of the year than China's. This staggered seasonality allows us to leverage our manufacturing capacity more effectively to fulfill such international demand for our vaccine.

Our Core Product, the quadrivalent subunit influenza vaccine, obtained a registration certificate and market authorization in Macau in May 2024. Additionally, we initiated the registration process in the Philippines in November 2024. We plan to file product registration applications in various other jurisdictions, including Thailand, Uruguay and Indonesia in 2025 and Canada, Singapore, Mexico and Hong Kong in 2026.

OUR PRODUCT AND PRODUCT CANDIDATES

Our Pipeline

As of the Latest Practicable Date, we had two Core Products, namely, our quadrivalent subunit influenza vaccine and lyophilized human rabies vaccine candidate, and 11 other product candidates, including (i) one product candidate in the NDA stage, namely our trivalent subunit influenza vaccine; and (ii) 10 product candidates in various stages of clinical and preclinical development.

The following chart summarizes our pipeline as of the Latest Practicable Date.

Product	Indication	R&D	Preclinical	IND Approval	Clinical			NDA Approval	Expected Near-term Milestone
					Phase I	Phase II	Phase III		
Quadrivalent subunit influenza vaccine*	Influenza (3 years and above)	Self-developed							Completion of post-approval safety study in Q4 2025
	Influenza (6 to 35 months)	Self-developed							NDA approval in 2025
Adjuvanted quadrivalent subunit influenza vaccine	Influenza (65 years and above)	Self-developed							Commencement of Phase I clinical trial in Q2 or Q3 2025
Trivalent subunit influenza vaccine	Influenza (3 years and above)	Self-developed							NDA approval in 2025
	Influenza (6 to 35 months)	Self-developed							NDA approval in 2025
Adjuvanted trivalent subunit influenza vaccine	Influenza (65 years and above)	Self-developed							Commencement of Phase I clinical trial in Q2 or Q3 2025
Lyophilized human rabies vaccine (human diploid cell)*	Rabies	Self-developed							Commencement of Phase III clinical trial in Q2 or Q3 2025
PPSV23	Invasive pneumococcal diseases	Acquired†							Commencement of Phase III clinical trial in Q4 2025 or Q1 2026
Recombinant zoster vaccine (CHO cell)	Herpes zoster	Self-developed							Commencement of Phase I clinical trial in Q1 2025
Recombinant RSV vaccine (CHO cell)	RSV LRTI	Self-developed‡							IND applications in Q2 or Q3 2025
mRNA RSV vaccine	RSV LRTI	Self-developed‡							Pre-IND application in Q3 or Q4 2025
mRNA monkeypox vaccine	Monkeypox	Self-developed							Pre-IND application in Q4 2025
PCV24	Invasive pneumococcal diseases	Self-developed							Pre-IND application in Q1 2026
Live attenuated varicella vaccine	Varicella	Self-developed							Pre-IND application in Q1 2026
Tetanus toxoid adsorbed vaccine	Tetanus	Self-developed							Pre-IND application in Q4 2025

* Core Product

† We contracted to acquire this asset before the clinical stage. We were and will continue to be responsible for clinical development. See "—Our Other Product Candidates—PPSV23" and "—Our Technology Transfer Arrangements—PPSV23 Technology Transfer Agreements."

‡ Self-developed with licensed antigen sequence

Clinical trial phase not required

LRTI: lower respiratory tract infection; PPSV: pneumococcal polysaccharide vaccine; PCV: pneumococcal conjugate vaccine; RSV: respiratory syncytial virus

Our Core Products

Quadrivalent Subunit Influenza Vaccine

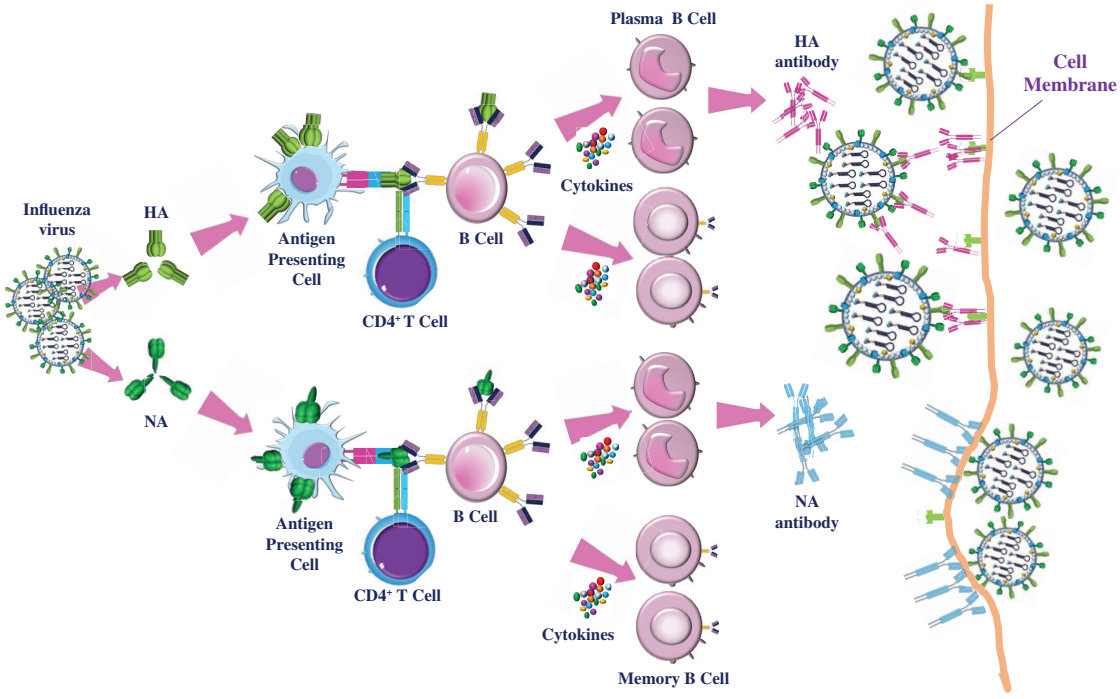
The quadrivalent subunit influenza vaccine, one of our Core Products, is designed to offer broad protection against two influenza A viruses (H1N1 and H3N2 subtypes) and two influenza B viruses (Yamagata and Victoria lineages). Among the four types of influenza viruses (namely, A, B, C and D), types A and B are responsible for seasonal flu epidemics. Although common symptoms of the flu are often mild, such as fever, headache and runny nose, influenza could lead to more serious conditions such as secondary bacterial infection of the lung (pneumonia), especially for the elderly over 65 years old, children under five years old and people with certain chronic medical conditions. Annual flu vaccination is considered the most effective way of prevention. China CDC has provided guidelines for influenza vaccination, emphasizing that vaccination should be provided to all people aged six months and above who are willing to be vaccinated and have no contraindications.

Compared to whole-pathogen or split-virion vaccines, subunit influenza vaccines contain only crucial components of the viruses and require further purification after virus split, thus facilitating precise antigen targeting and ensuring a better safety profile with lower risks of adverse reactions. In our Phase III clinical trials, the quadrivalent subunit influenza vaccine demonstrated a strong safety profile and robust immunogenic response.

Our quadrivalent subunit influenza vaccine received NDA approval from the NMPA in May 2023 for use in individuals aged three years and above (in the specification of 15μg/0.5ml in terms of viral hemagglutinin concentration) under the brand name Huierkangxin (慧爾康欣). It was the first and only quadrivalent subunit influenza vaccine approved in the PRC as of the Latest Practicable Date. Employing our in-house manufacturing facilities and sales and marketing team, we commenced commercialization of this vaccine after receiving approval and generated revenue of RMB217.2 million in the nine months ended September 30, 2024. Following the launch of our quadrivalent subunit influenza vaccine in 2023 and up to the Latest Practicable Date, we had achieved a 100.0% product qualification and lot release approval rate. As of the Latest Practicable Date, we were developing the quadrivalent subunit influenza vaccine for the 6-35 months age group and had submitted an NDA for this age group, which was accepted by the NMPA in June 2024. As of the same date, we were also developing an adjuvanted version of the vaccine for individuals aged 65 and above (see "—Our Other Product Candidates—Adjuvanted Quadrivalent Subunit Influenza Vaccine" for details).

Mechanism of Action

Subunit influenza vaccines are formulated with purified components of the virus, specifically, the surface glycoproteins hemagglutinin (HA) and neuraminidase (NA), which are the main antigenic substances and targets for protective antibodies. HA facilitates viral entry into host cells, while NA aids in the release of new viral particles after its replication. Upon vaccination, B cells recognize the HA protein and differentiate into plasma cells that produce neutralizing antibodies, preventing the virus from attaching to host cells. The NA component induces antibodies that inhibit its enzymatic activity, thereby limiting viral spread. The vaccine also activates $CD4^+$ T cells, or T-helper cells, which enhance responses from other immune cells and play central roles in the establishment of immunological memory. Although these antibodies provide extended protection, their levels can decline over time. Consequently, annual vaccinations are recommended to maintain effective immunity against evolving influenza virus strains. The following diagram illustrates the mechanism of action of our quadrivalent subunit influenza vaccine.



Market Opportunity and Competition

Influenza vaccines are classified into several major types based on their technical design: whole-virion inactivated vaccines, split-virion vaccines, inactivated subunit vaccines, live attenuated vaccines, recombinant vaccines and mRNA vaccines. See "Industry Overview—Influenza Vaccines—Overview of Influenza Vaccines" for details. Compared to whole-virion vaccines, which employ complete virus particles, and split-virion vaccines, which retain internal and surface viral proteins with a more complex antigenic composition, subunit vaccines focus on purified surface proteins, specifically HA and NA. This purification results in significantly improved safety and fewer side effects due to high antigen purity. Furthermore, subunit influenza vaccines can offer robust protective efficacy even for certain populations with weakened immune systems, provided that appropriate adjuvants are used when necessary. This contrasts with live attenuated vaccines, which mimic natural infections and are not suitable for individuals with compromised immune systems.

Influenza vaccines are also categorized by their valence, indicating their range of protection against various influenza virus strains. Currently marketed influenza vaccines include trivalent vaccines and quadrivalent vaccines. Trivalent vaccines protect against three influenza viruses: typically two influenza A viruses (H1N1 and H3N2) and one influenza B virus (Victoria lineage), targeting the most prevalent strains anticipated in each influenza season. However, they may not cover all circulating B strains. Quadrivalent vaccines extend trivalent formulations by including an additional B virus strain, Yamagata lineage. This inclusion addresses concerns about the co-circulation of dual lineages of influenza B viruses, enhancing the breadth of protection.

The influenza vaccine market in China grew significantly from RMB2.0 billion in 2019 to RMB8.8 billion in 2023, at a CAGR of 45.1%. The total number of lot release of influenza vaccines increased from 30.8 million in 2019 to 70.5 million in 2023. The influenza vaccine market in China is expected to further increase to RMB19.8 billion in 2032. As the first quadrivalent subunit influenza vaccine, developed by us, was approved by the NMPA in 2023, the subunit influenza vaccine market in China is estimated to grow rapidly from RMB0.4 billion in 2023 to RMB3.4 billion in 2032.

As of the Latest Practicable Date, there were 19 marketed influenza vaccines in China, including 10 trivalent vaccines (including 8 split-virion vaccines, 1 subunit vaccine and 1 live attenuated vaccine) and 9 quadrivalent vaccines (including 8 split-virion vaccines and 1 subunit vaccine (developed by us)). The following table sets forth details of our quadrivalent subunit influenza vaccine and other marketed influenza vaccines in China as of the Latest Practicable Date.

Type	Brand Name (Generic Name)	Technical Route	Manufacturer	NMPA approval date*	Age Coverage
Trivalent	Anflu (安爾來福)	Split Virion	Sinovac (科興)	2007/01	6 months of age and older
	Influenza vaccine	Split Virion	Shanghai Institute of Biological Products (上海生物製品研究所)	2007/05	6 months of age and older
	YUGANNING (御感寧)	Split Virion	Toyouvax (天元生物)	2007/06	6 months of age and older
	適普利爾	Split Virion	Changchun Institute of Biological Products (長春生物製品研究所)	2007/07	6 months through 3 years of age
	Influenza vaccine	Split Virion	Hualan Biological Bacterin (華蘭生物)	2008/04	6 months of age and older
	Influenza vaccine	Split Virion	Fosun Apexvac (復星雅立峰)	2009/06	3 years of age and older
	FLU-K (孚洛克)	Subunit	Zhongyianke Biotech (中逸安科)	2010/04	3 years of age and older
	VAXIGRIP (凡爾靈)	Split Virion	Sanofi Pasteur Biological Products	2013/06	3 years of age and older; 6-35 months of age
	Influenza vaccine	Split Virion	Adimmune (國光生物)	2015/10	3 years of age and older
	感霧	Live Attenuated	BCHT (百克生物)	2020/02	3-17 years of age
Quadrivalent	Influenza vaccine, quadrivalent	Split Virion	Hualan Biological Bacterin (華蘭生物)	2018/06	3 years of age and older
				2022/1	6-35 months of age
	迪福賽爾	Split Virion	GDK (金迪克生物)	2019/05	3 years of age and older
	Influenza vaccine, quadrivalent	Split Virion	Changchun Institute of Biological Products (長春生物製品研究所)	2020/03	3 years of age and older
	Influenza vaccine, quadrivalent	Split Virion	Wuhan Institute of Biological Products (武漢生物製品研究所)	2020/04	3 years of age and older
	Influenza vaccine, quadrivalent	Split Virion	Sinovac (科興)	2020/06	3 years of age and older
	Influenza vaccine, quadrivalent	Split Virion	Shanghai Institute of Biological Products (上海生物製品研究所)	2021/03	6 months of age and older
	安定伏	Split Virion	Adimmune (國光生物)	2022/02	3 years of age and older
	VaxigripTetra 凡爾佳	Split Virion	Sanofi Pasteur Biological Products	2023/02	6 months of age and older
	慧爾康欣	Subunit	***the Company***	2023/05	3 years of age and older

Note: The approval date is the time when the vaccine was first approved, without considering age-group expansion.

Sources: NMPA, Frost & Sullivan

As of the Latest Practicable Date, there were 16 influenza vaccine candidates under clinical development in China, including 4 trivalent vaccines (including 2 split-virion vaccines, 1 live attenuated vaccine and 1 subunit vaccine (developed by us)) and 12 quadrivalent vaccines (including 10 split-virion vaccines and 2 subunit vaccines). The following table sets forth details of our trivalent subunit influenza vaccine candidate and other influenza vaccine candidates in China as of the Latest Practicable Date.

Type	Technical Route	Manufacturer	Clinical Stage	First Posted Date*	Age Coverage
Trivalent	Subunit	***our Company***	BLA	2024/9	3 years of age and older
			BLA	2024/10	6-35 months of age
	Live Attenuated	BCHT (百克生物)	BLA	2024/4	3-59 years of age
	Split Virion	ZFSW (智飛生物)	BLA	2024/10	3 years of age and older
			BLA	2024/11	6-35 months of age
	Split Virion	Peisen Biotechnology (培森生物)	I (completed)	2022/3	3 years of age and older
Quadrivalent	Subunit	***our Company***	BLA	2024/6	6-35 months of age
	Subunit	Changchun Institute of Biological Products (長春生物製品研究所)	I	2024/04	3 years of age and older
	Split Virion	CuroVax (康潤生物)	BLA	2024/3	3 years of age and older
			I	2024/4	6-35 months of age
	Split Virion	Toyouvax (天元生物)	BLA	2023/12	3 years of age and older
			I	2024/3	6 months of age and older
	Split Virion	ZFSW (智飛生物)	BLA	2024/9	6-35 months of age
	Split Virion	Wuhan Institute of Biological Products (武漢生物製品研究所)	BLA	2024/11	3 years of age and older
	Split Virion	BioKangtai (康泰生物)	BLA	2024/11	3 years of age and older
	Split Virion	Chengda Biotechnology (成大生物)	III	2020/12	3 years of age and older
	Split Virion	Sinovac (科興)	III	2023/9	6-35 months of age
	Split Virion	Fosun Apexvac (復星雅立峰)	III	2023/10	6-35 months of age
	Split Virion	Walvax (沃森生物)	III	2024/10	3 years of age and older
	Split Virion	Hygiea Biotech (海基亞生物)	I	2020/10	6-35 months of age; 3 years of age and older

Note: The dates for products in BLA stage are the dates handled by the CDE.

Sources: CDE, Frost & Sullivan

Our Advantages

We believe our quadrivalent subunit influenza vaccine has the following advantages.

- *Enhanced safety profile*. Subunit influenza vaccines are designed to offer a robust safety profile due to their precise manufacturing process, which removes internal viral proteins and retains only high-purity HA and NA antigen components. This approach aims to reduce the risk of adverse reactions. In our Phase III clinical trial, the overall incidence of vaccination-related adverse events induced by our quadrivalent subunit influenza vaccine in participants aged 18 to 64 years was lower than that caused by the control quadrivalent split-virion vaccine (6.29% and 10.86%, respectively) and the difference was statistically significant (P = 0.031). These findings underscore the enhanced safety of our vaccine for certain target groups, making it an ideal choice for vaccinees with heightened safety awareness.

- *Robust immune response*. Our quadrivalent subunit influenza vaccine is able to elicit strong immune responses. In our Phase III clinical trial, in the total population of participants aged three years and above, our vaccine achieved seroprotection rates of 96.56%, 97.98%, 89.41% and 95.88% for the H1N1, H3N2, BV and BY virus strains, respectively, all above the widely used European Union standard of 70.0%. In the same group of participants, our vaccine also elicited significantly higher geometric mean titers (GMTs) of neutralizing antibodies against all four virus strains compared to the control quadrivalent split-virion influenza vaccine. These results highlight the vaccine's potential for more effective immunization, offering greater protection against influenza viruses.

- *Clear commercialization and market expansion strategy*. We began commercialization of our quadrivalent subunit influenza vaccine in 2023 and successfully completed a full influenza season which honed the capabilities of our manufacturing and sales and marketing teams. Currently, the commercialization of our vaccine is also supported by a robust network of third-party marketing service providers. Our quadrivalent subunit influenza vaccine has completed the market entry process in 30 provinces and been chosen by over 1,100 district- and county-level CDCs in local selections. With respect to overseas markets, we have completed registration in Macau and initiated the process in the Philippines. We will continue expanding into jurisdictions that have large vaccine markets and flu seasons timed differently from China's, such as Uruguay. This strategic expansion is poised to contribute to sustained sales growth, reinforcing our market presence both domestically and abroad.

Summary of Clinical Trials

We completed (i) a Phase I clinical trial of our quadrivalent subunit influenza vaccine in healthy participants aged 6 months or above in China in April 2020; (ii) a Phase III clinical trial in healthy participants aged 3 years or above in China in December 2021; and (iii) a separate Phase III clinical trial in healthy participants aged 6-35 months in China in April 2024. Below is a summary of such clinical trials in reverse chronological order.

Phase III Clinical Trial (6-35 months old)

- *Trial design*. This Phase III clinical trial was a randomized, blinded and positive-controlled trial in healthy participants aged between 6 and 35 months. The primary objectives were to evaluate the safety and immunogenicity of our quadrivalent subunit influenza vaccine in 15μg/0.5ml dose in this age group and the secondary objectives were to evaluate the safety and immunogenicity of our study vaccine in 7.5μg/0.25ml dose in this age group. The exploratory objectives were to (i) compare the differences in safety and immunogenicity between 0.5ml dose and 0.25ml dose in this age group and (ii) explore the immune persistence at 3 months and 6 months following the complete vaccination regimen of 0.5ml dose and 0.25ml dose in this age group.

In the clinical trial, a total of 2,772 participants would be randomly assigned in a 1:1:1 ratio into three groups to receive either vaccine 1 (our study vaccine in 15μg/0.5ml), vaccine 2 (our study vaccine in 7.5μg/0.25ml) or a control vaccine (a marketed quadrivalent split-virion influenza vaccine). Each participant would receive two doses of the respective vaccine, with an interval of 28 days between doses.

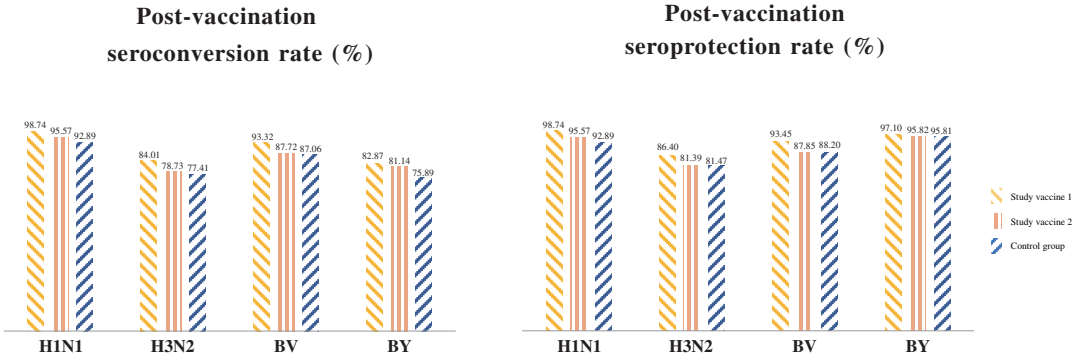
Following each inoculation, participants would undergo (i) immediate post-administration observation for 30 minutes and (ii) active systematic monitoring for safety for seven days. After seven days of the inoculation, the occurrence of adverse events would be assessed through a combination of weekly scheduled follow-ups and proactive reporting by the participants. Safety observations would be conducted from the day of each inoculation to 28 or 30 days thereafter. Serious adverse events (SAEs) occurred from the first dose administration through six months after completing the vaccination regimen would be documented. Blood samples of all participants would be collected before vaccination and 28 days after completion of the vaccination regimen for influenza virus haemagglutination inhibition (HI) antibody testing to evaluate immunogenicity. The main measurements for immunogenicity include post-vaccination seroconversion rate, seroprotection rate and GMT level.

- *Trial status*. The trial was initiated in February 2023 and completed in April 2024. A total of 2,772 participants were enrolled in the trial, among which 2,766 were included in the safety set total (SST), 2,764 were included in the immunogenicity full analysis set (FAS) and 2,372 were included in the immunogenicity per protocol set (PPS).

- *Safety.* There was no statistically significant difference in terms of the overall incidences of AE between any two of the vaccine 1, vaccine 2 and control groups. For the 30 days following the complete vaccination course, the overall incidences of vaccination-related AE for the vaccine 1, vaccine 2 and control groups were 29.64%, 33.33% and 29.64%, respectively. Most of the vaccination-related AEs were of grade 1 and grade 2, with 18, 8 and 6 instances of grade 3 vaccination-related AEs in the vaccine 1, vaccine 2 and control groups, respectively.

  There was no statistically significant difference between the incidences of SAEs of any two groups. All SAEs in the vaccine 2 group and the control group were unrelated to vaccination. Only 1 subject (aged 16 months) in vaccine 1 group experienced an SAE 11 days post-vaccination that was considered possibly related to the vaccination. The symptom was clinically diagnosed as diarrhea and the subject was hospitalized. The symptom developed relatively close to the vaccination date and is one of the more common adverse reactions to the vaccine. The subject was administered two antibiotics before hospitalization and the diarrhea occurred on the third day of antibiotic treatment, indicating a possible antibiotic-induced disruption of the normal microorganism communities. However, a connection to the vaccine cannot be completely ruled out, and this SAE was thus considered possibly related to the vaccination. One instance of death (car accident) was reported in the control group, and it was considered unrelated to the vaccination.

- *Immunogenicity*. In PPS, both vaccine 1 and vaccine 2 groups showed good immunogenicity as they achieved seroconversion rates (28 days after the completion of the vaccination course) of 98.74% and 95.57%, 84.01% and 78.73%, 93.32% and 87.72% and 82.87% and 81.14% for the H1N1, H3N2, BV and BY virus strains, respectively, all above the 30.0% standard set by the European Union for this age group. The corresponding seroprotection rates were 98.74% and 95.57%, 86.40% and 81.39%, 93.45% and 87.85%, 97.10% and 95.82%, respectively, all above the 60.0% standard set by the European Union for this age group. Both vaccine 1 and vaccine 2 groups demonstrated non-inferior seroconversion rates for all four virus strains compared to the control group. In particular, compared to the control group, the vaccine 1 group demonstrated a trend of higher seroconversion rates for all four virus strains, with differences in seroconversion rates of 5.85%, 6.59%, 6.27% and 6.98%, respectively. The charts below illustrate the post-vaccination seroconversion rates and seroprotection rates in vaccine 1 group, vaccine 2 group and control group.



Both vaccine 1 and vaccine 2 groups demonstrated non-inferior antibody geometric mean titer (GMT) levels for all four virus strains compared to the control group. In particular, vaccine 1 demonstrated higher antibody GMT levels for all four virus strains compared to the control group and the differences were statistically significant for the H1N1, H3N2 and BY strains. The conclusions from FAS were consistent with those based on PPS.

- *Conclusion*. Both vaccine 1 (15μg/0.5ml) and vaccine 2 (7.5μg/0.25ml) demonstrated good safety and immunogenicity when administered in a 2-dose regimen to healthy individuals aged 6 to 35 months and vaccine 1 offered relatively better immunogenicity results.

Phase III Clinical Trial (3 years and above)

- *Trial design*. This trial was a randomized, blinded and positive-controlled trial in healthy participants aged three years and above. The primary objectives were to evaluate the safety and immunogenicity of our quadrivalent subunit influenza vaccine administered in a single-dose regimen in this age group and the secondary objectives were to evaluate the safety of the study vaccine administered in a two-dose regimen (with a 28-day interval) in the 3-8 years age group, and to explore its immunogenicity compared to the single-dose regimen.

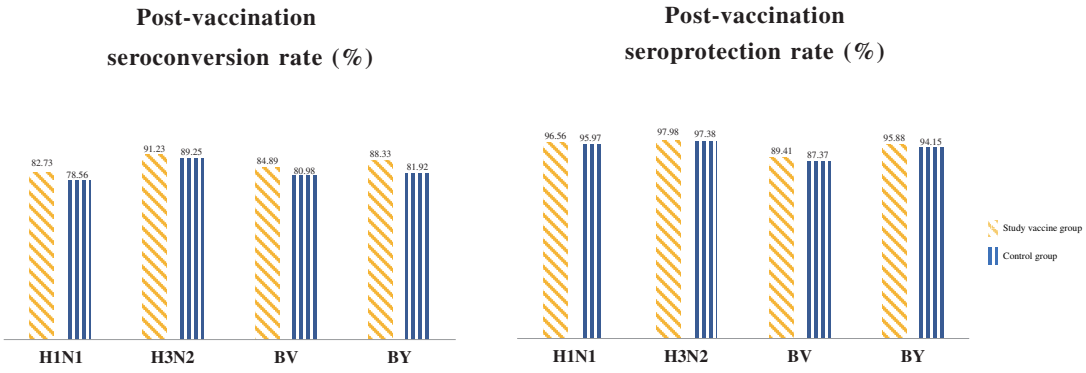
A total of 3,000 participants would be enrolled for this trial, with 800 participants in the 3 to 8 years age group, 700 participants in the 9 to 17 years age group, 700 participants in the 18 to 64 years age group and 800 participants in 65 years and above age group. Participants in each age group would be randomly assigned in a 1:1 ratio to receive either our study vaccine (15μg/0.5ml) or the control vaccine (a marketed quadrivalent split-virion influenza vaccine). Participants aged nine years and above would receive a single-dose regimen, while those aged three to eight years would receive a two-dose regimen (with a 28-day interval). Blood samples of all participants would be collected before vaccination and 28 days after completing the vaccination regimen for influenza virus HI antibody testing to evaluate immunogenicity. The main measurements for immunogenicity include post-vaccination seroconversion rate, seroprotection rate and GMT level. For the 3 to 8 years age group, additional blood samples would be collected 28 days after the first dose. Systematic safety observation would be conducted from the start of vaccination to 30 days post-completion of the immunization regimen, and long-term safety observation would be carried out from 31 days to 180 days post-completion of the vaccination regimen.

- *Trial status*. The trial was initiated in May 2020 and completed in December 2021. A total of 3,000 participants were enrolled in the trial, among which 2,997 were included in the SST and the immunogenicity FAS and 2,949 participants were included in the immunogenicity PPS.

- *Safety*. There was no statistically significant difference in terms of the overall incidences of AE between the study vaccine group and the control group. Within 30 days following vaccination according to the respective regimen, the overall incidences of vaccination-related AE in the study vaccine group and the control group were 10.67% and 11.21%, respectively. Vaccination-related AEs in both groups were predominantly of grade 1 and grade 2, with two instances of grade 3 AEs, one each in the study vaccine group and the control group, occurring in the ≥65 years age group, both being cases of fever. No grade 4 or higher vaccination-related AE occurred in either group. No vaccination-related SAE was reported in this trial.

  In the 18-64 years age group, the overall incidence of vaccination-related AEs in the study vaccine group (6.29%) was lower than that in the control group (10.86%) and the difference was statistically significant. In participants aged 9-17 years and in those aged 65 years and above, there was no statistically significant difference between the overall incidence of vaccination-related AEs in the study vaccine group and that in control group. In the 3 to 8 years age group, (i) within 28 days following the administration of the first dose, the overall incidence of vaccination-related AE was 9.75% in the study vaccine group and 13.78% in the control group, with no statistically significant difference; and (ii) within 30 days following the administration of the second dose, the overall incidence of vaccination-related AE was 8.16% in the study vaccine group and 6.08% in the control group, with no statistically significant difference. Both the study vaccine group and the control group showed a decrease in vaccination-related AEs after the second dose compared to the first dose, indicating that the safety profile of the study vaccine remains favorable despite an increase in the number of doses administered.

- *Immunogenicity*. In FAS, in the total cohort of participants aged 3 years and above, as well as in the participants aged ≥65 years and between 3-64 years, our study vaccine showed good immunogenicity after one dose as it demonstrated non-inferior seroconversion rates and antibody GMT levels for all four virus strains compared to the control group. The conclusions from PPS were consistent with those based on FAS. In particular, in the total cohort of participants aged three years and above, our study vaccine elicited higher GMT levels for all four virus strains than the control vaccine, and the differences were statistically significant. In the same group, the seroconversion rates for the H1N1, H3N2, BV and BY virus strains after one dose were 82.73%, 91.23%, 84.89% and 88.33%, respectively, all above the European Union standard of 40.0% for this age group. The corresponding seroprotection rates were 96.56%, 97.98%, 89.41% and 95.88%, respectively, all above the European Union standard of 70.0% for this age group. The charts below illustrate the post-vaccination seroconversion rates and seroprotection rates of the total cohort of participants aged three years and above in the study vaccine group in comparison with the control group.



In the 3 to 8 years age group, results from 28 days after the first dose and 28 days after the second dose in the study vaccine group showed that the antibody titer for BV strain was higher after two doses than after one, with a statistically significant difference. The seroconversion and seroprotection rates for all four strains were higher after two doses than after one, with statistically significant differences, indicating that in the 3 to 8 years age group, the two-dose regimen confers better immunogenicity compared to a single dose.

- *Conclusion*. In this trial in individuals aged 3 years and above, our quadrivalent subunit influenza vaccine demonstrated good immunogenicity and safety after one dose. In the 3 to 8 years age group, the two-dose regimen exhibit better immunogenicity, with good tolerability and safety.

Phase I Clinical Trial

- *Trial design*. This trial was a randomized, blinded and positive-controlled trial in healthy participants aged six months and above. The objectives of the trial were (i) to evaluate the safety of our quadrivalent subunit influenza vaccine administered in a single-dose regimen in healthy participants aged nine years and above and to conduct a preliminary

observation of its immunogenicity; and (ii) to evaluate the safety of the study vaccine in a two-dose regimen (with a 28-day interval) in healthy participants aged 6-35 months and 3-8 years and to conduct a preliminary observation of its immunogenicity.

320 participants would be separated into different age groups, in a sequential order progressing from the 18 years and above group (80 participants) to the 9-17 years group (80 participants), then to the 3-8 years group (80 participants), followed by the 6-35 months low dose group (40 participants), and finally the 6-35 months high dose group (40 participants). Participants in all age groups except the two 6-35 months groups would be randomly assigned in a 1:1 ratio to receive either our study vaccine (15μg/0.5ml) or the control vaccine (a marketed quadrivalent split-virion influenza vaccine). Participants in the 6-35 months low dose group would receive our study vaccine in the 7.5μg/0.25ml dose, while those in the 6-35 months high dose group would receive the study vaccine in the 15μg/0.5ml dose. Participants in the 18 years and above and 9-17 years groups would receive a single-dose regimen, while those in the 3-8 years and 6-35 months groups would receive a two-dose regimen (with a 28-day interval). Safety observation would be conducted from the start of vaccination to 30 days post-completion of the vaccination regimen, with long-term safety observation from 31 days to 180 days post-completion. Blood samples from all participants would be collected before vaccination and 28 days after completing the vaccination regimen for HI antibody testing. For the 3 to 8 years age group, additional blood samples would also be collected 28 days after the first dose.

- *Trial status*. The trial was initiated in August 2019 and completed in April 2020. The clinical study report (CSR) was updated in January 2022, according to then newly published regulations with respect to statistical analyses of safety and immunogenicity data in clinical trials of influenza vaccines. A total of 320 participants were enrolled in the trial, all of whom were included in the SST and the immunogenicity FAS. 311 participants were included in the immunogenicity PPS.

- *Safety*. Among all participants aged three years or above, there was no statistically significant difference in terms of the overall incidences of AE between the study vaccine group and the control group. Within 30 days following vaccination according to the respective regimen, the overall incidences of vaccination-related AE in the study vaccine group and the control group were 20.83% and 28.33%, respectively, with all reactions occurring within 0-7 days (including within 30 minutes) post-vaccination. Vaccination-related AEs in both the study vaccine group and the control group were predominantly of grade 1 and grade 2, with 2 instances of grade 3 vaccination-related AEs, both occurring in the ≥18 years control group. No grade 4 or higher vaccination-related AE was reported in either group. In the 6-35 months age groups, within 28 days after the first dose, the overall incidences of vaccination-related AE for the low dose group and the high dose group were 17.50% and 22.50%, respectively. Within 30 days after the second dose, the overall incidences were 10.00% and 20.00%, respectively, with no statistically significant difference between the groups. The AE incidences decreased after the second dose in both the low dose group and the high dose group, compared to after the first dose, indicating good safety with increased doses. No vaccination-related SAE was reported in this trial.

- *Conclusion*. Our quadrivalent subunit influenza vaccine demonstrated good safety and tolerability, achieving the safety targets set in the protocol, after administration in healthy participants aged 6-35 months, 3-8 years, 9-17 years and 18 years and above. Further Phase III clinical trials could be conducted to evaluate its immunogenicity and safety.

Summary of Preclinical Studies

We conducted a series of preclinical studies, including single- and repeat-dose toxicity test, active systemic anaphylaxis test and immunogenicity test, where our quadrivalent subunit influenza vaccine demonstrated good overall safety and immunogenicity profile.

Material Communications and Continuing R&D

We obtained an IND approval of our quadrivalent subunit influenza vaccine in individuals aged tree years and above in November 2017 and the NDA approval in May 2023. Leveraging our own in-house manufacturing facilities and sales and marketing team, we commenced commercial manufacturing and sales of our quadrivalent subunit influenza vaccine in 2023. According to the NDA approval, we are required to conduct a series of post-approval studies to continue monitoring the safety and efficacy of our vaccine in real world. Such continued studies include (i) a safety study in 3,000 participants aged three years and above, for which we had completed participant enrollment as of the Latest Practicable Date; (ii) a study to further explore immunization protocol in children aged 3-8 years, which we expect to begin in the first half of 2026; and (iii) a large-scale study to continue monitoring the vaccine's protective efficacy in a suitable age group. For the last study, we expect to enroll 10,000 participants and commence the study after the vaccine is approved for use in the 6-35 months age group. The NMPA's requirement for post-approval studies functions to monitor an approved vaccine's effectiveness and safety in broader, more diverse populations beyond controlled clinical trial settings, ensuring continued efficacy and identifying any rare adverse effects that may not have been apparent during clinical trials. These studies provide vital data on actual vaccine performance and contribute to ongoing public health protection. According to Frost & Sullivan, these post-approval study requirements align with standard practices for influenza vaccines. With respect to overseas markets, we have completed registration in Macau and initiated the process in the Philippines. We plan to apply for registration in Thailand, Uruguay and Indonesia in 2025 and in Canada, Singapore, Mexico and Hong Kong in 2026.

We filed a supplemental application for additional clinical studies of our quadrivalent subunit influenza vaccine (in the 0.5ml dosage) in the 6-35 months age group in June 2022 and received approval in September 2022. After completing a Phase III clinical trial for this age group, we submitted a supplemental NDA to expand the indicated population for our quadrivalent subunit influenza vaccine from individuals aged three years and above to those aged six months and above. The supplemental NDA was accepted by the NMPA in June 2024. Upon approval, the label for our vaccine will be updated to reflect the expansion of the indicated population. In addition, we expect that the NMPA will require post-approval studies

of the vaccine in the 6-35 months age group similar to those required for individuals aged three years and above. We plan to promptly initiate commercial manufacturing and sales of the product for use in such age group through our in-house manufacturing facilities and sales and marketing team.

In addition, in order to further establish the safety and efficacy profile of the vaccine, we initiated several other post-approval studies of the vaccine in collaboration with regulatory agencies and hospitals. For example, as an open project by the CDE, we are advancing a large-scale active safety monitoring in population aged over three years following administration of our quadrivalent subunit influenza vaccine. This multi-centered and open-label prospective study aims to include a total of 47,000 participants and is designed to establish a long-term mechanism for active post-marketing surveillance of the vaccine. We initiated the project in October 2023 and had enrolled over 40,000 participants as of the Latest Practicable Date. We expect to complete participant enrollment for the study by the end of 2025. As of the Latest Practicable Date, we were also advancing (i) a study in collaboration with Shanghai CDC on the safety and immunogenicity of our vaccine in pregnant women, which aims to provide data support for the vaccination among pregnant women in China and was undergoing ethical review at Shanghai CDC; (ii) a study in collaboration with a specialty hospital in Guangzhou on the immunogenicity and safety of the vaccine in children with nephrotic syndrome, aiming to evaluate the optimal timing and safety conditions for influenza vaccination in these children and to explore the differences in their immune response under various treatment regimens, which received ethical approval from the hospital in June 2024; and (iii) a study in collaboration with local CDCs to evaluate the safety and immunogenicity of our quadrivalent subunit influenza vaccine in combination with a marketed PPSV23, aiming to provide reference data for the development of a combined immunization strategy for the two vaccines, for which we had formulated a trial design and were in the process of selecting appropriate CDCs for collaboration.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QUADRIVALENT SUBUNIT INFLUENZA VACCINE FOR ALL INTENDED AGE GROUPS SUCCESSFULLY.

Lyophilized Human Rabies Vaccine (Human Diploid Cell)

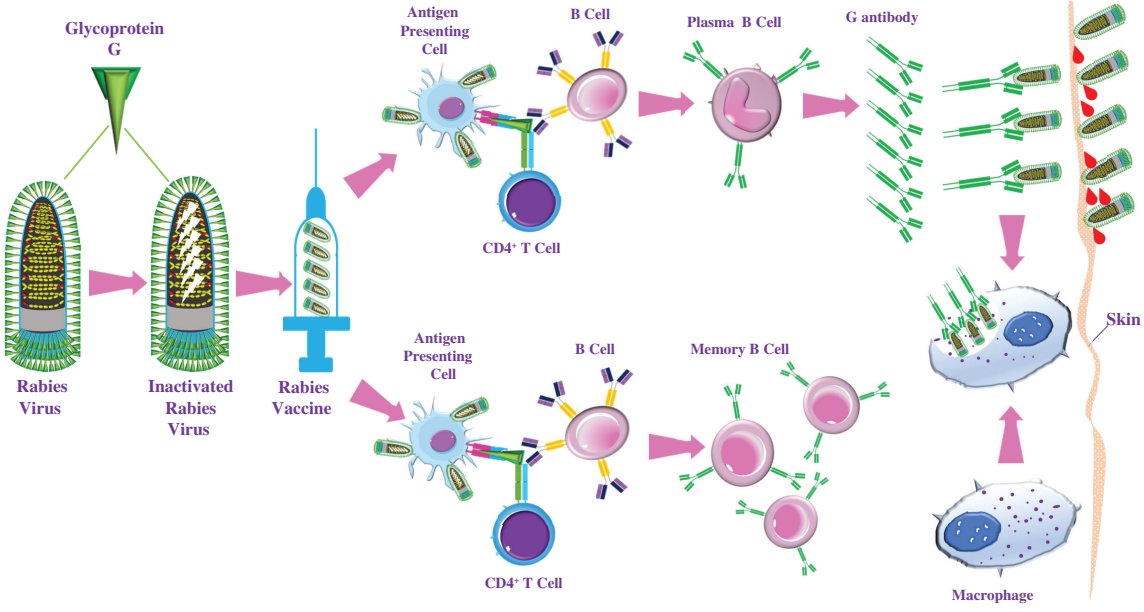
The lyophilized human rabies vaccine (human diploid cell) candidate is another of our Core Products. It is designed for prevention against rabies, a serious viral disease caused by the rabies virus, which could develop severe symptoms such as confusion and progressive paralysis. Rabies can be prevented with proper vaccination immediately after exposure to the virus but is almost always fatal once symptoms show. According to the UK Department of Public Health, regions across Asia, including China, are classified as high-risk regions for rabies exposure from land-based animals. In particular, developing countries in Asia and Africa account for over 95.0% of global human rabies deaths. The high mortality rates necessitate immediate post-exposure vaccination as a primary control measure.

Our rabies vaccine candidate is developed from human diploid cells, which are cells that contain two complete sets of chromosomes, the normal chromosome complement of most human cells. Human diploid cell vaccines can induce reliable immune response, generate high titers of neutralizing antibodies and have strong safety profile. The WHO recommends human diploid cells as one of the safest cell culture substrates for the production of viral vaccines. Rabies vaccines produced from human diploid cells are poised to serve as a favorable alternative to traditional rabies vaccines currently available in the China market. Our rabies vaccine candidate demonstrated a promising safety profile in its completed Phase I clinical trial.

We are developing the rabies vaccine candidate for three immunization regimens: Essen (five doses), Zagreb (four doses) and simplified four-dose. We obtained an IND approval for the Essen regimen in November 2022 and approval of our supplemental clinical trial application for the Zagreb and simplified four-dose regimens in April 2023. We completed a Phase I clinical trial of the candidate in October 2024 and plan to commence a Phase III clinical trial in the second or third quarter of 2025.

Mechanism of Action

Rabies vaccines produced using human diploid cells are developed through the inactivation of rabies virus grown in human embryonic lung fibroblast cell cultures. These vaccines retain the immunogenic properties of the virus, prompting B cells to recognize the viral antigens and produce rabies-specific neutralizing antibodies. These antibodies circulate in the bloodstream, binding to the rabies virus and preventing it from infecting host cells, while immune cells like macrophages clear the virus. Such vaccines also activate T-helper cells, enhancing the antibody response and promoting the formation of immunological memory. The following diagram illustrates the mechanism of action of our rabies vaccine candidate.



Market Opportunity and Competition

Currently marketed human rabies vaccines in China can be categorized into three types based on the cell lines used for cultivation: primary cell rabies vaccines, Vero cell rabies vaccines and human diploid cell rabies vaccines. Primary cells, such as chicken embryo and hamster kidney cells, have traditionally been employed for vaccine production due to their lower costs. However, they carry a higher risk of contamination and are less suited for large-scale production, diminishing their competitiveness against more advanced methods. Vero cells (a cell line derived from the kidney of African green monkeys) represent a significant advancement, leveraging bioreactor technology and suspension culture to enhance cell contact area and culture efficiency. Compared to vaccines developed from primary chicken embryo cells, primary hamster kidney cells and Vero cells, human diploid cell vaccines do not carry the risk of potential tumor-causing DNA residues or foreign protein allergens. As a result, they may offer a superior safety profile. Rabies vaccines developed using human diploid cells are anticipated to partially replace vaccines developed using primary cells and Vero cells.

According to Frost & Sullivan, the human rabies vaccine market in China, in terms of production value, increased from RMB3.8 billion in 2019 to RMB8.9 billion in 2023, at a CAGR of 23.9%. The total number of lot release increased from 58.8 million in 2019 to 70.4 million in 2023. The human rabies vaccine market in China is estimated to further increase to RMB12.5 billion in 2032, at a CAGR of 3.8% from 2023 to 2032.

As of the Latest Practicable Date, there were 23 marketed human rabies vaccines in China, including 15 vaccines developed from Vero cells, 6 vaccines developed from hamster kidney cells and 2 vaccines developed from human diploid cells, both of which are lyophilized vaccines like our candidate. The following table sets forth details of marketed human rabies vaccines in China as of the Latest Practicable Date.

Cell Line	Brand Name (Generic Name)	Manufacturer	NMPA approval date	Immunization Schedule
Human diploid cell (lyophilized)	–	Kanghua Biological Products (康華生物)	2012/01	Essen 5 doses
	–	Minhai (民海生物)	2023/09	Zagreb 4 doses & Essen 5 doses
Vero cell	武生旺寧	Wuhan Institute of Biological Products (武漢生物製品研究所)	2004/01	Essen 5 doses
	–	Chengda Biotechnology (成大生物)	2004/01	Zagreb 4 doses & Essen 5 doses
	–	HK Biotech (惠康生物)	2006/11	Essen 5 doses
	–	Fosun Apexvac (復星雅立峰)	2016/09	Essen 5 doses
Vero cell (lyophilized)	–	Yisheng Biopharma (依生生物)	2003/04	Essen 5 doses
	–	Chengda Biotechnology (成大生物)	2004/01	Zagreb 4 doses & Essen 5 doses
	武生欣寧	Wuhan Institute of Biological Products (武漢生物製品研究所)	2005/01	Essen 5 doses
	–	Rongan Biotech (榮安生物)	2007/01	Essen 5 doses
	–	Promise Biological (諾誠生物)	2008/01	Essen 5 doses
	–	Zhuoyi Biological (卓誼生物)	2016/11	Essen 5 doses
	–	Changchun Institute of Biological Products (長春生物製品研究所)	2021/04	Zagreb 4 doses & Essen 5 doses
	–	Yidu Biotechnology (亦度生物)	2021/07	Zagreb 4 doses & Essen 5 doses
	–	Hualan Biological Bacterin (華蘭生物)	2023/04	Zagreb 4 doses & Essen 5 doses
	–	CuroVax (康潤生物)	2023/09	Zagreb 4 doses & Essen 5 doses
	–	Fosun Apexvac (復星雅立峰)	2024/03	Essen 5 doses
Hamster kidney cell	–	Yatai Biopharmaceuticals (亞泰生物)	1999/01	Essen 5 doses
	–	CGE Healthcare (遠大生物)	2000/01	Essen 5 doses
	–	Lanzhou Institute of Biological Products (蘭州生物製品研究所)	2000/01	Essen 5 doses
	–	Zhongke Biotic (中科生物)	2000/02	Essen 5 doses
	–	AIM (艾美疫苗)	2006/01	Essen 5 doses
Hamster kidney cell (lyophilized)	–	Lanzhou Institute of Biological Products (蘭州生物製品研究所)	2005/01	Essen 5 doses

Sources: NMPA, Frost & Sullivan

As of the Latest Practicable Date, there were 19 human rabies vaccine candidates under clinical development in China, primarily including 11 vaccines developed from Vero cells and 6 vaccines developed from human diploid cells (including our rabies vaccine candidate). The following table sets forth details of our candidate and other human rabies vaccine candidates in China as of the Latest Practicable Date.

Cell Line	Manufacturer	Clinical Stage	First Posted Date*	Immunization Schedule
Human diploid cell	Minhai (民海生物)	BLA	2015/09	Essen 5 doses
	Chengda Biotechnology (成大生物)	BLA	2024/08	Zagreb 4 doses & Essen 5 doses & 1-1-1-1
	ZFSW (智飛生物)	BLA	2024/10	Zagreb 4 doses & Essen 5 doses
	Chengdu Institute of Biological Products (成都生物製品研究所)	III	2017/05	Zagreb 4 doses & Essen 5 doses
	Prokang Biotechnology (普康生物)	III	2024/07	Zagreb 4 doses & Essen 5 doses
	our Company	I (completed)	2023/11	Zagreb 4 doses & Essen 5 doses
Vero cell	Nuocheng Biological Products (諾辰生物)	BLA	2024/07	Zagreb 4 doses & Essen 5 doses
	GDK (金迪克生物)	III (completed)	2017/12	Essen 5 doses
	Maokangyuan Biotechnology (茂康源生物)	III	2019/12	Essen 5 doses
	ZFSW (智飛生物)	III	2020/12	Zagreb 4 doses & Essen 5 doses
	Chengda Biotechnology (成大生物)	III (completed)	2021/07	1-1-1-1
	BoaoVax (柏奧特克生物)	III (completed)	2021/08	1-1-1-1 & Essen 5 doses
	Ronsen (榮盛生物)	III	2022/06	Essen 5 doses
	RBSPH (銀河陽光生物製品)	III	2022/11	1-1-1-1 & Essen 5 doses
	Ningbo Rongan Biological (榮安生物藥業)	III	2023/07	Essen 5 doses
	Yisheng Biopharmaceutical (依生生物)	III	2024/11	1-1-1-1 & Zagreb 4 dose
	Yatai Biological Pharmaceutical (亞泰生物藥業)	I (completed)	2021/02	Essen 5 doses
Chicken Embryo Cell	King-cell Biotechnology (青賽生物)	BLA	2024/10	Zagreb 4 doses & Essen 5 doses
	Qingfeng/C-Fusion Biotechnology (青峰藥業/賽爾富森生物科技)	III	2022/01	Zagreb 4 doses & Essen 5 doses

Note: The dates for products in BLA stage are the dates handled by the CDE.

Sources: CDE, Frost & Sullivan

Our Advantages

We believe our lyophilized human rabies vaccine candidate has the following advantages.

- *Superior safety profile*. Rabies vaccines developed based on human diploid cells stand as the "gold standard" recommended by the WHO, showcasing superior safety profiles. A meta-analysis of 27 clinical studies involving 18,630 participants revealed that rabies vaccines developed based on human diploid cells had a significantly lower overall adverse reaction incidence compared to primary chicken embryo cell rabies vaccines and lower rates of fatigue and local pain/fever compared to vaccines developed based on Vero cells, evidencing their safety potential. In addition, our vaccine candidate is developed from 8^{th} generation human diploid cells, which are less prone to genetic mutation compared to the commonly used 10^{th}-30^{th} generation cells, ensuring better cell vitality, higher virus production efficiency and enhanced safety. Furthermore, our advanced purification technologies could reduce the residual bovine serum albumin (which may cause allergic reactions in certain population) well below the Chinese Pharmacopoeia standards, the regulatory benchmark for rabies vaccines in China.

- *Convenient administration with pre-filled diluent syringe*. Our rabies vaccine candidate leverages a combination of lyophilized formulation and pre-filled diluent syringe, providing a more convenient vaccination experience without compromising the efficacy of the active ingredients. Pre-filled syringe diluents simplify the vaccination process and lower contamination risks by eliminating the need for manual extraction and preparation, which is required for traditional vial-and-syringe methods.

- *Flexible vaccination schedules providing more options for vaccinees*. We are developing our rabies vaccine candidate under the Essen regimen (five doses), Zagreb regimen (four doses) and a simplified four-dose regimen, each offering distinct advantages. The four-dose regimens are particularly appreciated for their convenience and cost-effectiveness, potentially enhancing adherence to the vaccination schedule, while the five-dose regimen is widely adopted due to its established track record. All regimens are designed to ensure effective immunological protection, giving vaccinees and healthcare providers the flexibility to select the most suitable regimen based on individual needs or clinical circumstances. This adaptability strengthens our competitive standing in county-level tenders.

Summary of Clinical Trials

We conducted a Phase I clinical trial of our lyophilized human rabies vaccine candidate in healthy participants aged 10-60 years in China to evaluate the safety of the candidate. We completed such trial in October 2024 and plan to commence a Phase III clinical trial in the second or third quarter of 2025.

Phase I Clinical Trial

- *Trial design*. This trial was a randomized and single-arm trial with an age de-escalation design. The objective of the trial was to assess the safety of different immunization schedules for our rabies vaccine candidate (the study vaccine).

  Participants in the Essen group would receive 1 dose each (1.0ml per dose) on day 0, 3, 7, 14 and 28 (5 doses in total), while participants in the Zagreb group would receive 2 doses on day 0 and 1 dose each on day 7 and 21 (4 doses in total). The trial would begin with the enrollment of 40 participants aged 18-60 years, who would be randomized in a 1:1 ratio to the Essen or Zagreb group and receive the study vaccine. Following at least seven days of observation after the administration of the third dose, an initial safety assessment would be conducted. If the incidence of grade 3 or higher vaccination-related AEs did not exceed 15% and no vaccination-related deaths or life-threatening SAEs occurred, the study would proceed to enroll 40 participants aged 10-17 years. These participants would also be randomized in a 1:1 ratio to the Essen or Zagreb group to undergo safety evaluation. All participants were involved in safety assessments, with follow-up extending to 6 months after complete immunization. In the simplified four-dose

regimen, participants are required to receive a dose on days 0, 3, and 7 (the same as the Essen regimen), with the final dose administered between days 14 and 28. We believe its safety can be evaluated using safety data from the Essen regimen. Therefore, a separate group for the simplified four-dose regimen was necessary in this trial.

- *Trial status*. The trial was initiated in November 2023 and completed in October 2024. A total of 80 participants were enrolled in the trial, with 40 participants in the 18-60 years age group and 40 participants in the 10-17 years age group. Within each age group, 20 participants were allocated to the Essen group and 20 participants to the Zagreb group. The distribution of participants in each group was balanced and comparable with respect to baseline age and gender demographics. All participants were included in the SST.

- *Safety*. In this trial, 20 participants (50.0%) in the Essen group reported 49 instances of vaccination-related AEs, and 17 participants (42.5%) in the Zagreb group reported 42 instances of vaccination-related AEs. Vaccination-related AEs primarily occurred within the first seven days after the initial dose. There was no significant difference between the incidences of AE of the Essen and Zagreb groups within seven days following the initial dose. All AEs lasted approximately one to two days, with severity mainly of grade 1 and grade 2. Three participants reported three instances of grade 3 AEs (two in the Essen group and one in the Zagreb group), all of which were fever and likely vaccination-related. No AEs exceeding grade 3 were reported. No vaccination-related SAE was reported in this trial. All AEs were resolved with symptoms disappearing (no sequelae).

- *Conclusion*. Our rabies vaccine candidate demonstrated a favorable safety profile in participants aged 10-60 years under the Essen and Zagreb regimens.

Summary of Preclinical Study Results

We conducted a series of preclinical studies to characterize the safety and immunogenicity profile of our rabies vaccine candidate under different regimens.

- *Safety*. Our rabies vaccine candidate demonstrated a good safety profile in preclinical safety studies. In an active systemic anaphylaxis test of our rabies vaccine candidate conducted in guinea pigs, the minimum and maximum doses resulting in anaphylaxis (severe allergic reaction) were approximately 20 times and 200 times of the clinically intended dose of 1ml, respectively. In an acute toxicity test conducted in rats, the maximum tolerated dose was 2 doses (2ml per dose) per rat. In a muscle irritation test conducted in New Zealand rabbits, our rabies vaccine candidate was administered intramuscularly at a dose level of 1.0ml per rabbit with a total of 4 doses. Local irritation was observed approximately 72 hours and 14 days after the final administration, showing a trend toward recovery.

- *Immunogenicity*. Under the five-dose regimen, our rabies vaccine candidate elicited IgG antibody levels of greater than 0.5 IU/ml in mice 14 days after the first dose and average antibody levels higher than those elicited by the marketed rabies vaccine in the control group. Under the Zagreb and simplified four-dose regimens, our rabies vaccine candidate demonstrated non-inferior immunogenicity (as measured by neutralizing antibody titers and serum IgG antibody titers) in mice compared to the marketed five-dose regimen in the control group and achieved a 100% seroconversion rate 14 days after the first dose, indicating a favorable immunogenicity profile.

We also conducted stability tests of the finished lyophilized product of our rabies vaccine candidate, which exhibited good stability when stored at 37±2°C for 28 days, 25±2°C for 6 months and at 5±3°C for 24 months.

Material Communications and Next Steps

In November 2022, after reviewing our IND application, which included proposed trial designs for both Phase I and Phase III clinical trials, the NMPA granted an IND approval for Phase I and Phase III clinical trials of our lyophilized human rabies vaccine candidate (Essen regimen) in individuals aged 10-60 years. A Phase II trial may not be required for certain types of vaccines if prior data from similar vaccines demonstrate sufficient safety and immunogenicity, allowing regulatory agencies to expedite progression to Phase III trial review. According to Frost & Sullivan, it is not uncommon for the development of human rabies vaccines in China to proceed directly from a Phase I clinical trial to a Phase III trial. In April 2023, we received the approval for our supplemental clinical trial application (also including relevant trial designs for both Phase I and Phase III clinical trials) to incorporate the Zagreb and simplified four-dose regimens to our previously approved clinical trials. We completed the Phase I clinical trial in October 2024 and submitted a Development Safety Update Report ("DSUR") which included key safety results from the Phase I clinical trial to the NMPA in December 2024. We plan to initiate a Phase III clinical trial in the second or third quarter of 2025. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans. Based on the above circumstances, our PRC Legal Advisors are of the view that as of the Latest Practicable Date the NMPA had no objection to the expected commencement of our Phase III clinical trial. No material adverse changes had occurred since the IND approval and up to the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET LYOPHILIZED HUMAN RABIES VACCINE (HUMAN DIPLOID CELL) SUCCESSFULLY.

Our Other Product Candidates

PPSV23

PPSV23 is a well-established and widely accepted vaccine aimed at offering extensive protection against 23 different serotypes of *Streptococcus pneumoniae* (pneumococcus), which can lead to various pneumococcal diseases. These can be divided into invasive pneumococcal diseases, such as bacteremia (the presence of bacteria in the blood, which can progress to sepsis when the immune system overreacts to the infection and attacks normal tissues and organs), and non-invasive ones, such as otitis media (infection of the middle ear) and bronchitis (inflammation of the bronchial tubes). Currently, antibiotic therapy is the first choice for treatment of pneumococcal disease. However, pneumococcus bacteria have shown significant resistance to many commonly used antibiotics, which remains a significant issue in many Asian countries due to extensive antibiotic use and low vaccine coverage, according to Frost & Sullivan. Hence, preventive measures, especially the use of vaccines, are increasingly necessary. PPSV23 is the primary pneumococcal vaccine for adults in China. It is recognized for its efficacy across diverse age groups and authorized for use in all adults aged 50 or above and anyone aged two years or above with certain medical conditions that can lead to an increased risk for pneumococcal disease.

We acquired our PPSV23 candidate from Beijing Hua'an Science and Technology Innovation Biotechnology Co. Ltd.* (北京華安科創生物技術有限公司) ("Beijing Hua'an") in May 2020. Certain technologies underlying the PPSV23 candidate had been licensed by Beijing Hua'an from Tianjin CanSino Biotechnology Inc. (天津康希諾生物技術有限公司). Through a series of agreements, we (i) obtained a license to use the relevant technologies; and (ii) will obtain the ownership of such technologies upon full payment of certain milestone-installed fees. See "—Our Technology Transfer Arrangements—PPSV23 Technology Transfer Agreements" for more details.

We conducted and successfully completed a Phase I clinical trial of the PPSV23 candidate in April 2023, which demonstrated a promising safety and preliminary immunogenicity profile. Following the completion of the Phase I clinical trial, we conducted additional studies for process improvement, such as isolation and purification technology improvement, to enhance the safety profile of the PPSV23 candidate. As of the Latest Practicable Date, we were undertaking relevant process validation. We plan to initiate a Phase III clinical trial in the fourth quarter of 2025 or the first quarter of 2026 to further investigate the candidate's safety and protective efficacy across a broader population.

Mechanism of Action

PPSV23 contains purified polysaccharides from the outer capsule of 23 serotypes of the *Streptococcus pneumoniae*. Upon administration, B cells recognize the polysaccharides as antigens and produce specific antibodies against them. Such antibodies circulate in the bloodstream and bind to the *Streptococcus pneumoniae* when encountered, facilitating their subsequent destruction by other immune cells, such as macrophages and neutrophils, and preventing them from causing infection. While the antibodies produced by PPSV23 provide prolonged protection, the levels of these antibodies may wane over time. To maintain sustained immunity, booster vaccinations might be necessary, particularly for those at higher risk of pneumococcal diseases.

Market Opportunity and Competition

Pneumococcal vaccines can be classified into several types, among which polysaccharide vaccines, such as PPSV23, and conjugate vaccines are most commonly used for different age groups. PPSV23 and 13-valent pneumococcal conjugate vaccines (PCV13) are the only two types of pneumococcal vaccines currently available in the PRC. We are also developing a PCV candidate. See "—24-valent Pneumococcal Conjugate Vaccine (PCV24)" below for details. A number of pneumococcal vaccines are available outside China, including 7-valent pneumococcal conjugate vaccines (PCV7), 10-valent pneumococcal conjugate vaccines (PCV10), PCV13, 15-valent pneumococcal conjugate vaccines (PCV15), 20-valent pneumococcal conjugate vaccines (PCV20) and PPSV23.

The pneumococcal vaccine market in China increased from RMB5.1 billion in 2019 to RMB9.2 billion in 2023 in terms of production value, at a CAGR of 15.8%. It is expected to further increase to RMB19.0 billion in 2032, at a CAGR of 8.4% from 2023 to 2032.

Specifically, the PPSV23 market in China reached RMB1.8 billion in 2019 in terms of production value and 9.5 million in terms of the total number of lot release. Driven by the increasing awareness of pneumonia after the COVID-19 outbreak in 2020, the PPSV23 market increased significantly, in line with the overall pneumococcal vaccine market, to RMB3.4 billion in terms of production value and 17.4 million in terms of the total number of lot release in 2020. After the marketing of COVID-19 vaccines in 2021, the market size and lot release of PPSV23 declined, remaining at approximately the same level as in 2019. However, with the increasing number of available products in China, the PPSV23 market is expected to grow in the next few years, reaching RMB5.5 billion in 2032.

As of the Latest Practicable Date, there were nine marketed pneumococcal vaccines in China, including six PPSV23 and three PCV13. The following table sets forth details of marketed pneumococcal vaccines in China as of the Latest Practicable Date.

Type	Brand Name (Generic Name)	Technical Route	Manufacturer	NMPA approval date*	Age Coverage
23-valent	PNEUMOVAX (紐莫法)	Polysaccharide	MSD	2010/02	50 years of age and older; 2 years of age and older who are at increased risk
	沃朵菲		Walvax (沃森生物)	2017/03	2 years of age and older who are at increased risk
	維民菲樂		Minhai (民海生物)	2018/08	2 years of age and older who are at increased risk
	惠益康		Chengdu Institute of Biological Products (成都生物製品研究所)	2020/07	2 years of age and older who are at increased risk
	23-valent Pneumococcal Polysaccharide Vaccine		Sinovac (科興)	2020/12	2 years of age and older who are at increased risk
	優威克		ZFSW (智飛生物)	2023/08	2 years of age and older who are at increased risk
13-valent	Prevnar 13	Polysaccharide Conjugate	Pfizer	2016/10	6 weeks through 5 years of age
	維民菲寶		Minhai (民海生物)	2021/09	6 weeks through 5 years of age
	Weuphoria (沃安心13)		Walvax (沃森生物)	2019/12	6 weeks through 5 years of age

Note: The approval date is the time when the vaccine was first approved, without considering age-group expansion.

Sources: NMPA, Frost & Sullivan

As of the Latest Practicable Date, there were 20 pneumococcal vaccine candidates under clinical development in China, primarily including 9 PCV13, 4 PCV24 and 3 PPSV23 (including our PPSV23 candidate). The following table sets forth details of our PPSV-23 candidate and other pneumococcal vaccine candidates in China as of the Latest Practicable Date.

Type	Technical Route	Manufacturer	Clinical Stage	First Posted Date*	Age Coverage
23-valent	Polysaccharide	Lanzhou Institute of biological products (蘭州生物製品研究所)	III (completed)	2015/12	2 years of age and older
		AIM (艾美疫苗)	III	2023/8	2 years of age and older
		our Company	I (completed)	2020/9	2 years of age and older
13-valent	Polysaccharide conjugate	Lanzhou Institute of Biological Products (蘭州生物製品研究所)	BLA	2023/03	2 months through 5 years of age (at least 6 weeks of age)
		CanSino (康希諾)	III	2021/4	7 months through 5 years of age
			III	2021/4	6 weeks through 3 months of age
			BLA	2024/02	*The age for submitting BLA for this product has not been disclosed
		AIM (艾美疫苗)	BLA	2024/11	2 months through 5 years of age (at least 6 weeks of age)
		Fosun Adgenvax (復興安特金)	III	2022/5	2-3 months of age (at least 6 weeks of age)
		Sinovac (科興)	III	2023/10	2 months through 5 years of age (at least 6 weeks of age)
		Kunli Biopharmaceutical (坤力生物)	I	2021/7	2 months through 59 years of age (at least 6 weeks of age)
		Microvac Biotech (微超生物)	I	2022/3	2 months through 49 years of age (at least 6 weeks of age)
		BravoVax, Chengda (博沃生物，遼寧成大)	I	2022/10	2 months of age and older (at least 6 weeks of age)
		Chengdu Institute of Biological Products (成都生物製品研究所)	I	2023/3	2 months through 59 years of age (at least 6 weeks of age)
24-valent	Polysaccharide conjugate	ZFSW (智飛生物)	III	2020/12	2-3 months of age (at least 6 weeks of age)
		Reinovax (瑞宙生物)	II	2024/4	18 years of age and older
			I	2024/4	6 weeks through 5 years of age
		Kunli Biopharmaceutical (坤力生物)	I/II	2022/2	65 years of age and older
		Sinovac (科興)	I	2024/8	2-17 years of age
			I	2024/6	18 years of age and older
15-valent	Polysaccharide conjugate	ZFSW (智飛生物)	I/II	2024/8	2 months of age and older (at least 6 weeks of age)
26-valent	Polysaccharide conjugate	Microvac Biotech (微超生物)	I	2023/4	2 months through 55 years of age (at least 6 weeks of age)
20-valent	Polysaccharide conjugate	Innovax Biotech (萬泰滄海生物)	I	3023/3	6 weeks of age and older
	Polysaccharide conjugate	Minhai (民海生物)	I	2024/11	2 months through 59 years of age

Note: The dates for products in BLA stage are the dates handled by the CDE.

Sources: CDE, Frost & Sullivan

Our Advantages

We believe our PPSV23 candidate has the following advantages.

- *Comprehensive protection and promising immunogenicity*. Our PPSV23 candidate is designed to provide extensive protection against pneumococcal infections caused by 23 of the most prevalent and invasive serotypes. Our Phase I clinical trial demonstrated that the PPSV23 candidate generated robust immunogenic responses in participants aged two years and above, suggesting significant vaccine efficacy.

- *Enhanced safety profile through advanced manufacturing technologies*. In our Phase I clinical trial, the incidence of vaccination-related AEs was lower in the PPSV23 group compared to the control group (25.00% vs. 37.50%). In addition, we undertook significant process improvement, which include the use of ion-exchange chromatography instead of ethanol precipitation, thereby eliminating harmful substances like ethanol and phenol and enhancing product safety. Moreover, our production process employs a closed-system design that facilitates automation and sterile operation, thereby minimizing contamination risks and ensuring product safety. This design also improves operational efficiency by reducing the time and costs associated with cleaning and validating manufacturing facilities.

Summary of Clinical Trials

Following the transfer of the PPSV23 candidate, we organized and conducted a Phase I clinical trial in healthy participants aged two years and above in China. We were responsible for initiating, managing and organizing the Phase I clinical trial, ensuring its precise execution. Our specific responsibilities included (i) formulating trial design and obtaining requisite approval from ethics committee; (ii) engaging third parties including CROs and site managers for their services during the trial and monitoring their performance; (iii) reviewing and finalizing the CSR; and (iv) providing funding for the trial. Subsequent to the completion of the Phase I clinical trial in April 2023, we conducted further process improvement through independent research and development.

Phase I Clinical Trial

- *Trial design*. This trial was a randomized, blinded, parallel-controlled clinical trial in healthy participants aged two years and above. The objectives of the trial were to evaluate the safety and preliminarily explore the immunogenicity of our PPSV23 candidate in this age group.

  In a sequential enrollment design starting with the 18-59 years group, followed by the ≥60 years group, and then the 2-17 years group, 48 participants would be enrolled in each age group and randomly assigned in a 1:1 ratio to receive one dose of either our PPSV23 candidate (0.5ml) or the control vaccine (0.5ml of a marketed PPSV23 manufactured by an international pharmaceutical company). Safety evaluation would be conducted on day eight after the initial dose, and subsequent enrollment of the next age group would proceed only if preliminary safety assessment results could meet protocol requirements. The follow-up would include the monitoring of AEs from day 0 to day 28 post-vaccination and SAEs for six months. Blood samples would be collected before vaccination and 28 days post-vaccination for serum antibody testing.

- *Trial status*. The trial was initiated in September 2020 and completed in April 2023. A total of 144 participants (48 in each age group) were enrolled in this trial, all of whom were included in the SST and FAS and 143 were included in the PPS.

- *Safety*. In the entire participant population, the overall incidences of vaccination-related AE in the PPSV23 group and the control group were 25.00% and 37.50%, respectively. The vaccination-related AEs were mild, all being of grade 1 and grade 2. The most common symptoms were injection site pain and injection site redness. No vaccination-related SAE or AE of grade 3 or above was observed.

- *Immunogenicity*. In the overall participant population, the seroconversion rate of PN4 IgG neutralizing antibody was higher in the PPSV23 group compared to the control group and the seroconversion rate of PN20 antibody was lower in the PPSV23 group compared to the control group, with both differences being statistically significant. There were no statistically significant differences in seroconversion rates between the PPSV23 and control groups for the other 21 serotypes. The PPSV23 group showed lower geometric mean concentration (GMC) of PN20 IgG neutralizing antibody than the control group, with a statistically significant difference. This difference was primarily observed in the ≥60 years age group. For the other 22 serotypes, there were no statistically significant differences in antibody GMC levels between the PPSV23 group and the control group. Increases in the GMC of IgG neutralizing antibodies for all serotypes were observed post-vaccination in both the PPSV23 and control groups when compared to pre-vaccination levels.

- *Conclusion*. In this trial, our PPSV23 candidate demonstrated good safety in participants aged two years and above, while also preliminarily showing promising immunogenicity.

Post Phase I Clinical Trial Process Improvement

Our process improvement includes designing and constructing manufacturing facilities for process transfer, conducting process research and validation on a commercial scale and performing stability and container content compatibility studies on the final product.

We employed the ion-exchange column chromatography technique instead of ethanol precipitation, thereby eliminating harmful substances like ethanol and phenol and enhancing product safety. Additionally, we have undertaken multiple rounds of process optimization involving sample loading rates, loading volumes and buffer formulations, which have significantly improved the polysaccharide yield and purity for certain serotypes. Our production process employs a closed-system design that facilitates full automation control of the fermentation system, seamlessly integrating with the media preparation system, buffer preparation system, and clean-in-place station system. This allows for completely enclosed and sterile operations, significantly reducing contamination risks and ensuring product safety.

Material Communications and Next Steps

Subsequent to the completion of the Phase I clinical trial, we submitted DSURs, including one in December 2024, to the NMPA. We plan to initiate a Phase III clinical trial of the PPSV23 candidate in the fourth quarter of 2025 or the first quarter of 2026 to further investigate its safety and efficacy. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans and no material adverse changes had occurred in the development of the product candidate up to the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET PPSV23 SUCCESSFULLY.

Trivalent Subunit Influenza Vaccine

In order to better adapt to the evolving virological landscape of influenza viruses and cater to diverse immunization needs of the vast market in China, we decided to develop a trivalent subunit influenza vaccine in addition to our quadrivalent subunit influenza vaccine. Our trivalent subunit influenza vaccine candidate aims to provide protection against two influenza A viruses (H1N1 and H3N2 subtypes) and one influenza B virus (Victoria lineage), aligning with the coverage recommended by the WHO for the 2024-2025 northern hemisphere influenza season.

Our trivalent subunit influenza vaccine candidate leverages the established formulation of our approved quadrivalent subunit influenza vaccine, using the same bulk antigen with one influenza B virus subtype (Yamagata) omitted in the formulation. Given the substantial similarity in the production process, no additional clinical trials were required beyond those conducted for our quadrivalent vaccine. However, we were required to undertake immunogenicity studies to assess the protective efficacy of the trivalent formulation. In the immunogenicity studies conducted in mice, our trivalent subunit influenza vaccine candidate demonstrated significant protection, with markedly higher neutralizing antibody GMT levels in the vaccine group than the control group (with a marketed split-virion influenza vaccine). We also performed stability studies and compatibility assessments with internal packaging materials to ensure the integrity and efficacy of the trivalent vaccine.

Drawing on these findings, combined with preclinical and clinical results of our quadrivalent subunit influenza vaccine, we filed an NDA for the trivalent subunit influenza vaccine candidate for (i) individuals aged 3 years and above and (ii) the 6-35 months age group, which were accepted by the NMPA in September 2024. As of the Latest Practicable Date, we were also developing an adjuvanted version of the vaccine candidate for individuals aged 65 years and above. See "—Adjuvanted Trivalent Subunit Influenza Vaccine" for details.

Mechanism of Action

Our trivalent subunit influenza vaccine candidate has the same mechanism of action as our quadrivalent subunit influenza vaccine. See "—Our Core Products—Quadrivalent Subunit Influenza Vaccine—Mechanism of Action" for details.

Market Opportunity and Competition

As of the Latest Practicable Date, there were 19 marketed influenza vaccines in China, including 10 trivalent vaccines and 9 quadrivalent vaccines. As of the same date, there were 16 influenza vaccine candidates under clinical development in China, including 4 trivalent vaccines and 12 quadrivalent vaccines. See "—Our Core Products—Quadrivalent Subunit Influenza Vaccine—Market Opportunity and Competition" for details.

Our Advantages

See "—Our Core Products—Quadrivalent Subunit Influenza Vaccine—Mechanism of Action" for details.

Material Communications and Next Steps

The NDAs for our trivalent subunit influenza vaccine candidate for individuals aged 3 years and above and aged 6-35 months were accepted by the NMPA in September 2024. Upon approval, we expect the NMPA will require post-approval studies of the vaccine similar to those required for our quadrivalent vaccine. We plan to promptly initiate commercial manufacturing and sales of the vaccine leveraging our established in-house manufacturing facilities and sales team. See "—Manufacturing" and "—Commercialization" for details. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans and no material adverse changes had occurred since the submission of the NDA and up to the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TRIVALENT SUBUNIT INFLUENZA VACCINE SUCCESSFULLY.

Adjuvanted Quadrivalent Subunit Influenza Vaccine

We are developing an adjuvanted version of our quadrivalent subunit influenza vaccine indicated for individuals aged 65 years and above. The impact of influenza on the elderly, particularly those over the age of 65, is more severe due to the natural decline in immune function with age. This demographic is at heightened risk for severe illness and mortality from influenza infections, leading to significant health impacts and economic burdens. Recognizing the critical need for effective vaccination in this population, the FDA has approved adjuvanted and high-dose influenza vaccines indicated for individuals aged 65 years and above. We are the first company in China to obtain an IND approval for an adjuvanted quadrivalent subunit influenza vaccine, specifically formulated to enhance efficacy in this age group.

Our adjuvanted quadrivalent subunit influenza vaccine candidate employs the marketed MF59 adjuvant, an oil-in-water adjuvant composed primarily of squalene, which activates bone marrow-derived cells such as macrophages and dendritic cells upon injection. These activated cells produce chemokines that recruit various immune cells to the injection site, amplifying the immune response and helping activate B and T cells in the lymph nodes, which enhances both the strength and duration of the immune response. We manufacture the vaccine candidate using WHO-recommended influenza A and B viral strains, cultivated in chicken embryos, followed by a series of purification processes similar to those of our quadrivalent subunit influenza vaccine, before blending with the MF59 adjuvant to form the multi-strain formulation.

In various studies, MF59-adjuvanted influenza vaccines demonstrated significant advantages over non-adjuvanted versions, particularly in boosting antibody titers and efficacy among the elderly. In preclinical studies, our adjuvanted quadrivalent subunit influenza vaccine demonstrated strong immunogenic profile, with significantly higher neutralizing antibody titers post-immunization compared to (i) pre-immunization levels and (ii) those induced by non-adjuvanted vaccines. Our adjuvanted quadrivalent subunit influenza vaccine candidate also showed a good safety profile in our toxicity tests and active anaphylaxis tests. The toxicity tests showed no significant adverse changes except for the expected adjuvant-related local inflammation, which was reversible after a brief hiatus. In the active anaphylaxis tests in guinea pigs, subjects receiving a low dose of 0.2 doses (0.1ml) per animal of our vaccine candidate showed negative results, while those administered a high dose of 1 dose (0.5ml) per animal exhibited positive results, indicating a dose-dependent hypersensitivity response. The low dose administered corresponded to 20 times the intended clinical dose, suggesting a substantial safety margin.

We obtained an IND approval for our adjuvanted quadrivalent subunit influenza vaccine candidate in July 2024 and expect to initiate a Phase I clinical trial in the second or third quarter of 2025.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ADJUVANTED QUADRIVALENT SUBUNIT INFLUENZA VACCINE SUCCESSFULLY.

Adjuvanted Trivalent Subunit Influenza Vaccine

We are also developing an adjuvanted version of our trivalent subunit influenza vaccine candidate, which has similar mechanism of action, formulation process and manufacturing process as the adjuvanted quadrivalent subunit influenza vaccine candidate, with one influenza B virus subtype (Yamagata) omitted during formulation. We obtained an IND approval for our adjuvanted trivalent subunit influenza vaccine candidate in October 2024 and expect to initiate a Phase I clinical trial in the second or third quarter of 2025.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ADJUVANTED TRIVALENT SUBUNIT INFLUENZA VACCINE SUCCESSFULLY.

Recombinant Zoster Vaccine (CHO cell)

We are developing a recombinant zoster (shingles) vaccine candidate with self-developed dual adjuvants indicated for individuals aged 40 years and above. Herpes zoster is caused by the reactivation of the varicella-zoster virus (VZV) after initial infection. The reactivation typically occurs when an individual's immunity to VZV diminishes due to aging or immunosuppression. Therefore, herpes zoster's incidence rise significantly with advancing age and can lead to a general sense of malaise, fever, chills, muscle aches, headache, itching and intense pain for certain people.

In preclinical animal studies, our recombinant zoster vaccine candidate stimulated stronger cell-mediated immune responses crucial for fighting VZV infections compared to a marketed recombinant zoster vaccine developed by an international pharmaceutical company, which could potentially translate into stronger protective efficacy. We obtained an IND approval for Phase I and Phase II trials of our recombinant zoster vaccine candidate in August 2024 and plan to initiate a Phase I trial in the first quarter of 2025.

Mechanism of Action

The recombinant zoster vaccine utilizes DNA recombinant technology to integrate the truncated glycoprotein E (gE) coding sequence of the VZV into Chinese hamster ovary (CHO) cells. This process allows for the expression and subsequent purification of the gE protein antigen, which forms the core component of the vaccine. Following administration, the gE protein antigen, with the assistance of marketed adjuvants MF59 and CpG1018, activates the immune system to elicit a specific immune response. CpG1018 activates plasmacytoid dendritic cells (pDCs) and B cells, leading pDCs to secrete pro-inflammatory and antiviral cytokines and migrate to lymphoid tissues, thereby stimulating a T helper 1 (Th1) cell-mediated response. The activated B cells differentiate into antibody-secreting plasma cells. MF59 enhances antigen uptake, recruits immune cells to the injection site, and aids in the presentation and transport of antigen by monocytes and neutrophils to lymph nodes. When combined, MF59 and CpG1018 synergistically induce a more robust antibody production and Th1-type cellular immune response than either adjuvant alone, enabling a rapid immune reaction to prevent virus reactivation and thus effectively preventing herpes zoster.

Market Opportunity and Competition

Currently, marketed zoster vaccines include live attenuated vaccines and recombinant vaccines. The live attenuated zoster vaccine can enhance VZV-specific cell-mediated immunity in elderly individuals. However, its efficacy diminishes with increasing age and diminishes significantly after six to eight years post-vaccination. In contrast, the recombinant zoster vaccine demonstrates superior efficacy in elderly individuals and remains robust irrespective of the age of the vaccinee, with immune response persisting six to nine years after vaccination.

As of the Latest Practicable Date, there were two marketed zoster vaccines in China, including one recombinant vaccine and one live attenuated vaccine. As of the same date, there were nine zoster vaccine candidates under clinical development in China, including seven recombinant vaccines and two live attenuated vaccines.

Our Advantages

Our recombinant zoster vaccine candidate utilizes a proprietary gE sequence, paired with a highly efficient cell culture system, allowing protein expression levels to exceed 2g/L with stable processes and low commercial scale production costs. It adopts an innovative dual-adjuvant system that is expected to significantly enhance both cellular and humoral immune responses. Compared to a marketed recombinant zoster vaccine developed by an international pharmaceutical company, our vaccine candidate elicited superior cell-mediated immune responses in animal models (detected by ELISpot and ICS assays), indicating a potentially stronger immunogenicity profile. Specifically, our vaccine stimulated a higher frequency of IL-2 and IFN-γ secreting cells in ELISpot assays and a greater proportion of $CD4^+$ T cells expressing gE-specific cytokines such as IL-2, IFN-γ and TNF-α in ICS assays. Additionally, our investigational vaccine has demonstrated a good overall safety profile. See "—Summary of Preclinical Study Results" below for details.

Summary of Preclinical Study Results

We conducted a series of preclinical studies to characterize the safety and immunogenicity profile of our recombinant zoster vaccine candidate.

- *Safety*.

  Toxicity studies: In a single-dose toxicity study in rats, no animals in any group exhibited impending death, mortality or other severe toxic reactions, with the maximum tolerated dose (MTD) of our vaccine candidate being greater than two doses (50μg/0.5ml each dose) per rat. In the repeat-dose toxicity study in rats, no animals experienced impending death, mortality or other severe toxic reactions. The no observed adverse effect level (NOAEL) of our vaccine candidate was determined to be one dose (50μg/0.5ml) per rat. In the repeat-dose toxicity study in cynomolgus monkeys, no animals in any group showed impending death, mortality or other significant toxic reactions. The NOAEL was 2 doses per monkey.

Active systemic anaphylaxis tests: In a multiple-dose active systemic anaphylaxis test in Hartley guinea pig, where three consecutive doses (once every other day) of our vaccine candidate were administered through intramuscular injections, the test animals showed extremely positive systemic anaphylaxis. However, there were no allergic symptoms in cynomolgus monkey studies and considering that the intended clinical dosing frequency of our vaccine candidate is low, and the administration route is non-intravenous, it is postulated that clinical administration may not induce allergic reactions or severe anaphylaxis in humans. In conclusion, our recombinant zoster vaccine candidate exhibits a good safety profile, supporting its advancement into clinical trials in humans.

- *Immunogenicity*. In both the ELISpot and ICS assays conducted in mice and rats, our recombinant zoster vaccine candidate stimulated stronger cell-mediated immune responses compared to a marketed recombinant zoster vaccine developed by an international pharmaceutical company in terms of frequency of IL-2, IFN-γ and TNF-α secreting cells, indicating a potentially stronger immunogenicity profile. The vaccine candidate also demonstrated a robust cell-mediated immune response profile in similar studies conducted in cynomolgus monkeys.

Material Communications and Next Steps

We obtained an IND approval for recombinant zoster vaccine candidate in August 2024 and plan to initiate a Phase I clinical trial in the first quarter of 2025. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans and no material adverse changes had occurred in the development of the product candidate up to the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET RECOMBINANT ZOSTER VACCINE SUCCESSFULLY.

Recombinant RSV Vaccine (CHO Cell)

RSV is one of the significant pathogens responsible for respiratory tract infections in infants, the elderly and immunocompromized individuals. Clinically, it primarily manifests as symptoms of acute respiratory infection, with lower respiratory tract infection being the predominant form. Severe cases can be life-threatening. In China, RSV ranked second among pathogens causing acute respiratory infections in adults and first among those in children from 2009 to 2019, according to China CDC. According to Frost & Sullivan, there were approximately 4.1 million new cases of acute lower respiratory tract infections caused by RSV in China in 2023 and the incidence of RSV infection in adults increases with age. We are developing (i) the recombinant RSV vaccine candidate to provide protection for adults, including pregnant women, against acute RSV infections and associated severe lower respiratory tract diseases and (ii) the mRNA RSV vaccine candidate indicated for individuals aged 60 years and above. See "—mRNA RSV Vaccine" below for details.

Existing RSV vaccines primarily utilize the F protein as the immunogen, which exits in two states: prefusion (pre-F) and postfusion (post-F). Pre-F is notably more immunogenic than post-F. However, instability during *in vitro* expression often causes pre-F to transition to the less effective post-F form. Our recombinant RSV vaccine candidate employs a stabilized pre-F protein sequence, licensed from the U.S. National Institute of Allergy and Infectious Diseases (NIAID, see "—Our Technology Transfer Arrangements—NIAID Technology Licensing Agreement" for details), derived and refined from the first-generation RSV pre-F protein for enhanced thermal stability and immunogenicity. In addition, our recombinant RSV vaccine candidate also incorporates marketed MF59 and CpG1018 adjuvants that are designed to stimulate more robust antibody production and cellular immune response.

Our recombinant RSV vaccine candidate is developed based on CHO cells and expresses the modified pre-F protein. After extensive screening, we have obtained high-yield monoclonal cell lines capable of stably expressing the pre-F protein. In our preclinical studies, it demonstrated higher pre-F expression levels, better thermal stability and superior immunogenicity than the marketed recombinant RSV vaccines. According to their previously published results, the expression levels of the pre-F protein in marketed recombinant RSV vaccines range from 600mg/L to 800mg/L. In contrast, our high-yield cell line produces pre-F protein at approximately 1,000mg/L to 1,500mg/L. Preclinical studies showed that after storage at 40°C for 14 days, our pre-F protein retains over 95% activity, while marketed products decrease to around 50% activity. Due to its superior stability, our product is formulated as a liquid rather than a lyophilized form, unlike the approved products. In our preclinical immunogenicity study conducted in mice, our vaccine candidate achieved a much higher GMT of neutralizing antibodies than a similar marketed product. It also demonstrated a good safety profile in our toxicity studies and active systemic anaphylaxis test.

We submitted a pre-IND application to the NMPA for our recombinant RSV vaccine candidate in December 2024. As of the Latest Practicable Date, we had produced three pilot-scale batches of drug substance and drug product under GMP conditions, with protein purity exceeding 95.0%, and completed stability and safety tests for the vaccine candidate. We plan to submit an IND application to the NMPA and the FDA, respectively, in the second or third quarter of 2025.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET RECOMBINANT RSV VACCINE SUCCESSFULLY.

mRNA RSV Vaccine

Our mRNA RSV vaccine candidate is indicated for individuals aged 60 years and above and aims to provide protection against acute RSV infections and associated severe lower respiratory tract diseases.

The mRNA RSV vaccine candidate utilizes synthetic mRNA, which is engineered to encode the RSV pre-F protein and encapsulated in lipid nanoparticles (LNPs) that protect the mRNA from degradation and facilitate its cellular uptake. Once inside the target cells, the host ribosomes translate the mRNA into the pre-F protein, which is subsequently displayed on the cell surface. This presentation triggers the immune system, promoting the production of neutralizing antibodies by B cells and activating T cell-mediated immunity. Our mRNA RSV vaccine candidate utilizes the same pre-F protein design as our recombinant RSV vaccine candidate, with superior structural stability and an absence of non-functional exogenous sequences.

Except from protective neutralizing antibodies, the vaccine candidate's designed capability to induce strong cellular immune responses represents a unique advantage for improving protection in the elderly and immunocompromised populations. In addition, compared to traditional vaccines, mRNA vaccines can be designed and manufactured much faster. Once the genetic sequence of a new variant is known, the mRNA sequence could be quickly modified to encode for the new antigen, allowing for rapid response to emerging strains and ensuring efficacy of the vaccine.

Our mRNA RSV vaccine demonstrated a promising immunogenicity profile in preclinical animal studies, inducing high levels of pre-F-specific binding antibodies, neutralizing antibodies against RSV group A and B strains and antigen-specific $CD4^+$ T cell and $CD8^+$ T cell responses. Additionally, the $CD8^+$ T cell immune response exhibited a Th1 bias, indicating a lower risk of vaccine-enhanced disease (VED). As of the Latest Practicable Date, we were conducting preclinical studies of the vaccine candidate. We expect to submit a pre-IND application to the NMPA in the third or fourth quarter of 2025.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MRNA RSV VACCINE SUCCESSFULLY.

mRNA Monkeypox Vaccine

Monkeypox is caused by the monkeypox virus, a member of the orthopoxvirus genus in the poxvirus family. This genus comprises a wide group of viruses, including vaccinia virus, variola virus and ectromelia virus, among others. Our mRNA monkeypox vaccine candidate is designed to be a new-generation prophylactic vaccine, formulated using a quadrivalent orthopoxvirus antigen and mRNA-LNP technology platform. Currently, we are developing it for the prevention of monkeypox for individuals aged 18 years and above.

The vaccine candidate utilizes a quadrivalent orthopoxvirus antigen validated in non-clinical studies as the encoded antigen for mRNA. In preclinical studies, our vaccine candidate elicited significantly higher neutralizing antibody levels against monkeypox compared to the live-attenuated variola virus vaccine (Tian Tan strain) used in China, and it exhibited broad-spectrum cross-reactivity against a variety of orthopoxvirus antigens. Compared to the approved replication-defective monkeypox vaccines abroad, the outstanding immunogenicity of our mRNA monkeypox vaccine candidate provides a more suitable option for immunocompromised individuals (such as those who are HIV-positive).

As of the Latest Practicable Date, we were conducting preclinical studies of the vaccine candidate and expect to submit a pre-IND application to the NMPA in the fourth quarter of 2025.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MRNA MONKEYPOX VACCINE SUCCESSFULLY.

24-valent Pneumococcal Conjugate Vaccine (PCV24)

In addition to our PPSV23 candidate, which is indicated for individuals aged 2 year and above, we are also developing a PCV24 candidate that could potentially offer protection for a wider demographic, including infants below the two-year age limit. According to Frost & Sullivan, pneumococcal vaccines, particularly conjugate vaccines, have proven effective in preventing pneumococcal diseases, especially in children. We believe the PPSV23 and PCV24 candidates could form a synergetic product franchise for pneumococcal diseases, which underscores our commitment to capturing significant market opportunities while advancing vaccine technology.

Our PCV24 candidate could provide broad protection against 24 pneumococcal serotypes, significantly reducing the risk of invasive diseases such as meningitis, pneumonia and sepsis. It is designed by chemically binding (conjugating) polysaccharide antigens of pathogenic microorganisms to the carrier protein CRM197. This conjugation could induce a robust and durable immune response, effective in pediatric populations as well as adults. By facilitating immunologic memory, our PCV24 candidate is designed to ensure rapid and effective antibody production upon subsequent exposures.

The vaccine candidate employs a single carrier protein, CRM197, to ensure consistent immune responses while simplifying manufacturing, enhancing scalability and maintaining cost-effectiveness. We implement different coupling techniques for different pneumococcal capsular polysaccharides to activate their hydroxyl groups and conjugate them directly with CRM197, forming robust polysaccharide-protein conjugates. This methodology aims to improve polysaccharide recovery and enhance the quality of the conjugate solution. Moreover, it utilizes an animal-free fermentation medium, mitigating the risk of animal-derived biological factors and eliminating toxic residues linked to traditional phenol purification methods. Our PCV24 incorporates an aluminum phosphate adjuvant that is designed to enhance antigen uptake and stimulate stronger immune responses.

In preclinical studies conducted in animals, our PCV24 candidate demonstrated robust immunogenicity, eliciting strong immune responses against all 24 serotypes. Specifically, the GMT levels of antibodies elicited by our PCV24 candidate were comparable to or, for certain serotypes, higher than those elicited by the marketed PCV20 vaccine in the same studies. As of the Latest Practicable Date, we had completed process development for carrier protein CRM197 and cell banking, and initiated GMP production of CRM197. In addition, we had finished process development, pilot scale-up and process optimization. We plan to complete preclinical studies in 2025 and aim to submit a pre-IND application to the NMPA in the first quarter of 2026.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET PCV24 SUCCESSFULLY.

Live Attenuated Varicella Vaccine

Varicella, commonly known as chickenpox, is an acute systemic infectious disease caused by the VZV. While typically self-limiting in immunocompetent children, the disease can be more severe in adults and certain high-risk populations, including infants, pregnant women and immunocompromised individuals. According to Frost & Sullivan, there were approximately 527,700 reported cases of varicella in China in 2023. Vaccination remains the most effective preventive measure against varicella.

We are developing a live attenuated varicella vaccine candidate indicated for healthy, varicella-susceptible individuals aged 12 months and above. The vaccine candidate is developed utilizing the Oka strain of the VZV, which is propagated in human diploid cells (MRC-5) and subsequently lyophilized with stabilizing agents.

Upon administration, our live attenuated varicella vaccine candidate induces both humoral and cellular immunity. Once attenuated live viruses enter the human body, they are recognized by antigen receptors on B cells. Upon recognition and binding to the antigen, B cells are activated by cytokines secreted from Th cells. This activation prompts B cells to proliferate and differentiate into plasma cells and memory B cells. Plasma cells synthesize and release antibodies specific to VZV, which bind to the virus to block its adsorption to host cell surfaces, thereby inhibiting viral infection and spread. Additionally, $CD8^+$ T cells recognize the

antigen peptide derived from the virus, activating and transforming into cytotoxic T lymphocytes (CTLs). CTLs specifically target and destroy VZV-infected host cells, thereby eliminating the source of the viral infection.

We have completed the establishment of cell bank and seed lot for the live attenuated varicella vaccine candidate. We plan to initiate preclinical studies to evaluate safety and immunogenicity in the second quarter of 2025 and submit a pre-IND application to the NMPA in the first quarter of 2026.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET LIVE ATTENUATED VARICELLA VACCINE SUCCESSFULLY.

Tetanus Toxoid Adsorbed Vaccine

Tetanus is an acute specific infection caused by the entry of bacterium *clostridium tetani* into the body through wounds. It can be very dangerous and cause death. In cases of contaminated wounds, a tetanus booster immunization may be necessary. The prevention of tetanus critically relies on both proper wound management and immunization. Primary prevention through active immunization involves the administration of vaccines containing tetanus toxoid to foster long-term immunity, while secondary prevention utilizes passive immunization techniques, introducing immediate immune effectors such as tetanus antitoxin (TAT) or immunoglobulin for acute cases.

We are developing a vaccine candidate containing tetanus toxoid, with *clostridium tetani* cultivated in a suitable medium to produce the toxin, which is then refined, detoxified with formaldehyde and purified before being combined with an aluminum hydroxide–based adjuvant. Our tetanus toxoid adsorbed vaccine candidate aims to induce the production of protective antitoxin antibodies upon immunization.

In our production process, we employ disposable bioreactors, replacing the older glass bottle method, to cultivate *clostridium tetani*. This enables real-time control over parameters such as temperature, pH and dissolved oxygen levels, increasing bacterial density and toxin production with greater batch consistency. Additionally, we have added a chromatographic step post-detoxification to remove large molecules and impurities. This process achieves an antigen purity of over 3,500Lf(limit of flocculation)/mg protein nitrogen, which is superior to the Chinese Pharmacopoeia standard of 1,500Lf/mg and the United States Pharmacopoeia standard of 3,000Lf/mg.

We have completed the process scale-up and production of three pilot batches of drug substance of the tetanus toxoid adsorbed vaccine candidate. We plan to initiate preclinical studies to evaluate its safety and immunogenicity in the second quarter of 2025 and submit a pre-IND application to the NMPA in the fourth quarter of 2025.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TETANUS TOXOID ADSORBED VACCINE SUCCESSFULLY.

OUR TECHNOLOGY TRANSFER ARRANGEMENTS

PPSV23 Technology Transfer Agreements

On May 21, 2020, we entered into a technology transfer agreement with Beijing Hua'an Science and Technology Innovation Biotechnology Co. Ltd.* (北京華安科創生物技術有限公司) ("Beijing Hua'an") to acquire a then IND-approved PPSV23 candidate. Pursuant to the agreement, we would be responsible for conducting clinical trials and registration work with technical support from Beijing Hua'an, at our cost. After clinical trials are successfully completed, we shall be the named applicant in the NDA application. We agreed to pay Beijing Hua'an a transfer fee payable in installments upon achievement of certain development milestones. After commercialization of the PPSV23 product, Beijing Hua'an would also be entitled to royalties for a number of years.

The PPSV23 candidate we acquired from Beijing Hua'an contained certain technologies (the "Licensed Technology") Beijing Hua'an had licensed from Tianjin CanSino Biotechnology Inc. (天津康希諾生物技術有限公司) ("CanSino"), a predecessor of CanSino Biologics Inc., a biopharmaceutical vaccine company whose shares are listed on the Stock Exchange (stock code: 6185). In light of our acquisition, CanSino and Beijing Hua'an entered into a supplemental agreement to their original transfer agreement and we entered into a tripartite technology transfer agreement with Beijing Hua'an and CanSino on September 18, 2021, which provided, among other things, that (i) CanSino approved the sub-license of the Licensed Technology from Beijing Hua'an to us; (ii) Beijing Hua'an shall pay a new fixed fee to CanSino, also payable in installments upon achievement of certain development milestones, which shall be paid by us to CanSino directly, deducting our transfer fee payable to Beijing Hua'an; and (iii) upon full payment of such new fixed fee, the Licensed Technology shall be transferred to us.

NIAID Technology Licensing Agreement

We entered into a technology licensing agreement with the United States National Institute of Allergy and Infectious Diseases (NIAID) on April 10, 2023, under which we were granted a non-exclusive license in China, Latin America, Canada, Asia and Asia Pacific, United States, Africa and Europe to make, use and sell any of our products resulting from using NIAID technology, know-how and other technical information related to the sequence of RSV prefusion F (RSVpreF) antigen in the field of RSV vaccine for the prevention, cure, amelioration or treatment of RSV infection in humans. We paid an upfront license fee to the NIAID in 2023. We also agreed to pay the NIAID certain milestone payments as we advance the development of our RSV vaccines and royalties after commercialization.

RESEARCH AND DEVELOPMENT

We are a China-based vaccine maker dedicated to the research, development, manufacturing and commercialization of innovative vaccines and traditional vaccines adopting new technical methods. We have established a vaccine portfolio consisting of our Core Products, quadrivalent subunit influenza vaccine and rabies vaccine (human diploid cell), and 11 other vaccine candidates. We believe research and development is critical to our ability to remain competitive in the industry and have built up strong research and development capabilities to identify and develop high-potential and high-quality vaccines. We conduct our R&D activities through an in-house team as well as engagement of external CROs, as is in line with industry practice.

In 2023 and the nine months ended September 30, 2023 and 2024, we incurred research and development expenses of RMB283.2 million, RMB164.9 million and RMB142.6 million, respectively. See "Financial Information—Description of Selected Components of Consolidated Statements of Profit or Loss—Research and Development Expenses."

In-House Research and Development Team

Our in-house research and development team is responsible in all stages of vaccine candidate development, from preclinical studies, laboratory research, to clinical trials, regulatory filings and manufacturing process development. Our research and development activities are led by a team of experienced scientists. Our in-house research and development team consists of a preclinical team, a clinical development team and a regulatory affairs team. Our preclinical teams are in charge of design and optimization of antigen molecule, process development and optimization, immunogenicity studies, method development and quality research, with the support of our vaccine development platforms. Our preclinical team is led by Dr. Chen Ze, who is our chief scientist and has nearly 28 years of experience in the fields of virology, pharmaceuticals and biotechnology, and Dr. Yelin Xiong, who has over 35 years in the fields of pharmaceuticals and biotechnology and currently oversees our mRNA Vaccine Research Platform and Polysaccharide Conjugation Technology Platform. Our key preclinical development personnel also include Dr. Zhang Hongbo (director of our microbes and immunity research platform), Dr. Liu Zhihua (project director in our research and development team),

Mr. Xu Qi (manager of our process development department) and Ms. Leng Wenna (manager of our quality research department), each of whom has around ten years of experience in the research and development of vaccines. Our clinical development team oversees the design and conduct of clinical trials, as well as the drafting and review of study reports for all product candidates. Our regulatory affairs team oversees the application and ongoing management of regulatory filings for our products and product candidates. As of the Latest Practicable Date, our in-house research and development team consisted of 94 members, 45.8% of whom held doctoral or master's degrees, majoring in immunology, molecular biology, pathogen biology, clinical medicine or related fields.

In-House Research and Development Process

During the Track Record Period, the research and development of our vaccine products and vaccine candidates was primarily conducted by our in-house R&D team. The following summarizes our in-house R&D process in vaccine candidate development.

- *Early-stage research*. We have a dedicated team mainly responsible for researching the product candidates to be developed. We usually conduct a detailed analysis before initiating the R&D activities, including a feasibility study based on technology barriers, competitive landscape and prevalence of the disease. Our management team will review the study and determine whether we shall proceed to further R&D activities.

- *Preclinical development*. For each vaccine candidate that passes the discovery stage study, we will establish a specific product development team who are directly responsible for preclinical R&D activities. The team will be supported by staff from our different vaccine development platforms and research and development functions, including process development and quality research.

- *Clinical development*. Our clinical management team closely follow up with investigators and regulatory bodies to ensure that our clinical trials are conducted in an efficient way and all the issues arising from clinical trials can be addressed in a timely manner. In addition, we also engaged reputable CROs to manage, conduct and support our clinical trials during the Track Record Period. See "—Collaboration with CROs" below for details.

- *Continuous CMC development*. We conduct continuous CMC development during the preclinical and clinical development process, including process development and quality research. The continuous CMC development aims to address the issues and risks we observed during the clinical trial and the scaling-up in manufacturing capacities, to assure process performance consistency and product quality, safety and efficacy, and fulfill the regulatory expectation of marketing approval.

Regulatory Affairs

Our regulatory affairs team is responsible for the regulatory approval process of our vaccine candidates from clinical research to the commercialization stage, including assembling application dossiers for IND applications and BLAs, addressing inquiries from relevant regulatory authorities and monitoring ongoing R&D projects to ensure compliance with relevant laws and regulations. Our regulatory affairs team members are deeply familiar with regulatory processes of relevant governmental agencies, such as the NMPA, and had successfully obtained 9 IND approvals from NMPA for our vaccine candidates as of the Latest Practicable Date. We believe our team's extensive experience in navigating the regulatory process will be critical for our commercial success.

Our Vaccine Development Platforms

We have established three comprehensive vaccine development support platforms, namely our genetic engineering and protein expression and purification platform, mRNA vaccine research platform and adjuvant development and production platform, enabling the discovery and development of new vaccines across various categories. These are complemented by our distinctive proprietary technology platforms, including our large-scale amplification platform, polysaccharide conjugation technology platform and microbes and immunity research platform, to further enhance our innovative capabilities.

Genetic Engineering and Protein Expression and Purification Platform

Our genetic engineering and protein expression and purification platform is dedicated to the research and development of upstream fermentation and downstream purification process as well as the formulation screening process for both prokaryotic cells and eukaryotic cells, the two main protein expression systems. This platform is also responsible for the pilot-scale GMP production of a variety of protein-based vaccine candidates, including our PCV24 (utilizing a prokaryotic expression system) and recombinant zoster vaccines and recombinant RSV vaccines (utilizing a eukaryotic expression system). Prokaryotic cell systems provide a simpler mechanism for basic protein production, whereas eukaryotic systems, such as Chinese hamster ovary (CHO) cells, facilitate more complex protein modifications essential for therapeutic applications. For example, for CHO cell recombinant vaccines, we synthesize target genes and integrate such genes into recombinant expression vectors, which are then introduced into CHO cells. We then screen the CHO cells to select a monoclonal cell line that can robustly express the desired protein for our cell bank. This platform is also responsible for the preparation of pilot-scale samples. This comprehensive platform enables us to efficiently advance vaccine development from discovery to GMP-compliant manufacturing. This platform supports the development of our PCV candidate, recombinant zoster vaccine candidate and recombinant RSV vaccine candidate.

mRNA Vaccine Research Platform

Our mRNA vaccine research platform is dedicated to the development and optimization of mRNA molecular design, synthesis and purification process of mRNA, mRNA encapsulation and lyophilized formulations of mRNA vaccines. Our mRNA vaccines employ sophisticated design strategies to enhance the mRNA stability and translation efficiency. The platform optimizes the mRNA synthesis and purification process to safeguard the quality and boost production volume of mRNA vaccines. mRNA encapsulation is a key process in delivering mRNA into cells. The platform aims to optimize the encapsulation technology to ensure safe and efficient cellular delivery, which ensures effective targeting of mRNA to desired cells and thus efficacy of our mRNA vaccines. Recognizing the challenges of storage and transportation of mRNA vaccines, our platform includes the development of lyophilized formulations. This approach has successfully stabilized mRNA vaccines for storage at temperatures ranging from 2°C to 8°C, facilitating easier distribution and storage whilst maintaining product efficacy, which is essential to advance vaccine accessibility. This platform ensures our production of mRNA vaccines' drug substance with high quality, stability and productivity. Our mRNA vaccine research platform supports the development of our mRNA RSV vaccine candidate and mRNA monkeypox vaccine candidate.

Adjuvant Development and Production Platform

Adjuvants are substances used in conjunction with antigens to assist in antigen presentation and enhance immune responses. Our adjuvant development and production platform is dedicated to the development of the sophisticated adjuvant absorption process and research on the adjuvant-antigen interactions. The adjuvant absorption process is vital in vaccine preparation. For instance, the adsorption of aluminum-containing adjuvants involves critical process parameters such as antigen concentration, aluminum concentration, buffer system, ionic strength and pH, all of which significantly impact adsorption efficacy. Our adjuvant development and production platform also conducts comprehensive adjuvant-antigen interaction studies, as varying adjuvants affect immunogenicity differently. Accordingly, selection and optimization of adjuvants are crucial to maximizing vaccine efficacy. Our adjuvant development and production platform is responsible for pilot-scale GMP production of self-developed MF59-like emulsion adjuvant, while also supports the development of nanoscale aluminum-containing adjuvant and novel liposome adjuvant. This platform ensures our adjuvant quality to meet regulatory standards. Enabling tailored adjuvant formulations for different vaccines, the platform supports the development of our adjuvanted trivalent and quadrivalent subunit influenza vaccine candidate, the recombinant zoster vaccine candidate and the adsorbed tetanus vaccine candidate.

Large-Scale Amplification Platform

Our large-scale amplification platform is designed to optimize virus cultivation and amplification processes, which are critical for large-scale vaccine manufacturing. This platform focuses on enhancing both yield and quality of virus production, ensuring that vaccine manufacturing can meet demand efficiently and effectively. The primary focuses of our large-scale amplification platform include the refinement of cultivation processes for chicken embryo and human diploid cell and bioreactor virus amplification process. By refining the cultivation processes for chicken embryo, we aim to optimize the viral replication at harvest and thus increase our production capacity of influenza vaccines. The platform can support high-throughput chicken embryo virus amplification, managing 100,000 chicken embryos per batch. Although the human diploid cells offer good safety profile due to minimal DNA residue contamination, they are traditionally challenging to cultivate. The platform's efforts are concentrated on overcoming such challenges to achieve large-scale cultivation of the human diploid cells. This platform enables us to achieve optimal cell growth conditions and continuous passaging capability, with rabies virus titers reaching 10^8 CCID50/ml. The platform also includes a bioreactor scale-up system, designed with 26 parallel reactors, that could utilize either perfusion culture or fed-batch suspension culture to achieve sustained high-density cell growth. By refining the bioreactor virus amplification process, we also aim to reduce the production costs and enhance production efficiency of our viral vaccines.

Polysaccharide Conjugation Technology Platform

Our polysaccharide conjugation technology platform is responsible for the conjugation and purification of polysaccharide-protein conjugates. Central to the conjugation process is the exploitation of polysaccharide-protein interactions to forge stable chemical bonds, thereby enhancing immunogenicity. Our research emphasizes the development of conjugation methodologies tailored to different pneumococcal serotypes to boost polysaccharide recovery and the quality of conjugate solutions. In other words, our polysaccharide conjugation technology platform aims to improve the efficacy and cost-efficiency of our polysaccharide conjugation vaccine candidates. In addition, our polysaccharide conjugation technology platform focuses on the optimization of purification process of polysaccharide-protein conjugates, to enhance the efficacy and safety of our polysaccharide conjugation vaccine candidates. Our polysaccharide conjugate vaccine platform supports the development of our PCV24 candidate.

Microbes and Immunity Research Platform

Our microbes and immunity research platform is dedicated to investigating the pathogenic mechanisms of a wide range of microorganisms, including various pathogenic bacteria and viruses. Building on traditional vaccine development principles, the platform introduces innovative research and development strategies covering the fields of vaccine antigen design and formulation. This platform aims to facilitate comprehensive investigations into immune responses (and their mechanisms) elicited by vaccines to thoroughly evaluate and improve the immunogenicity and effectiveness of vaccines. This platform conducts an extensive array of R&D activities such as collecting different samples from animals, culturing viruses and host cells, and constructing a wide range of animal infection models, including those for influenza, RSV, rabies and tetanus, which allow for comprehensive evaluation of vaccine efficacy and preliminary safety. It focuses on monitoring both humoral and cellular immunity, evaluating immune persistence and establishing immunization protocols of our vaccine candidates. To assess humoral immunity, we perform neutralizing antibody assays to determine the efficiency of antibodies in preventing viruses from infecting cells. Through these comprehensive evaluations, the platform plays a critical role in understanding the enhancement of the immunological properties of our vaccine candidates, as well as the mechanisms by which they provide strong and lasting immune protection. Furthermore, the platform is also capable of detecting and analyzing cellular immune responses through technologies such as ELISPOT and flow cytometry.

Collaboration with CROs

In line with industry norm, we engage CROs that are independent from our Group to support our preclinical and clinical studies from time to time. We select CROs based on various factors, including their past experience in vaccine-related preclinical and clinical studies, their reputation and influence in the industry, their qualifications, professional experience of their employees and pricing. The work scope of these organizations in the development of our vaccine candidates may vary, subject to our overall management and instructions. With respect to preclinical studies, CROs typically provide us with service related to preclinical safety and immunogenicity evaluations of our vaccine candidates in accordance with our study design under our supervision. We are required to engage GLP-certified CROs to conduct safety evaluations studies under relevant laws and regulations. We engaged CROs to conduct preclinical safety and immunogenicity studies for our Core Products. With respect to clinical studies, CROs typically provide us with a comprehensive suite of services required in complex clinical trials in accordance with our trial design and under our supervision. We engaged CROs for all completed and ongoing clinical trials of our Core Products.

We have set in place various procedures regarding the management and monitoring of the performance by CROs. Our clinical development department is responsible for managing the overall clinical trial process and overseeing CROs' work. We hold regular progress meetings with CROs and provide specific directions to ensure the quality and efficiency of the trial execution. We conduct regular and *ad hoc* on-site audits of CROs, including interviewing their employees, reviewing documentations and records, such as relevant trial data and reports. We would keep formal records of such audits and follow up regarding issues discovered in the process. For clinical CROs, we would also refer to the NMPA compliance record of their previous clinical trials. Our CROs are also required to fully cooperate with our monitoring and inspection activities and rectify any issue identified during such inspections.

After we select a CRO to support our preclinical and clinical studies, we will enter into an agreement with the organization. Key terms of our agreements with CROs are summarized as follows.

- *Services.* With respect to preclinical studies, the CROs mainly help us conduct safety and immunogenicity evaluation by conducting tests on animals. With respect to clinical trials, the CROs are responsible for assisting in preparing clinical trial protocols and trial plans, clinical monitoring and inspection, clinical research coordination, data management, and medical monitoring.

- *Term.* For preclinical studies, contract term ranges from six months to five years, depending on the estimated duration of such studies. The agreements for clinical trials typically do not have a fixed term, and agreements generally expire after the completion of the relevant clinical trials and passing of NMPA inspection.

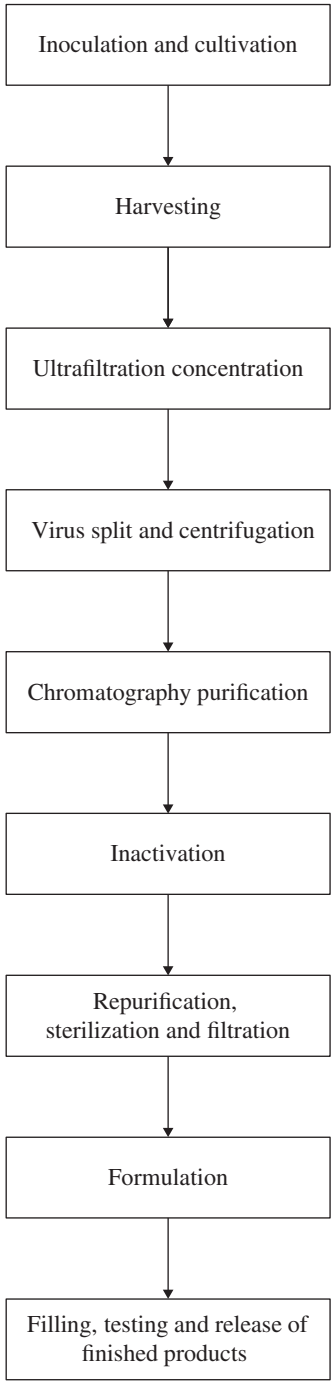
- *Payments.* We are typically required to make payments to CROs by installments according to milestones of respective services during the trials and clinical studies.

- *Intellectual Property and Confidentiality.* We own all intellectual property and trial results and the CROs must maintain strict confidentiality with respect to the information they acquire during the trials.

MANUFACTURING

Manufacturing Process

The following diagram summarizes the key steps in our manufacturing process of quadrivalent subunit influenza vaccines.



The following is a brief description of the key steps in our manufacturing process.

- *Inoculation and cultivation.* We cultivate our influenza vaccines in chicken embryos. We carefully inspect chicken embryos before inoculating the viral seed into the allantoic, or the primitive bladder, of chicken embryos, which is a sack-like hollow. We use automated inoculation machines to control the inoculation concentration and volume of viral seed solution. The temperature, humidity and cultivation duration are crucial for the cultivation process. As such, we exercise strict and precise control over these parameters for our cultivation process.

- *Harvesting.* After cultivation, we inspect and cool the embryos before harvesting the allantoic fluid into containers. The harvested fluid is then centrifuged and clarified where the liquid and solid are separated.

- *Ultrafiltration concentration.* The clarified liquid is then subject to ultrafiltration using membrane cassettes. We carefully select the membrane cassettes with appropriate pore size and control the operating pressure of ultrafiltration to achieve the desired concentration rate.

- *Virus split and centrifugation.* We use chemical agents to disrupt the viral envelope to extract the HA and NA antigen components and separate such components from protein impurities though centrifugation. We perform virus split and centrifugation simultaneously to produce the centrifugated solution.

- *Chromatography purification.* The solution then undergoes chromatography purification and elution to become the chromatographic solution.

- *Inactivation*. We conduct a test of the protein content of the chromatographic solution sample and add formaldehyde to inactivate the virus. We then conduct a safety test of the inactivated solution to confirm complete inactivation of the virus.

- *Repurification, sterilization and filtration*. We then perform a repurification using ultrafiltration membranes to wash and filter the inactivated solution, followed by sterilization and filtration to obtain the monovalent drug substance.

- *Formulation.* After we produce the monovalent drug substance for each of the four valent for our quadrivalent subunit influenza vaccines, we formulate the drug substance based on the approved formula. The formulated drug substance then undergo another sterilization and filtration process before they become semi-finished products.

- *Filling, testing and release of finished products.* We fill the products in vials. We then inspect each finished product according to the production process and pursuant to national and international Pharmacopoeias, including identification, physical appearance, fill volume, chemical verification, sterility and toxicity. If the testing and inspection results satisfy the quality requirement, we will release the finished products.

Manufacturing Facilities and Production Capacity

Manufacturing Facilities and Equipment

During the Track Record Period and up to the Latest Practicable Date, all of our quadrivalent subunit influenza vaccine products and our vaccine candidates used in our clinical trials were manufactured by our in-house manufacturing team. As of the Latest Practicable Date, our manufacturing team had 249 employees. The team is led by Mr. Jia Chunyu, who has over 16 years of experience in vaccine manufacturing.

Our current manufacturing facility is located at our headquarters in Taizhou, Jiangsu and has a GFA of over 48,000 sq.m. (the "No. 1 Manufacturing Facility"). During the Track Record Period and up to the Latest Practicable Date, we passed all GMP inspections conducted by the NMPA or its local counterparts on our No. 1 Manufacturing Facility. We have equipped our No. 1 Manufacturing Facility with advanced equipment and machinery procured from leading international and domestic brands, such as bioreactors, large-scale centrifuges, ultra-filtration system and large-scale purification system and product filling and packaging lines. As of the Latest Practicable Date, we owned all the equipment and machinery used in our production process. We regularly inspect and maintain our equipment and machinery to ensure that they remain in good condition for operation. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material or prolonged interruptions to our production process due to equipment or machinery failure.

As of the Latest Practicable Date, our No. 1 Manufacturing Facility had one influenza production line (the "First Influenza Vaccine Production Line"), one rabies vaccine production line and one pneumococcal vaccine production line. Our First Influenza Vaccine Production Line is equipped with drug substance facilities processing 100,000 chicken embryos per batch and 20 to 30 million embryos annually. The First Influenza Vaccine Production Line is also equipped with vaccine product facilities, which fill and package the influenza vaccines. The drug product facilities has a designed production capacity of 80,000 doses per batch, or 4.0 million doses of quadrivalent and trivalent subunit influenza vaccines annually. Our rabies vaccine production line currently has a designed annual production capacity of 5.0 million doses of rabies vaccines and our pneumococcal vaccine production line currently has a designed annual production capacity of 15.0 million doses of PPSV23 and PCV24. In anticipation of commercialization of our trivalent subunit influenza vaccines and quadrivalent subunit influenza vaccines for use in people aged 6-35 months, we had another influenza vaccine production line undergoing process validation (the "Second Influenza Vaccine Production Line") as of the Latest Practicable Date. The Second Influenza Vaccine Production Line has same designed annual production capacity as our existing production line. We expect to complete GMP compliance inspection and commence production by the end of 2026 for the Second Influenza Vaccine Production Line. In 2023 and the nine months ended September 30, 2024, we manufactured 1.2 million and 1.8 million doses of quadrivalent subunit influenza vaccine, representing a utilization rate of 30.2% and 61.0%, respectively. As our influenza vaccines are seasonal-type vaccine against major circulating viruses during each influenza season, our manufacturing activities peaked between March and August 2024, during which time our utilization rate reached 91.5%. We also manufactured a small amount of PPSV23 and rabies vaccines for our clinical trials.

New Production Facilities

In anticipation of the market demand of our clinical-stage vaccine candidates, we are constructing a second manufacturing facility (the "No. 2 Manufacturing Facility") and a third manufacturing facility (the "No. 3 Manufacturing Facility") in our headquarters in Taizhou.

No. 2 Manufacturing Facility

Our No. 2 Manufacturing Facility is designed to expand our manufacturing capacity of influenza vaccines in anticipation of commercialization of our trivalent subunit influenza vaccines and quadrivalent subunit influenza vaccines for use in people aged 6-35 months and 65 years and above. It has a planned GFA of approximately 82,000 sq.m. As of the Latest Practicable Date, the No. 2 Manufacturing Facility were in the process of road and landscape construction. Our No. 2 Manufacturing Facility is expected to have a designed annual production capacity of 10.0 million doses of influenza vaccines.

No. 3 Manufacturing Facility

Our No. 3 Manufacturing Facility is responsible of manufacturing recombinant protein vaccines. It has a planned GFA of nearly 27,000 sq.m. As of the Latest Practicable Date, we had completed construction of the main structure of the No. 3 Manufacturing Facility. Our No. 3 Manufacturing Facility is expected to have a designed annual production capacity of 20.0 million doses of recombinant protein vaccines. We expect to commence production of recombinant protein vaccines for Phase III clinical trials by the end of 2026.

Quality Management

The quality and safety of our vaccine products are crucial. We endeavor to ensure the quality of our products through a comprehensive quality management system. Our quality management system was formulated in accordance with applicable national standards, including the GMP standards, covering substantially every aspect of our operations including product design, raw materials and manufacturing, among others.

Quality Control System

We have an experienced quality management team, consisting of 110 employees as of the Latest Practicable Date with an average of eight years' experience in quality assurance, quality control and validation, all of whom have received professional trainings in regulations, GMP standards and quality control analysis methods.

We have implemented quality management systems that conform to international standards, national regulations and industry guidelines and adopted standard operating procedures. All of our manufacturing facilities are designed in conformity with GMP standards adopted by NMPA in the PRC. GMP is the basic principles of pharmaceutical manufacturing and quality management for ensuring that products are consistently produced while achieving the required quality. The current operating production line of our No. 1 Manufacturing Facility is GMP certified in the PRC.

Quality Control of Raw Materials

We have established detailed internal rules governing the selection of raw material suppliers and raw material quality control. We purchase raw materials only from suppliers of which we have verified business qualifications and product quality. After initial screening by our procurement department, we typically request product samples from a supplier, which is examined by our quality management team. The examination result provides an important basis for our supplier selection decisions. In addition, we would conduct on-site quality audit at the supplier's production facilities, and we require the supplier to execute a quality guarantee agreement with us. Our quality control team, together with our raw material management team, inspection team and procurement team, conducts initial inspection of our raw material suppliers upon engagement and periodic follow up inspections. We also conduct for-cause inspections of suppliers upon notice of certain red-flags. For supplies that do not pass our inspection, they will be transferred to our warehouse, categorized as unqualified supplies, pursuant to our protocols regarding non-conforming products. We stringently implement and follow our return and exchange policies, based upon which we would return any nonconforming raw material supplies that do not satisfy our quality control standards.

Quality Control of Manufacturing

Our quality management team is responsible for ensuring that our manufacturing processes consistently conform to applicable standards through regular on-site inspections. After completing each step of the manufacturing process, we perform cleaning and maintenance procedures to prevent contamination or cross-contamination before we proceed to the next step. Each batch or our product is subject to strict internal inspection before lot release inspections. We conduct sample testing on certain work in progress at certain stages of manufacturing. Our quality assurance department also inspects the documentation relating to product quality, including the laboratory control records and production process records. Products that do not meet our quality standards are destroyed or otherwise disposed of in accordance with the relevant disposal requirements. To better monitor the quality of our products and detect any risk or error in the quality control process, we have implemented an information management system. We have also completed the connection with the national vaccine electronic traceability collaboration platform to enable tracing of vaccines.

During the Track Record Period and up to the Latest Practicable Date, we passed all GMP inspections conducted by the NMPA or its local agencies with no material issues identified in any of the inspections. During the Track Record Period and up to the Latest Practicable Date, all of our finished products sold had approved lot releases, the series number of which can be found on the NIFDC websites, and there had not been any material product quality or safety issues.

COMMERCIALIZATION

We sell our quadrivalent subunit influenza vaccines, which are Class II vaccines, directly to CDCs at the district or county level. According to the Vaccine Administration Law, the CDCs purchase vaccine products from vaccine suppliers such as us. We are responsible for delivering vaccines to the CDCs, which then supply vaccine products to points of vaccination (POVs), which are regulated by CDCs. Our quadrivalent subunit influenza vaccines, as Class II vaccines, are supplied to such POVs without any price mark-up. CDCs may entrust qualified logistics service providers to deliver vaccines to the POVs, which provide ancillary delivery services only and do not own any vaccine products delivered by them. According to our PRC Legal Advisors, POVs are not allowed to purchase vaccines from entities other than CDCs under the law.

Sales Network

As of the Latest Practicable Date, we had an in-house sales and marketing team with 52 experienced staff covering sales, marketing, medical affairs and operations. Our sales team is responsible for the sale of our quadrivalent subunit influenza vaccines and to prepare for the commercialization of our vaccine candidates. Our marketing team is responsible for formulating overall marketing and promotion strategies, attending academic conferences and communications with CDCs on medical and scientific information of our vaccine products. Our medical affairs team is responsible for post-approval studies of the vaccine in different geographic areas. Our sales operations team is responsible for management of third-party marketing service providers, order management and shipment. We engage third-party marketing service providers to conduct promotional activities based on the promotional plans and strategies formulated by our in-house marketing team. By engaging third-party marketing service providers, we can leverage local resources and the experience of third-party marketing service providers to assist our marketing and promotion activities, which we believe is the most cost-effective manner to increase our market outreach and penetration. Supported by the third-party marketing service providers, our sales and marketing team has completed the market entry process in 30 provinces for our quadrivalent subunit influenza vaccine, which has been chosen by over 1,100 district- and county-level CDCs in local selections.

We select third-party marketing service providers based on their industry experience and expertise, local resources such as CDC and POV coverage, compliance and credit history, financial condition and management capabilities. We typically enter into one-year agreements, which may be renewed upon mutual agreement. Third-party marketing service providers promote our products primarily by conducting market research, organizing academic conferences, reporting to us on the latest market trends and demands, educating the general public to raise awareness of the benefits of vaccination, promoting the advantages of our products, assisting in public tender document preparations and site-visiting CDCs and POVs. We typically settle service fees with third-party marketing service providers quarterly or annually, which is capped by a pre-approved budget. The service fees are determined based on promotional activities conducted by the third-party marketing service provider. Under our agreements with the third-party marketing service providers, they are required to comply with applicable regulatory requirements on marketing activities and our sales policies. Our agreements with third-party marketing service providers may be terminated by mutual consent, and we may unilaterally terminate the contract under a range of circumstances, which usually include (i) if the third-party marketing service provider fails to effectively promote our vaccine product; (ii) if the third-party marketing service provider violates our policies on the management of third-party marketing service providers; (iii) if the third-party marketing service provider breaches any laws and regulations applicable to the provision of marketing services; and (iv) if the third-party marketing service provider breaches any anti-bribery law. As of December 31, 2023 and September 30, 2024, we had 37 and 58 third-party marketing service providers, respectively.

Marketing Strategies

Our sales and marketing efforts put a strong emphasis on academic promotion where we provide professional knowledge of the safety and efficacy of our products and information of targeted disease to our target customers. We keep frequent communications with CDCs, local POVs and related healthcare professionals through academic events, regular visits, on-site trainings and post-administration follow-ups on the safety and effectiveness of our product. Our third-party marketing service providers promote our products to CDCs by organizing promotional activities such as academic conferences and regular visits to CDCs. They also help us collect feedback on our vaccine product.

We have also developed the following marketing strategies to explore, penetrate and develop the markets for our vaccine candidates.

- *Focus on high-end vaccines to replace traditional products and imported products in China.* We closely track global trends in infectious disease incidence and vaccine R&D, focusing on high-end vaccines to replace traditional products and imported products in China and extend our competitive edge into international markets. We aim to provide more and better vaccination options to the public. All of our product and product candidates are currently classified as Class II vaccines in China. The Class II vaccine market has less sales volume in terms of doses but higher value than the Class I vaccine market, and therefore has greater growth potential. See "Industry Overview—Overview of the Human Vaccine Market—The Chinese Human Vaccine Market." We believe that our product candidates will compete effectively for their quality and innovation, and will be able to meet the increasing needs of the Class II vaccine market.

- *Promotion of market and brand recognition.* We engage in academic promotional activities and attend academic conferences, during which our scientists and commercialization team engage in information exchange and academic discussions with healthcare professionals including CDCs, physicians and KOLs in the vaccine or disease prevention industry, on the latest industry trends, research progress and advantages of our product candidates.

- *Pre-launch market research and analysis*. We plan to increase public awareness of the benefits of vaccination for different populations by targeting high-risk populations, such as pregnant women and people with chronic diseases. We also plan to conduct comprehensive research and analysis to better understand our targeted markets and populations to formulate more effective sales and marketing strategies.

Public Tenders

We are required to participate in the public tender and re-tender process held by provincial-level CDCs to sell our vaccine product, which is a Class II vaccine, in China. For Class II vaccines, public tenders and re-tenders serve as an admission for entry to market of the relevant province. Following the public tenders, we are required to participate in the local selection process held by district- or county-level CDCs to sell our vaccine product to specific districts or counties. The public tenders and local selections do not specify the volume to be admitted and each CDC will negotiate with us on the actual supply volume based on demand.

We generally compete with competitors on the technical designs, registration classification, bid price, clinical effectiveness and quality of product, as well as reputation. Once we win a public tender, we will be eligible for selling vaccine products to CDCs. Our quadrivalent subunit influenza vaccines are sold to district- and county-level CDCs. As of the Latest Practicable Date, we had participated in public tenders in 30 provinces and completed the market entry process in all 30 provinces, with a tender success rate of 100.0%. Through successful bids at public tenders, our quadrivalent subunit influenza vaccine has been selected by over 1,100 district- and county-level CDCs.

Pricing

Under the Vaccine Administration Law, Class II vaccine companies are required to follow reasonable pricing principles, which is generally understood by the market players as setting prices with reference to market factors and purchase demand of CDCs. For our quadrivalent subunit influenza vaccine, we participate in provincial-level centralized bidding processes, prior to which we also set bidding prices in a reasonable and independent manner. If we win the bids, our bidding prices become the selling price of such product in the respective province. Therefore, we and our competitors will consider and submit pricing information to the relevant CDCs. The bidding price of our products is one of the factors considered by provincial CDCs. As Class II vaccines are paid by vaccinees, our pricing for such vaccines is primarily market driven. We take into consideration factors such as our costs of production, price quotations of competing products in the bidding process, our technological advantages, product quality and market trends, vaccinees' purchasing power, as well as changes in the levels of supply and demand.

Vaccine Transportation and Storage

Temperature, hygiene and physical containment of vaccine products are among the key aspects of our storage and transportation processes. The Vaccine Administration Law requires cold-chain transportation and storage in the entire delivery process of vaccines in order to ensure constant monitoring and control of temperature. We are also required to implement a tracking system to keep proper records of the temperature of vaccines during transportation and storage under relevant laws and regulations. See "Regulatory Overview." To fully comply with these requirements, we have engaged logistic companies with cold-chain capabilities to transport our products. Our agreements with such logistic companies require them to provide cold-chain transportation services with tracking systems that are suitable for vaccines or medical products. Upon delivery, the logistic companies are required to provide the temperature monitor records for the entire delivery process, and we are entitled to inspect their compliance with all applicable requirements. The logistic companies are also obligated to deliver our products on time and are responsible for losses and damages in transportation. While CDCs would generally require logistics companies to provide relevant licenses to show their eligibility to transport vaccine products, we also audit the logistic companies periodically to ensure the quality of their service. Our payments to the logistic companies are generally settled on a monthly basis. In addition to engaging cold chain logistic companies, as of the Latest Practicable Date, we used 24 qualified storage centers located in 24 provinces.

After-Sale Services

Our sales and marketing team is responsible for maintaining contact with CDCs after sales to gather timely feedback. If we receive a complaint about our products, our responsible point of contact will forward it to our relevant departments, which will then follow up on such complaint. Our pharmacovigilance team and quality control department handle complaints involving adverse effects. Our quality control department conducts internal investigations and report to the sales and marketing department, who then respond to the complaining customer. They also make investigations as necessary and coordinate with other departments internally, including our pharmacovigilance team, to respond until the complaint is resolved. We also have self-checking and recall protocol in place, which will be activated when we consider a recall is necessary. We are required to make a report to the NMPA if we initiate a product recall. During the Track Record Period and up to the Latest Practicable Date, we had not received any material complaints on the quality of our vaccine product or been involved in any significant litigation or disputes arising from customer complaints, nor have we initiated a product recall.

Return and Exchange

In line with industry practice, we accept returns of (i) unused products that are expired or about to expire; (ii) products that are defective or are substandard; (iii) products with damaged packaging; and (iv) products that are otherwise unmarketable due to any fault on our part. As our influenza vaccines are seasonal-type vaccines against specific circulating viruses during each season, we also voluntarily accept unused influenza vaccines after the end of each influenza season, usually starting from April. Vaccinees or CDCs that return products are required to provide a written statement clarifying the reasons of the return while we typically bear the cost of the return from the CDCs to our warehouse. Such returns were primarily due to return of unsold and unused products that expired after the end of an influenza season. We dispose of any returned vaccine products in accordance with relevant laws and regulations. During the Track Record Period and up to the Latest Practicable Date, there were no product returns due to product quality issues or improper handling in transportation.

SEASONALITY

As our influenza vaccines are seasonal-type vaccines against major circulating viruses during each flu season, our sales and return of influenza vaccines are affected by seasonal fluctuations in demand of vaccines in season, as affected by the seasonal outbreak of flus and seasonal circulating virus. According to Frost and Sullivan, while influenza viruses spread year-round, flu activity peaks between October and March of the following year and administration of influenza vaccines peaks between September and January of the following year. Accordingly, our manufacturing activities tend to peak between March and August and our sales of influenza vaccines tend to be more concentrated between July and September. See "Financial Information—Major Factors Affecting Our Results of Operations and Financial Condition—Seasonality."

INTELLECTUAL PROPERTY

As a company focusing on the research, development and commercialization of vaccine products, we believe that intellectual property is crucial to our business. We actively seek patent protection for our vaccine product and candidates and file additional patent applications, when appropriate, to cover certain proteins, formulations and production processes. We have developed a significant portfolio of intellectual property rights to protect our technologies and products. As of the Latest Practicable Date, we had 187 patents in China, including 34 invention patents and 153 utility models. As of the same date, we had 12 patent applications in China and two patent applications overseas. All of our patents and patent applications as of the Latest Practicable Date were self-owned.

As of the Latest Practicable Date, we had registered 31 trademarks in China. As of the same date, we were also the registered owner of four domain names in China. See "Appendix VI—Statutory and General Information" to this document for further information.

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any material proceeding in respect of, and we had not received notice of any material claim of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent that may have a material adverse impact on us.

The table below lists the material patents and patent applications of our Core Products, quadrivalent subunit influenza vaccine and lyophilized human rabies vaccine, as of the Latest Practicable Date.

Product/Candidate	Patent/ Application Number	Type of Patent	Patent/ Application	Status	Application Date	Expiration Date
Subunit influenza vaccines (quadrivalent and trivalent)	202010901382.0	Invention	a storage device for preventive subunit influenza vaccines	Granted	September 1, 2020	August 31, 2040
	202210303948.9	Invention	a negative pressure exhaust sterilization system for influenza vaccines research and development	Granted	March 25, 2022	March 24, 2042
	202210321531.5	Invention	a system for research and development of universal influenza vaccines based on ferritin	Granted	March 25, 2022	March 24, 2042

Product/Candidate	Patent/ Application Number	Type of Patent	Patent/ Application	Status	Application Date	Expiration Date
	202310322102.4	Invention	an automatic embryo egg inoculation machine	Granted	March 29, 2023	March 28, 2043
	202310426763.1	Invention	a concentration and purification device for manufacturing of influenza vaccines	Granted	April 20, 2023	April 19, 2043
	202310623540.4	Invention	a disinfection device for inoculation machine needles	Granted	May 30, 2023	May 29, 2043
Subunit influenza vaccines (adjuvanted); recombinant zoster vaccine (adjuvanted) .	202310388310.4	Invention	a nano-emulsion adjuvant	Pending	April 12, 2023	N/A
Quadrivalent subunit influenza vaccine . . .	202210517954.4	Invention	a safety workbench for the research and development of quadrivalent subunit influenza vaccines	Granted	May 12, 2022	May 11, 2042
	202210303949.3	Invention	a demulsification and separation system for processing quadrivalent subunit influenza vaccines	Granted	March 25, 2022	March 24, 2042
	202210453638.5	Invention	an anti-vibration transport box for quadrivalent subunit influenza vaccines	Granted	April 24, 2022	April 23, 2042
	202210714823.5	Invention	a shaking and mixing system for preparing quadrivalent subunit influenza vaccines	Granted	June 23, 2022	June 22, 2042

Product/Candidate	Patent/ Application Number	Type of Patent	Patent/ Application	Status	Application Date	Expiration Date
Rabies vaccine (human diploid cell)	202011404241.4	Invention	a cultivation device for research and development of rabies vaccines	Granted	December 3, 2020	December 2, 2040
	202211034799.7	Invention	a stirring device for processing of rabies vaccines	Granted	August 26, 2022	August 25, 2042
	202211112152.1	Invention	a heating and separation device for manufacturing of rabies vaccines	Granted	September 13, 2022	September 12, 2042
	202211083453.6	Invention	a cross-method for screening rabies vaccine viruses based on *in vivo* and *in vitro* and its application	Granted	September 6, 2022	September 5, 2042

OUR CUSTOMERS

During the Track Record Period, our customers were district- or county-level CDCs, to which we typically grant a credit period of six to nine months. We usually enter into sales agreements with CDCs from time to time based on their purchase orders, instead of long-term agreements, and such sales agreements are typically not subject to renewal. Typically, pursuant to the relevant sales agreements, we are required to deliver products to CDCs at our cost in the quantity and at the time stipulated in the agreements. CDCs are obliged to inspect the vaccines upon receipt. The purchase price must be the price determined in the public tender process according to the provisions in the public tender agreements and the sales agreements typically require payment of the purchase price by wire. Our sales to the five largest customers in each year/period during the Track Record Period were no more than 30% of our total sales for the same periods.

RAW MATERIALS AND SUPPLIERS

Our Raw Materials

Raw materials for our vaccine products mainly include chicken embryo cells, human albumin, fetal bovine serum, peptone and syringes. A majority of the raw materials are widely available, and we are able to purchase them from numerous suppliers across China. Certain critical raw materials, such as peptone and fetal bovine serum, are available from a limited number of suppliers in China and overseas. We have maintained stable business relationships with a number of suppliers that can provide such raw materials with consistently high quality and in sufficient volumes. During the Track Record Period, we purchased raw materials based on the estimated clinical progress of our vaccine candidates and production volume of our vaccine product and we did not experience any shortage of supply. Our suppliers of raw materials are responsible for quality defects in our products that are directly caused by the bad quality of the raw materials supplied. Under our standard supplier contract, we have the right to return or exchange products if quality issues are discovered during inspection of the products. During the Track Record Period, we did not encounter any material dispute with our suppliers or any material breach of our purchase agreements, nor did we experience any material shortage, delay or price fluctuation in the supply of our major raw materials.

Our Suppliers

During the Track Record Period, our major suppliers primarily included (i) suppliers of raw materials and consumables for our vaccine products and candidates; (ii) suppliers of equipment for our R&D and manufacturing process and (iii) service providers such as cold-chain storage and transport services, construction services and CROs. We maintain a list of qualified suppliers and we will conduct qualification review and on-site audit for key materials suppliers. We only procure raw materials from qualified suppliers. We conduct regular review on qualified suppliers and suppliers that failed to pass such review will be removed from the list of qualified suppliers. We select our suppliers by considering their qualifications, compliance with relevant regulations and industry standards, quality, prices, business scale, market share, reputation and after-sales service quality.

During the Track Record Period, we did not encounter any material dispute with our suppliers or any material breach of our purchase agreements, nor did we experience any material shortage, delay or price fluctuation in the supply of our raw materials. For risks related to supply of our raw materials, see "Risk Factors—Risks Relating to the Manufacturing and Supply of Our Vaccine Products—If we are not able to source sufficient quantity of raw materials of required quality at commercially acceptable cost, our business could be harmed."

In 2023 and the nine months ended September 30, 2024, our purchases from our five largest suppliers were RMB170.8 million and RMB143.5 million, respectively, accounting for approximately 28.0% and 42.8%, respectively, of our total purchases for the respective periods. In the same periods, purchases from our largest supplier were RMB67.3 million and RMB58.9 million, respectively, accounting for approximately 11.0% and 17.5%, respectively, of our total purchases for the respective periods.

The following tables set forth details of our five largest suppliers during the Track Record Period.

Supplier	Principal Business	Products/ service purchased	Purchase Amount	% of Total Purchase	Number of Years of Cooperation	Credit Terms
			(RMB'000)			
Nine months ended September 30, 2024						
A.	Construction engineering, municipal public works, and power engineering	Construction services	58,895	17.5	5	three days
B.	Construction and electrical installation services	Construction services	45,214	13.5	2	one week/ ten days/ prepayment
C.	Chicken breeding	Raw material – chicken embryo	13,602	4.1	6	30 days
D.	Constructs and operates power grids	Electricity	13,565	4.0	6	30 days
E.	Manufacturing and sales of specialized packaging equipment	Syringe filing line	12,212	3.6	4	15 days or prepayment
Total . . .			143,488	42.8		

Supplier	Principal Business	Products/ service purchased	Purchase Amount	% of Total Purchase	Number of Years of Cooperation	Credit Terms
			(RMB'000)			
Year ended December 31, 2023						
A.	Construction engineering, municipal public works and power engineering	Construction services	67,253	11.0	4	three days
F.	Biopharmaceutical R&D and contract manufacturing services	Pre-clinical technology development	29,221	4.8	1	Settle in accordance with the payment schedule in the contract
G.	Development and manufacturing of bioreactors and laboratory products	Bioreactor	27,917	4.6	1	30 days
H.	Import and export of goods and technology	Import equipment agency services	23,877	3.9	2	15 working days or prepayment
I	Import and export of goods and technology	Import equipment agency services	22,530	3.7	3	ten days or prepayment
Total . . .			170,798	28.0		

None of our five largest suppliers was our customers during the Track Record Period. To the best of our knowledge, all of our five largest suppliers during each year/period of the Track Record Period are independent third parties. As of the Latest Practicable Date, none of our Directors, their close associates or any Shareholders which, to the knowledge of our Directors, owned more than 5% of the issued share capital of our Company as of the Latest Practicable Date, had any interest in any of our five largest suppliers during the Track Record Period.

Inventory Management

Our inventory primarily consists of raw materials and consumables used for manufacturing of our vaccine products and research and development of our vaccine candidates, work-in-progress and finished products. As of December 31, 2023 and September 30, 2024, we had inventories of RMB41.8 million and RMB62.7 million, respectively. We have established an inventory management system to monitor each stage of the warehousing process. Some of our inventories have strict storage temperature requirements. Warehouse personnel are responsible for the inspection, storage and distribution of raw materials. Raw materials are separately stored in different areas of the warehouse according to their storage condition requirement, usage and batch number.

Since our influenza vaccines are seasonal-type vaccines, we manufacture such vaccines and manage our finished products inventory in accordance with pre-approved annual manufacturing plan, which is formulated based on seasonal demand and regulatory requirements. We also maintain regular contact with the CDCs with which we have orders to better estimate the local needs and adjust our manufacturing plans and subsequently our inventory levels as needed.

COMPETITION

Vaccine markets in China and globally are intensely competitive and rapidly evolving. We face potential competition from many difference entities, including large multi-national and domestic pharmaceutical and biotechnology companies that have commercialized or are commercializing or pursuing the development of vaccines that target specific diseases as we do. We compete primarily based on our vaccine pipeline, technology platforms and manufacturing facilities and process. Our key competitors vary by vaccine types. For further details of market opportunities and competition in respect of our vaccine pipeline, see "Industry Overview" and "—Our Product and Product Candidates."

LICENSE, PERMITS AND APPROVALS

As a company based in China engaged in the developing, manufacturing and commercialization of vaccine products, we are required to maintain or renew the necessary permits, licenses and certifications for our business. We are also subject to regular inspections, examinations and audits by relevant authorities. During the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations. The table below sets forth the relevant details of the material license we hold for our operations in China.

License/Permit	Holder	Issuing Authority	Issue Date	Expiration Date
Drug Manufacturing Certificate (藥品生產許可證)	our Company	Jiangsu Medical Products Administration	November 11, 2019 (last renewed on August 9, 2024)	September 20, 2025
Experimental Animal Use Permit (實驗動物使用許可證). .	our Company	Jiangsu Science & Technology Committee	January 29, 2024	January 28, 2029
Biosafety Laboratory Registration (生物安全實驗室備案). .	our Company	Taizhou Health Committee	November 1, 2024	October 31, 2026

AWARDS AND RECOGNITIONS

The following table sets out a summary of the major awards and recognition we have received as of the Latest Practicable Date.

Year	Awards or Recognition	Issuing Authority
2024 . . .	Potential Unicorn in Jiangsu High-tech Industrial Development Zone (江蘇省高新技術產業開發區潛在獨角獸)	Productivity Center of Jiangsu Province (江蘇省生產力促進中心)
2024 . . .	Jiangsu Smart Manufacturing Demonstration Workshop (江蘇省智能製造示範車間)	Jiangsu Industry and Information Technology Department (江蘇省工業和信息化廳)
2024 . . .	Jiangsu Private Technology Enterprise (江蘇省民營科技企業)	Jiangsu Association of Private Technology Enterprises (江蘇省民營科技企業協會)
2024 . . .	Taizhou Engineering Research Center (泰州市工程研究中心)	Taizhou Development and Reform Commission (泰州市發展和改革委員會)
2024 . . .	Jiangsu "Specialized, Refined, Distinctive, and Innovative" Small and Medium-sized Enterprises (江蘇省專精特新中小企業)	Jiangsu Industry and Information Technology Department (江蘇省工業和信息化廳)
2024 . . .	Taizhou Engineering Technologies Research Center (泰州市工程技術研究中心)	Science and Technologies Bureau of Taizhou Municipal (泰州市科技技術局)
2024 . . .	Jiangsu Postdoctoral Innovation Practice Base (江蘇省博士後創新實踐基地)	Jiangsu Human Resources and Social Security Department (江蘇省人力資源和社會保障廳)
2023 . . .	Gazelle Enterprise in Jiangsu High-tech Industrial Development Zone (江蘇省高新技術產業開發區瞪羚企業)	Productivity Center of Jiangsu Province (江蘇省生產力促進中心)
2023 . . .	Intellectual Property Management System Certification (知識產權管理體系認證)	Qizhi (Beijing) Certification Co., Ltd. (企知(北京)認證有限公司)

INSURANCE

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. In line with industry practice in China, we maintain different types of insurance policies, such as product liability insurance policies (specifically, insurance policies for adverse reactions to vaccination), clinical trials liability insurance and key personnel insurance. Our Directors consider that our existing insurance coverage is generally in line with the industry practice in China. See "Risk Factors—Other Risks Relating to Our Business—We have limited insurance coverage, which could expose us to significant costs and business disruption."

EMPLOYEES

As of the Latest Practicable Date, we had a total of 588 employees, substantially all of whom were located in the PRC. The following table sets forth the details of our employees by function.

Function	Number of Employees	Percentage
Research and development	94	16.0%
Manufacturing	249	42.4%
Sales and marketing team	52	8.8%
Quality assurance	110	18.7%
Management and administrative	83	14.1%
Total	588	100.0%

We recruit our employees primarily through recruiting websites, job fairs, third-party recruiters and internal referral. In compliance with the applicable labor laws, we enter into individual employment contracts with our employees covering matters such as wages, employee benefits, workplace safety and grounds for termination. Our standard employment contract also contains a confidentiality clause and an assignment clause, under which we own all the rights to all inventions, technologies, know-how and trade secrets derived during the course of our employee's work. We also enter into standard non-compete agreements with all employees.

To maintain a stable workforce and retain key personnel in our Company, we offer our employee competitive remuneration packages. Our employees' remuneration comprises salary and bonus, which are generally based on their qualifications, position and performance. We offer remuneration packages based on individuals' qualifications and experiences and generally match the market rate for salary to stay competitive in the labor market. We also take into consideration the long-term growth and advancement of our employees and offer opportunities for both job promotion and technical development. During the Track Record Period, we made contributions to social insurance and housing provident funds in compliance with applicable PRC laws and regulations in all material respects. We conduct new employee training, as well as professional and safety training programs for all employees in accordance with our internal procedures. We also established an Employee Incentive Scheme to better retain and motivate our employees, with eligible participants comprising Directors, management members and other key employees of our Group. Some of our employees are currently represented by labor unions, and we consider our relations with our employees to be good. During the Track Record Period and up to the Latest Practicable Date, we did not experience any strikes or labor disputes which had a material effect on our business.

PROPERTIES

Owned Properties

We are headquartered in Taizhou, Jiangsu province. As of the Latest Practicable Date, we owned the buildings of our headquarters and No. 1 Manufacturing Facility of 48,694 sq.m. in gross floor area and three parcels of land housing our headquarters and manufacturing facilities of 115,095 sq.m.

As advised by our PRC Legal Advisors, during the Track Record Period and up to the Latest Practicable Date, save for certain buildings and facilities as described below, we had obtained the real estate title certificate for such land parcel and properties.

As of the Latest Practicable Date, we had not obtained the building ownership certificates for certain self-constructed ancillary buildings and facilities with a total GFA of 1,354 sq.m. As advised by our PRC Legal Advisors, according to the relevant PRC laws and regulations, the relevant government authorities may require us to dismantle the related properties and impose fines up to 10% of the construction costs if we fail to obtain the requisite building ownership certificates and fail to rectify in the time periods stipulated by the relevant authorities.

During the Track Record Period and up to the Latest Practicable Date, no material administrative action, fine or penalty had been imposed by the relevant regulatory authorities with respect to such title defects. In addition, we had not had any dispute in relation to the ownership of such properties as of the Latest Practicable Date. As the aggregate GFA of these properties accounted for only approximately 4.8% of the total GFA of our owned properties and we have obtained an indemnity from our Controlling Shareholders to indemnify our Group against any claims, fines and other liabilities arising from such property title defects, our Directors are of the view that even if we were ordered to demolish all of the relevant buildings and facilities, our business operations would not experience any material disruption. Accordingly, our PRC Legal Advisors are of the view that the risk of the relevant government authorities requiring us to dismantle the relevant ancillary buildings and facilities or imposing any other administrative penalties for failing to obtain the requisite building ownership certificates is low.

During the Track Record Period, we did not submit an environmental assessment document to the relevant government authorities for approval before we commenced construction of our No. 3 Manufacturing Facility. As advised by our PRC Legal Advisors, according to the relevant PRC laws and regulations, local authorities may issue orders to stop construction and impose a fine of between 1% to 5% of the total investment of the construction project, and may also issue orders to restore the original conditions before the construction, and the persons directly in charge and other directly responsible persons of us shall be subject to administrative action under the law.

During the Track Record Period and up to the Latest Practicable Date, no material administrative action, fine or penalty had been imposed by the relevant regulatory authorities with respect to such incident, nor had we received any order or been informed to stop construction or demolish such properties or pay related penalty fines. As our No. 3 Manufacture Facility is designed to manufacture recombinant protein vaccines and such products had not entered the clinical stage as of the Latest Practicable Date, our Directors are of the view that even if we were ordered to stop construction of such property, our business operations would not experience any material disruption. We have also obtained an indemnity from our Controlling Shareholders to indemnify our Group against any claims, fines and other liabilities arising from such incident. We are currently preparing the environmental assessment document, which we expect to submit to the relevant government authorities by March 2025 for approval. Accordingly, our PRC Legal Advisors are of the view that the risk of the relevant government authorities requiring us to stop construction or restore the original condition or imposing any other administrative penalties for failing to submit the environmental assessment document is low.

We will continue to strengthen our internal control systems to prevent future occurrence of such incidents. We conduct trainings for our administrative and legal staff on the relevant license and permit requirements on building construction and operation.

As of the Latest Practicable Date, no single property interest forming part of our Group's property activities had a carrying amount of 1% or more of our total assets and no single property interest forming part of our Group's non-property activities had a carrying amount of 15% or more of our total assets. According to section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice, this document is exempt from the requirements of section 342(1)(b) of the Companies (Winding up and Miscellaneous Provisions) Ordinance to include all interests in land or buildings in a valuation report as described under paragraph 34(2) of the Third Schedule to the Companies (Winding up and Miscellaneous Provisions) Ordinance.

Leased Properties

As of the Latest Practicable Date, we leased 18 properties with an aggregate gross floor area of 7,307 sq.m. in Taizhou, Shanghai and Beijing for our daily business operations, R&D functions and staff dormitory. As of the Latest Practicable Date, we had not completed lease registrations for 11 of our leases, with an aggregate gross floor area of 606 sq.m., with the relevant regulatory authorities due to the inaction of the landlords to cooperate with the registration procedure. As advised by our PRC Legal Advisors, the non-registration of lease agreements will not affect the validity of such lease agreements, but the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and we may be subject to a fine between RMB1,000 and RMB10,000 per lease for any delay in making these registrations, which we do not believe would have a material adverse impact on our operation. However, we will consult with our legal advisors and aim to address the issue appropriately during the lease negotiation process in the future. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of the lease agreements.

SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

We are subject to various social, health, safety and environmental laws and regulations and our operations are regularly inspected by local government authorities. We believe we have adequate policies ensuring compliance with all social, health, safety and environmental protection regulations. Particularly, we believe our continued growth rests on integrating social values into our business. We intend to create a lasting positive environmental, social and governance ("ESG") impact on our customers, suppliers and the broader community whom our operation may impact. We acknowledge our responsibilities on environmental protection, social responsibilities and are aware of the climate-related issues that may have impact on our business. We are committed to complying with ESG reporting requirements upon Listing.

Our core management team is responsible for adopting and adjusting our overall ESG vision and principle and we plan to establish an ESG committee within one year of Listing, which will be responsible for assessing and managing our ESG-related risks and monitoring the compliance of our operations with environment, health and safety laws and regulations. We have adopted company-wide environmental, health and safety (EHS) manuals and standard operating procedures that include management systems and procedures relating to emissions of air, water and other waste, handling, use, storage, treatment and disposal of hazardous substances, third party safety management, product stewardship, waste treatment, process safety management, worker health and safety requirements and emergency planning and response.

As a biotech 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 regulation, 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 alternation to our business operations. See "Risk Factors—Risks Relating to the Manufacturing and Supply of Our Vaccine Products—We deal with potentially harmful biological materials and other hazardous materials that may cause environmental contamination or injury to others" and "Risk Factors—Risks Relating to the Jurisdictions in Which Our Business Operates—We are subject to environmental protection, health and safety laws and regulations, and if we fail to comply with these laws and regulations, we could be subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business" for more details on the potential impact of such risks.

To better identify, assess and manage ESG-related risks, we have established risk management policies including "Three Wastes Management Policy," "Safety Production Policy" and "Anti-Fraud Policy." In the medium- and long-term, as a company that is committed to sustainability and responsible business practices, we will keep abreast of the regulatory standards and advancements in scientific and technical solutions to environmental issues and update our related policies, procedures and resources accordingly.

Environmental Matters

We rely on various metrics to measure the impact of our business on the environment, which are broadly aligned with industry standards. Such metrics include the amount of resource consumption, amount of waste (including wastewater and solid waste) generated and greenhouse gas emissions. We have also set various goals to reduce our environmental impact, and we continue to take significant steps toward these targets. The following table sets forth our resource use and emission-related indicators during the Track Record Period.

	Year ended December 31,	Nine months ended September 30,
	2023	2024
Resource consumption		
Electricity (MWh)	11,944	16,415
Water (tons)	526,280	173,379
Emission		
Wastewater (tons)	166,629	124,972
Hazardous solid waste (tons)	41	47
Greenhouse gas emissions (tons of CO2 equivalent)	9,645	11,642
– Scope 1 (direct emissions)	1,242	94
– Scope 2 (indirect emissions)	8,403	11,548
Greenhouse gas emission intensity (tCO2e/RMB million Revenue)	185	54

Resource Consumption

We incorporate the concept of resource conservation into our corporate culture and the daily operation of our laboratories and offices, monitor our resource consumption and established internal resource consumption management systems for laboratories and offices. We actively implement energy-saving measures in our daily operation, such as installing energy-efficient devices and optimize system control to increase our manufacturing efficiency. We focus on water resources issue and actively shoulder the social responsibility of protecting water resources. We recycle water resources from production, and collect rainwater to partially substitute the water used in production. We also strive to reduce the consumption of residential water by inspecting and eliminating leaks in the underground water supply network.

Emissions

The waste we produce is divided into hazardous waste (such as chemical waste and liquid) and non-hazardous waste (such as waste from general office operations). The hazardous waste generated are processed by qualified third-party waste treatment companies. We have set up an online monitoring system to monitor real-time wastewater discharge and a water treatment system to pre-treat concentrated wastewater for collection. We use single-use bioreactors in our manufacturing facilities, which can significantly reduce the need for sterilization. With respect to exhaust gas emission, we utilize natural gas boilers with low-nitrogen combustion technology to reduce greenhouse gas emissions. Additionally, we installed various gas collection devices such as ventilation hoods and range hoods to collect exhaust gas, which would be treated with activated carbon adsorbents before being discharged.

Our greenhouse gas emissions primarily consist of Scope 1 and Scope 2 emissions. Scope 1 direct emissions include the direct greenhouse gas emissions from our own manufacturing facilities. Scope 2 energy indirect emissions primarily include the greenhouse gas emissions from our usage of purchased electricity. In response to the national target of carbon neutrality, we actively focus on reducing the greenhouse gas emissions generated during our operations. Other indirect emissions that occur outside of our operation but are related to our activities and ESG goals are categorized as Scope 3 indirect emissions. Such emissions include both upstream and downstream emissions, such as emissions by our suppliers in their production of raw materials or disposables and in product transport, emissions from business travels by our employees and emissions due to electricity used for sewage processing by the relevant government agency. While we have limited control over the activities that directly contribute to Scope 3 emissions, we firmly believe in the positive impact by fostering an environmentally conscious operational culture in our own operation. This includes opting for qualified domestic suppliers to minimize energy consumption and greenhouse gas emissions during product transport, prioritizing virtual meetings over unnecessary business trips, as well as upgrading our manufacturing facilities/methods as appropriate to reduce waste production and thereby reduce downstream emissions.

With the expansion of our business, we endeavor to curb the increase in our resource consumption and emissions and aim to keep them relatively stable. We will continue to adopt a wide range of environment conservation measures to limit resource consumption and emissions. With respect to resource consumption, we will (i) install energy efficient facilities for our daily office operation and manufacturing process; (ii) limit business air travels and replace long-journey in-person meetings with virtual conferences where possible; and (iii) cultivate a corporate culture of environmental protection through employee training and office policies, such as switching off certain equipment or setting up automatic power shutdown for certain systems and devices when not in use. With respect to waste generation and greenhouse gas emissions, we will (i) regularly monitor and assess sources of hazardous waste generation and update to more environment-friendly manufacturing processes and facilities when appropriate; and (ii) continue to work with qualified professional waste processors and enhance our on-site waste treatment capacities.

In 2025, we aim to control our (i) total amount and intensity of resource consumption (primarily electricity and water), (ii) total amount and intensity of wastewater and solid waste generation, and (iii) greenhouse gas emission at 95% to 105% of that recorded in 2024.

Our Board will set targets for each material KPIs at the beginning of each financial year in accordance with the disclosure requirements of the Listing Rules and other relevant rules and regulations upon listing. The relevant targets on material KPIs will be reviewed on an annual basis to ensure that they remain appropriate to the needs of our Group. In setting targets for the ESG-related KPIs, we will take into account our respective historical consumption or discharge levels during the Track Record Period, and our future business expansion in a thorough and prudent manner with a view of balancing business growth and environmental protection to achieve sustainable development.

In 2023 and the nine months ended September 30, 2024, our expenses in relation to environmental compliance matters were RMB0.7 million and RMB0.3 million, respectively. During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant environmental laws and regulations in all material aspects.

Occupational Health and Work Safety

We strive to provide a safe working environment that guards the health and safety of our employees and communities. We are subject to occupational health and safety laws and regulations in the PRC. We have implemented work safety guidelines setting out safety practices, accident prevention and accident reporting. In particular, we have established and implemented guidelines in accordance with relevant PRC laws and regulations on the storage, management, handling and use of viruses and bacteria. These guidelines include those related to the recording and inspection of batches of viruses and bacteria, a multi-department approval process to obtain viruses and bacteria from our inventory, as well as the safe disposal of viruses and bacteria. Our employees with specified responsibilities, including handling certain equipment and conducting animal research, are required to hold relevant qualifications, as well as wearing proper safety gear when working. We regularly conduct safety inspections of our manufacturing facilities and hold work safety training sessions for our employees.

During the Track Record Period and as of the Latest Practicable Date, we complied with the relevant occupational health and safety laws and regulations in the PRC and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or results of operations during the same period.

Social Responsibilities

In respect of social responsibilities, we are committed to offering a fair and caring working environment to our employees. We have transparent policies on recruitment, compensation, dismissal, equal opportunities, diversity and anti-discrimination. We hire employees based on their merits and it is our corporate vision to offer equal opportunities to our employees. We encourage our employees who encounter any discrimination to seek immediate assistance, which also allows us to conduct timely investigation and follow up as needed. In addition, we provide training programs on industry and regulatory developments to our employees.

RISK MANAGEMENT AND INTERNAL CONTROL

We are subject to various risks during our operations. See "Risk Factors." We have established a consolidated risk management system and relevant policies and procedures which we consider suitable for our business operations. Our policies and procedures are aimed at managing and monitoring our business performance.

To monitor the continuous implementation of risk management policies and corporate governance measures after the Listing, 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. Our audit committee consists of three members: Ms. Li Xiaoqing, chairman of the committee, Mr. Li Xiangming and Mr. Cheng Qianwen. For the qualifications and experiences of these members, see "Directors, Supervisors and Senior Management";

- adopt various policies to ensure the compliance with the Listing Rules, including but not limited to policies in respect of risk management, connected transactions and information disclosure;

- provide regular anti-corruption and anti-bribery compliance training for senior management and employees in order to enhance their knowledge of and compliance of applicable laws and regulations; and

- arrange our Directors and senior management to attend training seminars on Listing Rules requirements and the responsibilities as directors of a Hong Kong-listed company.

We have appointed an internal control consultant to review the effectiveness of our internal control measures related to our major business processes in Oct 2024, to identify the deficiencies for improvement, advise on the rectification measures and review the implementation of such measures. The scope of such review was agreed among our Group, the Sole Sponsor and the internal control consultant. During the review process of our internal

control consultant, certain internal control matters were identified, and we have adopted corresponding internal control measures to improve on these matters. We have adopted the recommendations made by the internal control consultant and our internal control consultant has completed the follow-up procedures in January 2025 on our internal control system and have not identified any further material deficiencies in our internal control system.

LEGAL PROCEEDINGS AND COMPLIANCE

We may be involved in legal proceedings in the ordinary course of business from time to time. During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any litigation, arbitration or administrative proceedings which could have a material adverse impact on our business, financial condition or results of operations. As of the Latest Practicable Date, we were not aware of any pending or threatened litigation, arbitration or administrative proceedings against us which may have a material and adverse impact on our business, financial condition or results of operations.

During the Track Record Period and as of the Latest Practicable Date, we had not had any non-compliance incidents which our Directors believe would, individually or in the aggregate, have a material operational or financial impact on our company as a whole.