OVERVIEW

We are a leading global innovative pharmaceutical company rooted in China. We have been ranked as one of the global Top 50 pharmaceutical companies by Pharm Exec for six consecutive years since 2019. We were also ranked 8th on the list of "Top 25 Global Pharma Companies by Pipeline Size" published by Citeline in 2024. Furthermore, as a strong validation of our innovation results, we had a leading position among Chinese pharmaceutical companies, in terms of revenue from NME drugs in 2023 and the number of NME drug candidates in clinical or later stages of development as of the Latest Practicable Date, according to Frost & Sullivan.

These achievements have been enabled by Hengrui's ecosystem, comprising great talent, organization, and culture, which underlies our research, clinical, manufacturing, and commercialization capabilities. Through decades of efforts, we have substantially transformed into a leading global pharmaceutical company focused on highly innovative therapies to address immense unmet medical needs worldwide. Our persistent R&D investments and dedicated innovation, especially since our IPO of A Shares in 2000, have contributed to the establishment of a large portfolio of differentiated innovative drugs, including several potential blockbusters. Our commitment to innovation is evidenced by our capital allocation, with our R&D expenses as a percentage of our total revenue being 21.7% in 2023.

Focus on Immense Unmet Medical Needs

We strategically focus on comprehensive therapeutic areas with significant unmet medical needs and growth potential. These mainly include: (i) oncology, (ii) metabolic and cardiovascular diseases, (iii) immunological and respiratory diseases, and (iv) neuroscience. According to Frost & Sullivan, the aggregate global pharmaceutical market of these major therapeutic areas in 2023 was US$845.8 billion, accounting for 57.4% of the overall global pharmaceutical market for the same year; and it is expected to grow at a CAGR of 6.4% from 2023 to 2028, surpassing the CAGR of 5.7% for the overall global pharmaceutical market growth during the same period.

Differentiated Innovative Product Matrix

We have developed an industry-leading and highly differentiated matrix of innovative products, including several potential blockbusters. Our oncology portfolio has strategically expanded from solid tumors to hematological malignancies and provides a comprehensive coverage of neoadjuvant, adjuvant and later lines of treatment. We also provide therapeutics for prevention and treatment of major chronic diseases. As of the Latest Practicable Date, we had a portfolio of 17 commercialized NME drugs and a pipeline of over 90 NME drug candidates in clinical or later stages of development. We expect to maintain strong growth momentum in the rollout of innovative products. For example, we submitted eight NDAs/BLAs for our innovative drugs in 2024. To demonstrate our R&D efforts and productivity, from 2022 to 2024, research and clinical studies investigating our products and product candidates resulted in 1,019 peer-reviewed papers in international academic journals, including high-impact journals such as *The Lancet*, *British Medical Journal, JAMA, Nature Medicine, and Journal of Clinical Oncology*, with a cumulative impact factor of approximately 7,173 across these publications.

Leading R&D Capabilities

Multi-pronged Approach and Leading Technology Platforms. We strategically employ a multi-pronged approach to researching and developing drug assets with varying properties for identified druggable targets. Over the decades, we have extended our research beyond small molecules to encompass a wide range of additional modalities, including PROTACs, peptides, mAbs, BsAbs, multi-specific antibodies, ADCs, and RLTs. This multi-pronged approach supported by our leading technology platforms allows us to achieve paradigm-shifting innovation and significantly shorten the lead times for identifying and validating potentially first-in-class or best-in-class compounds. Leveraging our industry foresight and 14 R&D centers strategically located around the world, we have built each of our technology platforms with robust, differentiated functionalities and capabilities across the entire process of innovative drug R&D. Notably, our Hengrui Rapid Modular ADC Platform (HRMAP) and bispecific antibody platforms—Hengrui Obscurin Titin-Ig (HOT-Ig) and Half Antibody Recombination Technology-IgG (HART-IgG)—are our proprietary platforms incorporating cutting-edge technologies that have demonstrated the ability to generate differentiated new molecules.

We make modular evolutions to our platforms and capitalize on platform synergies to rapidly iterate and optimize our conjugates as potential drug candidates. For example, through our ADC platform, we have successfully extended our research to construct a new series of "AXC" drugs, where X can be a peptide, oligonucleotide, or small molecule protein degrader. In addition, on the antibody component of these drugs, we are utilizing our translational medicine expertise to identify novel tumor (or target)-associated-antigens (TAAs) and create synergies between different TAAs. Furthermore, in terms of conjugation methods, we are developing various site-specific conjugation methods in addition to conventional cysteine conjugation. In respect of the payload component, we are actively exploring cytotoxic payloads with new mechanisms of action (MOAs) and expanding our payload library to cover various modalities in therapeutic areas beyond oncology. We have also pioneered the development of DACs and AOCs. DACs and AOCs are novel targeted therapies with differentiated MOAs compared to ADCs. In contrast to molecular glue degraders, DACs, with protein degraders as payloads carried by antibodies, have demonstrated favorable efficacy and safety profiles and the potential to overcome drug resistance in preclinical settings. AOCs, by combining the targeting capabilities of antibodies with the gene regulatory potential of oligonucleotides, precisely modulate disease-causing proteins.

End-to-end Clinical Development. We have built strong end-to-end clinical development capabilities to ensure the superior efficiency and quality of our drug development process. We pursue a patient-oriented clinical strategy—which involves fast proof of concept, patient stratification, adaptive trial designs, and modular evolution in combination therapies—to efficiently bring differentiated high-quality therapeutics to the global market. As of December 31, 2024, our in-house clinical development team covered approximately 5,000 clinical investigators, and we were conducting approximately 400 clinical trials for over 90 innovative drug candidates. In 2024, we enrolled nearly 20,000 participants in our clinical studies. From 2018 to the Latest Practicable Date, we had obtained approximately 60 facilitated regulatory pathways in China, the U.S., the EU, and other overseas markets. Our in-house clinical development capabilities allow us to efficiently expedite regulatory timelines while ensuring the robust quality of our clinical trials.

In addition to our superior efficiency, under the "patient first" guidepost, our pharmacovigilance professionals continuously monitor drug safety data to ensure patients' well-being and the integrity of our clinical development. Furthermore, we maintain robust quality assurance for the entire process of our clinical trials through a dedicated team of highly experienced clinical quality professionals. During the Track Record Period and up to the Latest Practicable Date, our clinical programs achieved a 100% pass rate with zero critical deficiencies in approximately 90 GCP inspections conducted by the NMPA and the U.S. FDA. In particular, in March, October, and November 2024, the U.S. FDA conducted bioresearch monitoring inspections at three of our oncology clinical trial sites, and all of these inspections resulted in a classification of "NAI," representing the highest standard of GCP compliance and the best outcome of a U.S. FDA inspection.

Talent and Culture of Innovation. To maintain our competitive strengths in the areas described above, we have made significant investments in and place great emphasis on first-tier talent and a culture of innovation. Our all-round, top-notch R&D team is at the core of our superior R&D and CMC capabilities. Nearly 60% of our over 5,500 R&D team members as of September 30, 2024 hold a master's or higher degree. Many of them have years of experience at leading multinational pharmaceutical companies and renowned research institutes. Moreover, over 30% of our mid-level or above management members as of November 30, 2024 have overseas education or work experience. We benefit from their cross-disciplinary expertise that spans a variety of fields, such as chemistry, biology, pharmacology, toxicology, pharmacovigilance, and translational and clinical research. Leveraging our great talent and culture, we are able to efficiently and swiftly develop highly differentiated innovative pharmaceutical products.

Global-standard Manufacturing System

Leveraging our over 50 years of manufacturing experience, we have established a global-standard manufacturing system to ensure quality excellence, supply stability, and cost efficiency. Our quality management system is designed in accordance with applicable GMP standards, and our exported products comply with or exceed global quality standards including the EU GMP, the U.S. cGMP, and the ICH Quality Guidelines. In addition, we have extensive compliance experience under the manufacturing and quality-related requirements of overseas regulators such as the EMA and the U.S. FDA. For example, we obtained U.S. FDA approval for a total of three ANDAs for our first-to-market generics in January, July, and October 2024. Separately, we frequently receive inspections from our existing and potential global partners, leading to many long-term collaborations. These achievements reaffirm the global recognition of our quality management system. Moreover, in line with our global expansion and to address the increasingly stringent regulatory scrutiny, we have further reinforced our CMC system and strengthened our quality team. In particular, we have recently hired our Chief Quality Officer, an industry veteran with over 30 years of global experience (including experience working at the U.S. FDA) in the pharmaceutical industry. At the same time, our manufacturing infrastructure is industry-leading among Chinese pharmaceutical companies in terms of site area, annual designed production capacity, and range of pharmaceutical products produced.

Robust Commercialization Capabilities

We have established industry-leading commercialization capabilities to propel our sustainable growth. This is demonstrated by our comprehensive and tiered channel coverage enabled by our robust sales force. Our highly specialized sales force has been carefully curated into complementary functions to effectively market and promote our products. As of September 30, 2024, we had a dedicated in-house sales and marketing team of approximately 9,000 employees, which was an industry-leading scale among Chinese pharmaceutical companies, according to Frost & Sullivan. As of the same date, our sales network covered over 22,000 hospitals and over 200,000 offline retail pharmacies across over 30 provincial-level regions in China, which was an industry-leading coverage among Chinese pharmaceutical companies, according to Frost & Sullivan. In addition, we focus on academic promotion to enhance the market awareness of our brand and innovation, including collaborating with clinical investigators and key opinion leaders, publishing our R&D results in high-impact journals and presenting at renowned medical conferences.

Accelerated Global Expansion

In recent years, we have been accelerating our global expansion to unlock and maximize the potential of our product matrix and technology platforms. As of the Latest Practicable Date, we had initiated over 20 overseas clinical trials, including in the U.S., Europe, Australia, Japan, and South Korea, and had commercialized our products in over 40 countries. In 2024, we obtained three fast track designations and three ANDAs from the U.S. FDA for our products. In addition, since 2018, we have carried out 12 out-licensing transactions with global partners, involving 15 molecular entities. The aggregate deal value of these transactions was approximately US$12 billion, with total upfront payments of approximately US$400 million, in addition to equity interest in certain collaboration partners. Among these transactions, our transaction with Kailera Therapeutics, with a total deal value of approximately US$6 billion, was a landmark partnering transaction in China's pharmaceutical industry. In addition, these transactions included our out-licensing to a fully owned subsidiary of Merck KGaA, Darmstadt, Germany ("MRKDG") and IDEAYA Biosciences.

Remarkable Financial Performance

Through continuous innovation, we have achieved remarkable financial performance. Specifically, our total revenue reached RMB22.8 billion in 2023, representing an approximately 14% CAGR from 2013, compared to an approximately 4% CAGR for the global pharmaceutical market during the same period. Moreover, innovative drugs have become a major source of our revenue. Our revenue from sales of innovative drugs as a percentage of our total revenue increased from 38.1% in 2022 to 43.4% in 2023 and further to 47.7% in the nine months ended September 30, 2024. In addition, our healthy profitability and strong cash flows enable us to continue investing in R&D activities to propel long-term sustainable growth, thus supporting a virtuous cycle. Our net profit margin increased from 17.9% in 2022 to 18.7% in 2023 and further to 22.9% in the nine months ended September 30, 2024. Over these same respective periods, we generated operating cash inflows of RMB1,265.3 million, RMB7,643.7 million, and RMB4,585.4 million.

We are also committed to good corporate governance, social responsibility, and the environmental sustainability of our business. Our achievements in this respect are highlighted by an ESG rating of "A" that we have received from MSCI for two consecutive years since 2023.

OUR STRENGTHS

Leading global innovative pharmaceutical company rooted in China

We are a leading global innovative pharmaceutical company rooted in China. We have been ranked as one of the global Top 50 pharmaceutical companies by Pharm Exec for six consecutive years since 2019. We were also ranked 8th on the list of "Top 25 Global Pharma Companies by Pipeline Size" published by Citeline in 2024. Furthermore, as a strong validation of our innovation results, we had a leading position among Chinese pharmaceutical companies, in terms of revenue from NME drugs in 2023 and the number of NME drug candidates in clinical or later stages of development as of the Latest Practicable Date, according to Frost & Sullivan.

We have developed an industry-leading, highly differentiated matrix of innovative products, including several potential blockbusters. As of the Latest Practicable Date, we had a portfolio of 17 commercialized NME drugs and a pipeline of over 90 NME drug candidates in clinical or later stages of development. We expect to maintain strong growth momentum of innovative product rollouts. For example, in 2022, 2023, and the nine months ended September 30, 2024, in China, we initiated six, 18, and 22 pivotal clinical studies for our innovative drugs and drug candidates, and obtained the approval for first-in-human clinical studies of 19, 23, and 19 of our innovative drug candidates, respectively. Additionally, we submitted eight NDAs/BLAs for our innovative drugs in 2024. To demonstrate our R&D efforts and productivity, from 2022 to 2024, research and clinical studies investigating our products and product candidates resulted in 1,019 peer-reviewed papers in international academic journals, including high-impact journals such as *The Lancet*, *British Medical Journal*, *JAMA*, *Nature Medicine*, and *Journal of Clinical Oncology*, with a cumulative impact factor of approximately 7,173 across these publications.

At the same time, to solidify our leadership in innovation, we have invested heavily in R&D. In 2022, 2023, and the nine months ended September 30, 2024, our R&D expenses were RMB4,886.6 million, RMB4,953.9 million, and RMB4,548.9 million, respectively, representing 23.0%, 21.7%, and 22.5% of our total revenue in these same respective periods. Even given these significant R&D investments, we consistently maintained an attractive net profit margin and generated significant operating cash inflows during the Track Record Period. Our healthy profitability and strong cashflows enable us to continue investing in R&D activities to propel long-term sustainable growth, thus supporting a virtuous cycle.

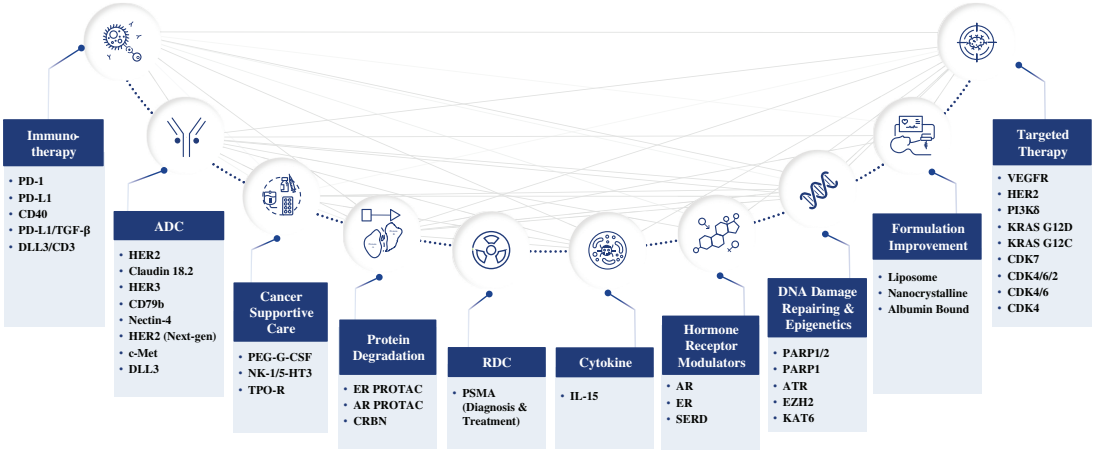
In recent years, we have been accelerating our global expansion to unlock and maximize the potential of our product matrix and technology platforms. As of the Latest Practicable Date, we had initiated over 20 overseas clinical trials, including in the U.S., Europe, Australia, Japan, and South Korea, and had commercialized our products in over 40 countries. In 2024, we obtained three fast track designations and three ANDAs from the U.S. FDA for our products. In addition, since 2018, we have carried out 12 out-licensing transactions with global partners, involving 15 molecular entities. The aggregate deal value of these transactions amounted to approximately US$12 billion, with total upfront payments of approximately US$400 million, in addition to equity interest in certain collaboration partners. These achievements substantially enhanced our global presence and industry recognition.

Differentiated innovative product matrix targeting comprehensive therapeutic areas with significant unmet medical needs and growth potential

Leveraging our leading technology platforms, we have developed a highly differentiated matrix of innovative products, including several potential blockbusters. We strategically focus on comprehensive therapeutic areas with significant unmet medical needs and growth potential.

Oncology. In 2023, globally, there were approximately 20.8 million new cancer cases and 10.0 million cancer deaths, according to Frost & Sullivan. These unmet medical needs for oncology require the revolution of cancer treatment.

As illustrated in the diagram below, we have established a comprehensive toolkit that enables us to develop high-quality oncology drugs in diverse modalities, covering essential cancer types around the globe.



Source: Company data

The breadth of our portfolio maximizes the potential of combination therapies, allowing us to explore regimens that provide meaningful improvements, in particular, on patients' progression-free survival and overall survival, over the current standard of care. Our continued progress in novel cancer therapies and paradigm-shifting innovation efforts are best exemplified by the following product clusters.

Immuno-oncology Drugs

Immunotherapy is a proven method used for the treatment of cancer by regulating anti-tumor immune responses. However, tumor cells escape immune detection by developing immunological tolerance through many pathways, including the upregulation of immunological checkpoint molecules such as PD-1 and PD-L1. As part of our cancer immunotherapies, we have commercialized the following novel anti-PD-1 and anti-PD-L1 antibodies:

- *Camrelizumab*, a novel anti-PD-1 antibody. Camrelizumab had been approved by the NMPA for nine indications as of the Latest Practicable Date. In the global Phase III CARES 310 clinical study, camrelizumab in combination with apatinib (also known as rivoceranib) as a first-line treatment for advanced HCC achieved a median overall survival (mOS) of 23.8 months (compared with an mOS of 15.2 months for sorafenib). The mOS of 23.8 months was the longest among all first-line therapies for uHCC with published clinical study results as of the Latest Practicable Date, according to Frost & Sullivan.

- *Adebrelimab*, a novel anti-PD-L1 antibody. Adebrelimab in combination with carboplatin and etoposide was approved by the NMPA as a first-line treatment for extensive-stage small cell lung cancer (ES-SCLC). Adebrelimab relieves PD-L1-mediated immune suppression and enhances the function of cytotoxic T cells. Adebrelimab functions as a backbone component in various combination therapies. As of the Latest Practicable Date, we were conducting several clinical studies in China to further expand the spectrum of combination therapies using adebrelimab, including in combination with SHR-8068 (an anti-CTLA-4 antibody), ADC drugs, and RAS-targeting agents.

Additionally, we have developed a series of next-generation immuno-checkpoint modulator candidates with paradigm-shifting potential:

- *Retlirafusp alfa (SHR-1701)*, a PD-L1/TGF-β bifunctional fusion protein with first-in-class potential. Retlirafusp alfa was the first PD-L1/TGF-β bifunctional fusion protein to have submitted the NDA/BLA as a first-line therapy for gastric or gastroesophageal junction adenocarcinoma, and it is currently under NDA/BLA review by the NMPA. As of the Latest Practicable Date, it was the most clinically advanced PD-L1/TGF-β bifunctional fusion protein globally, and the only PD-L1/TGF-β bifunctional fusion protein with published Phase III clinical study results for the treatment of advanced gastric cancer, according to Frost & Sullivan.

- *Anti-DLL3/CD3 bispecific antibody*. We are developing an anti-DLL3/CD3 bispecific antibody. It specifically binds to both the DLL3 protein and the CD3 protein, enriching CD3-positive T cells around tumor cells expressing the DLL3 antigen, inducing the activation of T cells and enabling them to exert targeted killing effects on tumor cells. Its CD3 binding affinity was designed to be relatively low. This low CD3 binding affinity mitigates non-specific T-cell activation and reduces inflammatory cytokine production in the periphery.

Currently, we are also expanding our research into CD3-based T cell engagers, γδ T cell engagers, and NK cell engagers.

ADC Drugs

ADC is an innovative biologics drug modality consisting of a biologic component (*i.e.*, the antibody) attached to a small molecule drug (*i.e.*, the cytotoxic payload) via a specifically designed linker. We have established HRMAP, our proprietary ADC platform. It encompasses payloads with different MOAs, optimal conjugation linkers/methods, and well-established antibody discovery and engineering ability. The following are descriptions of the development status of some of our ADC drugs as of the Latest Practicable Date:

- *Trastuzumab rezetecan (SHR-A1811)*, a HER2 ADC with best-in-class potential. Compared to other HER2 ADCs, trastuzumab rezetecan potentially has good efficacy and better safety profiles. Trastuzumab rezetecan was under a priority NDA/BLA review by the NMPA for the treatment of locally advanced or metastatic HER2 mutant NSCLC adult patients who previously received at least one prior line of systemic therapy. Trastuzumab rezetecan (SHR-A1811) had received breakthrough therapy designations from the NMPA for seven indications, which were the most among all clinical-stage drug candidates in China as of the Latest Practicable Date, according to Frost & Sullivan.

- *SHR-A2102*, a Nectin-4 ADC with best-in-class potential. We were conducting a Phase III clinical study of SHR-A2102 versus an investigator-selected therapy in locally advanced or metastatic urothelial carcinoma previously treated with platinum-containing chemotherapy and anti-PD-(L)1 antibodies, with or without ADC. It had received a breakthrough therapy designation from the NMPA and a fast track designation from the U.S. FDA.

- *SHR-1826*, a c-Met ADC. We were conducting a Phase Ib/II clinical study of SHR-1826 in China to evaluate its safety, tolerability, and efficacy in combination with other anti-tumor agents in patients with advanced solid tumors. We were also conducting a Phase I clinical study of SHR-1826 in patients with advanced solid tumors.

- *SHR-A1904*, a CLDN18.2 ADC with best-in-class potential. We were conducting a Phase III clinical study to confirm SHR-A1904 as a second-line treatment for advanced or metastatic gastric or gastroesophageal junction adenocarcinoma. In October 2023, we out-licensed an exclusive option to develop, manufacture, and commercialize SHR-A1904 worldwide (outside of mainland China) to a fully owned subsidiary of MRKDG. For details, see "—Collaboration and Licensing Arrangements—Major Out-Licensing Arrangements—Strategic Collaboration and License Agreement with a Fully Owned Subsidiary of Merck KGaA, Darmstadt, Germany."

- *SHR-4849*, a DLL3 ADC. SHR-4849 has strong proliferation inhibitory activity against different tumor cell lines with high and medium expression of DLL3. It also exhibits a significant bystander effect, capable of killing DLL3 low-expressing cells by releasing toxins from the killing of DLL3 high-expressing cells. In May 2024, we obtained the IND approval from the NMPA for conducting a Phase I clinical study of SHR-4849 for the treatment of advanced malignant solid tumors. In December 2024, we out-licensed to IDEAYA Biosciences the exclusive rights to develop, manufacture, and commercialize SHR-4849 worldwide (excluding the Greater China region). For details, see "—Collaboration and Licensing Arrangements—Major Out-Licensing Arrangements—Collaboration and License Agreement with IDEAYA Biosciences."

- *SHR-A2009*, a HER3 ADC with best-in-class potential. SHR-A2009 potentially has better efficacy. We were conducting a Phase III clinical study of SHR-A2009 to confirm its efficacy compared to platinum-based chemotherapy in patients with EGFR mutant, advanced or metastatic NSCLC who have failed EGFR-TKI treatment. It had received a fast track designation from the U.S. FDA.

- *SHR-A1912*, a CD79b ADC with best-in-class potential. We were conducting a Phase I clinical study of SHR-A1912 as a monotherapy, and a Phase II clinical study of SHR-A1912 in combination therapy. SHR-A1912 had received a fast track designation from the U.S. FDA for the treatment of relapsed/refractory diffuse large B-cell lymphoma in patients who have previously received at least two lines of treatment.

ER- and CDK-Targeting Drugs

HR-positive breast cancer accounts for approximately 60%-70% of all breast cancer cases. In addition to our existing product matrix for the treatment of HER2-positive breast cancer, we take a holistic approach to developing potent breast cancer therapies by regulating ER and CDK simultaneously:

- *Regulating the expression of ERs*. We have developed HRS-2189, a novel KAT6-specific inhibitor. HRS-2189 regulates the expression of a variety of downstream oncogenes by inhibiting the acetylation of histone lysine, thus enabling an anti-tumor effect.

- *Degrading expressed ERs*. We have developed the following drug candidates to degrade expressed estrogen receptors.

  - *HRS-8080*, a novel, oral, small molecule SERD. HRS-8080 degrades ER in a highly effective and selective manner. It exerts anti-tumor effects by lowering ER protein levels and thus downstream signals, thereby inhibiting tumor cell proliferation. The efficacy in treating breast cancer is improved when used in combination with dalpiciclib, our approved CDK4/6 inhibitor. In a Phase II clinical study, HRS-8080 in combination with dalpiciclib showed durable responses and a favorable safety profile.

  - *HRS-1358*, a novel, oral, small molecule ER PROTAC that elicits ER degradation. HRS-1358 potently and selectively degrades ER protein levels and thus downstream signals, thereby inhibiting the proliferation of tumor cells and exerting anti-tumor effects. As of the Latest Practicable Date, we were conducting a Phase II clinical study of HRS-1358 in combination therapy for the treatment of breast cancer.

- *Regulating downstream kinase under tiered coverage.* We have commercialized dalpiciclib, a novel, orally available CDK4/6 inhibitor that targets cells with a dysregulated cell cycle.

  Intrinsic and acquired resistance to CDK4/6 inhibitors and hematotoxicity of CDK6 inhibitors remain major challenges in the medical community. Currently, treatment options for this patient group remain limited, including PI3K/mTORi, endocrine, and chemotherapies. In response, we have developed the following drug candidates to address this drug resistance problem.

  - *Highly selective CDK4 inhibitor*. HRS-6209, a novel, highly efficient, highly selective CDK4 inhibitor. HRS-6209 potently inhibits CDK4/cyclin D complex and downstream signals, and induces tumor cell arrest at G1 phase, thus inhibiting tumor cell proliferation and exerting anti-tumor effects. Compared to a CDK4/6 inhibitor, the acceptable efficacy and lower toxicity profiles of a CDK4 inhibitor make it a suitable therapeutic option for patients who require a long-term treatment cycle. As of the Latest Practicable Date, we were conducting a Phase I clinical study of HRS-6209 as monotherapy for the treatment of advanced solid tumor and a Phase Ib/II clinical study of HRS-6209 in combination therapy for the treatment of breast cancer.

  - *CDK7 inhibitor*. We are developing a novel, highly potent and highly selective CDK7 inhibitor. It blocks CDK7-mediated oncogenic effects on the cell cycle through phosphorylation of other CDKs, and transcription initiation by phosphorylating RNA polymerase II. Cell growth inhibition studies showed its broad activity against a wide range of tumor cell lines. Encouraging activity

was also observed *in vivo*. As of the Latest Practicable Date, we were conducting a multicenter, open-label Phase I clinical study to evaluate its safety and tolerability in patients with advanced solid tumors.

- *CDK4/6/2 inhibitor*. We are developing a novel, small molecule CDK4/6/2 inhibitor, with well-balanced CDK4 and CDK2 inhibiting activities. Early translational research suggested that upregulating cyclin E expression, CDK2 hyperphosphorylation, and CDK6 overexpression are potential mechanisms that lead to CDK4/6 inhibitor resistance in breast cancer patients. It is hypothesized that these types of resistance might be overcome by simultaneous inhibition of CDK2, CDK4 and CDK6.

RAS-Targeting Agents

RAS is one of the most important oncogenes. The RAS signaling pathway is involved in many important cellular processes such as cell proliferation and survival, differentiation, apoptosis, cytoskeletal movement, protein transport, and secretion. RAS has three different isoforms: KRAS, NRAS, and HRAS, among which KRAS mutations occur in approximately 85% of the cancers with RAS alterations.

According to Frost & Sullivan, RAS pathway mutations are implicated in approximately 20% of the total solid tumor incidence globally. In 2023, globally, there were approximately 4.2 million new cancer cases with RAS mutations, including approximately 1.0 million in China. Mutant KRAS (mKRAS), in particular, drives 25% of solid tumors including non-small cell lung cancer (NSCLC), pancreatic ductal adenocarcinoma (PDAC), and colorectal cancer (CRC), which makes KRAS a promising cancer drug target. The dominant oncogenic mutations of KRAS occur at the codon 12 position, in particular G12D, G12V, and G12C. KRAS has long been considered a challenging therapeutic target. Currently approved KRAS-targeted therapies have shown proof of efficacy; however, their duration of response is relatively short.

We have strategically developed a cluster of innovative drugs within the KRAS family.

- *KRAS G12C inhibitor.* As of the Latest Practicable Date, worldwide, four KRAS G12C inhibitors had been approved to treat patients with advanced NSCLC harboring KRAS G12C mutations, according to Frost & Sullivan. However, due to intrinsic or acquired resistance caused by cellular, molecular, and genetic mechanisms, challenges remain in prolonging patients' response to the KRAS G12C inhibitor therapy.

HRS-7058 is a novel, potent, highly selective, next-generation KRAS G12C inhibitor for the treatment of patients with advanced solid tumors harboring KRAS G12C mutations. HRS-7058 is designed to inhibit both active and inactive forms of KRAS G12C. As of the Latest Practicable Date, we were conducting a Phase I clinical study of HRS-7058 for patients with advanced solid tumor with KRAS G12C mutations.

- *KRAS G12D inhibitor.* Compared to G12C, G12D is most commonly seen in pancreatic ductal adenocarcinoma (PDAC), a dismal disease with an average 5-year survival rate of 12% due to difficulties in early diagnosis and the lack of effective treatments, according to Frost & Sullivan. As of the Latest Practicable Date, no KRAS G12D inhibitors had been approved worldwide, according to the same source.

  HRS-4642 is a novel, potent, long-acting, and highly selective KRAS G12D inhibitor in liposomal injectable form, with first-in-class potential. HRS-4642 was the first inhibitor targeting KRAS G12D to have reported clinical data globally, according to Frost & Sullivan. In addition, we seek to develop next-generation KRAS G12D inhibitors in orally available formulation.

Metabolic and Cardiovascular Diseases. Metabolic disorders, including diabetes and obesity, typically increase the risks of cardiovascular, cerebrovascular, and renal diseases. Cardiovascular diseases, including high blood pressure and high cholesterol levels, can lead to high-mortality conditions such as coronary artery disease, heart failure, and stroke. While patients benefit from existing treatment options in these therapeutic areas, there is growing demand for innovative treatments that address the unmet medical needs and provide more flexible drug administration and enhanced efficacy and/or better safety profiles.

To meet the significant unmet medical needs in this area, we have strategically developed a portfolio of GLP-1 drug candidates across multiple modalities, in both oral and injectable forms. Following below are descriptions of our selected innovative product candidates in the GLP-1 family:

- *HRS-7535*, a novel, oral, small molecule GLP-1R agonist, which offers convenient drug administration benefits. In a Phase I clinical study, HRS-7535 exhibited a safety and tolerability profile consistent with other GLP-1R agonists and showed pharmacokinetics properties suitable for once-daily dosing. As of the Latest Practicable Date, we had completed the first-patient-in for its Phase III clinical study to confirm the efficacy and safety of HRS-7535 in adults with type 2 diabetes, and the last-patient-in for its Phase II clinical study on obesity treatment. As of the same date, we were also conducting a Phase II clinical study of HRS-7535 for patients with diabetic kidney disease.

- *HRS9531*, a novel, once-weekly, GLP-1 and GIP receptor dual agonist, with best-in-class potential. HRS9531 effectively reduced body weight, blood glucose, blood pressure, and triglycerides, while demonstrating a favorable safety profile, in Phase II clinical studies in overweight/obese participants and patients with type 2 diabetes. Relevant clinical results were presented at the 2024 American Diabetes Association (ADA) Annual Meeting and the 2024 European Association for the Study of Diabetes Annual Meeting. As of the Latest Practicable Date, we were conducting Phase III clinical studies in overweight/obese participants and patients with type 2 diabetes to confirm efficacy and safety of HRS9531.

- *HRS-4729*, a GLP-1, GIP, and GCG receptor tri-agonist formulated as a long-acting injectable peptide. By activating multiple targets, HRS-4729 improves the secretion of insulin, while controlling blood glucose, food intake, and body weight. As of the Latest Practicable Date, there were no approved GLP-1/GIP/GCG receptor tri-agonists globally, according to Frost & Sullivan.

In May 2024, we out-licensed to Kailera Therapeutics the exclusive rights to develop and commercialize three of our proprietary incretin-based drug candidates, HRS-7535, HRS9531, and HRS-4729, worldwide (except for the Greater China region).

In addition, capitalizing on recent scientific insights, we have developed a robust pipeline of other innovative drug candidates for the treatment of metabolic and cardiovascular diseases, including:

- *Myosin inhibitor*. We are developing a novel myosin inhibitor for the treatment of hypertrophic cardiomyopathy and related heart failure. It potentially offers a superior efficacy profile in reducing obstructive symptoms among target patients and a superior safety profile in preventing or reducing adverse events due to decreased contractility.

- *Lp(a) inhibitor*. We are developing an oral, small molecule inhibitor targeting Lp(a). It exhibits the potential in preventing the risk of atherosclerotic cardiovascular disease by potently lowering Lp(a). Oral administration is also expected to provide patients with greater convenience.

- *SHR6508*, a novel allosteric modulator of the calcium-sensing receptor for the treatment of hemodialysis patients with secondary hyperparathyroidism. SHR6508 is given intravenously to potentially improve patient compliance and reduce gastrointestinal adverse events.

siRNA has become a compelling targeted therapeutic modality, especially against undruggable targets for the treatment of a wide spectrum of diseases. With the capability of precise gene silencing and advancements in delivery systems, siRNA therapeutics reduce dosage frequency and improve patient compliance. Following below are descriptions of our selected siRNA drug candidates:

- An siRNA drug candidate targeting APOC3. It inhibits the expression of APOC3 protein through RNA interference. It effectively reduces triglycerides and thereby reduces the risk of ASCVD in patients with hypertriglyceridemia. As of the Latest Practicable Date, we were conducting a Phase I clinical study of this drug candidate.

- An siRNA drug candidate targeting AGT. AGT is a promising new target for the treatment of resistant hypertension. The AGT gene encodes a protein that is a precursor to angiotensin II, a potent vasoconstrictor that plays a critical role in the regulation of blood pressure. We are developing an siRNA drug targeting AGT to improve patient compliance, reduce blood pressure fluctuations, and reduce the incidence of adverse reactions of traditional antihypertension drugs while ensuring effective blood pressure reduction. As of the Latest Practicable Date, we were conducting a Phase I clinical study of this drug candidate.

Immunological and Respiratory Diseases. The healthcare landscape globally faces a significant burden from immunological and respiratory diseases, primarily due to the high prevalence of patients with long-term medication needs. In 2023, the global population with psoriasis, rheumatoid arthritis, asthma, and chronic obstructive pulmonary diseases was approximately 136.6 million, 40.9 million, 786.9 million, and 246.2 million, respectively, according to Frost & Sullivan. Innovative drugs with extended half-lives, improved patient accessibility, higher adherence, and optimized safety profile, are expected to be future growth drivers in this area.

To address these unmet medical needs, we strategically focus on a wide array of key autoimmune pathologic targets such as T cells, B cells, and complementary pathways. To enhance the effectiveness of our treatments and cater to patients' various needs in these areas, we also employ diversified modalities, including small molecules, peptides, monoclonal and bispecific antibodies, fusion proteins, and inhalation therapies. Following below are descriptions of our selected innovative products and product candidates for the treatment of immunological and respiratory diseases:

- *Vunakizumab (SHR-1314)*, an anti-IL-17A antibody, with best-in-class potential. Vunakizumab exhibited high IL-17A affinity through a novel epitope and reduced immunogenicity due to an extremely low content of mouse components. Vunakizumab was the first domestically developed anti-IL-17A antibody approved by the NMPA, according to Frost & Sullivan.

- *Ivarmacitinib (SHR0302)*, a highly selective JAK1 inhibitor, with best-in-class potential. Compared to other JAK inhibitors, ivarmacitinib exhibits potency and selectivity for JAK1. Ivarmacitinib is currently under NDA review in China for the treatment of moderate-to-severe atopic dermatitis, ankylosing spondylitis, moderate-to-severe active rheumatoid arthritis, and alopecia areata. As of the Latest Practicable Date, it was the most clinically-advanced domestically developed JAK1 inhibitor for the treatment of immunological diseases in China, according to Frost & Sullivan.

- *SHR-1905*, a long-acting anti-TSLP antibody with best-in-class potential. Compared to other anti-TSLP antibodies, SHR-1905 has a longer half-life, which allows a lower frequency of drug administration. The prolonged half-life of SHR-1905 leads to longer dosing intervals than those of the only anti-TSLP antibody approved worldwide, according to Frost & Sullivan. As of the Latest Practicable Date, SHR-1905 was undergoing a Phase II clinical study for treatment of severe uncontrolled asthma, a Phase II clinical study for treatment of chronic rhinosinusitis with nasal polyps (CRSwNP).

- *SHR-1703*, a novel, long-acting anti-IL-5 antibody. SHR-1703 exhibited high IL-5 affinity and prolonged half-life, enabling reduced eosinophil-mediated inflammation and damage. As of the Latest Practicable Date, we were conducting a Phase III clinical study to confirm the efficacy and safety of SHR-1703 in patients with asthma. In addition, as of the Latest Practicable Date, we were conducting a Phase II/III study for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA).

Neuroscience. The neuroscience pharmaceutical market broadly covers neurology, analgesia (or pain management), and anesthesia. Alzheimer's Disease and Parkinson's Disease are two major neurodegenerative disorders worldwide. According to Frost & Sullivan, there were estimated to be 58.3 million people affected by dementia worldwide in 2023, with Alzheimer's Disease contributing to 60-70% of dementia cases. In the same year, there were 9.4 million people affected by Parkinson's Disease globally. There are significant unmet medical needs for disease-modifying therapies which target clearly-defined pathogenic mechanisms and have the potential to delay the disease progression. Furthermore, stroke is a leading cause of death and disability globally. We have been developing various therapies with differentiated MOAs to improve the treatment paradigm of stroke.

Pain management is another critical issue both in China and globally. Chronic pain affects over 20% of the general population. Insufficient symptom control, poor tolerance of medications, and opioid overuse are still challenges in clinical practice, especially in the treatment of chronic pain. In addition, anesthesia and related fields such as perioperative management and critical care also show significant growth potential.

Following below are descriptions of our selected innovative drug candidates in the field of neuroscience:

- *SHR-1707*, a novel anti-Aβ IgG1 antibody. In a Phase Ib clinical study, SHR-1707 demonstrated significant brain amyloid load reduction in mild Alzheimer's Disease subjects. In preclinical studies, a higher affinity to beta-amyloid fibrils was demonstrated, which may predict a stronger effect of amyloid clearance than the products currently in use. In behavior tests of the animal model for Alzheimer's Disease, improvement of cognitive functions was also observed. As of the Latest Practicable Date, we were conducting a Phase II clinical study of SHR-1707 for the treatment of Alzheimer's Disease.

- *HRG2010*, a novel extended-release fixed-dose combination composed of carbidopa and levodopa. HRG2010 has been developed for a better control of motor fluctuations in Parkinson's Disease patients with long-term use of levodopa. As of the Latest Practicable Date, we were conducting a Phase III clinical study of HRG2010 for the treatment of Parkinson's Disease.

- *$Na_V1.8$ inhibitor*. We are developing a highly selective inhibitor of voltage-gated sodium ion channel subunit 1.8 ($Na_V1.8$), which presents significant potential for non-opioid pain management. Compared with the current standard of care, it is expected to have a better safety profile and tolerability. There were no $Na_V1.8$ inhibitors approved in the world for acute pain or chronic pain as of the Latest Practicable Date, according to Frost & Sullivan.

Multi-pronged research capabilities and leading technology platforms that enable us to develop potential blockbuster products

We are dedicated to generating a continuous flow of first-in-class and best-in-class molecules that benefit global patients. To this end, we strategically employ a multi-pronged approach to researching and developing drug assets with varying properties for identified druggable targets. Over the decades, we have extended our research beyond small molecules to encompass a wide range of additional modalities, including PROTACs, peptides, mAbs, BsAbs, multi-specific antibodies, ADCs, and RLTs. Benefitting from our comprehensive toolkit and deep insights in drug pathways and molecule designs, we have developed several drug clusters, such as immuno-oncology drugs, ADCs, ER and CDK-targeting drugs, and RAS-targeting agents, to address significant unmet medical needs.

This multi-pronged approach supported by our leading technology platforms allows us to achieve paradigm-shifting innovation and significantly shorten the lead times for identifying and validating potentially first-in-class or best-in-class compounds. A good case in point is our HRS-4642, a potentially first-in-class KRAS G12D inhibitor globally. Leveraging our liposomal technology, we design HRS-4642 with a liposomal formulation for targeted delivery, controlled and sustained drug release, and reduced systemic toxicity.

Our continuous innovation is fueled by a number of leading innovative technology platforms. Leveraging our industry foresight and 14 R&D centers strategically located around the world, we have built each of these technology platforms with robust, differentiated functionalities and capabilities across the entire process of innovative drug R&D. Notably, our Hengrui Rapid Modular ADC Platform (HRMAP) and bispecific antibody platforms—Hengrui Obscurin Titin-Ig (HOT-Ig) and Half Antibody Recombination Technology-IgG (HART-IgG)—are our proprietary platforms incorporating cutting-edge technologies that have demonstrated the ability to generate differentiated new molecules. Specifically, our HRMAP platform encompasses payloads with different MOAs, optimal conjugation linkers/methods, and well-established antibody discovery and engineering ability that empower our capability to create an ADC with desired *in vitro* and *in vivo* properties within a short period of time. Among our bispecific antibody platforms, HOT-Ig utilizes the Ig-like domain pair from human obscurin and titin to replace the CH1/CL domains, avoiding heavy and light chain mispairing. By leveraging this platform, we can create a variety of bispecific antibodies with multiple formats, great stability, and high compatibility for diverse sequences. On the other hand, HART-IgG is our newly-developed versatile platform to efficiently prepare bispecific antibodies. Bispecific antibodies developed via our HART-IgG platform show robust physicochemical properties and good druggability comparable with those of canonical mAbs. Furthermore, our HART-IgG technology is compatible with other engineering/conjugation technologies, and as a result, can be used to develop bispecific antibody conjugates.

Our technology platforms are undergoing modular evolutions, and we capitalize on platform synergies to rapidly iterate our drug candidates and generate novel therapies with greater safety, efficacy, and convenience. This modular and complementary evolution is best exemplified by our efforts in deepening our research in ADC. We began our research on ADCs and other bioconjugate drugs in 2010. As of the Latest Practicable Date, we had advanced over ten differentiated ADC molecules to the clinical stage. In particular, as of the same date, trastuzumab rezetecan (SHR-A1811) had received breakthrough therapy designations from the NMPA for seven indications, which were the most among all clinical-stage drug candidates in China, according to Frost & Sullivan. We constantly advance our technologies to substantially expand our bioconjugate component library and research on "AXC" drugs. Specifically, with respect to the antibody component, we utilize our translational medicine expertise to identify novel TAAs. Our antibody engineering capability allows us to develop not only monoclonal antibodies, but also bispecific and multi-specific antibodies, aiming for the synergies between different TAAs. With respect to conjugation methods, besides the conventional cysteine conjugation method, we are developing various site-specific conjugation methods, including glycosite-specific conjugation and engineered cysteine site-specific conjugation. With respect to the payload component of AXCs, we are actively exploring cytotoxic payloads with new MOAs to overcome the resistance of commonly used cytotoxic payloads. We are also expanding our payload library to cover various modalities, such as degraders (molecular glues and PROTACs) for oncology. By conjugating peptides and oligonucleotides onto antibodies of interest, we further explore new molecular entities in therapeutic areas beyond oncology. We pioneered the development of DACs and AOCs. DACs and AOCs are novel targeted therapies with differentiated MOAs compared to ADCs. In contrast to molecular glue degraders, DACs, with protein degraders as payloads carried by antibodies, have demonstrated favorable efficacy

and safety profiles and the potential to overcome drug resistance in preclinical settings. AOCs, by combining the targeting capabilities of antibodies with the gene regulatory potential of oligonucleotides, precisely modulate disease-causing proteins. More recently, we have structured our Hengrui-LingShu platform and bioinformatics platform to streamline various aspects of our R&D, including drug discovery, molecular design, drug property prediction and optimization.

End-to-end clinical development capabilities aligned with our patient-oriented strategy to efficiently bring high-quality drugs to the global market

We have built strong end-to-end clinical development capabilities to ensure the efficiency and quality of our drug development process. We pursue a patient-oriented clinical strategy—which involves fast proof of concept, patient stratification, adaptive trial designs, and modular evolution in combination therapies—to efficiently bring differentiated high-quality therapeutics to the global market. As of December 31, 2024, our in-house clinical development team covered approximately 5,000 clinical investigators, and we were conducting approximately 400 clinical trials for over 90 innovative drug candidates. In particular, we have initiated multi-regional clinical trials in regions including the U.S., Europe, Australia, Japan, and South Korea, for a number of products demonstrating global potential such as SHR-A1904, SHR-A1811, and camrelizumab in combination with apatinib. In addition, we adhere to stringent global standards when conducting clinical trials in China for our product candidates with global potential. Applying this approach, we can pursue concurrent IND submissions worldwide and accelerate multi-regional clinical trials for potentially first-in-class or best-in-class drug candidates.

Our patient-oriented clinical development strategy and end-to-end clinical development capabilities enable us to achieve superior operational efficiency in clinical development. For example, it took us around four years to advance our trastuzumab rezetecan (SHR-A1811) from the commencement of the clinical trial to obtaining the NMPA's acceptance of the NDA. From 2018 to the Latest Practicable Date, we had obtained approximately 60 facilitated regulatory pathways in China, the U.S., the EU, and other overseas markets. In addition, in 2024, we enrolled nearly 20,000 participants in our clinical studies. Our in-house clinical development capabilities allow us to efficiently expedite regulatory timelines for our products.

In addition to our superior efficiency, under the "patient first" guidepost, our pharmacovigilance professionals continuously monitor drug safety data to ensure patients' well-being and the integrity of our clinical development. Furthermore, we maintain robust quality assurance for the entire process of our clinical trials through a dedicated team of highly experienced clinical quality professionals. During the Track Record Period and up to the Latest Practicable Date, our clinical programs achieved a 100% pass rate with zero critical deficiencies in approximately 90 GCP inspections conducted by the NMPA and the U.S. FDA. In particular, in March, October, and November 2024, the U.S. FDA conducted bioresearch monitoring inspections at three of our oncology clinical trial sites, and all of these inspections resulted in a classification of "NAI," representing the highest standard of GCP compliance and the best outcome of a U.S. FDA inspection.

Global-standard and industry-leading in-house manufacturing system ensuring quality excellence, supply stability, and cost efficiency

We are committed to achieving quality manufacturing system. Leveraging over 50 years of manufacturing experience, we have established a global-standard CMC management system. Our quality management system is designed in accordance with applicable GMP standards, and our exported products comply with or exceed global quality standards including the EU GMP, the U.S. cGMP, and the ICH Quality Guidelines. In addition, we have extensive compliance experience under the manufacturing and quality-related requirements of overseas regulators such as the EMA and the U.S. FDA. We obtained U.S. FDA approval of three ANDAs for our first-to-market generics in 2024. For example, in October 2024, the U.S. FDA approved our paclitaxel for injection (albumin bound) as chemotherapy, which was a first-to-market generic product approved by the U.S. FDA. In addition, we frequently receive visits and inspections from our existing and potential global partners, leading to many long-term collaborations. These achievements reaffirm the global recognition of our quality management system. Moreover, in line with our global expansion and to address the increasingly stringent regulatory scrutiny, we have further reinforced our CMC system and strengthened our quality team. In particular, we have recently hired our Chief Quality Officer, an industry veteran with over 30 years of global experience (including experience working at the U.S. FDA) in the pharmaceutical industry.

In addition, we manufacture our pharmaceutical products fully in-house, except for a limited number of in-licensed products. This in-house manufacturing capability allows us to effectively control the quality and costs of our products and, more importantly, ensure stable product supplies. We can also achieve economies of scale and optimize our production costs by leveraging the large scale and complementary functions of our 12 manufacturing facilities across nine cities in China. Furthermore, our manufacturing infrastructure is industry-leading among Chinese pharmaceutical companies in terms of site area, annual designed production capacity, and range of pharmaceutical products produced. Specifically, as of September 30, 2024, our manufacturing facilities across China had a total site area of 1.2 million square meters. In 2023, we had annual designed production capacity of 222.5 million vials of injectables and 3.4 billion pieces of oral solids (including tablets and capsules). Complementing this scale, we can manufacture a wide spectrum of modalities across small molecules and biologics—from drug substances (such as APIs) to drug products—in dosage forms such as injectables, oral tablets and capsules, oral solutions, film agents and ointments.

Industry-leading commercialization capabilities to propel our sustainable growth

We have established industry-leading commercialization capabilities to propel our sustainable growth. This is demonstrated by our comprehensive, tiered-channel coverage that is enabled by our robust sales force. As of September 30, 2024, we had a dedicated in-house sales and marketing team of approximately 9,000 professionals, which was an industry-leading scale among Chinese pharmaceutical companies, according to Frost & Sullivan. Our highly specialized marketing and sales team has been strategically curated into complementary functions, including strategic planning, marketing medical affairs, sales management, sales

force effectiveness, and market access, to effectively promote the clinical benefits of our products and enhance our sales productivity. In terms of channel coverage, our sales network spanned over 22,000 hospitals and over 200,000 offline retail pharmacies across over 30 provincial-level regions in China, which was an industry-leading coverage among Chinese pharmaceutical companies, according to Frost & Sullivan. We also have deep penetration in lower-tier cities and rural areas, which enables us to capture broader market opportunities. Aside from offline retail pharmacies, our professional prescription drug sales team also covered all mainstream online pharmacy platforms as of September 30, 2024. At the same time, we have established a specialized direct-to-patient ("DTP") team dedicated to expanding our DTP pharmacy channel to satisfy patients' diversified medical needs. Furthermore, we have utilized various channels and platforms, such as community healthcare service centers, to better serve patients with oncology and chronic diseases and improve their long-term treatment outcomes.

We focus on academic promotion to facilitate market adoption of our innovations. Leveraging our over 50 years' industry experience and our premium brand, we have built long-term academic relationships with many renowned physicians and other healthcare professionals. We have also supported investigator-initiated trials and performed various post-market real-world studies to benefit more patients and collect clinical evidence to further validate our products. In addition, we publish results of our clinical trials in high-impact journals such as *The Lancet, British Medical Journal, JAMA, Nature Medicine,* and *Journal of Clinical Oncology*. We believe that these publications are instrumental in endorsing our products' high quality and driving their adoption by the medical community. Moreover, we regularly organize and participate in a wide variety of major domestic and international academic conferences, seminars, and symposia to enhance the scientific awareness of our innovative product matrix alongside our brand recognition. Many of our product studies have been presented at major international academic conferences such as the American Society of Clinical Oncology (ASCO) Annual Meeting, the European Lung Cancer Conference, the American Society of Gynecological Oncology Annual Meeting, the European Breast Cancer Conference, the World Conference on Lung Cancer, the ADA Annual Meeting, and the American Academy of Dermatology Annual Meeting, among which we have presented major research studies in the ASCO Annual Meeting for 13 consecutive years.

Supported by our superior commercialization capabilities, we achieved remarkable sales performance during the Track Record Period. We recognized revenue of RMB21.3 billion, RMB22.8 billion, and RMB20.2 billion in 2022, 2023, and the nine months ended September 30, 2024, respectively. In particular, our revenue from sales of innovative drugs as a percentage of our total revenue increased from 38.1% in 2022 to 43.4% in 2023 and further to 47.7% in the nine months ended September 30, 2024.

Accelerated expansion into the global market, unlocking the potential of our product matrix and technology platforms

Leveraging our established platforms and capabilities, we are committed to expanding our global footprint to unlock and maximize the potential of our product matrix and technology platforms. As of the Latest Practicable Date, we had initiated over 20 overseas clinical trials, including in the U.S., Europe, Australia, Japan, and South Korea, and had commercialized our products in over 40 countries. We proactively seek to launch our products in the global market. From 2018 to the Latest Practicable Date, we had obtained approximately 60 facilitated regulatory pathways, spanning priority review, breakthrough therapy, fast track, and orphan drug designations, including eight from the U.S. FDA and the EMA.

In addition, we proactively explore value-accretive partnerships with leading pharmaceutical companies, particularly global peers, to maximize the commercial value of our drugs. Over the years, our drugs have drawn increasing attention from potential global partners seeking innovative drugs, particularly our drugs with best-in-class or first-in-class potential, culminating in multi-bidder out-licensing transactions. Since 2018, we have carried out 12 out-licensing transactions with global partners, involving 15 molecular entities. The aggregate deal value of these transactions was approximately US$12 billion, with total upfront payments of approximately US$400 million, in addition to equity interest in certain collaboration partners. Set forth below are representative examples of our out-licensing arrangements in the past two years:

Kailera Therapeutics *(formerly known as Hercules).* In May 2024, we out-licensed to Kailera Therapeutics the exclusive rights to develop and commercialize three of our proprietary GLP-1 drug candidates—HRS-7535, HRS9531, and HRS-4729—worldwide (excluding the Greater China region). Kailera Therapeutics agreed to provide us with an upfront payment of US$100 million, a near-term technology transfer milestone payment of US$10 million, and 19.9% of its equity interest. With a total deal value of approximately US$6 billion, this transaction was a landmark partnering transaction in China's pharmaceutical industry. With this collaboration, we aim to capture a portion of the huge global market in metabolism and learn the best practices in global clinical development and commercialization for a broader product pipeline.

Merck KGaA, Darmstadt, Germany. In October 2023, we entered into a strategic collaboration and license agreement with a fully owned subsidiary of Merck KGaA, Darmstadt, Germany, or MRKDG. Pursuant to this agreement, we out-licensed to this fully owned subsidiary of MRKDG certain exclusive rights or options to develop, manufacture, and commercialize HRS-1167 (our proprietary PARP1 inhibitor) and SHR-A1904 (our proprietary CLDN18.2 ADC) worldwide (outside of mainland China), and an option to co-promote HRS-1167 and SHR-A1904 with us within mainland China. Under this agreement, this fully owned subsidiary of MRKDG agreed to provide us with an upfront payment of €160 million, additional payments upon the achievement of certain development, regulatory and commercial milestones, as well as tiered royalties on net sales by this fully owned subsidiary of MRKDG. Potential payments may total up to €1.4 billion.

IDEAYA Biosciences. In December 2024, we entered into a collaboration and license agreement with IDEAYA Biosciences, a precision medicine oncology company headquartered in the United States. Pursuant to this agreement, we out-licensed to IDEAYA Biosciences the exclusive rights to develop, manufacture, and commercialize SHR-4849 worldwide (excluding the Greater China region). Under this agreement, IDEAYA Biosciences agreed to provide us with an upfront payment of US$75 million. We are also entitled to receive payments of up to US$970 million upon the achievement of certain development, approval and sales milestones, as well as single- to double-digit sales royalties based on future actual annual net sales of SHR-4849 worldwide (excluding the Greater China region).

Internationally competitive team of industry veterans led by visionary leaders

We boast a highly sophisticated and experienced management team with global vision. We benefit from their visionary leadership, remarkable accomplishments, and complementary expertise across the pharmaceutical industry value chain, both in China and globally.

Mr. Sun Piaoyang, our chairman, is a visionary industry veteran with extensive expertise and experience in the pharmaceutical industry. Mr. Sun plays a pivotal role in our success and growth on the global stage. Since 1990, he has successfully led the transformation of our company into a leading global pharmaceutical company focused on high-quality innovative drugs. Under Mr. Sun's leadership, we have built up Hengrui's ecosystem comprising great talent, organization, and culture, which underlies our research, clinical, manufacturing, and commercialization capabilities.

Under Mr. Sun's leadership, we have adopted a dedicated and experienced core management team to steer our growth path:

- Mr. Dai Hongbin, our Executive Director and General Manager (President), primarily leads our overall business operations. Mr. Dai has over 24 years of industry experience and sophisticated management and execution skills. He has been instrumental in our growth and transformation over the past two decades.

- Mr. Zhang Lianshan, our Executive Director and Executive Vice President, is in charge of our overall R&D. Mr. Zhang has over 42 years of experience in the biomedical research and pharmaceutical industry.

- Mr. Jiang Frank Ningjun, our Executive Director, Executive Vice President, and Chief Strategy Officer, is in charge of our clinical development and business development. Mr. Jiang has over 40 years of experience in the medical/pharmaceutical industry, including over 35 years of experience and expertise in medical and clinical research in the U.S., Canada, and China.

Our senior management team is well supported by a pool of internationally competitive talent. We attract high-caliber talent globally through diverse channels and benefit tremendously from the strong support of our elite R&D team, including top-notch scientists. As of September 30, 2024, we had an R&D team of over 5,500 professionals in various therapeutic areas. Nearly 60% of our R&D team members hold a master's degree or a Ph.D. or M.D. Many of them have prior work experience at multinational pharmaceutical companies, such as Pfizer, Novartis, Merck, and Eli Lilly and Company, as well as renowned research institutes, such as Yale School of Medicine, Heidelberg University, and the University of Texas Southwestern Medical Center. Moreover, over 30% of our mid-level or above management members as of November 30, 2024 have overseas education or work experience. We believe that our talented team has played a critical role in our growth and will continue to drive our innovation and success in developing effective innovative therapies.

OUR STRATEGIES

Our mission is to promote a healthier life for humankind through advancements in science. We will implement the following strategies to achieve our goal:

Accelerate our global expansion to address immense unmet medical needs worldwide

Leveraging our well-established leading position in China, global network of business partners and R&D centers, and sales coverage in more than 40 overseas markets, we are committed to accelerating our global expansion and leveraging our global-standard innovation capabilities to address immense unmet medical needs worldwide.

We will accelerate our integration into the global pharmaceutical market by increasing our innovative drugs' international recognition and accessibility. To achieve this goal, we will carry out and advance multi-regional clinical trials for more of our innovative drugs and further expand the therapeutic areas and indication coverages of our innovative products for the global market. In addition, we will seek to obtain facilitated regulatory pathways for more of our drug candidates from overseas regulators to quickly bring them to the market and benefit patients.

As part of our global strategy, we will focus on developing innovative drugs with first-in-class or best-in-class potential to quickly penetrate key markets around the globe and enhance our brand's global recognition. Along with this strategy and leveraging our robust innovative product pipeline, we will proactively explore more out-licensing opportunities to augment our global presence. We plan to partner with global peers that we believe can help accelerate development and commercialization of our innovative products in overseas markets and maximize the value of our highly differentiated innovative drugs and drug candidates. We will also pursue overseas collaboration opportunities for our drugs with a view to promoting our brand recognition in the medical community and boosting our global market share.

Moreover, we will explore in-licensing and co-development opportunities for global peers' drug candidates, particularly those with innovative modalities or targets and great market potentials. We intend to in-license drugs that complement our existing product matrix in our major therapeutic areas and potentially deliver favorable treatment outcomes to address significant medical needs in China and globally.

Aside from organic growth, we also intend to selectively acquire or invest in overseas pharmaceutical or biotechnology companies, including those with attractive drug assets or strong R&D, manufacturing, or commercialization capabilities. Through these acquisitions and investments around the globe, we expect to rapidly and efficiently deepen our penetration in key markets, complement our existing product matrix, and achieve synergies with our existing capabilities and network.

To support our global footprint, we will boost our brand recognition in the global pharmaceutical community through enhanced branding initiatives. We will also participate in exhibitions, conferences, and seminars to showcase our products, connect with global peers, and enhance our international influence. In line with our commitment to social responsibility, we will continue to contribute to international charity endeavors, which we believe can further enhance our brand image.

Further bolster our R&D capabilities to develop more highly differentiated innovative drugs

Building on our decades of innovation efforts, we have established an industry-leading matrix of commercialized and pipeline innovative drugs. We intend to solidify and advance this position by further bolstering our R&D capabilities to develop more differentiated, high-quality innovative drugs, with an aim to address significant and growing unmet medical needs. In particular, as part of our China strategy, we will follow a multi-pronged R&D approach and devote more resources to developing therapeutics with our extensive toolkit of technologies and modalities and in different dosage forms, as well as combination therapies, that provide comprehensive treatment options for high-incidence diseases, such as Alzheimer's Disease, Parkinson's Disease, HCC, and cardiovascular diseases. In addition, we will maintain our seamless drug roll-out cycle by advancing clinical development, registration, and commercialization of our drug candidates, while at the same time swiftly replenishing our pipeline through continuous research and drug discovery.

We will continue to upgrade our comprehensive technology platforms and accelerate the evolution of our existing modalities to propel our development of more innovative monotherapies and combination therapies that offer better safety and efficacy to satisfy the significant unmet medical needs. For example, we are developing a new generation of site-specific conjugation techniques with proprietary intellectual property to enhance ADC homogeneity. In addition, we are developing new payloads (toxin molecules) with various MOAs for different tumor types. These innovative small molecule toxins will help us overcome ADC resistance, expand therapeutic areas and indications, and yield a more diverse AXC product portfolio. We also seek to apply PROTAC technology in more indications and therapeutic areas in combination with our other drugs or modalities. We expect that continuous enhancements to our platforms will allow us to rapidly roll out new drugs to cover a broader spectrum of indications, thus significantly expanding our patient reach.

In addition to self-development, we will actively explore opportunities to collaborate with leading biopharmaceutical companies, universities, and research institutes through arrangements such as technology in-licensing, joint laboratories, and collaborative research to accelerate our adoption of cutting-edge technologies. We also intend to selectively pursue strategic alliances, joint ventures, and acquisitions to deepen our research in areas such as RNA drugs and polymer drugs, thus creating a diversified innovation ecosystem. Meanwhile, we intend to provide all-round support and services to startup companies by building a comprehensive incubation platform integrating incubation of research results, entrepreneurship counseling, investment, financing, and market access. Through these efforts, we expect to collaborate with startups on promising projects at an early stage, thus providing additional impetus to our innovation capabilities.

Identifying differentiated, high-value innovative targets to treat diseases at an early stage will remain a key research focus for our drug discovery. We will actively screen novel targets worldwide to enhance our ability to discover first-in-class molecules. At the same time, we will use our expertise in translational medicine to improve the predictability and success of our drug discovery and expedite the validation of molecule candidates.

Furthermore, by applying our patient-oriented clinical development strategy, we will aim to swiftly and cost-effectively advance the clinical development of our product candidates by leveraging our end-to-end clinical development capabilities and extensive network of clinical investigators and trial sites. For our potentially first-in-class or best-in-class products, we will proactively advance their multi-regional clinical trials to achieve concurrent IND submissions globally and pursue facilitated regulatory pathways to accelerate their time to market. As part of this approach, we will actively monitor our trials' adherence to regulatory standards and enhance communications with regulatory authorities to facilitate a smooth regulatory approval process.

In line with our global expansion, we intend to expand our R&D network by establishing and expanding our presence in biotechnology hubs to focus on cutting-edge technologies and collaboration with more top-tier research institutes and biotechnology companies. We will also pursue seamless collaboration among our R&D teams around the globe to expedite the commercialization of our research results. Moreover, we will continue to monitor developments in emerging technologies, such as biotechnology, new materials, and artificial intelligence, and we may consider acquiring technologies through investments and collaborations to drive innovation.

Further strengthen our manufacturing system supported by global-standard quality system

In line with the expansion of our matrix of innovative products, we intend to expand our production capacity in China, in particular to support the ongoing commercialization of our innovative product candidates. In addition, we will continue to upgrade our existing production facilities, with a focus on improving our production efficiency, increasing the modalities we manufacture, and ensuring compliance with global GMP standards, to meet increasing demand for our high-quality innovative drugs in China and around the globe. For example, we are upgrading our production facility in Xiamen, which will primarily manufacture high-end drug substances for modalities such as siRNAs and peptides across multiple therapeutic areas. This production facility will comply with global quality standards, including the EU GMP and the U.S. cGMP, and adopt cutting-edge automated production lines and intelligent management systems to significantly enhance production efficiency. Upon completion of its construction, this production facility will substantially increase our high-end API production capacity, thus further strengthening our manufacturing capabilities across both drug substances and products.

In addition, we intend to strengthen our manufacturing capabilities by establishing production facilities in key markets around the globe. We plan to prioritize regions with adequate supply chain facilities, cost advantages, and a favorable regulatory environment. By establishing overseas production facilities, we expect to further optimize our supply chains and reduce logistical expenses associated with our drugs for clinical trials, registration approvals, and commercialization in those markets. This will also allow us to be more responsive to local patients' demand for timely access to our products. Along with these initiatives, we also plan to strengthen our collaboration and coordination with our domestic and international suppliers to ensure stable supplies of drug substances and other raw materials.

We are committed to building and upgrading our production facilities with state-of-the-art equipment supported by global-standard quality system. To fulfill this commitment, we intend to ensure that our relevant production facilities comply with or exceed applicable GMP standards, such as the EU GMP, the U.S. cGMP, and the ICH Quality Guidelines. We believe this approach will enable us to effectively manage our scale-up process, ensure our products' compliance with world-class safety and quality standards, and reinforce our reputation as a trusted pharmaceutical manufacturer.

Further enhance our commercialization capabilities in China and around the globe

We are committed to further enhancing our commercialization capabilities in China and around the globe to efficiently bring our drug candidates efficiently from bench to bedside. To increase the market acceptance and sales volume of our differentiated innovative drugs, we plan to strengthen our academic promotion efforts and promote their clinical benefits to patients, physicians, and the medical community. We will continue to organize and participate in academic conferences and seminars and collaborate with leading research institutes, key opinion leaders, and scholars to enhance our brand recognition. More importantly, we intend to strengthen the medical knowledge of our sales and marketing team and enhance their capabilities in addressing post-market technical issues of our innovative drugs.

We place strong emphasis on increasing our market penetration and sales productivity. We intend to maximize our market reach in China by expanding our coverage of medical institutions in lower-tier cities, rural areas and community healthcare service centers. In addition, we will continue improving our sales productivity by accelerating our digital transformation, including by optimizing our sales management processes, strengthening our online sales capabilities, and enhancing our chronic disease services. Specifically, to boost our strength in the fields of oncology and chronic diseases, we intend to further enhance patient services and improve their long-term disease management through various channels and platforms.

Furthermore, we intend to strengthen our global commercialization. We plan to collaborate with leading local pharmaceutical distribution companies and leverage their channel resources and marketing network to swiftly penetrate key markets around the globe. In addition, to promote the global rollout of our products, we will augment our in-house sales force and increase our local presence by establishing sales offices in key markets around the globe.

Based on the nature of our products and the characteristics of domestic and overseas markets, we will dynamically adjust our pricing strategy, providing a combination of reimbursed products targeting hospitals and self-paid products oriented at consumers. For the products we commercialize in key markets around the globe, we also aim to rapidly integrate them into the relevant health insurance payment systems to maximize their commercial value.

Recruit and retain top-notch talent to fuel our innovation and global expansion

Our talent strategy is driven by the requirements of our business operations. The success of our business growth and global expansion will depend on our ability to recruit and retain highly talented professional R&D, manufacturing, and sales and marketing personnel, as well as an experienced management team.

We will further strengthen our elite scientific research, clinical development, and CMC teams across diverse therapeutic areas. In particular, we intend to recruit top-notch scientists specialized in fields such as biotechnology and precision medicine to accelerate our drug discovery and improve our drug development success rate. These efforts are expected to elevate our overall research capabilities and international competitiveness. In addition, to support our global expansion, we will seek R&D talent with international exposure, including by engaging with global pharmaceutical organizations to build a broad network of international talent connections. To drive innovation, we will also strengthen our training of R&D personnel and provide incentive compensation and other rewards to employees who make outstanding contributions to our innovation efforts.

We also plan to recruit management professionals with extensive strategic planning and execution experience. We intend to leverage their expertise to effectively source, evaluate, and analyze potential M&A and other business development targets to drive the expansion of our global footprint.

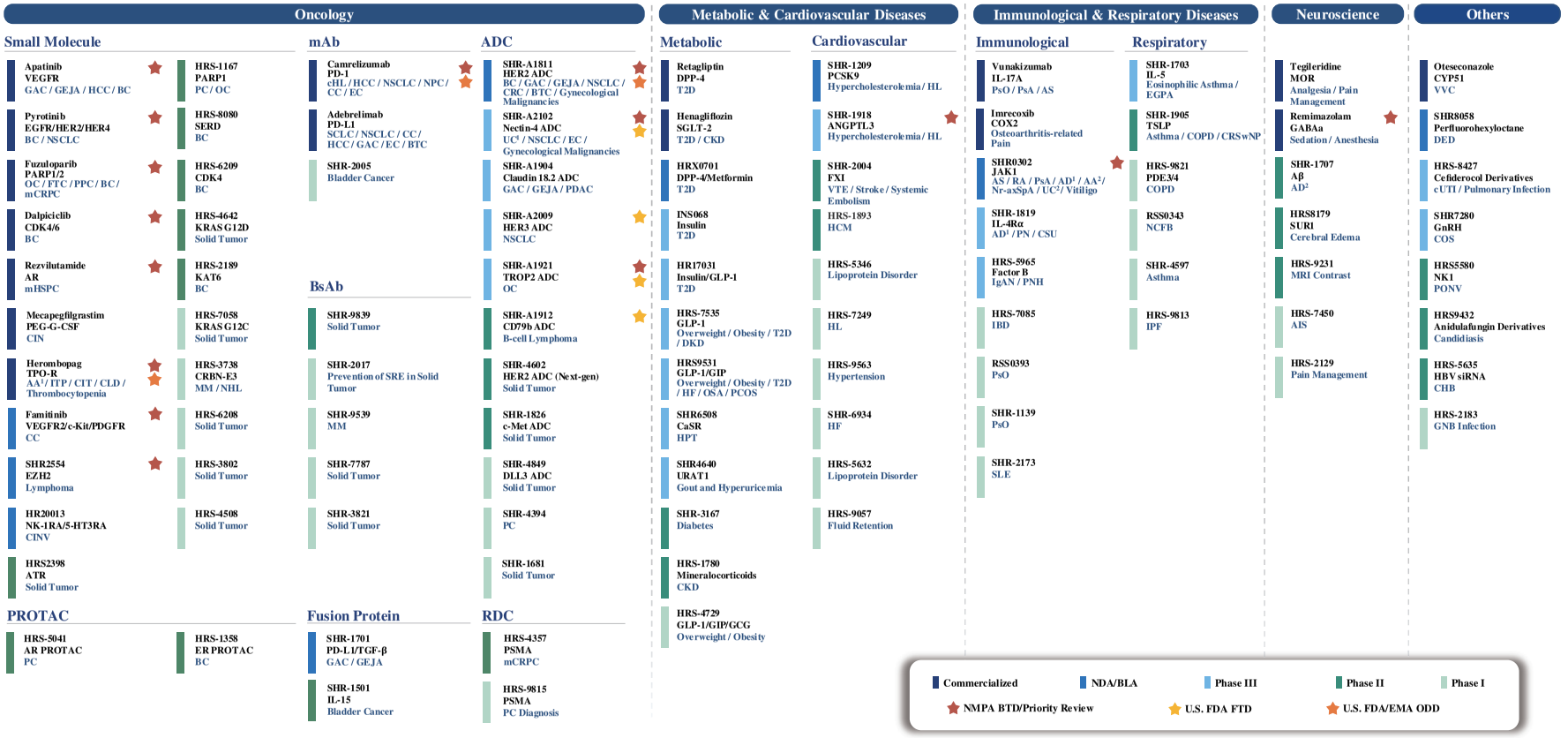
Moreover, we are committed to fostering a culture of continuous learning and innovation among our employees and continuously improving our employees' job satisfaction and stability. As we grow our team internationally, we will also enhance cross-cultural communication within our Group and conduct training to enhance our employees' global perspectives. For example, we intend to provide our staff with more opportunities to participate in overseas training programs and international conferences and help them stay abreast of global cutting-edge technologies. To attract and retain exceptionally talented staff, we will provide better career development opportunities and competitive benefits to incentivize them.

OUR PRODUCTS AND PRODUCT CANDIDATES

Overview

We have an extensive drug portfolio that strategically covers a wide spectrum of therapeutic areas with significant unmet medical needs and growth potential. As of the Latest Practicable Date, we had over 110 commercialized drugs, including 17 NME drugs and four other innovative drugs. In addition, we maintain a sustainable drug roll-out cycle by swiftly replenishing our pipeline through continuous drug discovery and development. For example, in 2022, 2023, and the nine months ended September 30, 2024, in China, we initiated six, 18, and 22 pivotal clinical studies for our innovative drugs and drug candidates, and obtained the approval for first-in-human clinical studies of 19, 23, and 19 of our innovative drug candidates, respectively. Additionally, we submitted eight NDAs/BLAs for our innovative drugs in 2024. As of the Latest Practicable Date, we had a pipeline of over 90 NME drug candidates and eight other innovative drug candidates in clinical or later stages of development, including over 30 innovative drug candidates in pivotal clinical studies or later stages of development.

The chart below presents certain information about our commercialized NME drugs and NME drug candidates in clinical or later stages of development as of the Latest Practicable Date.



Notes: 1. The list is non-exhaustive; 2. Clinical stage of each product/product candidate represents for its most advanced indication(s); 3. Facilitated regulatory pathways from 2018 to the Latest Practicable Date; 4. We have the co-development and exclusive commercialization rights for linperlisib (PI3Kδ) in the Greater China region

Abbreviations: AA[1] = Aplastic Anemia; AA[2] = Alopecia Areata; AD[1] = Atopic Dermatitis; AD[2] = Alzheimer's Disease; AIS = Acute Ischemic Stroke; AS = Ankylosing Spondylitis; BC = Breast Cancer; BTC = Biliary Tract Cancer; CC = Cervical Cancer; CHB = Chronic Hepatitis B; cHL = classic Hodgkin Lymphoma; CIN = Chemotherapy-induced Neutropenia; CINV = Chemotherapy-induced Nausea and Vomiting; CIT = Chemotherapy-induced Thrombocytopenia; CKD = Chronic Kidney Disease; CLD = Chronic Liver Disease; COPD = Chronic Obstructive Pulmonary Disease; COS = Controlled Ovarian Stimulation; CRC = Colorectal Cancer; CRSwNP = Chronic Rhinosinusitis with Nasal Polyps; CSU = Chronic Spontaneous Urticaria; cUTI = complicated Urinary Tract Infection; DED = Dry Eye Syndrome; DKD = Diabetic Kidney Disease; EC = Esophageal Cancer; EGPA = Eosinophilic Granulomatosis with Polyangiitis; FTC = Fallopian Tube Carcinoma; GAC = Gastric Adenocarcinoma; GEJA = Gastroesophageal Junction Adenocarcinoma; GNB = Gram-negative Bacteria; HCC = HepatocellularCarcinoma; HCM = Hypertrophic Cardiomyopathy; HF = Heart Failure; HL = Hyperlipidemia; HPT = Hyperparathyroidism; IBD = Inflammatory Bowel Disease; IgAN = IgA Nephropathy; IPF = Idiopathic Pulmonary Fibrosis; ITP = Immune Thrombocytopenia; LC = Lung Cancer; mCRPC = Metastatic Castration-Resistant Prostate Cancer; mHSPC = Metastatic Hormone Sensitive Prostate Cancer; MM = Multiple Myeloma; MRI = Magnetic Resonance Imaging; NCFB = Non Cystic-Fibrosis Bronchiectasis; NHL = Non-Hodgkin Lymphoma; NPC = Nasopharyngeal Carcinoma; Nr-axSpA = Non-radiographic Axial Spondyloarthritis; NSCLC = Non-Small Cell Lung Cancer; OC = Ovarian Cancer; OSA = Obstructive Sleep Apnea; PC = Prostate Cancer; PCOS = Polycystic Ovary Syndrome; PDAC = Pancreatic Ductal Adenocarcinoma; PN = Prurigo Nodularis; PNH = Paroxysmal Nocturnal Hemoglobinuria; PONV = Postoperative Nausea and Vomiting; PPC = Primary Peritoneal Carcinoma; PsA = Psoriatic Arthritis; PsO = Psoriasis; RA = Rheumatoid Arthritis; SCLC = Small Cell Lung Cancer; SLE = Systemic Lupus Erythematosus; SpA = Spondyloarthritis; SRE = Skeletal-related Event; T2D = Type 2 Diabetes; UC[1] = Urothelial Carcinoma; UC[2] = Ulcerative Colitis; VTE = Venous Thromboembolism; VVC = Vulvovaginal Candidiasis

Our revenue from sales of innovative drugs as a percentage of our total revenue increased from 38.1% in 2022 to 43.4% in 2023 and further to 47.7% in the nine months ended September 30, 2024. The following table summarizes selected information relating to our 17 commercialized NME drugs.

Therapeutic Area	Product	Target (Modality)	Approved Indication(s)	Time of First Approval	Year of First Inclusion in NRDL	Source
Oncology	Adebrelimab (AiRuiLi®)	PD-L1 (mAb)	• Combo with carboplatin and etoposide for 1L ES-SCLC	February 2023	NA	In-house developed
	Linperlisib (YinTaRui®)★	PI3Kδ (small molecule)	• r/r FL in adult patients after 2L+ systematic treatment	November 2022	2023	Note (1)
	Rezvilutamide (AiRuiEn®)★	AR (small molecule)	• mHSPC with high tumor burden	June 2022	2022	In-house developed
	Dalpiciclib (AiRuiKang®)★	CDK4/6 (small molecule)	• Combo with fulvestrant for relapsed or metastatic HR+/HER2- BC progressed after ET; and • Combo with aromatase inhibitor for 1L ET in LA/M HR+/HER2- BC	December 2021	2022	In-house developed
	Herombopag (HengQu®)★	TPO-R (small molecule)	• Adult patients with chronic primary ITP who have previously responded poorly to treatments such as glucocorticoids and immunoglobulins; and • Adult patients with severe AA who are refractory to ISx therapy	June 2021	2021	In-house developed
	Fuzuloparib (AiRuiYi®)★	PARP1/2 (small molecule)	• Maintenance therapy for advanced EOC, FTC, or PPC in adult patients after CR/PR from platinum-containing chemo; • Platinum-sensitive gBRCA-mut recurrent OC, FTC, or PPC after 2L+ chemo; • Maintenance therapy for platinum-sensitive recurrent EOC, FTC, or PPC in adult patients after platinum-containing chemo; and • Monotherapy or combo with apatinib for gBRCA-mut metastatic HER2- BC in adult patients	December 2020	2021	In-house developed
	Camrelizumab (AiRuiKa®)★	PD-1 (mAb)	• r/r cHL after at least two systematic therapies; • Advanced HCC after sorafenib and/or lenvatinib and/or oxaliplatin-containing chemo; • Combo with pemetrexed+carboplatin for unresectable LA/M EGFR-mut negative ALK-negative 1L NSCLC; • LA/M ESCC progressed after or intolerable to 1L chemo; • Advanced NPC progressed after or intolerable to 2L+ chemo; • Combo with cisplatin+gemcitabine for 1L locally relapsed or metastatic NPC; • Combo with cisplatin+paclitaxel for 1L unresectable locally advanced/relapsed or metastatic ESCC; • Combo with carboplatin+paclitaxel for 1L LA/M sNSCLC; and • Combo with apatinib for 1L unresectable or metastatic HCC	May 2019	2020	In-house developed
	Mecapegfilgrastim (AiDuo®)	PEG-G-CSF (small molecule)	• Chemo-induced neutropenia in adults with nonmyeloid malignant cancers	May 2018	2019	In-house developed
	Pyrotinib (AiRuiNi®)★	EGFR/HER2/HER4 (small molecule)	• Combo with trastuzumab+docetaxel for relapsed or metastatic advanced HER2+ BC patients without previous HER2 treatment; • Combo with capecitabine for relapsed or metastatic HER2+ BC with/without previous trastuzumab treatment; and • Combo with trastuzumab+docetaxel for neoadjuvant treatment for early or LA HER2+ BC	August 2018	2019	In-house developed
	Apatinib (AiTan®)★	VEGFR (small molecule)	• Advanced GAC or GEJA progressed or relapsed after at least 2Ls of systematic chemo; • Advanced HCC failed or intolerable after at least 1L systemic therapy; • Combo with camrelizumab for 1L unresectable or metastatic HCC; and • Combo with fuzuloparib for gBRCA-mut metastatic HER2- BC in adult patients	October 2014	2017	In-house developed

Therapeutic Area	Product	Target (Modality)	Approved Indication(s)	Time of First Approval	Year of First Inclusion in NRDL	Source
Metabolic and Cardiovascular Diseases	Retagliptin (RuiZeTang®)	DPP-4 (small molecule)	• Monotherapy/combo with metformin to improve glycemic control in adult patients with type 2 diabetes, in combination with diet and exercise	June 2023	2023	In-house developed
	Henagliflozin (RuiQin®)	SGLT-2 (small molecule)	• Monotherapy/combo with metformin/combo with metformin + retagliptin to improve glycemic control in adult patients with type 2 diabetes, in combination with diet and exercise	December 2021	2022	In-house developed
Immunological and Respiratory Diseases	Vunakizumab (AnDaJing®)	IL-17A (mAb)	• Adults with moderate-to-severe plaque PsO who are eligible for receiving systemic therapy or phototherapy	August 2024	NA	In-house developed
	Imrecoxib (HengYang®)	COX2 (small molecule)	• Osteoarthritis-related pain	June 2011	2017	In-house developed
Neuroscience	Tegileridine (AiSuTe®)	MOR (small molecule)	• Post-operative moderate-to-severe analgesia for abdominal surgeries	January 2024	2024	In-house developed
	Remimazolam (RuiBeiNing®)★	GABAa (small molecule)	• Sedation and anesthesia in non-intubated surgery/operation; and induction and maintenance of general anesthesia	December 2019	2021	In-house developed
Others	Oteseconazole (Rubicam®)	CYP51 (small molecule)	• Severe VVC	June 2023	2024	Note (2)

Abbreviations: 1L = first -line; 2L = second-line; AA = aplastic anemia; AS = ankylosing spondylitis; BC = breast cancer; BRCA = BReast CAncer gene; cHL = classic Hodgkin Lymphoma; chemo = chemotherapy; combo = combination; EOC = epithelial ovarian carcinoma; ESC = esophageal squamous carcinoma; ESCC = esophageal squamous cell carcinoma; ES-SCLC = extensive-stage small cell lung cancer; ET = endocrine therapy; FL = follicular lymphoma; FTC = fallopian tube carcinoma; GAC = gastric adenocarcinoma; GEJA = gastroesophageal junction adenocarcinoma; HCC = hepatocellular carcinoma; HER2- = human epidermal growth factor receptor 2-negative; HR = hormone receptor; ITP = immune thrombocytopenia; ISx = immunosuppressive; LA = locally advanced; LA/M = locally advanced or metastatic; mHSPC = metastatic hormone sensitive prostate cancer; NPC = nasopharyngeal carcinoma; NSCLC = non-small cell lung cancer; OC = ovarian cancer/carcinoma; PPC = primary peritoneal carcinoma; r/r = relapsed, refractory; PsO = psoriasis; sNSCLC = squamous non-small cell lung cancer; VVC = vulvovaginal candidiasis

★ Indicates that the product has received facilitated regulatory pathway for certain indication(s), such as the NMPA breakthrough therapy designation, NMPA priority review, U.S. FDA fast track designation, U.S. FDA orphan drug designation, or EMA orphan drug designation.

(1) In February 2021, we entered into a strategic cooperation agreement with Yingli Pharma, pursuant to which Yingli Pharma granted us the right to co-develop and the exclusive right to commercialize linperlisib, a new generation of small molecule inhibitor of phosphoinositide 3-kinase delta (PI3Kδ), in the Greater China region. See "—Collaboration and Licensing Arrangements—In-Licensing and Co-Development Arrangements—Strategic Cooperation Agreement with Yingli Pharma."

(2) In June 2019, we entered into an exclusive agreement with Mycovia Pharmaceuticals to develop and commercialize its investigational drug, otesaconazole (also known as VT-1161), in the Greater China region. For details, see "—Collaboration and Licensing Arrangements—In-Licensing and Co-Development Arrangements—Collaboration and License Agreement with Mycovia Pharmaceuticals."

We are conducting clinical studies targeting an array of indications for our commercialized innovative drugs, both as a monotherapy and as part of a combination therapy, in China and around the globe. The following chart sets forth selected information on the indication expansions of our commercialized NME drugs as of the Latest Practicable Date.

	Drug Name/ Code	Target(s)	Mono/Combo	Indication(s)	Phase I	Phase II	Phase III	NDA/BLA
Oncology	Adebrelimab	PD-L1	Combo	1L limited-stage SCLC	China			
			Combo	Perioperative treatment of resectable Stage II/III NSCLC	China			
			Combo (SHR-8068 + doublet chemo)	1L STK11/KEAP1/KRAS mutated advanced or metastatic non-squamous NSCLC	China			
			Combo (SHR-8068 + bevacizumab)	Advanced HCC	China			
			Combo	Locally advanced CC	China			
			Combo (SHR-8068 + chemo)	Advanced NSCLC	China			
			Combo (SHR-8068 + chemo)	Advanced GAC or EC	China			
			Combo (SHR-8068 + chemo)	1L advanced BTC	China			
	Camrelizumab	PD-1	Combo (famitinib)	Recurrent metastatic CC	China			
			Combo (apatinib)	1L advanced HCC	U.S., EU, APAC (including China)[1]			
			Mono	Relapsed and refractory cHL	China			
			Combo (TACE + apatinib)	Unresectable HCC	China			
			Combo	Unresectable locally advanced EC	China			
			Combo (famitinib)	1L advanced CC	China			
	Dalpiciclib	CDK4/6	Combo	Adjuvant therapy for HR+/HER2- BC	China			
	Fuzuloparib	PARP1/2	Combo (abiraterone)	mCRPC	U.S., EU, APAC (including China)			
	Pyrotinib	EGFR/ HER2/HER4	Mono	Extended adjuvant therapy for HER2+ BC	China			
			Mono	Advanced non-squamous NSCLC with HER2 mutation	U.S., EU, APAC (including China)			
	Rezvilutamide	AR	Mono	mHSPC	EU, China[2]			
	Herombopag	TPO-R	Combo	Primary treatment of severe AA	China			
			Mono	CIT	China			
			Mono	Children with ITP	China			
			Mono	CLD with thrombocytopenia from invasive procedures or surgeries	China			
			Mono	CIT	U.S., EU, AU			
			Combo	Primary treatment of non-severe AA	China			
Metabolic	Henagliflozin	SGLT-2	Mono	CKD	China			
Immunological	Vunakizumab	IL-17A	Mono	Active AS in adults	China			
			Mono	Moderate-to-severe chronic plaque PsO in children and adolescents	China			
			Mono	PsA	China			
Neuroscience	Tegileridine	MOR	Mono	Moderate-to-severe pain after orthopedic surgery	China			
	Remimazolam	GABAa	Mono	ICU sedation with mechanical ventilation	China			

Notes:

(1) China: approved; U.S.: BLA filed; Europe: Phase III

(2) China: approved; Europe: Phase III

The following chart sets forth selected information on our NME drug candidates in clinical or later stages of development as of the Latest Practicable Date.

		Drug Name/ Code	Target(s)	Mono/Combo	Indication(s)	Phase I	Phase II	Phase III	NDA/BLA
Oncology	Small Molecule	SHR2554	EZH2	Mono	Relapsed and refractory PTCL	China			
				Combo	T-cell lymphoma	China			
				Mono	Relapsed and refractory FL	China			
				Mono	Refractory/relapsed T-cell lymphoma	China			
		HR20013	NK-1RA/ 5-HT3RA	Mono (FDC)	Highly emetogenic CINV	China			
				Mono (FDC)	Nausea and vomiting caused by anti-tumor drugs that pose moderate emetic risk	China			
		HRS2398	ATR	Combo	Advanced solid tumors	China			
		HRS-1167	PARP1	Combo	Advanced PC	China			
				Combo (bevacizumab)	Relapsed OC	China			
				Mono	Advanced solid tumors	China			
		HRS-8080	SERD	Combo (dalpiciclib)	ER+/HER2- unresectable or metastatic BC	China			
				Mono/Combo	Advanced BC	China			
		HRS-6209	CDK4	Combo (HRS-8080/HRS-1358)	Advanced BC	China			
				Mono	Advanced solid tumors	China			
		HRS-4642	KRAS G12D	Combo	Advanced solid tumors with KRAS G12D mutations	China			
				Mono	Advanced solid tumors	China			
		HRS-2189	KAT6	Combo	Advanced BC	China			
				Mono	Advanced malignant tumors	China			
		HRS-7058	KRAS G12C	Mono	Advanced solid tumors	China			
		HRS-3738	CRBN-E3	Mono/Combo	MM and NHL	China			
		HRS-6208	-	Mono	Advanced malignant solid tumors	China			
		HRS-3802	-	Mono	Advanced malignant solid tumors	China			
		HRS-4508	-	Mono	Advanced malignant solid tumors	China			
	PROTAC	HRS-5041	AR PROTAC	Combo	Advanced PC	China			
				Mono	mCRPC	China			
				Mono	mCRPC	AU			
		HRS-1358	ER PROTAC	Mono/Combo (dalpiciclib)	Advanced BC	China			
	Fusion Protein	SHR-1701	PD-L1/TGF-β	Combo (chemo)	1L advanced or metastatic GAC/GEJA	China			
				Mono	Advanced solid tumors	AU			
		SHR-1501	IL-15	Combo (BCG bladder perfusion)	Non-muscle invasive bladder cancer	China			
	mAb	SHR-2005	-	Mono	Bladder cancer	China			
	BsAb	SHR-9839	-	Combo	Advanced solid tumors	China			
				Mono	Advanced solid tumors	China			
		SHR-2017	-	Mono	Prevention of SRE in patients with bone metastases from solid tumors	China			
		SHR-9539	-	Mono	MM	China			
		SHR-7787	-	Mono	Advanced malignant solid tumors	China			
		SHR-3821	-	Mono	Advanced malignant solid tumors	China			
	ADC	SHR-A1811	HER2 ADC	Mono	2L+ locally advanced or metastatic HER2 mutant NSCLC	China			
				Mono	HER2+ metastatic BC	China			
				Mono	HER2-low recurrent/metastatic BC	China			
				Mono	Adjuvant therapy for HER2+ BC	China			
				Combo	HER2+ recurrent or metastatic BC	China			
				Mono	3L advanced HER2+ CRC	China			
				Mono	1L HER2-mutated advanced or metastatic NSCLC	China			
				Combo (fuzuloparib)	Advanced solid tumors with HER2 expression	China			
				Combo (pyrotinib/adebrelimab)	1L advanced NSCLC with HER2 mutation, amplification, or overexpression	China			
				Combo	HER2-low metastatic or unresectable BC	China			
				Mono	HER2-expressing gynecological malignancies	China			
				Combo (adebrelimab + chemo)	Advanced HER2-expressing GAC/GEJA	China			
				Mono	Locally advanced unresectable or recurrent metastatic BTC with HER2 expression/amplification	China			
				Mono	GAC/GEJA and CRC	China			
				Mono	Advanced solid tumors	U.S., AU, APAC(1)			

Note:

(1) Including China.

		Drug Name/ Code	Target(s)	Mono/Combo	Indication(s)	Phase I	Phase II	Phase III	NDA/BLA
Oncology	ADC	SHR-A2102	Nectin-4 ADC	Mono	2/3L locally advanced or metastatic UC	China			
				Combo (adebrelimab)	Locally advanced or metastatic EC	China			
				Mono	Advanced gynecological malignancies	China			
				Combo	Locally advanced or metastatic NSCLC	China			
				Combo (adebrelimab)	Advanced UC	China			
				Mono	Advanced solid tumors	U.S.			
				Mono	Advanced solid tumors	China			
		SHR-A1904	Claudin 18.2 ADC	Mono	2L advanced CLDN18.2+ GAC/GEJA	China			
				Combo (adebrelimab)	Advanced CLDN18.2+ solid tumors	China			
				Mono	Advanced PDAC	China			
				Mono	Advanced solid tumors	China			
				Mono	Advanced solid tumors	U.S., AU			
		SHR-A2009	HER3 ADC	Mono	EGFR-mutated advanced or metastatic NSCLC with failed EGFR TKI therapy	China			
				Combo	Advanced solid tumors	China			
				Mono	Advanced or metastatic solid tumors	China			
				Mono	Advanced solid tumors	Japan, Korea			
		SHR-A1921	TROP2 ADC	With/Without carboplatin	Platinum-sensitive recurrent epithelial OC	China			
				Mono	Platinum-resistant recurrent epithelial OC	China			
				Combo	Advanced solid tumors	China			
				Mono	Advanced solid tumors	U.S., AU			
		SHR-A1912	CD79b ADC	Combo	B-cell NHL	China			
				Mono	B-cell lymphoma	China			
				Mono	B-cell NHL	U.S.			
		SHR-4602	HER2 ADC (Next-gen)	Combo	Advanced HER2-expressing or -mutated solid tumors	China			
				Mono	HER2-expressing or -mutated solid tumors	China			
		SHR-1826	c-Met ADC	Combo	Advanced solid tumors	China			
				Mono	Advanced malignant solid tumors	China			
		SHR-4849	DLL3 ADC	Mono	Advanced malignant solid tumors	China			
		SHR-4394	-	Mono	PC	China			
		SHR-1681	-	Mono	Advanced malignant solid tumors	China			
	RDC	HRS-4357	PSMA	Mono	mCRPC	China			
		HRS-9815	PSMA	Mono	PC diagnosis	China			
Metabolic and Cardiovascular Diseases	Metabolic	HRX0701	DPP-4/ Metformin	Mono (FDC)	T2D	China			
		INS068	Insulin	Mono	T2D	China			
		HR17031	Insulin/ GLP-1	Mono (FDC)	T2D	China			
		HRS-7535	GLP-1 (oral)	Mono	T2D	China			
				Mono	Overweight or obesity	China			
				Mono	DKD	China			
		HRS9531	GLP-1/GIP (injectable)	Mono	Overweight or obesity	China			
				Mono	T2D	China			
				Mono	Obesity with HF	China			
				Mono	Obesity with OSA	China			
				Mono	Obesity with PCOS	China			
			GLP-1/GIP (oral)	Mono (tablet)	T2D and weight management	China			
		SHR6508	CaSR	Mono	Secondary HPT in patients with CKD on MHD	China			
		SHR4640	URAT1	Mono	Primary gout with hyperuricemia	China			
				Combo (febuxostat)	Gout patient with hyperuricemia	China			
		SHR-3167	-	Mono	Diabetes	China			
		HRS-1780	Mineralocorti-coids receptors	Mono	CKD	China			
		HRS-4729	GLP-1/GIP/ GCG	Mono	Overweight or obesity	China			

		Drug Name/ Code	Target(s)	Mono/Combo	Indication(s)	Phase I	Phase II	Phase III	NDA/BLA
Metabolic and Cardiovascular Diseases	Cardiovascular	SHR-1209	PCSK9	Mono	Primary hypercholesterolemia and mixed HL	China			
				Combo (statin)	Primary hypercholesterolemia and mixed HL with poor lipid control	China			
				Mono	Heterozygous FH	China			
		SHR-1918	ANGPTL3	Mono	Homozygous FH	China			
				Mono	HL	China			
		SHR-2004	FXI	Mono	Prevention of VTE after TKA	China			
				Mono	Prevention of postoperative VTE in patients undergoing surgery for OC	China			
				Mono	Reducing the risk of stroke and systemic embolism in patients with AFib	China			
		HRS-1893	-	Mono	Obstructive HCM	China			
		HRS-5346	-	Mono	Lipoprotein disorders	China			
		HRS-7249	-	Mono	HL	China			
		HRS-9563	-	Mono	Hypertension	China			
		SHR-6934	-	Mono	HF	China			
		HRS-5632	-	Mono	Lipoprotein disorders	China			
		HRS-9057	-	Mono	Fluid retention due to HF	China			
Immunological and Respiratory Diseases	Immunological	SHR0302	JAK1	Mono	Moderate-to-severe AD	China, Canada[1]			
				Mono	AS	China			
				Mono	Moderate-to-severe active RA	China			
				Mono	Alopecia areata	China			
				Mono	PsA	China			
				Mono	Active nr-axSpA	China			
				Mono (alkaline ointment)	Mild-to-moderate AD	China			
				Mono	Ulcerative colitis	U.S., Europe, China			
				Mono (alkaline gel)	Vitiligo	China			
		SHR-1819	IL-4Rα	Mono	AD	China			
				Mono	PN	China			
				Mono	CSU	China			
				Mono	AD in children and adolescents	China			
				Mono	AD (healthy volunteers)	China, AU			
		HRS-5965	Factor B	Mono	Anti-C5 naïve PNH	China			
				Mono	Anti-C5 treated PNH	China			
				Mono	IgAN	China			
		HRS-7085	-	Mono	IBD	China			
				Mono	IBD (healthy volunteers)	AU			
		RSS0393	-	Mono	PsO	China			
		SHR-1139	-	Mono	PsO	China			
		SHR-2173	-	Mono	SLE	China			
	Respiratory	SHR-1703	IL-5	Mono	EGPA	China			
				Mono	Eosinophilic asthma	China			
		SHR-1905	TSLP	Mono	Asthma	China			
				Mono	CRSwNP	China			
				Mono	COPD	China			
				Mono	Asthma (healthy volunteers)	AU			
		HRS-9821	PDE3/4	Mono	COPD	China			
		RSS0343	-	Mono	NCFB	China			
		SHR-4597	-	Mono	Asthma	China			
		HRS-9813	-	Mono	IPF	China			
Neuroscience		SHR-1707	Aβ	Mono	Alzheimer's Disease	China			
				Mono	Alzheimer's Disease	AU			
		HRS8179	SUR1	Mono	Cerebral edema associated with LHI	China			
		HRS-9231	-	Mono	Brain/body MRI contrast	China			
				Mono	MRI contrast	AU			
		HRS-7450	-	Mono	AIS	China			
		HRS-2129	-	Mono	Pain management	China			
Others		SHR8058	Perfluorohexylo ctane	Mono	DED associated with MGD	China			
		HRS-8427	Cefiderocol derivatives	Mono	Complicated UTI	China			
				Mono	Pulmonary infection	China			
		SHR7280	GnRH	Mono	COS in ART	China			
		HRS5580	NK1	Mono	Prevention of PONV	China			
		HRS9432	Anidulafungin derivatives	Mono	Candidemia or invasive candidiasis	China			
		HRS-5635	HBV siRNA	Mono	CHB	China			
		HRS-2183	-	Mono	Serious infection caused by gram-negative bacteria	China			

Note:

1. China: NDA filed; Canada: Phase III.

In addition to NME drugs, as of the Latest Practicable Date, we had commercialized four other innovative drugs and developed eight other innovative drug candidates to clinical or later stages of development. These other innovative drugs and drug candidates either contain a new active ingredient other than an NME, or are in a new dosage form of an approved or marketed active ingredient. For example, in December 2023, the NMPA approved our abiraterone acetate tablets (II) (Iregi®) as a new dosage form with prednisone or prednisolone for the treatment of mCRPC and mHSPC. This drug was the first abiraterone acetate nanocrystal preparation approved by the NMPA, according to Frost & Sullivan. It comes with significantly improved bioavailability and mitigates the impact of dietary intake, compared with traditional formulations, thereby improving patient medication adherence. In the same month, the NMPA approved our irinotecan hydrochloride liposomal injection (II) as a new dosage form which, in combination with fluorouracil and leucovorin, is indicated for the treatment of patients with unresectable locally advanced or metastatic pancreatic cancer who failed gemcitabine-based chemotherapy. The clinical study for this drug was the first in the field of pancreatic cancer in China, according to Frost & Sullivan.

Furthermore, as of the Latest Practicable Date, we had 93 commercialized generic drugs, including 55 first-to-market generic drugs approved in China and around the globe. For example, our butorphanol tartrate injection (for pain management) and ioversol injection (for contrast imaging) were both first-to-market generic products approved by the NMPA. We also obtained U.S. FDA approval of three ANDAs for our first-to-market generics in 2024. For example, in October 2024, the U.S. FDA approved our paclitaxel for injection (albumin-bound) as chemotherapy, which was a first-to-market generic product approved by the U.S. FDA.

Oncology

The global oncology pharmaceutical market reached US$228.9 billion in 2023, and is expected to further increase at a CAGR of 9.5% from 2023 to US$360.6 billion in 2028. China's oncology pharmaceutical market reached RMB241.6 billion in 2023, and is expected to further increase at a CAGR of 13.2% from 2023 to RMB448.4 billion in 2028. The unmet medical needs in oncology require the evolution of cancer treatment.

We have established a comprehensive toolkit that enables us to develop high-quality oncology drugs in diverse modalities, covering essential cancer types in China. The breadth of our portfolio maximizes the potential of combination therapies, allowing us to explore regimens that provide meaningful improvements, in particular, on patients' progression-free survival and overall survival, over the current standard of care. We also offer holistic supportive care across the cancer continuum from diagnosis to treatment and prognosis. For example, we offer therapies indicated for the prevention and management of adverse effects during cancer treatment, such as chemotherapy-induced neutropenia, thrombocytopenia, and nausea and vomiting. We aim to improve the patients' quality of life.

Our continued progress in novel cancer therapies and paradigm-shifting innovation efforts are best exemplified by the following product clusters.

Immuno-oncology Drugs

Immunotherapy is a proven method used for the treatment of cancer by regulating anti-tumor immune responses. However, tumor cells escape immune detection by developing immunological tolerance through many pathways, including the upregulation of immunological checkpoint molecules such as PD-1 and PD-L1. As part of our cancer immunotherapies, we have commercialized camrelizumab, a novel anti-PD-1 antibody, and adebrelimab, a novel anti-PD-L1 antibody. For details, see "—Major Commercialized Products—Camrelizumab (AiRuiKa®) (卡瑞利珠單抗(艾瑞卡®))" and "—Major Commercialized Products—Adebrelimab (AiRuiLi®) (阿得貝利單抗(艾瑞利®))."

Additionally, we have developed a series of next-generation immuno-checkpoint modulator candidates with paradigm-shifting potential, such as retlirafusp alfa (SHR-1701), a PD-L1/TGF-β bifunctional fusion protein, and our anti-DLL3/CD3 bispecific antibody. For details, see "—Major Product Candidates—Retlirafusp alfa (SHR-1701)" and "—Major Product Candidates—Anti-DLL3/CD3 Bispecific Antibody."

ADC Drugs

ADC is an innovative biologics drug modality consisting of a biologic component (*i.e.*, the antibody) attached to a small molecule drug (*i.e.*, the cytotoxic payload) via a specifically designed linker. We have established HRMAP, our proprietary ADC platform. It encompasses payloads with different MOAs, optimal conjugation linkers/methods, and well-established antibody discovery and engineering ability. The following are descriptions of the development status of some of our ADC drugs as of the Latest Practicable Date:

- *Trastuzumab rezetecan (SHR-A1811)*, a HER2 ADC with best-in-class potential. Compared to other HER2 ADCs, trastuzumab rezetecan potentially has good efficacy and better safety profiles. Trastuzumab rezetecan was under a priority NDA/BLA review by the NMPA for the treatment of locally advanced or metastatic HER2 mutant NSCLC adult patients who previously received at least one prior line of systemic therapy. Trastuzumab rezetecan (SHR-A1811) had received breakthrough therapy designations from the NMPA for seven indications, which were the most among all clinical-stage drug candidates in China as of the Latest Practicable Date, according to Frost & Sullivan.

- *SHR-A2102*, a Nectin-4 ADC with best-in-class potential. We were conducting a Phase III clinical study of SHR-A2102 versus an investigator-selected therapy in locally advanced or metastatic urothelial carcinoma previously treated with platinum-containing chemotherapy and anti-PD-(L)1 antibodies with or without ADC. It had received a breakthrough therapy designation from the NMPA and a fast track designation from the U.S. FDA.

- *SHR-1826*, a c-Met ADC. We were conducting a Phase Ib/II clinical study of SHR-1826 in China to evaluate its safety, tolerability, and efficacy in combination with other anti-tumor agents in patients with advanced solid tumors. We were also conducting a Phase I clinical study of SHR-1826 in patients with advanced solid tumors.

- *SHR-A1904*, a CLDN18.2 ADC with best-in-class potential. We were conducting a Phase III clinical study to confirm SHR-A1904 as a second-line treatment for advanced or metastatic gastric or gastroesophageal junction adenocarcinoma. In October 2023, we out-licensed an exclusive option to develop, manufacture, and commercialize SHR-A1904 worldwide (outside of mainland China) to a fully owned subsidiary of MRKDG. For details, see "—Collaboration and Licensing Arrangements—Major Out-Licensing Arrangements—Strategic Collaboration and License Agreement with a Fully Owned Subsidiary of Merck KGaA, Darmstadt, Germany."

- *SHR-4849*, a DLL3 ADC. SHR-4849 has strong proliferation inhibitory activity against different tumor cell lines with high and medium expression of DLL3. It also exhibits a significant bystander effect, capable of killing DLL3 low-expressing cells by releasing toxins from the killing of DLL3 high-expressing cells. In May 2024, we obtained the IND approval from the NMPA for conducting a Phase I clinical study of SHR-4849 for the treatment of advanced malignant solid tumors. In December 2024, we out-licensed to IDEAYA Biosciences the exclusive rights to develop, manufacture, and commercialize SHR-4849 worldwide (excluding the Greater China region). For details, see "—Collaboration and Licensing Arrangements—Major Out-Licensing Arrangements—Collaboration and License Agreement with IDEAYA Biosciences."

- *SHR-A2009*, a HER3 ADC with best-in-class potential. SHR-A2009 potentially has better efficacy. We were conducting a Phase III clinical study of SHR-A2009 to confirm its efficacy compared to platinum-based chemotherapy in patients with EGFR mutant, advanced or metastatic NSCLC who have failed EGFR-TKI treatment. It had received a fast track designation from the U.S. FDA.

- *SHR-A1912*, a CD79b ADC with best-in-class potential. We were conducting a Phase I clinical study of SHR-A1912 as a monotherapy, and a Phase II clinical study of SHR-A1912 in combination therapy. SHR-A1912 had received a fast track designation from the U.S. FDA for the treatment of relapsed/refractory diffuse large B-cell lymphoma in patients who have previously received at least two lines of treatment.

ER- and CDK-Targeting Drugs

Hormone receptor-positive breast cancer accounts for approximately 60-70% of all breast cancer cases. In addition to our existing product matrix for the treatment of HER2-positive breast cancer, we take a holistic approach to developing potent breast cancer therapies by regulating both ER and CDK:

- *Regulating the expression of ERs*. We have developed HRS-2189, a novel KAT6-specific inhibitor. HRS-2189 regulates the expression of a variety of downstream oncogenes, including ER, by inhibiting the acetylation of histone lysine, thus enabling an anti-tumor effect.

- *Degrading expressed ERs*. We have developed the following drug candidates to degrade expressed estrogen receptors.

    - *HRS-8080*, a novel, oral, small molecule SERD. HRS-8080 degrades ER in a highly effective and selective manner. It exerts anti-tumor effects by lowering ER protein levels and thus downstream signals, thereby inhibiting tumor cell proliferation. The efficacy in treating breast cancer is improved when used in combination with dalpiciclib, our approved CDK4/6 inhibitor. In a Phase II clinical study, HRS-8080 in combination with dalpiciclib showed durable responses and a favorable safety profile.

    - *HRS-1358*, a novel, oral, small molecule ER PROTAC that elicits ER degradation. HRS-1358 potently and selectively degrades ER protein levels and thus downstream signals, thereby inhibiting the proliferation of tumor cells and exerting anti-tumor effect. As of the Latest Practicable Date, we were conducting a Phase II clinical study of HRS-1358 in combination therapy for the treatment of breast cancer.

- *Regulating downstream kinase under tiered coverage.* We have commercialized dalpiciclib, a novel, orally available CDK4/6 inhibitor that targets cells with a dysregulated cell cycle.

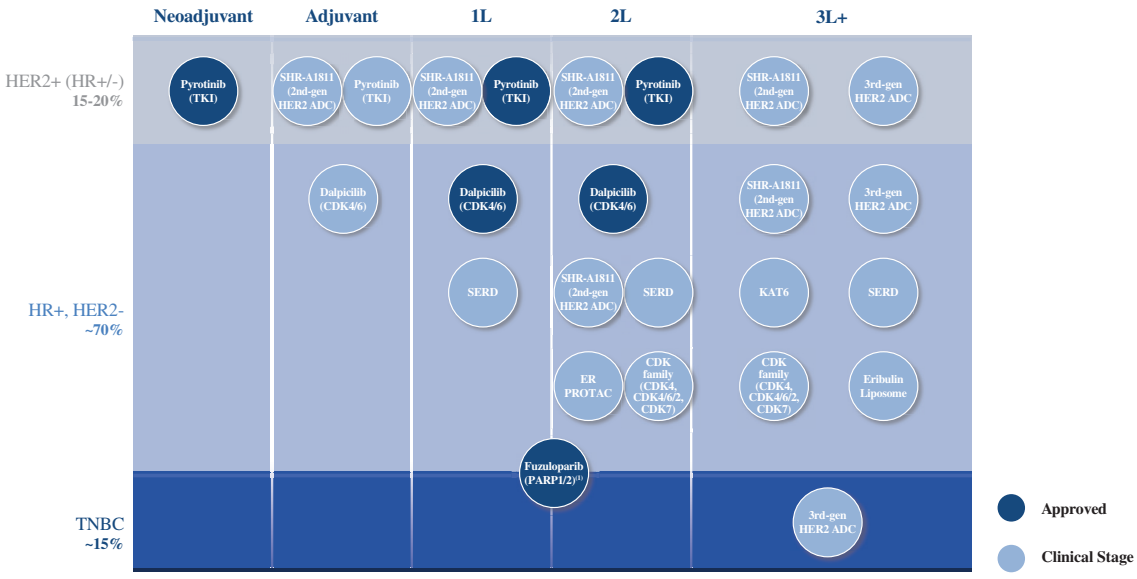
  Intrinsic and acquired resistance to CDK4/6 inhibitors and hematotoxicity of CDK6 inhibition remain major challenges in the medical community. Currently, treatment options for this patient group remain limited, including PI3K/mTORi, endocrine, and chemotherapies. In response, we have developed the following drug candidates.

  - *Highly selective CDK4 inhibitor.* HRS-6209, a novel, highly efficient, highly selective CDK4 inhibitor. HRS-6209 potently inhibits CDK4/cyclin D complex and downstream signals, and induces tumor cell arrest at G1 phase, thus inhibiting tumor cell proliferation and exerting anti-tumor effects. Compared to a CDK4/6 inhibitor, the acceptable efficacy and lower toxicity profiles of a CDK4 inhibitor make it a suitable therapeutic option for patients who require a long-term treatment cycle. As of the Latest Practicable Date, we were conducting a Phase I clinical study of HRS-6209 as monotherapy for the treatment of advanced solid tumor and a Phase Ib/II clinical study of HRS-6209 in combination therapy for the treatment of breast cancer.

  - *CDK7 inhibitor.* We are developing a novel, highly potent and highly selective CDK7 inhibitor. It blocks CDK7-mediated oncogenic effects on the cell cycle through the phosphorylation of other CDKs, and transcription initiation by phosphorylating RNA polymerase II. Cell growth inhibition studies showed its broad activity against a wide range of tumor cell lines. Encouraging activity was also observed *in vivo*. As of the Latest Practicable Date, we were conducting a multicenter, open-label Phase I clinical study to evaluate its safety and tolerability in patients with advanced solid tumors.

  - *CDK4/6/2 inhibitor.* We are developing a novel, small molecule CDK4/6/2 inhibitor, with well-balanced CDK4 and CDK2 inhibiting activities. Early translational research suggested that upregulating cyclin E overexpression, CDK2 hyperphosphorylation, and CDK6 overexpression are potential mechanisms that lead to CDK4/6 inhibitor resistance in breast cancer patients. It is hypothesized that these types of resistance might be overcome by the simultaneous inhibition of CDK2, CDK4 and CDK6.

We have developed a broad drug portfolio targeting a variety of breast cancer subtypes through different therapeutic options, such as ADCs, PARP inhibitors, TKIs, CDK inhibitors, and PROTACs, summarized in the diagram below.



Note:

(1) BRCA mutation, applicable to 1/2L HER2-BC

Source: Company data

RAS-Targeting Agents

RAS is one of the most important oncogenes. The RAS signaling pathway is involved in many important cellular processes such as cell proliferation and survival, differentiation, apoptosis, cytoskeletal movement, protein transport, and secretion. RAS has three different isoforms: KRAS, NRAS, and HRAS, among which KRAS mutations occur in approximately 85% of the cancers with RAS alterations.

According to Frost & Sullivan, RAS pathway mutations are implicated in approximately 20% of the total solid tumor incidence globally. In 2023, globally, there were approximately 4.2 million new cancer cases with RAS mutations, including approximately 1.0 million in China. Mutant KRAS (mKRAS), in particular, drives 25% of solid tumors including non-small cell lung cancer (NSCLC), pancreatic ductal adenocarcinoma (PDAC), and colorectal cancer (CRC), which makes KRAS a promising cancer drug target. The dominant oncogenic mutations of KRAS occur at the codon 12 position, in particular G12D, G12V, and G12C. KRAS has long been considered a challenging therapeutic target. Currently approved KRAS-targeted therapies have shown proof of efficacy; however, their duration of response is relatively short.

We have strategically developed a cluster of innovative drugs targeting the KRAS family.

- *KRAS G12C inhibitor.* As of the Latest Practicable Date, worldwide, four KRAS G12C inhibitors had been approved to treat patients with advanced NSCLC harboring KRAS G12C mutations, according to Frost & Sullivan. However, due to intrinsic or acquired resistance caused by cellular, molecular, and genetic mechanisms, challenges remain in prolonging patients' response to the KRAS G12C inhibitor therapy.

  HRS-7058 is a novel, potent, highly selective, next-generation KRAS G12C inhibitor for the treatment of patients with advanced solid tumors harboring KRAS G12C mutations. HRS-7058 is designed to inhibit both active and inactive forms of KRAS G12C. As of the Latest Practicable Date, we were conducting a Phase I clinical study of HRS-7058 for patients with advanced solid tumor with KRAS G12C mutations.

- *KRAS G12D inhibitor.* Compared to G12C, G12D is most commonly seen in PDAC, a dismal disease with an average 5-year survival rate of 12% due to difficulties in early diagnosis and the lack of effective treatments, according to Frost & Sullivan. As of the Latest Practicable Date, no KRAS G12D inhibitors had been approved worldwide, according to the same source.

  HRS-4642 is a novel, potent, long-acting, and highly selective KRAS G12D inhibitor in liposomal injectable form, with first-in-class potential. HRS-4642 was the first inhibitor targeting KRAS G12D to have reported clinical data globally, according to Frost & Sullivan. In addition, we seek to develop next-generation KRAS G12D inhibitors in orally available formulation.

Major Commercialized Products

Camrelizumab (AiRuiKa®) (*卡瑞利珠單抗(艾瑞卡®)*)

Camrelizumab is a novel anti-PD-1 antibody.

Camrelizumab specifically binds to PD-1, blocking interactions of PD-1 with its ligands. This allows T lymphocyte cells to restore immune response to tumors. After administration, camrelizumab rapidly occupies a large quantity of PD-1 receptors, and it maintains a high level of occupancy. Clinical studies have demonstrated that receptor occupancy continues to exceed 95%, 22 days after the administration of camrelizumab. In addition, camrelizumab has a relatively short half-life, which reduces autoimmune adverse events and facilitates recovery from such events.

Notably, camrelizumab was given in combination with apatinib in a randomized, open-label, international Phase III CARES-310 clinical study, where a total of 543 patients with unresectable or metastatic HCC who had not previously received systemic therapy were included. The clinical study was conducted at 95 trial sites across 13 countries and regions worldwide. In a head-to-head comparison, camrelizumab given in combination with apatinib significantly prolonged the overall survival (OS) and the progression-free survival (PFS), and increased the objective response rate (ORR) as compared with sorafenib, a standard first-line treatment for uHCC, as illustrated in the figure below.

	camrelizumab plus apatinib (n = 272)	**sorafenib (n = 271)**
median OS (95% CI)	23.8 months (20.6-27.2)	15.2 months (13.2-18.5)
median PFS (95% CI)	5.6 months (5.5-7.4)	3.7 months (3.1-3.7)
ORR (95% CI)	26.8 (21.7-32.5)	5.9 (3.4-9.4)

Source: Journal of Clinical Oncology 2024, Volume 42, Number 16 suppl, 4110-4110

The mOS of 23.8 months was the longest among all first-line therapies for uHCC with published clinical study results as of the Latest Practicable Date, according to Frost & Sullivan. The interim results of this Phase III clinical study were published in *The Lancet*, marking it the first such publication for the global Phase III clinical study led by Chinese clinical investigators in oncology.

As of the Latest Practicable Date, camrelizumab in combination with apatinib was the only successful "immunology in combination with TKI" treatment for unresectable and metastatic HCC in China, according to Frost & Sullivan. As of the same date, camrelizumab was an anti-PD-1 antibody approved by the NMPA as a first-line treatment for lung cancer, esophageal cancer, and nasopharyngeal carcinoma, according to the same source.

Camrelizumab received two breakthrough therapy designations from the NMPA in 2020 and 2022, respectively. As of the Latest Practicable Date, camrelizumab had been approved by the NMPA for the treatment of nine indications across various tumor types, all of which had been included in China's NRDL. In addition, in April 2021 and July 2024, respectively, the U.S. FDA and the EMA granted orphan drug designations to camrelizumab as a first-line treatment for advanced HCC.

In terms of indication expansion, in December 2023, the NDA/BLA of camrelizumab in combination with famitinib was accepted by the NMPA for the treatment of patients with relapsed or metastatic cervical cancer that have previously been treated with platinum-based chemotherapy. In October 2024, the U.S. FDA accepted the submission of an NDA for rivoceranib (also known as apatinib) and a BLA for camrelizumab for the combination of

rivoceranib and camrelizumab as a first-line therapy for uHCC made by us, together with our collaboration partner, assigning a Prescription Drug User Fee Act target action date of March 23, 2025, a goal date for the U.S. FDA to decide whether or not to approve such new medication.

As of the Latest Practicable Date, camrelizumab and apatinib had been recommended by several guidelines published by the NHC and the Chinese Society of Clinical Oncology (CSCO).

Pyrotinib (AiRuiNi®) (吡咯替尼(艾瑞妮®))

Pyrotinib is a novel, irreversible, and selective EGFR/HER2/HER4 TKI.

The EGFR family, especially HER2, overexpression features prominently in breast cancer with a significant relation to poor prognosis. Pyrotinib effectively suppresses the growth of these tumor cells through covalent binding to the adenosine triphosphate binding site of the intracellular kinase domains of EGFR, HER2, and HER4. This MOA prevents the formation of homo/hetero-dimers of the EGFR family, inhibits autophosphorylation, and blocks the activation of downstream signaling pathways.

In August 2018, based on a pivotal Phase II clinical study, the NMPA authorized conditional approval of pyrotinib for the treatment of HER2-positive advanced or metastatic breast cancer in patients who had previously been treated with anthracycline or taxane chemotherapy. In 2020, pyrotinib received full approval from the NMPA. In 2022, pyrotinib in combination with trastuzumab and docetaxel was approved by the NMPA for the neoadjuvant treatment of HER2-positive early or locally-advanced breast cancer patients. In 2023, pyrotinib in combination with trastuzumab and docetaxel was further approved by the NMPA as a first-line treatment of HER2-positive patients with relapsed or metastatic breast cancer.

In its confirmatory Phase III clinical study, pyrotinib in combination with capecitabine achieved significantly prolonged mOS compared with lapatinib in combination with capecitabine for HER2-positive metastatic breast cancer (39.4 months versus 28.6 months). In another Phase III clinical study for first-line metastatic breast cancer patients, pyrotinib in combination with trastuzumab and docetaxel significantly prolonged the median PFS as compared with trastuzumab in combination with docetaxel (24.3 months versus 10.4 months). This median PFS of 24.3 months was the longest among all clinical studies of first-line treatments of HER2-positive advanced breast cancer as of the Latest Practicable Date, according to Frost & Sullivan. Based on this positive result, pyrotinib received a breakthrough therapy designation from the NMPA in 2022.

Pyrotinib was (i) the first domestically developed innovative small molecule drug targeting HER2 to have been approved by the NMPA, (ii) the first small molecule drug as a neo-adjuvant treatment for breast cancer to have been approved by the NMPA, and (iii) the first therapy for solid tumors to have received conditional approval in China based on a Phase II clinical study, according to Frost & Sullivan.

As of the Latest Practicable Date, pyrotinib had been recommended by the NHC breast cancer guideline and CSCO guidelines for breast cancer and lung cancer.

Rezvilutamide (AiRuiEn®) (瑞維魯胺(艾瑞恩®))

Rezvilutamide is a second-generation androgen receptor antagonist. In June 2022, rezvilutamide was approved by the NMPA for the treatment of high-volume metastatic hormone-sensitive prostate cancer (mHSPC).

An androgen receptor is a crucial protein involved in the progression of prostate cancer. At the core of rezvilutamide's mechanism is its ability to inhibit the androgen receptor. By blocking the binding of androgen to the androgen receptor, rezvilutamide prevents the subsequent translocation of the androgen receptor to the cell nucleus. This interruption halts the transcription of androgen-responsive genes, which is essential for the growth and survival of prostate cancer cells.

Compared to first-generation androgen receptor antagonists, rezvilutamide innovates on the molecular structure, offering a more favorable pharmacokinetic profile. It demonstrates high binding affinity to the androgen receptor, ensuring effective inhibition at lower dosages. Furthermore, given low blood-brain barrier penetration, the incidence of off-target central nervous system effects associated with rezvilutamide is lower as compared to other androgen receptor pathway inhibitors.

In a randomized, open-label Phase III CHART clinical study, rezvilutamide showed superior efficacy and improved safety profiles. The frequency of serious adverse events such as fatigue and rash caused by rezvilutamide were lower than bicalutamide in combination with ADT, and no seizure of any grade was reported among patients administered with rezvilutamide in this study.

Rezvilutamide was the first domestically developed androgen receptor antagonist approved by the NMPA for the treatment of prostate cancer, according to Frost & Sullivan. As of the Latest Practicable Date, rezvilutamide had been recommended by the CSCO prostate cancer treatment guideline.

Mecapegfilgrastim (AiDuo®) (硫培非格司亭(艾多®))

Mecapegfilgrastim is a novel, long-acting PEGylated recombinant granulocyte colony-stimulating factor (G-CSF) therapy.

In May 2018, mecapegfilgrastim was approved by the NMPA for reducing the incidence of infections manifesting as febrile neutropenia, when adult patients with non-myeloid malignancies receive myelosuppressive anti-cancer drugs that are likely to cause febrile neutropenia.

Mecapegfilgrastim uses innovative polyethylene-glycol-modified protein technology to introduce a thioether group between polyethylene glycol and G-CSF, making the structure safer and more reliable than short-acting G-CSF. In a randomized, multicenter, active-controlled Phase III clinical study, comparing mecapegfilgrastim with short-acting G-CSF, mecapegfilgrastim showed significantly better efficacy compared to short-acting G-CSF.

Prior to the approval of mecapegfilgrastim, filgrastim was the most widely used G-CSF in China for the prevention of chemotherapy-induced neutropenia. However, due to its relatively short half-life, daily filgrastim injections were required to stimulate neutrophil recovery. Mecapegfilgrastim was the only product in China that demonstrates efficacy superior to filgrastim as of the Latest Practicable Date, according to Frost & Sullivan. In particular, the duration of grade ≥3 neutropenia was significantly shortened by 48%. Moreover, mecapegfilgrastim enables once-per-chemotherapy cycle injection, rather than daily injection, contributing to a relatively high medication adherence.

Dalpiciclib (AiRuiKang®) (達爾西利(艾瑞康®))

Dalpiciclib is a novel, orally-administered, selective inhibitor targeting cyclin-dependent kinase 4 and 6 (CDK4/6).

In December 2021, dalpiciclib was approved by the NMPA for the treatment of relapsed or metastatic HR-positive/HER2-negative breast cancer following progression after an endocrine therapy. In June 2023, dalpiciclib in combination with letrozole or anastrozole was approved by the NMPA as a first-line treatment for locally-advanced and metastatic HR-positive/HER2-negative breast cancer.

CDK4/6 inhibitors prevent the G1-to-S phase transition, induce cell-cycle arrest of tumor cells, and selectively inhibit the proliferation of tumor cells with high expression of retinoblastoma protein (Rb). The expression of Rb is found to be highly prevalent in breast cancers, the inhibition of which is critical to the success of CDK4/6 inhibitor therapy.

Dalpiciclib was the first domestically developed innovative CDK4/6 inhibitor approved in China, according to Frost & Sullivan. As of the Latest Practicable Date, dalpiciclib had been recommended by the CSCO breast cancer treatment guideline.

As of the Latest Practicable Date, we were conducting a Phase III clinical study for dalpiciclib as an adjuvant therapy for HR-positive/HER2-negative breast cancer. With a sample size of over 5,000 participants, it was the largest tumor registrational study initiated by a Chinese pharmaceutical company as of the Latest Practicable Date, according to Frost & Sullivan. Moreover, as of the same date, we were conducting a Phase Ib/II clinical study to evaluate the safety and efficacy of dalpiciclib in combination with our HRS-8080 (SERD) for the treatment of ER-positive, HER2-negative unresectable or metastatic breast cancer.

Adebrelimab (AiRuiLi®) (阿得貝利單抗(艾瑞利®))

Adebrelimab is a novel anti-PD-L1 antibody.

In February 2023, adebrelimab in combination with carboplatin and etoposide was approved by the NMPA as a first-line treatment for extensive-stage small cell lung cancer (ES-SCLC). Adebrelimab relieves PD-L1-mediated immune suppression and enhances the function of cytotoxic T cells, enabling it to function as a backbone component in various combination therapies.

As of the Latest Practicable Date, adebrelimab had been recommended by the CSCO guidelines for treatment of lung cancer. As of the same date, we were conducting several clinical studies in China to further expand the spectrum of combination therapies using adebrelimab, including in combination with SHR-8068 (an anti-CTLA-4 antibody), ADC drugs and RAS-targeting agents.

Herombopag (HengQu®) (海曲泊帕(恒曲®))

Herombopag is an orally available, small molecule, non-peptide thrombopoietin receptor (TPO-R) agonist for the treatment of thrombocytopenia (TP) and severe aplastic anemia (SAA). In June 2021, herombopag was approved by the NMPA as second-line treatment for primary immune thrombocytopenia (ITP) and SAA in adults.

Thrombopoietin (TPO) and its receptor TPO-R are the primary regulators of platelet production. Herombopag selectively binds to the transmembrane region of the TPO-R, which, by activating certain signaling pathways, stimulates the proliferation and differentiation of megakaryocytes and promotes platelet production.

Herombopag has demonstrated efficacy in increasing platelet counts, and it is well tolerated with a manageable safety profile. Clinical studies of herombopag demonstrated that patients' platelet counts began to increase within one week of administration, and platelet levels remained above baseline values 18 days after finishing the treatment. Additionally, the incidence of hepatotoxicity and treatment-related adverse reactions was significantly lower than that of competing products for the treatment of these conditions.

Herombopag was the first domestically developed TPO-R agonist approved by the NMPA for the treatment of both SAA and ITP in China, and the oral, small molecule TPO-R agonist with the largest number of indications approved globally, according to Frost & Sullivan. As of the Latest Practicable Date, herombopag was the only small molecule TPO-R agonist classified with a Level II recommendation for the treatment and secondary prevention of the cancer treatment-induced TP (CTIT) in the *CSCO Guidelines for the Diagnosis and Treatment of CTIT (2023 Edition)*.

Major Product Candidates

Trastuzumab rezetecan (SHR-A1811)

Trastuzumab rezetecan, also known as SHR-A1811, is a HER2 ADC with best-in-class potential. It is composed of (i) trastuzumab, an anti-HER2 antibody, (ii) a cleavable linker, and (iii) a novel topoisomerase I inhibitor (TOP1i) payload (*i.e.,* SHR9265).

SHR9265 is an optimized exatecan derivative with high membrane permeability, potent cell-killing efficacy, and an enhanced safety profile. Trastuzumab rezetecan has an optimized drug-to-antibody ratio of 6 and has shown HER2-dependent growth inhibition. Furthermore, it exhibits superior bystander effect, or the ability to induce cell death in neighboring, antigen-negative cancer cells through the release of cytotoxic agents. In a global Phase I clinical study, it demonstrated an ORR of 76.3% in patients with HER2-positive breast cancer and an ORR of 60.4% in patients with HER2 low-expressing breast cancer. In addition, the incidence of interstitial lung diseases (ILD), a key safety indicator, was as low as 2.6% among patients dosed with trastuzumab rezetecan in the same study.

As of the Latest Practicable Date, trastuzumab rezetecan was under a priority NDA/BLA review by the NMPA for the treatment of locally advanced or metastatic HER2-mutant NSCLC adult patients who previously received at least one prior line of systemic therapy. As of the same date, trastuzumab rezetecan had received breakthrough therapy designations from the NMPA for seven indications, which were the most among all clinical-stage drug candidates in China, according to Frost & Sullivan. These seven indications include lung cancer, breast cancer, colorectal cancer, gastric or gastroesophageal junction adenocarcinoma, bile duct cancer, and ovarian cancer.

SHR-A1904

SHR-A1904 is a CLDN18.2 ADC with best-in-class potential. SHR-A1904 is composed of (i) an anti-CLDN18.2 antibody, (ii) a cleavable linker, and (iii) a TOP1i payload (*i.e.*, SHR9265). CLDN18.2 is a tight junction protein and isoform of Claudin 18 that is expressed on a variety of tumor cells. CLDN18.2 is observed in a large fraction of gastric cancers. Approximately 70%-80% of gastric cancer patients exhibit expression of CLDN18.2 in their cancer tissue. In addition, CLDN18.2 is aberrantly expressed in a variety of epithelial solid tumors, including pancreatic, esophageal, ovarian, and lung tumors. SHR-A1904 specifically targets and binds to CLDN18.2 expressed on tumor cells. Upon binding and internalization, the cytotoxic agent is released and kills the CLDN18.2-expressing cancer cells.

In October 2024, we initiated a Phase III clinical study to confirm SHR-A1904 as a second-line treatment for advanced or metastatic gastric or gastroesophageal junction adenocarcinoma.

We have completed a Phase I clinical study in China to evaluate the safety, tolerability, pharmacokinetics, and efficacy of SHR-A1904 in patients with advanced solid tumors. Among patients who had a baseline assessment and at least one post-baseline assessment, ORR and disease control rate (DCR) were 55.6% and 88.9% at 6.0 mg/kg, respectively. As of the Latest Practicable Date, we were conducting a global Phase I/IIa clinical study to evaluate the safety, tolerability, pharmacokinetics, and efficacy of SHR-A1904 in patients with advanced solid tumors.

In October 2023, we out-licensed an exclusive option to develop, manufacture, and commercialize SHR-A1904 worldwide (outside of mainland China) to a fully owned subsidiary of MRKDG. For details, see "—Collaboration and Licensing Arrangements—Major Out-Licensing Arrangements—Strategic Collaboration and License Agreement with a Fully Owned Subsidiary of Merck KGaA, Darmstadt, Germany."

HRS-1167

HRS-1167 is a next-generation highly-selective PARP1 inhibitor with best-in-class potential. In the past, we successfully developed and commercialized fuzuloparib, which was one of the six first-generation PARP inhibitors approved globally. Our extensive experience and in-depth know-how accumulated from our development of this first-generation PARP inhibitor enabled us to expedite our development of HRS-1167.

HRS-1167 exhibited higher selectivity over PARP1 and limited inhibition on PARP2 compared to multi-targeted PARP inhibitors. These features lead to higher efficacy and lower hematotoxicity.

Based on its robust preclinical and clinical data, we out-licensed to a fully owned subsidiary of MRKDG exclusive rights to develop, manufacture, and commercialize HRS-1167 worldwide (outside of mainland China). For details, see "—Collaboration and Licensing Arrangements—Major Out-Licensing Arrangements—Strategic Collaboration and License Agreement with a Fully Owned Subsidiary of Merck KGaA, Darmstadt, Germany." HRS-1167 is currently being investigated with other anti-tumor therapies in global studies.

HRS-4642

HRS-4642 is a novel, potent, long-acting, and highly selective KRAS G12D inhibitor, with first-in-class potential. HRS-4642 uses our proprietary liposomal formulation, and has achieved targeted delivery and longer retention in tumor tissues, thus decreasing systemic toxicities.

As of the Latest Practicable Date, we were conducting Phase Ib/II clinical studies to evaluate the safety, tolerability, and efficacy of HRS-4642 in combination with anti-tumor agents in patients with advanced solid tumors harboring KRAS G12D mutations. HRS-4642 was the first inhibitor targeting KRAS G12D to have reported clinical data globally, according to Frost & Sullivan.

Retlirafusp alfa (SHR-1701)

Retlirafusp alfa, also known as SHR-1701, is a bifunctional fusion protein with first-in-class potential. It is composed of an anti-PD-L1 antibody fused to the extracellular domain of transforming growth factor beta (TGF-β) receptor II.

Retlirafusp alfa is designed to simultaneously block two immunosuppressive signaling pathways, offering a novel therapeutic approach to the treatment of advanced and metastatic cancers. TGF-β plays a critical role in tumor microenvironments. Activation of the TGF-β pathway not only promotes cancer invasiveness, migration, and metastasis, but also has nonredundant immunosuppressive functions compared with the PD-1/PD-L1 pathway. Blocking the TGF-β pathway may enhance T-cell activation and function, making tumors more susceptible to the effects of anti-PD-1/PD-L1 therapy.

Retlirafusp alfa is currently under NDA/BLA review by the NMPA as a first-line therapy for gastric or gastroesophageal junction adenocarcinoma. As of the Latest Practicable Date, retlirafusp alfa was the most clinically advanced PD-L1/TGF-β bifunctional fusion protein globally, and the only PD-L1/TGF-β bifunctional fusion protein with published Phase III clinical study results for the treatment of advanced gastric cancer, according to Frost & Sullivan.

SHR2554

SHR2554 is an oral, small molecule inhibitor exhibiting potent selectivity for enhancer of zeste homolog 2 (EZH2). EZH2 has an essential role in the development of certain lymphomas. SHR2554 effectively inhibits the enzymatic activity of EZH2.

In a Phase I/II clinical study, SHR2554 monotherapy was shown to have achieved significant and clinically meaningful improvement in patients with relapsed or refractory PTCL. In January 2023, the NMPA granted a breakthrough therapy designation to SHR2554 for this indication. In October 2024, the NMPA designated SHR2554 for priority review with respect to its indication for treatment of relapsed or refractory PTCL that had previously received at least first-line systemic treatment.

Anti-DLL3/CD3 Bispecific Antibody

We are developing an anti-DLL3/CD3 bispecific antibody. It specifically binds to both the DLL3 protein and the CD3 protein, enriching CD3-positive T cells around tumor cells expressing the DLL3 antigen. This induces the activation of T cells, and enables them to exert targeted killing effects on tumor cells.

The CD3 binding affinity of this drug candidate was designed to be relatively low, which mitigates non-specific T-cell activation and reduces inflammatory cytokine production in periphery. As of the Latest Practicable Date, we were conducting a Phase I/II clinical study to evaluate its safety, tolerability, pharmacokinetics and efficacy in patients with advanced solid tumors.

HR20013

HR20013 is a mixed formulation of HRS5580 (a novel NK-1 receptor antagonist) and palonosetron (a 5-HT3 antagonist) for intravenous infusion. In combination, these two drugs simultaneously inhibit NK-1 and 5-HT3 pathways. Upon administration, HR20013 aims to suppress chemotherapy-induced nausea and vomiting, as well as nausea and vomiting caused by anti-tumor drugs during treatment that pose moderate emetic risk. Co-administration of multiple antiemetics that inhibit several molecular pathways involved in emesis is required to optimize control of highly emetogenic chemotherapy-induced nausea and vomiting.

In December 2023, our NDA application of injectable HR20013 was accepted by the NMPA for the treatment of patients with highly emetogenic chemotherapy-induced nausea and vomiting.

Anti-RANKL/NGF Bispecific Antibody

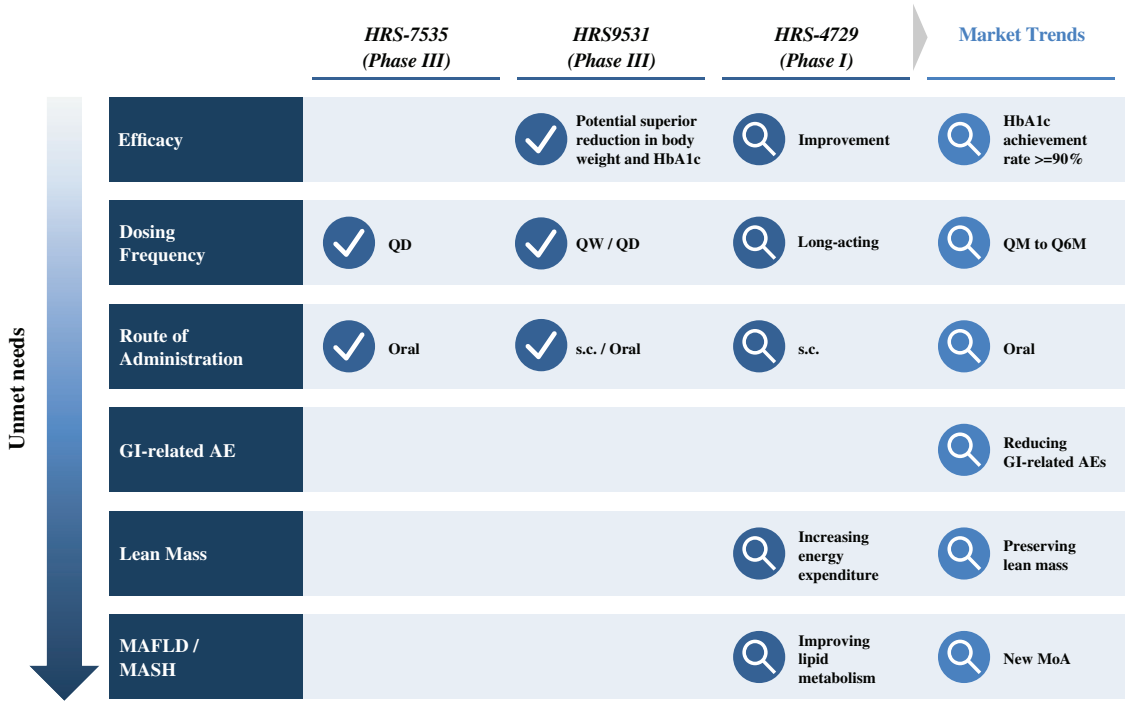
We are developing an IgG4 subtype bispecific antibody targeting receptor activator of NF-κβ ligand (RANKL) and nerve growth factor (NGF). The specific binding of anti-RANKL with RANKL blocks the interaction between RANKL and RANK, inhibits osteoclast formation, proliferation, and therefore inhibits bone resorption and enables bone protection; anti-NGF blocks the binding of NGF to the receptor and its pathway, inhibits pain signaling, and alleviates the pain of bone metastasis. This drug candidate is intended for the prevention of skeletal-related events in patients with bone metastases from solid tumors.

As of the Latest Practicable Date, we were conducting a Phase Ib clinical study to evaluate its safety, tolerability, pharmacokinetics, pharmacodynamic, and efficacy in patients with bone metastases from solid tumors.

Metabolic and Cardiovascular Diseases

The global metabolic and cardiovascular drug market reached US$258.8 billion in 2023, and is expected to further increase at a CAGR of 5.5% from 2023 to US$338.5 billion in 2028. China's metabolic and cardiovascular drug market reached RMB289.3 billion in 2023, and is expected to further increase at a CAGR of 7.4% from 2023 to RMB414.3 billion in 2028.

There has been growing demand for innovative treatments that address the unmet medical needs and provide more flexible drug administration and enhanced efficacy and/or better safety profiles. To address the significant unmet medical needs, as illustrated in the diagram below, we have strategically developed a portfolio of GLP-1 drugs with distinct MOAs and superior clinical profile across multiple modalities, available in both oral and injectable forms. By taking a differentiated approach, we seek to develop drug candidates that enhance energy expenditure, offering a possible therapeutic for obesity.



Source: Company data

Capitalizing on recent scientific insights, we have developed a robust pipeline of highly innovative drug candidates for the treatment of metabolic and cardiovascular diseases, such as a novel myosin inhibitor, a small molecule Lp(a) inhibitor, a novel allosteric modulator of the calcium-sensing receptor, and our anti-ANGPTL3 antibody. Furthermore, we have developed a portfolio of siRNA drug candidates, including an siRNA drug candidate targeting APOC3, and an siRNA drug candidate targeting AGT. With the capability of precise gene silencing and advancements in delivery systems, siRNA therapeutics reduce dosage frequency and improve patient compliance.

Major Commercialized Products

Retagliptin (RuiZeTang®) (瑞格列汀(瑞澤唐®))

Retagliptin is a highly selective, orally-active dipeptidyl peptidase-4 (DPP-4) inhibitor. In June 2023, retagliptin was approved by the NMPA for the treatment of type 2 diabetes. By inhibiting DPP-4, retagliptin prolongs the action of Glucagon-like peptide-1 (GLP-1), which plays a crucial role in the regulation of glucose homeostasis, thereby enhancing glucose-stimulated insulin secretion and reducing blood glucose levels. In terms of the safety profile, retagliptin does not induce risks of weight gaining and hypoglycemia. Based on results of Phase III clinical studies, retagliptin (100 mg QD) as a monotherapy was found to reduce HbA1c (a measure of blood sugar levels over the preceding two to three months) of type 2 diabetes patients by 1.13%. In addition, retagliptin (50 mg BID) as an add-on therapy to metformin was found to reduce HbA1c of type 2 diabetes patients by 1.18%. Retagliptin offers a new therapeutic option for treating patients with type 2 diabetes and is generally well tolerated.

Henagliflozin (RuiQin®) (恒格列淨(瑞沁®))

Henagliflozin is a novel SGLT-2 inhibitor. In December 2021, henagliflozin was approved by the NMPA for the treatment of type 2 diabetes. In June 2024, henagliflozin in combination with metformin and retagliptin was approved by the NMPA for the treatment of type 2 diabetes.

SGLT-2 inhibitors lower blood glucose levels through inhibiting the reabsorption of glucose and sodium in the kidneys, thereby excreting glucose in urine and causing osmotic diuresis. It has demonstrated clinical efficacy in the reduction of HbA1c and fasting blood glucose. Due to SGLT-2 inhibitors' cardiovascular and renal benefits, they have shown promising efficacy in the treatment of patients with type 2 diabetes who have accompanying risk factors.

Based on results of Phase III clinical studies, henagliflozin (5 mg and 10 mg QD) exerted effective glycemic control, reduced body weight and blood pressure, and was generally well tolerated among patients with type 2 diabetes when dosing as monotherapy, add-on therapy to metformin and in combination therapy with metformin and retagliptin. After 24 weeks of treatment, henagliflozin monotherapy achieved a reduction in HbA1c of 0.91% compared to the placebo group (for similar drugs, the reduction ranged from 0.7% to 0.74%). Henagliflozin, adding on to metformin, saw a decrease in HbA1c of 0.76% compared to the placebo group (for similar drugs, the reduction ranged from 0.57% to 0.76%). In addition, the co-administration of henagliflozin and retagliptin and metformin was found to reduce HbA1c by 1.54%. Henagliflozin also demonstrated significant advantages in both its safety profile and patient tolerability, with lower rates of hypoglycemia and urinary tract infection, thus better satisfying patients' long-term medication needs as part of their chronic disease management.

Additionally, in December 2023, a fixed-dose combination of henagliflozin with a metformin sustained-release layer (恒格列淨二甲雙胍(RuiQinDa®(瑞沁達®)) was approved by the NMPA for the treatment of type 2 diabetes in conjunction with dietary control and exercise.

Henagliflozin was the first domestically developed novel SGLT-2 inhibitor approved by the NMPA, according to Frost & Sullivan. As of the Latest Practicable Date, henagliflozin had been recommended by several authoritative treatment guidelines and expert consensuses.

Major Product Candidates

HR17031

HR17031 is a once-daily, novel combination of basal insulin analog (insulin sudelidec, also known as INS068) and GLP-1 receptor agonist (noiiglutide, also known as SHR20004), with best-in-class potential.

HR17031 has demonstrated promising efficacy and a favorable safety profile in a Phase II clinical study. When administered lower dosage, the efficacy of HR17031 for reducing blood glucose levels has been found to be superior to that of basal insulin. Additionally, HR17031 also reduces the risk of hypoglycemia and avoid adverse reactions such as weight gain associated with insulin therapy, providing benefits for patients with type 2 diabetes.

As of the Latest Practicable Date, HR17031 was under Phase III clinical studies. These clinical studies aim to confirm the efficacy and safety of HR17031 injectable solution with insulin glargine among type 2 diabetes patients with poor glycemic control.

HRS-7535

HRS-7535 is a novel, oral, small molecule GLP-1 receptor agonist, which offers convenient drug administration benefits. HRS-7535 activates GLP-1 receptors to promote glucose-stimulated insulin secretion, reduce glucagon secretion, and inhibit gastric emptying. HRS-7535 also enhances satiety and suppresses appetite through central mechanisms, directly reducing energy intake, thereby helping to treat type 2 diabetes and reduce body weight.

In a Phase I clinical study, HRS-7535 exhibited a safety and tolerability profile consistent with other GLP-1R agonists and showed pharmacokinetics properties suitable for once-daily dosing.

As of the Latest Practicable Date, we had completed the first-patient-in for its Phase III clinical studies to confirm the efficacy and safety of HRS-7535 in adults with type 2 diabetes, and the last-patient-in for its Phase II clinical study on obesity treatment. As of the same date, we were also conducting a Phase II clinical study of HRS-7535 for patients with diabetic kidney disease.

HRS9531

HRS9531 is a novel GLP-1 and GIP receptor dual agonist, with best-in-class potential. Regulating GLP-1 and GIP receptors promotes insulin secretion and suppress appetite, thereby helping to reduce weight and lower blood glucose levels. As of the Latest Practicable Date, HRS9531 had been formulated as (i) a once-weekly subcutaneous injection and (ii) a once-daily oral tablet.

In a Phase II clinical study, once-weekly subcutaneous injection of HRS9531 demonstrated that it effectively reduced body weight, blood glucose, blood pressure, and triglycerides in obese adults without diabetes, while demonstrating a favorable safety profile. The clinical results were presented at the 2024 ADA Annual Meeting. At week 24, changes from baseline in body weight were up to -16.8% (placebo: -0.1%). The proportion of participants achieving body weight reduction of at least 5% were up to 92% (placebo: 10.2%).

In another Phase II clinical study on patients with type 2 diabetes, HRS9531 demonstrated that it effectively reduced blood glucose, blood pressure, body weight, while maintaining a favorable safety profile. The clinical results were presented at the 2024 European Association for the Study of Diabetes Annual Meeting. At week 20, changes from baseline in HbA1c were up to -2.7% (placebo: -0.3%). The proportion of patients achieving a target of HbA1c <7.0% and HbA1c <6.5% were up to 90.2% (placebo: 12.8%), and 90.0% (placebo: 2.6%), respectively. Mean percentage changes in body weight reductions from baseline to week 20 were up to -7.1% (placebo: -0.6%).

As of the Latest Practicable Date, we were conducting Phase III clinical studies in overweight/obese participants and patients with type 2 diabetes to confirm efficacy and safety of HRS9531. In addition, as of the same date, we were conducting Phase II clinical studies of HRS9531 for the treatment of other obesity related indications, such as obstructive sleep apnea (OSA), polycystic ovary syndrome (PCOS), and heart failure with preserved ejection fraction (HFpEF).

With respect to the oral formulation of HRS9531, we had obtained the IND approval from the NMPA for its Phase I clinical study as of the Latest Practicable Date.

HRS-4729

HRS-4729 is a GLP-1, GIP, and GCG receptor tri-agonist formulated as a long-acting injectable peptide.

By activating multiple targets, HRS-4729 improves the secretion of insulin, while controlling blood glucose, food intake and body weight. As of the Latest Practicable Date, there were no approved GLP-1/GIP/GCG receptor tri-agonists globally, according to Frost & Sullivan.

In December 2024, we obtained the IND approval of HRS-4729 from the NMPA. In May 2024, we out-licensed to Kailera Therapeutics the exclusive rights to develop and commercialize three of our proprietary GLP-1 drug candidates, HRS-7535, HRS9531, and HRS-4729, worldwide (excluding the Greater China region). For details, see "—Collaboration and Licensing Arrangements—Major Out-Licensing Arrangements—Collaboration and License Agreement with Kailera Therapeutics."

Recaticimab (SHR-1209)

Recaticimab, also known as SHR-1209, is an anti-PCSK9 antibody with best-in-class potential. PCSK9, or proprotein convertase subtilisin/kexin type 9, plays a critical role in regulating cholesterol levels in the blood. PCSK9 inhibitors block the interaction of PCSK9 and the lipoprotein cholesterol receptor LDL receptor. This mechanism enhances LDL-C clearance from blood plasma by increasing hepatic expression of LDL receptors.

In June 2023, our NDA application for SHR-1209 for the treatment of hypercholesterolemia was accepted by the NMPA.

Myosin Inhibitor

We are developing a novel myosin inhibitor for the treatment of hypertrophic cardiomyopathy and related heart failure. This drug candidate potentially offers a superior efficacy profile in reducing obstructive symptoms among target patients and a superior safety profile in preventing or reducing adverse events due to decreased contractility. As of the Latest Practicable Date, we were conducting a Phase II clinical study to evaluate its efficacy and safety in the treatment of obstructive hypertrophic cardiomyopathy.

Lp(a) Inhibitor

We are developing an oral, small molecule inhibitor targeting Lp(a). It exhibits the potential in preventing the risk of atherosclerotic cardiovascular diseases by potently lowering Lp(a). Oral administration is also expected to provide patients with greater convenience. As of the Latest Practicable Date, we were conducting a Phase I clinical study on safety, tolerability, pharmacokinetics, pharmacodynamics and food effects of single and multiple oral doses in healthy subjects.

SHR6508

SHR6508 is a novel allosteric modulator of the calcium-sensing receptor for the treatment of hemodialysis patients with secondary hyperparathyroidism. The calcium-sensing receptor functions to monitor and control calcium levels by releasing parathyroid hormone (PTH) that controls calcium levels in the blood. With enhanced sensitivity to calcium ions, upon administration, SHR6508 may reduce PTH secretion among hemodialysis patients with secondary hyperparathyroidism.

SHR6508 is given intravenously to potentially improve patient compliance and reduce gastrointestinal adverse events. As of the Latest Practicable Date, we were conducting a randomized, double-blinded, double-dummy, multicenter Phase III clinical study for SHR6508 to confirm its efficacy and safety in hemodialysis patients with secondary hyperparathyroidism.

SHR-2004

SHR-2004 injection is an anti-Factor XI(FXI) antibody for the prevention and treatment of arterial and venous thrombosis. FXI is an important component of the intrinsic coagulation pathway which contributes to thrombosis development while plays a relatively limited role in normal hemostasis. SHR-2004 inhibits the activation of FXI by FXIIa with high affinity, leading to the prolongation of activated partial thromboplastin time (APTT) and the reduction of thrombus formation with reduced bleeding risk.

As of the Latest Practicable Date, we had completed a Phase II clinical study of SHR-2004 for the prevention of venous thromboembolism (VTE) after total knee arthroplasty (TKA), and we were conducting a multicenter Phase II clinical study of SHR-2004 for the prevention of VTE after surgery for ovarian cancer.

siRNA Drug Candidate Targeting APOC3

We are developing an siRNA drug candidate targeting APOC3, which inhibits the expression of APOC3 protein through RNA interference. It effectively reduces triglycerides and thereby reduces the risk of ASCVD in patients with hypertriglyceridemia. As of the Latest Practicable Date, we were conducting a Phase I clinical study of this drug candidate.

siRNA Drug Candidate Targeting AGT

We are developing an siRNA drug candidate targeting AGT. AGT is a promising new target for the treatment of resistant hypertension. The AGT gene encodes a protein that is a precursor to angiotensin II, a potent vasoconstrictor that plays a critical role in the regulation of blood pressure. This drug candidate aims to improve patient compliance, reduce blood pressure fluctuations, and reduce the incidence of adverse reactions of traditional antihypertension drugs while ensuring effective blood pressure reduction. As of the Latest Practicable Date, we were conducting a Phase I clinical study of this drug candidate.

Immunological and Respiratory Diseases

The global immunological and respiratory drug market reached US$228.3 billion in 2023, and is expected to further increase at a CAGR of 5.2% from 2023 to US$294.6 billion in 2028. China's immunological and respiratory drug market reached RMB109.0 billion in 2023, and is expected to further increase at a CAGR of 13.4% from 2023 to RMB204.4 billion in 2028.

Innovative drugs with extended half-lives, improved patient accessibility, higher adherence, and optimized safety profile are expected to be future growth drivers in the immunological and respiratory drug market. In line with this trend, we leverage different MOAs to deliver a comprehensive and science-driven solution for immunological and respiratory diseases.

Major Commercialized Products

Vunakizumab (AnDaJing®) (夫那奇珠單抗(安達靜®))

Vunakizumab is a subcutaneous (SC) recombinant anti-IL-17A antibody. In August 2024, vunakizumab was approved by the NMPA for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic treatment or phototherapy.

Vunakizumab is composed of a 0.8% mouse component, retains 6 CDR regions from the mouse, and has an innovative binding epitope to ensure high affinity for IL-17A. It accurately combines with IL-17A and effectively blocks the IL-17 pathway. At the same time, its lower mouse-derived components reduce potential immunogenicity. This MOA benefits the systemic treatment of autoimmune diseases related to the IL-17 pathway, including psoriasis, ankylosing spondylitis, and psoriatic arthritis. Vunakizumab exhibited high IL-17A affinity and strong inhibition of IL-17A/IL-17R interaction. In addition, the clinical response with vunakizumab was fast onset, with a mean percentage reduction in PASI of >50% by week 2 and 56.6% of subjects reaching PASI 75 response by week 4.

Vunakizumab was the first domestically developed anti-IL-17A antibody approved by the NMPA, according to Frost & Sullivan.

Major Product Candidates

Ivarmacitinib (SHR0302)

Ivarmacitinib is an orally administered, highly selective JAK1 inhibitor, exhibits potency and selectivity for JAK1. Its physicochemical properties allow for both oral and topical administration.

Ivarmacitinib is currently under NDA review in China for the treatment of moderate-to-severe atopic dermatitis, ankylosing spondylitis, moderate-to-severe active rheumatoid arthritis, and alopecia areata. As of the Latest Practicable Date, it was the most clinically-advanced domestically developed JAK1 inhibitor for the treatment of immunological diseases in China, according to Frost & Sullivan.

SHR-1819

SHR-1819 is a novel anti-IL-4Rα antibody. Interleukin (IL)-4 and IL-13 are critical pathogenic factors for type 2 inflammation-related allergic diseases. They share the mutual receptor subunit IL-4Rα. SHR-1819 was found to show high binding affinity to IL-4Rα. This mechanism significantly blocks certain signaling pathways that induce allergic responses, which indicates a promising treatment option for a wide array of autoimmune diseases caused by type 2 inflammation, such as atopic dermatitis, prurigo nodularis, and chronic spontaneous urticaria.

As of the Latest Practicable Date, SHR-1819 was undergoing a Phase III clinical study for the treatment of moderate-to-severe atopic dermatitis, and a Phase II/III clinical study for the treatment of prurigo nodularis.

In addition, we obtained the IND approval from the NMPA for conducting a Phase Ib/II clinical study to evaluate the efficacy and safety of SHR-1819 in adolescents (aged between 6 to 17) with atopic dermatitis in November 2024, as well as the IND approval from the NMPA for a Phase II clinical study to evaluate the efficacy and safety of SHR-1819 in chronic spontaneous urticaria in December 2024.

SHR-1905

SHR-1905 is a long-acting anti-TSLP antibody with best-in-class potential. SHR-1905 targets thymic stromal lymphopoietin, or TSLP, which is a driver of chronic immunological or inflammatory diseases, including severe asthma, chronic rhinosinusitis and chronic obstructive pulmonary disease.

Compared to other anti-TSLP antibodies, SHR-1905 has better potency and prolonged half-life, which allows longer dosage interval and better patient compliance. Through a YTE mutation of Fc segment, SHR-1905 exhibits enhanced affinity to FcRn, leading to a prolonged serum half-life, significantly longer than that of tezepelumab. As of the Latest Practicable Date, SHR-1905 was undergoing a Phase II clinical study for treatment of severe uncontrolled asthma, a Phase II clinical study for treatment of chronic rhinosinusitis with nasal polyps (CRSwNP).

SHR-1703

SHR-1703 is a novel, long-acting anti-IL-5 antibody. SHR-1703 binds to IL-5 and inhibits its binding to IL-5R on the surface of eosinophils. This mechanism inhibits the IL-5/IL-5R signaling pathway and the proliferation and activation of eosinophils to reduce eosinophil-mediated inflammation and damage. The YTE mutation of Fc segment enhances the affinity of SHR-1703 to FcRn, leading to a prolonged half-life of 72-100 days in humans, supporting every 6-month dosing in asthma. SHR-1703 aims to provide new treatment options for patients with chronic diseases such as asthma and EGPA that have T-helper type 2 (Th2) inflammation as the main mechanism.

As of the Latest Practicable Date, we were conducting a Phase III clinical study to confirm the efficacy and safety of SHR-1703 in patients with asthma. In addition, as of the Latest Practicable Date, we were conducting a Phase II/III study for the treatment of EGPA.

HRS-5965

HRS-5965 is an oral, novel, highly selective, small molecule inhibitor of complement Factor B, a key component of the alternative pathway. Complement-mediated intravascular hemolysis is a characteristic of paroxysmal nocturnal hemoglobinuria (PNH). HRS-5965 inhibits the alternative pathway and therefore controls both intravascular and extravascular hemolysis. As of the Latest Practicable Date, we were conducting Phase III clinical studies to confirm the efficacy and safety of HRS-5965 used in patients with PNH.

HRS-5965 controls glomerular inflammation by alleviating complement activation in IgA nephropathy (IgAN). As of the Latest Practicable Date, we were also conducting a Phase II clinical study to evaluate the efficacy of HRS-5965 in reducing proteinuria and delaying the progression of renal dysfunction.

Anti-IFNAR1/TACI Fusion Protein

We are developing an anti-IFNAR1 (interferon α and β receptor subunit 1) / TACI (TNF receptor superfamily member 13B) fusion protein with first-in-class potential. It exerts anti-inflammatory and immunosuppressive biological effects by targeting abnormally activated immune cells, with the potential to reduce autoantibody levels and improve disease activity in patients with autoimmune disorders, offering a new treatment option for these patients. As of the Latest Practicable Date, we were conducting a Phase I clinical study of this drug candidate for the treatment of systemic lupus erythematosus.

Anti-IL-23p19/IL-36R Bispecific Antibody

We are developing a novel, long-acting, anti-IL-23p19/IL-36R bispecific antibody, with first-in-class potential. It exhibited high IL-23 and IL-36R affinity and prolonged half-life, making it the first long-acting anti-IL-23p19/IL-36R bispecific antibody globally, according to Frost & Sullivan. It had entered the Phase I clinical study in moderate-to-severe plaque psoriasis in China as of the Latest Practicable Date.

Anti-IL-4Rα Antibody Glucocorticoid Conjugate

We are developing an antibody targeting IL-4Rα conjugated glucocorticoid, with first-in-class potential. It is administered through inhalation. It is expected to exert a localized, highly efficient anti-inflammatory effect by blocking key inflammatory pathways in asthma, with the potential to provide an effective and safe treatment option for patients with asthma and other chronic airway diseases. As of the Latest Practicable Date, it was undergoing Phase I clinical studies.

Neuroscience

The neuroscience pharmaceutical market broadly covers neurology, analgesia (or pain management), and anesthesia. Alzheimer's Disease and Parkinson's Disease are two major neurodegenerative disorders worldwide. According to Frost & Sullivan, there were estimated to be 58.3 million people affected by dementia worldwide in 2023, with Alzheimer's Disease contributing to 60-70% of dementia cases. In the same year, there were estimated to be 9.4 million people affected by Parkinson's Disease globally. According to the same source, in 2023, China had 14.0 million people affected by Alzheimer's Disease and approximately 43.4 million people at the MCI stage, compared with 3.2 million people affected by Parkinson's Disease. There are significant unmet medical needs for disease-modifying therapies which target clearly-defined pathogenic mechanisms and have the potential to delay the disease progression. Furthermore, stroke is a leading cause of death and disability globally. We have been developing various therapies with differentiated MOAs to improve the treatment paradigm of stroke.

Pain management is another critical issue both in China and globally. Chronic pain affects over 20% of the general population. Insufficient symptom control, poor tolerance of medications, and opioid overuse are still challenges in clinical practice, especially in the treatment of chronic pain. In addition, anesthesia and related fields such as perioperative management and critical care also show significant growth potential.

Commercialized Product

Tegileridine (AiSuTe®) (泰吉利定(艾蘇特®))

Tegileridine is a novel small molecule μ-opioid receptors (MOR) agonist. In January 2024, tegileridine was approved by the NMPA for the treatment of post-operative analgesia after abdominal surgeries.

Tegileridine selectively activates the G-protein-coupled pathway, while only weakly activating the β-arrestin-2 pathway. This mechanism provides analgesic efficacy and mitigates adverse events, such as respiratory depression and gastrointestinal dysfunction.

We conducted a randomized, double-blind, placebo- and active-controlled Phase III clinical study to confirm the analgesic efficacy of tegileridine compared with placebo and morphine in patients with acute postoperative pain following abdominal surgeries. Results of the clinical study showed that the time weighted sum of pain intensity differences (SPID) over 24 hours for tegileridine (0.75 mg and 1.0 mg) were superior compared with the placebo, and SPID over 24 hours for tegileridine (1.0 mg) was comparable to morphine, which indicated tegileridine's improved efficacy for pain relief.

Tegileridine was the first domestically developed innovative MOR agonist approved by the NMPA for the treatment of postsurgical pain, according to Frost & Sullivan. In December 2023, tegileridine's NDA application for the treatment of moderate-to-severe pain after orthopedic surgeries was accepted by the NMPA.

Butorphanol (NuoYang®) (布托啡諾(諾揚®))

Butorphanol tartrate injection is primarily indicated for the treatment of various types of cancer-related pain and postoperative pain. It is a mixed opioid receptor agonist and antagonist that provides effective visceral analgesia and alleviates respiratory depression. It also effectively reduces the incidence and severity of propofol injection pain. As of the Latest Practicable Date, our butorphanol tartrate injection was the first-to-market generic version of this pharmaceutical product in China, according to Frost & Sullivan.

Major Product Candidates

SHR-1707

SHR-1707 is a novel anti-Aβ IgG1 antibody that binds to Aβ fibrils and monomers to block the formation of Aβ plaques or to promote the microglial phagocytosis of Aβ.

In a Phase Ib clinical study, SHR-1707 demonstrated significant brain amyloid load reduction in mild Alzheimer's Disease subjects. In preclinical studies, a higher affinity to beta-amyloid fibrils was demonstrated, which may predict a stronger effect of amyloid clearance than the products currently in use. In behavior tests of the animal model for Alzheimer's Disease, improvement of cognitive functions was also observed.

As of the Latest Practicable Date, we were conducting a Phase II clinical study of SHR-1707 for the treatment of Alzheimer's Disease.

HRG2010

HRG2010 is a novel extended-release fixed-dose combination composed of carbidopa and levodopa. HRG2010 has been developed for a better control of motor fluctuations in Parkinson's Disease patients with long-term use of levodopa.

As of the Latest Practicable Date, we were conducting a Phase III clinical study of HRG2010 for the treatment of Parkinson's Disease.

Na_V1.8 Inhibitor

We are developing a highly selective inhibitor of voltage-gated sodium ion channel subunit 1.8 (Na_V1.8), presenting significant potential for non-opioid pain management.

Gaines and losses of function mutations in selective sodium channel subtypes, Na_V1.7 and Na_V1.8, are associated with human pain syndromes. The Na_V1.8 channel is a genetically validated target for pain, and it is mostly expressed in the peripheral nervous system. Compared with the current standard of care, our Na_V1.8 inhibitor is expected to have a better safety profile and tolerability. There were no Na_V1.8 inhibitors approved in the world for acute pain or chronic pain as of the Latest Practicable Date, according to Frost & Sullivan.

We have received the IND approval from the NMPA to initiate a clinical study for this drug candidate in the treatment of acute pain. As of the Latest Practicable Date, our Na_V1.8 inhibitor was undergoing Phase I clinical development.

Others

In addition to the drugs and drug candidates described above, we have developed other pharmaceutical products including contrast agents and anti-infectives.

Ioversol (碘佛醇)

Ioversol is our contrast agent product, and it is used primarily in various vascular radiographic imaging examinations. Contrast agents are injected or taken into human tissues or organs to enhance the effect of image observation. They are essential diagnostic and

differential diagnostic drugs for medical imaging disciplines. Ioversol injection is a novel, non-ionic, low-osmolar, water-soluble contrast agent for vascular use. Ioversol injection does not have any significant impact on blood coagulation, unlike ionic contrast agents.

As of the Latest Practicable Date, our ioversol injection was the first-to-market generic version of this pharmaceutical product in China, according to Frost & Sullivan.

SHR7280

SHR7280 is our proprietary non-peptide, oral, small molecule gonadotropin-releasing hormone (GnRH) receptor antagonist, with first-in-class potential. Upon oral administration, SHR7280 competes with GnRH for receptor-binding. By blocking the binding of endogenous GnRH to its receptor, SHR7280 inhibits the synthesis and release of gonadotropins and reduces testosterone and estradiol levels.

In recent years, non-peptide oral GnRH antagonists have been developed as a promising treatment strategy for patients with sex hormone-dependent diseases, such as endometriosis, uterine fibroid, polycystic ovary syndrome, and precocious puberty, and are applied in the field of assisted reproduction. For example, elagolix, an oral GnRH antagonist, has been approved by the U.S. FDA to treat moderate-to-severe pain associated with endometriosis. However, in several countries and regions, including China, elagolix has not been approved for use in women with sex hormone-related diseases. SHR7280 is a novel treatment with the potential to fill in the gap.

As of the Latest Practicable Date, we were conducting a randomized, double-blinded, parallel group, placebo-controlled, multicenter Phase II/III clinical study for SHR7280 to evaluate its efficacy and safety in subjects with menorrhagia with uterine fibroids.

HRS-5635

HRS-5635 is an N-acetyl-galactosamine (GalNAc)-conjugated, double-stranded RNA interference (RNAi) agent. The GalNAc moiety enables targeted delivery of HRS-5635 into the liver via uptake by asialoglycoprotein receptors (ASGPR) expressed on the hepatocyte surface, and specifically targets the HBV genome X-region through RNA interference (RNAi) pathway to inhibit the expression of HBV-related proteins, like HBsAg.

HRS-5635 is administered as a long-acting, subcutaneous injection for the treatment of chronic hepatitis B (CHB), aiming at high functional cure rates of CHB patient. In the pre-clinical studies, HRS-5635 showed excellent antiviral activity against all HBV genotypes, and exert efficient and durable antiviral effect.

The first-in-human (proof-of-concept) study of HRS-5635 showed a favorable safety profile as well as marked and durable reductions in HBsAg. As of the Latest Practicable Date, we were conducting a Phase II study to evaluate the efficacy and safety of HRS-5635 for the treatment of CHB.

COLLABORATION AND LICENSING ARRANGEMENTS

We are committed to maximizing the commercial value of our high-quality innovative drugs through out-licensing arrangements and expanding our product matrix through in-licensing and co-development collaborations. These initiatives have helped to expand our global footprint to unlock and maximize the potential of our product matrix and technology platforms.

Major Out-Licensing Arrangements

Collaboration and License Agreement with IDEAYA Biosciences

In December 2024, we entered into a collaboration and license agreement with IDEAYA Biosciences, a precision medicine oncology company headquartered in the United States. Pursuant to this agreement, we out-licensed to IDEAYA Biosciences the exclusive rights to develop, manufacture, and commercialize SHR-4849 worldwide (excluding the Greater China region). Under this agreement, IDEAYA Biosciences agreed to provide us with an upfront payment of US$75 million. We are also entitled to receive development and approval milestone payments of up to US$200 million. In addition, IDEAYA Biosciences agreed to provide us with sales milestone payments of up to US$770 million and single- to double-digit sales royalties, based on future actual annual net sales of SHR-4849 worldwide (excluding the Greater China region).

Collaboration and License Agreement with Kailera Therapeutics

In May 2024, we entered into a collaboration and license agreement with Kailera Therapeutics, under which we out-licensed to Kailera Therapeutics the exclusive rights to develop and commercialize three of our proprietary GLP-1 drug candidates—HRS-7535, HRS9531, and HRS-4729—worldwide (excluding the Greater China region).

Kailera Therapeutics agreed to provide us with an upfront payment of US$100 million, a near-term technology transfer milestone payment of US$10 million and 19.9% of its equity interest. We are also entitled to receive potential clinical development and regulatory related milestone payments of up to US$200 million, sales milestone payments of up to US$5.725 billion, and sales royalties ranging from low single digit to low double digits. The total deal value for this transaction is approximately US$6 billion.

Strategic Collaboration and License Agreement with a Fully Owned Subsidiary of Merck KGaA, Darmstadt, Germany

In October 2023, we entered into a strategic collaboration and license agreement with Merck Healthcare KGaA, a fully owned subsidiary of Merck KGaA, Darmstadt, Germany, or MRKDG, a multinational chemical, pharmaceutical, and life sciences corporation. Pursuant to the agreement, we (i) out-licensed to this fully owned subsidiary of MRKDG the exclusive rights to develop, manufacture, and commercialize HRS-1167 worldwide (outside of mainland China), (ii) granted this fully owned subsidiary of MRKDG an exclusive option to develop, manufacture, and commercialize SHR-A1904 worldwide (outside of mainland China), and (iii) granted this fully owned subsidiary of MRKDG an option to co-promote HRS-1167 and SHR-A1904 with us within mainland China.

Under this agreement, the fully owned subsidiary of MRKDG agreed to provide us with an upfront payment of €160 million and we are entitled to receive additional payments upon the achievement of certain development, regulatory and commercial milestones, as well as tiered royalties on net sales by this fully owned subsidiary of MRKDG. Potential payments may total up to €1.4 billion.

In-Licensing and Co-Development Arrangements

Collaboration Agreements with CStone

In November 2021, we and CStone, an innovation-driven biopharmaceutical company focused on the R&D of anti-cancer therapies, entered into a strategic partnership and exclusive licensing agreement on CS1002/SHR-8068 (an anti-CTLA-4 antibody). According to this agreement, we obtained the exclusive rights for the research, development, registration, manufacturing, and commercialization of this anti-CLTA-4 antibody in the Greater China region, while CStone retained the rights to develop and commercialize CS1002 outside of the Greater China region. Under this agreement, we agreed to provide CStone with an upfront payment and potential milestone payments up to approximately US$200 million in addition to double-digit percentage sales royalties.

In addition, in July 2024, we entered into an agreement with CStone to obtain the exclusive commercial promotion rights of CStone's precision therapy drug Ayvakit (avapritinib) in mainland China. Under this agreement, we agreed to provide CStone with an upfront payment of RMB35 million, and we may charge CStone service fees for promoting Ayvakit in mainland China.

Strategic Cooperation Agreement with Yingli Pharma

In February 2021, we entered into a strategic cooperation agreement with Yingli Pharma, a pharmaceutical company focused on hematologic tumors, solid tumors, and kidney-related metabolic diseases. Under this agreement, we agreed to invest US$20 million in an equity stake in Yingli Pharma, and received co-development and exclusive commercialization rights for linperlisib, a PI3Kδ inhibitor, in the Greater China region. In addition, we agreed to provide Yingli Pharma with milestone payments totaling up to RMB30 million, and Yingli Pharma agreed to pay us commercialization fees based on sales performance of linperlisib.

Collaboration and License Agreement with Novaliq

In November 2019, we entered into an exclusive agreement with Novaliq, a Germany-based biopharmaceutical company focused on ocular therapeutics, to obtain the exclusive rights to develop, manufacture, and commercialize Novaliq's drugs for the treatment of dry eye diseases, CyclASol (a 0.1% cyclosporine A formulation) and NOV03 (perfluorohexyloctane), in the Greater China region.

Under this agreement, we agreed to provide Novaliq with an upfront payment of US$6 million, in addition to a payment of US$3 million upon the granting of the first core patent for NOV03 in China. We also agreed to make development milestone payments of up to US$12 million to Novaliq with respect to the development and regulatory objectives of the two products. In addition, we agreed to make sales milestone payments of up to US$144 million to Novaliq based on the sales performance of the products and tiered percentage royalties on annual net sales of the products in the Greater China region.

Collaboration and License Agreement with Mycovia Pharmaceuticals

In June 2019, we entered into an exclusive agreement with Mycovia Pharmaceuticals, a U.S.-based pharmaceutical company focused on innovative antifungal therapies, to develop, register, manufacture, and commercialize Mycovia Pharmaceuticals' investigational drug, oteseconazole (also known as VT-1161), in the Greater China region for the treatment or prevention of a range of fungal conditions, including recurrent vulvovaginal candidiasis, onychomycosis, and invasive fungal infections.

Under this agreement, we agreed to provide Mycovia Pharmaceuticals with (i) a R&D payment of US$7.5 million in eight installments within two years, (ii) development milestone payments of up to US$9 million, (iii) sales milestone payments of up to US$92 million based on the sales performance, and (iv) tiered percentage royalties on annual net sales of the product in Greater China region.

RESEARCH AND DEVELOPMENT

Our robust in-house R&D capabilities are the cornerstone of our competitive advantages and an important driver of our growth. We are committed to improving our innovation capabilities and making paradigm-shifting breakthroughs.

Intellectual diversity and depth of talent are at the core of our R&D success. With decades of pharmaceutical R&D experience, we have gathered a professional team of scientists, engineers, and technicians that enable us to continuously develop first-in-class and best-in-class innovative drugs. Our all-round R&D team comprises experts with extensive experience throughout the entire R&D cycle of innovative drugs, spanning drug discovery, preclinical development, CMC, clinical development, and regulatory affairs. As of September 30, 2024, our highly experienced R&D team consisted of over 5,500 employees. Nearly 60% of them hold a master's or higher degree, and more than 12% hold a Ph.D. or M.D. Many of them have years of industry experience at leading multinational corporations, such as Pfizer, Novartis, Merck, and Eli Lilly and Company, as well as renowned research institutes, such as Yale School of Medicine, Heidelberg University, and the University of Texas Southwestern Medical Center. Currently, we have 14 R&D centers, with complementary functions, in China, Japan, the U.S., Australia and Switzerland. Our R&D capabilities are demonstrated by a strong portfolio of issued patents and patent applications in China and around the globe. For more details, see "—Intellectual Property Rights" and Appendix IV to this document.

In line with our commitment to innovation and technology breakthroughs, we invested heavily in R&D activities. In 2022, 2023 and the nine months ended September 30, 2024, our R&D expenses were RMB4,886.6 million, RMB4,953.9 million, and RMB4,548.9 million, respectively, representing 23.0%, 21.7%, and 22.5% of our total revenue for these same respective periods.

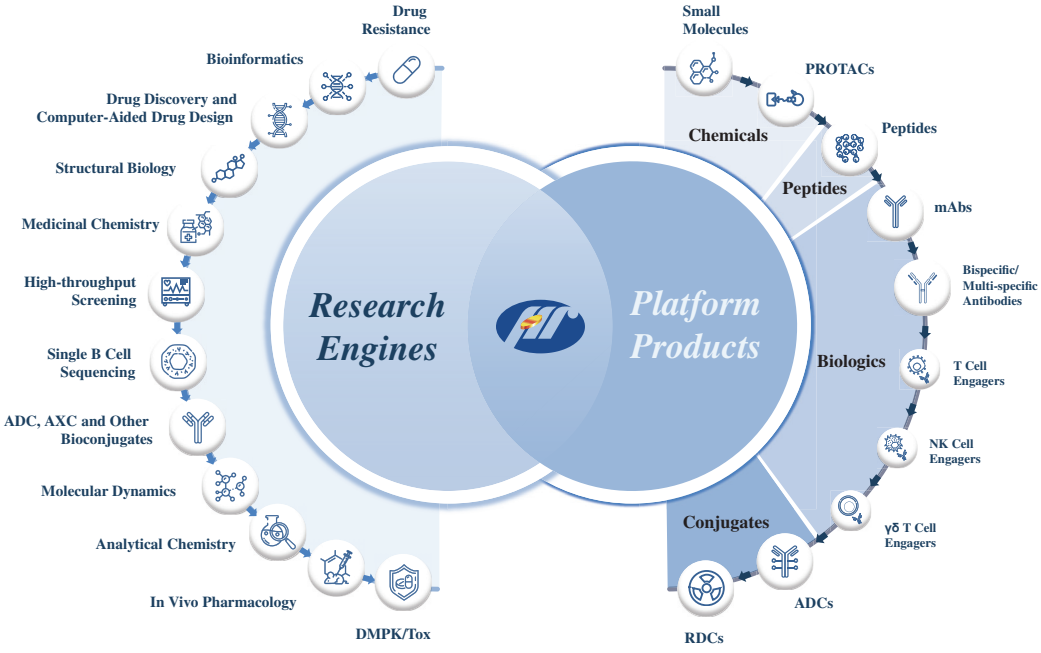
Technology Platforms

We have developed comprehensive technology platforms that drive our continuous innovation. They encompass the stages of drug discovery and drug evaluation, and, either individually or collectively, empower and sustain the roll-out of our novel and differentiated drugs.

Small molecules have been our initial research focus, and remain to be our strength. Leveraging our platform, as of the Latest Practicable Date we had developed a portfolio of over ten approved innovative small molecule drugs, and they had all been included in the NRDL. Building on our experience in the discovery and development of small molecules, we are expanding our technology platforms to encompass a broader range of modalities.

Over the decades, we have extended our research beyond small molecules to encompass a wide range of additional modalities, including PROTACs, peptides, mAbs, BsAbs, multi-specific antibodies, ADCs, and RLTs.

The matrix below is illustrative of our technology platforms.



Following below is a description of our selective technology platforms.

Bioinformatics

At the core of our bioinformatics platform is our omics database, which integrates genomics, transcriptomics, proteomics, single-cell transcriptomics, and spatial transcriptomics. Our bioinformatic platform can streamline and optimize various aspects of our R&D:

- *Therapeutic target identification*. By deploying graph neural networks (GNN) and other algorithms, we have substantially reduced the time required to identify potential targets. The platform enables us to complete a comprehensive analysis of the knowledge graph for a specific disease in weeks instead of months, while enhancing the precision of target identification.

- *Literature analysis*. We use advanced tools available on our bioinformatics platform to perform processing and extracting tasks during the process of literature review and analysis, thereby enhancing efficiency and minimizing human error. This rapid assimilation of research allows us to stay abreast of the latest developments. The user-friendly interface also enables our biologists to evaluate targets and develop drugs more efficiently, shortening their time spent on data retrieval and initial assessment.

- *Clinical datasets analysis*. Our bioinformatics platform significantly expedites our analysis of complex clinical trial datasets, leading to faster discovery of key predictive biomarkers, from data collection to obtaining actionable insights. The accuracy of these identifications aids in better patient stratification and a deeper understanding of therapeutic mechanisms. This leads to a substantial reduction in the attrition rate of clinical trials, saving costs associated with our drug development.

Drug Discovery and Computer-Aided Drug Design

By combining cutting-edge computational methods and tools, we have built the "Hengrui-LingShu" drug discovery and computer-aided drug design platform to empower our discovery of small molecule drugs and biologics.

With an accurate prediction of the target-molecule binding mode, "Hengrui-LingShu" platform facilitates a rational drug design. By combining computational simulations with structure-based and *de novo* design, it further contributes to the generation of innovative molecules with superior activity and properties.

In addition, the platform offers molecular modeling and advanced computational methods. These enable us to design antigens for screening antibodies with desired functions. The platform also integrates antibody-antigen complex structure predication with protein design and experimental validation, which allows us to efficiently optimize our antibody drugs. Furthermore, we can leverage this platform to perform *in silico* assessment of the antibody developability. This allows us to identify molecules with optimal physicochemical properties in an early stage, while improving the success rate of our drug development.

Structural Biology

We have developed an integrated platform for protein production, structural biology and biophysical analysis, which supports the development of both small molecule drugs and biologics. With a cutting-edge, high-throughput protein crystallography pipeline, this platform enables us to generate high-resolution protein-ligand and antigen-antibody complex structures routinely from amenable samples. In particular, for large molecule discovery, we routinely perform hydrogen/deuterium exchange mass spectrometry (HDX-MS) for epitope and paratope

mapping. Utilizing our deep learning-assisted prediction framework, we achieve accurate and rapid prediction of antigen-antibody interactions. This enables us to elucidate the molecular mechanism of antibody drugs and facilitate antibody engineering and optimization.

We capitalize on our structural biology platform to develop an in-depth understanding of molecular interactions, facilitating the molecule design and optimization. We also utilize the cryogenic electron microscopy (cryo-EM) approach to elucidating the structure of a wide range of macromolecules including membrane proteins and large multiple subunit proteins which are challenging to crystallize.

Single B Cell Sequencing

Our single B cell sequencing platform is primarily focused on high-throughput single B cell sequencing and automated antibody production. This platform provides efficient bioinformatics sequence analysis tools, and enables high-throughput expression and purification. It has demonstrated significant advantages over conventional approaches in terms of speed, diversity, and developability. We usually obtain hundreds of unique antigen-binding clones within a one-month timeframe for downstream validation.

Antigen-specific B-cells are experimentally enriched and sequenced through next-generation sequencing (NGS). Advanced algorithms are developed to streamline the process of prioritizing the hundreds-to-thousands of hits generated from antibody discovery campaigns for small-scale production and functional assays. We further implement a high-throughput automated protein production system following NGS. With the advancement of precise protein structure prediction methods and the potential for extensive exploration of the immune repertoire, this platform holds great promise for enhancing high-throughput therapeutic antibody discovery and optimization in real-world scenarios.

ADC, AXC and Other Bioconjugates

We pioneer the development of ADCs in China. Building on over a decade of experience, we have built a proprietary Hengrui Rapid Modular ADC Platform, or HRMAP, in researching ADCs and other bioconjugate drugs.

Our HRMAP platform encompasses payloads with different MOAs, optimal conjugation linkers/methods, and well-established antibody discovery and engineering ability that empower our capability to create an ADC with desired *in vitro* and *in vivo* properties within a short period of time.

DXh, a topoisomerase I inhibitor (TOP1i), is a differentiated payload that exemplifies the strength of our ADC platform. DXh is a delicately selected exatecan derivative. It is purposely designed to increase the steric hindrance between the free toxin and the linker. This leads to enhanced chemical stability and avoids uncontrolled release of the toxin in plasma, thus avoiding the toxic side effects associated with premature toxin release. In addition, it improves the permeability of the toxin, leading to an enhanced bystander killing effect of the ADC. Its

good solubility also allows for improved flexibility in the drug-to-antibody ratio. DXh is designed to allow for a rapid removal from circulation, which helps minimize adverse reactions caused by free toxins. Compared to peers, ADC molecules developed on our platform exhibits strong tumor-suppressing effects while demonstrating better plasma stability and lower free toxin exposure in the body. This is directly correlated with the lower incidence of interstitial lung disease (ILD) observed in clinical studies, as well as lower incidence of hematological toxicity and gastrointestinal toxicity. As of the Latest Practicable Date, we had advanced over ten differentiated ADC drug candidates with our purposely designed DXh payload to the clinical stage, including trastuzumab rezetecan (or SHR-A1811, a HER2 ADC), SHR-A1904 (a CLDN18.2 ADC), and SHR-4849 (a DLL3 ADC). In particular, as of the same date, trastuzumab rezetecan (SHR-A1811) had received breakthrough therapy designations from the NMPA for seven indications, which were the most among all clinical-stage drug candidates in China, according to Frost & Sullivan.

We constantly advance our conjugation technologies to expand our bioconjugate component library and research on "AXC" drugs. We take a modular approach to efficiently extending our research of bioconjugates beyond ADCs by conjugating various payloads in addition to chemical drugs with antibodies, or creating AXCs:

- *Antibodies*. We utilize our translational medicine expertise to identify novel TAAs. Our antibody engineering capability allows us to develop not only monoclonal antibodies, but also bispecific and multi-specific antibodies, aiming for the synergies of different tumor (or target)-associated-antigens.

- *Conjugation methods*. Besides the conventional cysteine conjugation method, we are developing various site-specific conjugation methods, including glycosite-specific conjugation and engineered cysteine site-specific conjugation.

- *Payloads*. We are actively exploring cytotoxic payloads with new MOAs to overcome the resistance of commonly used cytotoxic payloads. We are also expanding our payload library to cover various modalities, such as degraders (molecular glues and PROTACs) for oncology. By conjugating peptides and oligonucleotides onto antibodies of interest, we further explore new molecular entities in therapeutic areas beyond oncology.

Additionally, our research in the field of new bioconjugates spans DACs, antibody-peptide conjugates, AOCs, and radionuclide drug conjugates (RDCs). We pioneered the development of DACs and AOCs. DACs and AOCs are novel targeted therapies with differentiated MOAs compared to ADCs. In contrast to molecular glue degraders, DACs, with protein degraders as payloads carried by antibodies, have demonstrated favorable efficacy and safety profiles and the potential to overcome drug resistance in preclinical settings. AOCs, by combining the targeting capabilities of antibodies with the gene regulatory potential of oligonucleotides, precisely modulate disease-causing proteins.

PROTACs

We deploy our innovative PROTAC platform to detect PROTAC ternary complexes and research into the mechanisms and kinetics of target protein degradation.

PROTAC is a bifunctional molecule that combines an active site selective for binding to the target of interest and a ligand of E3 ubiquitin ligase to drive selective proteasome mediated degradation. Popular PROTAC targets in cancer are well characterized by soluble proteins such as CDK2, BTK, and ER.

As of the Latest Practicable Date, we had two PROTAC programs, namely the ER PROTAC coded as HRS-1358 and the AR PROTAC coded as HRS-5041, in the clinical stage. Both HRS-1358 and HRS-5041 have potent *in vitro*/*vivo* activity and favorable pharmacokinetic profiles in preclinical studies. Additionally, we have numerous ongoing PROTAC programs covering both oncology and non-oncology indications. We endeavor to leverage our PROTAC platform to address historically undruggable targets.

Bispecific Antibody Construction

Bispecific antibodies, or BsAbs, are artificial proteins that simultaneously bind to two different types of antigen or two different epitopes on the same antigen. Our bispecific antibody platforms—Hengrui Obscurin Titin-Ig (HOT-Ig) and Half Antibody Recombination Technology-IgG (HART-IgG)—are our proprietary platforms incorporating cutting-edge technologies that have demonstrated the ability to generate differentiated new molecules:

- HOT-Ig utilizes the Ig-like domain pair from human obscurin and titin to replace the CH1/CL domains, avoiding heavy and light chain mispairing. By leveraging this platform, we create a variety of bispecific antibodies with multiple formats, great stability, and high compatibility for diverse sequences. As of the Latest Practicable Date, we had two BsAb drug candidates under clinical development.

- HART-IgG is our newly-developed versatile platform to efficiently prepare bispecific antibodies. Bispecific antibodies developed via our HART-IgG platform show robust physicochemical properties and good druggability comparable with those of canonical mAbs. Furthermore, our HART-IgG technology is compatible with other engineering/conjugation technologies, and as a result, facilitates the development of bispecific antibody conjugates.

T-cell Activation

We have a bispecific and multi-specific T cell engager (TCE) platform for hematological malignancies and autoimmune diseases, and have established a cutting-edge TCE prodrug platform for solid tumors aiming at enhancing the safety profile of TCE.

CD3, or cluster of differentiation 3, is a component of the TCR/CD3 complex that plays an essential role in T-cell activation. With the approvals of several CD3 bispecific antibodies, TCEs for hematological malignancies have proved impressive efficacies. However, TCEs for solid tumors are facing significant hurdles due to on-target off-tumor toxicity in healthy tissues. To overcome the narrow therapeutic window induced by healthy tissue damages, a proprietary TCE prodrug platform has been established recently. Our novel proprietary TCE format features a small molecule weight, which has the potential to enable better tumor penetration. Moreover, its conditional activation in the tumor microenvironment avoids on-target off-tumor toxicity. In terms of pharmacokinetics, our TCE prodrug is an inactive compound that becomes active only after conditional activation in tumor microenvironment, thereby improving the safety profile. After turning into an active molecule, it can be rapidly cleared in circulation due to a short half-life conversion. Our TCE prodrug platform successfully balances the functionality, manufacturability, and multifunctional expandability. We believe that breakthroughs in this area may compensate for the limitations of ADCs in target antigen of low-expressing tumor cells.

We are also actively exploring to add co-stimulating signaling to traditional TCE in multi-specific modalities. We aim to achieve enhanced efficacy through the second signal activation, while effectively controlling the side effects. As of the Latest Practicable Date, we had several bispecific and multi-specific TCE drug candidates developed from our in-house TCE platform at various stages of development.

NK Cell Engagers

Natural killer (NK) cells are innate lymphocytes that kill a wide range of cells in distress, particularly tumor cells and cells infected with viruses. Among immune cell candidates, NK cells have drawn significant attention in the medical community. Unlike T cells, they possess a unique ability to recognize and eliminate target cells without antigen-specific activation. Preclinical and clinical studies have demonstrated safety and efficacy of allogeneic NK cells against both hematological and solid tumors. We have built our proprietary NK cell engager platform to engineer the receptor-binding fragment crystallizable (Fc) region of antibodies, screen NK cell agonists, and construct NK cell engagers.

γδ T Cell Engagers

In recent years, researchers are developing new therapeutic strategies for targeting specific T cell subsets, such as unconventional gamma delta (γδ) T cells. γδ T cells directly recognize and kill transformed cells independently of human leukocyte-antigen presentation, which makes them a highly promising effector-cell compartment for cancer immunotherapy. We have built our proprietary γδ T cell engager platform to delve into biological mechanisms of γδ T cells, screen novel agonists, and construct γδ T cell engagers.

Based on insights accumulated over decades, we have also established a few other platforms that facilitate our drug discovery and development, such as our drug resistance platform that encompasses a comprehensive summary of drug-resistant cell lines, preclinical drug resistance models and the collection of real-world clinically resistant samples; our *in vivo* pharmacology platform characterized by a rich portfolio of disease-centric models that facilitate our pharmacological evaluation during the drug discovery; our drug metabolism, pharmacokinetics and toxicology (DMPK/Tox) platform that expedites the discovery, optimization, and nomination of preclinical candidates through robust *in vitro* absorption, distribution, metabolism, and excretion (ADME) assessments, *in vivo* DMPK studies, and dose range-finding testing; and our high-throughput screening platform that capitalizes on high-throughput display technology to perform antibody screening, while optimizing the affinity and druggability properties of molecules.

R&D Process

Each R&D project begins with a thorough market analysis. We apply a market-oriented approach to identifying differentiated innovative targets with significant clinical value to treat diseases with significant unmet medical needs and market potential.

We carefully review each R&D proposal and submit it for approval by our innovative drugs R&D management committee led by Mr. Sun Piaoyang, our Chairman and Executive Director; Mr. Zhang Lianshan, our Executive Director and Executive Vice President; and Mr. Jiang Frank Ningjun, our Executive Director, Executive Vice President, and Chief Strategy Officer. Our R&D management committee includes representatives from various functional departments across early research, preclinical development, CMC, clinical development, and marketing and sales. For approved projects, we also conduct periodic reviews and discontinue projects that fail to make satisfactory progress.

Below is a summary of the key steps of an R&D project:

- *Target identification and validation*. In the earliest stage, we explore targets that we believe may offer first-in-class or best-in-class potential through in-depth research on the pathogenesis of diseases and the MOA of targets and by monitoring the latest research published in international conferences. We may also apply advanced technology to streamline our drug discovery, molecular design, drug property prediction and optimization.

- *Molecule discovery and modification*. After we select a target, we test and screen the compounds on our technology platforms to select (i) the hit compound—a compound that displays the desired biological activity towards a drug target and reproduces this activity when retested, (ii) the lead compound—a compound within a defined chemical series having demonstrated a robust pharmacological and biological activity on a specific therapeutic target, and, eventually, (iii) the preclinical candidate compound.

- *Preclinical studies*. Following the identification of a clinical candidate compound, we conduct preclinical studies on it. These include pharmacodynamic studies, pharmacokinetic studies, pharmacology and toxicology studies, and CMC studies.

- *IND application.* After a preclinical candidate compound has undergone sufficient and comprehensive preclinical validation and achieved the predefined efficacy and safety profile, we will submit an IND application to the applicable regulatory authority, such as the NMPA.

- *Clinical trials*. Once we have obtained the IND approval, we proceed to conduct clinical trials through qualified medical institutions. Our responsibilities include designing the clinical protocols, securing funding for the clinical trials, and supervising and managing the trials to ensure data quality, procedural compliance, and adherence to GCP standards. We also monitor the safety and efficacy of the investigational product throughout the trial process and ensure that all regulatory requirements are met.

- *NDA/BLA submission.* Upon successful completion of the clinical trials and the collection of sufficient data to demonstrate the drug's safety and efficacy, we submit an NDA or a BLA to the applicable regulatory authority, such as the NMPA. This submission includes comprehensive data packages from preclinical studies, clinical trials, and CMC. The regulatory authority then typically conducts a thorough review of the application materials, which may include onsite inspections of clinical trial sites and manufacturing facilities to verify the data integrity and compliance with applicable GMP requirements.

- *Commercial launch.* Following the regulator's approval of the NDA or BLA and issuance of the new drug certificate and drug approval number, we initiate the commercial launch of the drug. This involves activities such as manufacturing scale-up, distribution, marketing, and making the drug available to the public.

- *Post-marketing surveillance studies*. After the drug is launched, ongoing monitoring of its efficacy and adverse reactions is crucial to determine the clinical benefits and safety in the broader patient population. This includes conducting post-marketing surveillance studies to collect data on the drug's performance in real-world settings, which leads to further understanding of its risks and benefits.

For further details about the laws and regulations related to the registration of pharmaceutical products in China, see "Regulatory Overview—Overview of Laws and Regulations in the PRC—Laws and Regulations in Relation to New Drugs."

Moreover, we have developed a digital project management platform that covers the entire R&D cycle described above. We leverage this unified platform to integrate, store, and share all necessary information throughout our R&D projects. Our use of this platform ensures the smooth execution of each project in a timely and cost-efficient manner.

Clinical Development

We have built strong end-to-end clinical development capabilities to ensure the efficiency and quality of our drug development process. As of December 31, 2024, our in-house clinical development team covered approximately 5,000 clinical investigators, and we were conducting approximately 400 clinical trials for over 90 innovative drug candidates. In 2024, we enrolled nearly 20,000 participants in our clinical studies.

We pursue a patient-oriented strategy to quickly and cost-effectively progress clinical development. This strategy contains the following main components:

- *Fast proof of concept.* We conduct rapid proof-of-concept studies with clear endpoint definitions to establish preliminary efficacy and safety signals, which efficiently inform the design of our clinical development programs, help mitigate clinical development risks, and facilitate quicker go/no-go decisions. By quickly eliminating ineffective drugs, we can focus resources on promising candidates, reducing our overall cost of development.

- *Patient stratification.* Through clear patient stratification, we typically enroll only those patients who are most likely to achieve clinical benefits from our product candidates. By evaluating multiple cohorts of patients based on their specific characteristics, such as genomic alterations, or by using biomarkers to select patients who are more likely to benefit from the treatment, we can enhance trial efficacy, accelerate timelines, and pursue an accelerated regulatory approval pathway for certain targeted patient populations.

- *Adaptive trial design.* For some trials, we use accumulated data to perform interim analysis and decide how to modify aspects of an ongoing clinical trial, such as dosage, patient population, and treatment regimens, without undermining the validity and integrity of the trial. This flexibility makes the trial more efficient, potentially reducing the number of patients needed and shortening the timeline. The interim analysis also allows quicker go/no-go decisions, enabling us to halt ineffective treatments earlier to save time and resources.

- *Modular evolution in combination therapies.* While evaluating each module, we can quickly pivot and test various modules systematically. Applying this approach, we can shorten the overall timeline of exploring effective combination therapy options, thus accelerating our product development and iteration processes, and addressing various unmet medical needs. By enabling the progressive integration of new candidates, modifying treatment regimens based on emerging insights, and personalizing therapy based on patient characteristics, this approach can enhance the efficacy and safety of our treatments, particularly for complex and evolving diseases.

Besides our patient-oriented strategy, we adhere to stringent global standards when conducting clinical trials in China for our product candidates with global potential. Applying this approach, we can pursue concurrent IND submissions worldwide and accelerate multi-regional clinical trials for potentially first-in-class or best-in-class drug candidates. We have initiated multi-regional clinical trials in regions, including the U.S., Europe, Australia, Japan, and South Korea, for a number of products demonstrating global potential such as SHR-A1904, SHR-A1811, and camrelizumab in combination with apatinib.

Our end-to-end clinical development capabilities enable us to achieve superior operational efficiency in clinical development. For example, it took us around four years to advance our trastuzumab rezetecan (SHR-A1811) from the commencement of the clinical trial to obtaining the NMPA's acceptance of the NDA. From 2018 to the Latest Practicable Date, we had obtained approximately 60 facilitated regulatory pathways in China, the U.S., the EU, and other overseas markets. Our in-house clinical development capabilities allow us to efficiently expedite regulatory timelines for our products.

In addition to our superior efficiency, under the "patient first" guidepost, our pharmacovigilance professionals continuously monitor drug safety data to ensure patients' well-being and the integrity of our clinical development. Furthermore, we maintain robust quality assurance for the entire process of our clinical trials through a dedicated team of highly experienced clinical quality professionals. Our dedicated professionals implement stringent quality management over the entire process of clinical development. During the Track Record Period and up to the Latest Practicable Date, our clinical programs achieved a 100% pass rate with zero critical deficiencies in approximately 90 GCP inspections conducted by the NMPA and the U.S. FDA. In particular, in March, October, and November 2024, the U.S. FDA

conducted bioresearch monitoring inspections at three of our oncology clinical trial sites, and all of these inspections resulted in a classification of "NAI," representing the highest standard of GCP compliance and the best outcome of a U.S. FDA inspection.

R&D Publications

To demonstrate our R&D efforts and productivity, from 2022 to 2024, research and clinical studies investigating our products and product candidates resulted in 1,019 peer-reviewed papers in international academic journals, including high-impact journals such as *The Lancet*, *British Medical Journal, JAMA, Nature Medicine, and Journal of Clinical Oncology*, with a cumulative impact factor of approximately 7,173 across these publications. Impact factor is a measure of academic journals' scientometric index and reflects the yearly main number of citations of articles published in the last two years in a given journal.

The table below provides our selected influential publications.

Our Product(s)/ Product Candidate(s)	Article	Journal
Camrelizumab plus apatinib (also known as rivoceranib) . . .	Camrelizumab plus rivoceranib versus sorafenib as first-line therapy for unresectable hepatocellular carcinoma (CARES-310): a randomized, open-label, international phase 3 study	The Lancet
Camrelizumab plus famitinib . .	Optimizing first-line subtyping-based therapy in triple-negative breast cancer (FUTURE-SUPER): a multi-cohort, randomised, phase 2 trial	Lancet Oncology
Camrelizumab . . .	Camrelizumab versus Placebo in Combination with Chemotherapy as Neoadjuvant Treatment in Patients with Early or Locally Advanced Triple-Negative Breast Cancer	JAMA-Journal of the American Medical Association
Pyrotinib	Pyrotinib versus placebo in combination with trastuzumab and docetaxel as first-line treatment in patients with HER2-positive metastatic breast cancer (PHILA): a randomized, double-blind, multicenter, phase 3 trial	BMJ-British Medical Journal
	Pyrotinib plus capecitabine versus lapatinib plus capecitabine for the treatment of HER2-positive metastatic breast cancer (PHOEBE): a multicentre, open-label, randomised, controlled, phase 3 trial	Lancet Oncology
	Pyrotinib in HER2-Mutant Advanced Lung Adenocarcinoma After Platinum-Based Chemotherapy: A Multicenter, Open-Label, Single-Arm, Phase II Study	Journal of Clinical Oncology
	Pyrotinib or Lapatinib Combined With Capecitabine in HER2—Positive Metastatic Breast Cancer With Prior Taxanes, Anthracyclines, and/or Trastuzumab: A Randomized, Phase II Study	Journal of Clinical Oncology

Our Product(s)/ Product Candidate(s)	Article	Journal
	Phase I Study and Biomarker Analysis of Pyrotinib, a Novel Irreversible Pan-ErbB Receptor Tyrosine Kinase Inhibitor, in Patients With Human Epidermal Growth Factor Receptor 2—Positive Metastatic Breast Cancer	Journal of Clinical Oncology
Adebrelimab	Adebrelimab or placebo plus carboplatin and etoposide as first-line treatment for extensive-stage small-cell lung cancer (CAPSTONE-1): a randomised, placebo-controlled, phase 3 trial	Lancet Oncology
Dalpiciclib	Dalpiciclib or placebo plus fulvestrant in hormone receptor-positive and HER2-negative advanced breast cancer: a randomized, phase 3 trial	Nature Medicine
Fuzuloparib.	Fuzuloparib Maintenance Therapy in Patients with Platinum-sensitive, Recurrent Ovarian Carcinoma (FZOCUS-2): A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase III Trial	Journal of Clinical Oncology
Rezvilutamide . . .	Rezvilutamide versus bicalutamide in combination with androgen-deprivation therapy in patients with high-volume metastatic hormone-sensitive prostate cancer (CHART): a randomised, open-label, phase 3 study	Lancet Oncology
Irinotecan	Irinotecan hydrochloride liposome HR070803 in combination with 5-fluorouracil and leucovorin in locally advanced or metastatic pancreatic ductal adenocarcinoma following prior gemcitabine-based therapy (PAN-HEROIC-1): a phase 3 trial	Signal Transduction and Targeted Therapy
Retlirafusp alfa . .	Neoadjuvant retlirafusp alfa with or without chemotherapy in unresectable stage III non-small-cell lung cancer: A proof of concept, phase 2 trial	Cancer Cell
SHR-A1811.	Safety, Efficacy, and Pharmacokinetics of SHR-A1811, a Human Epidermal Growth Factor Receptor 2—Directed Antibody-Drug Conjugate, in Human Epidermal Growth Factor Receptor 2—Expressing or Mutated Advanced Solid Tumors: A Global Phase I Trial	Journal of Clinical Oncology
	SHR-A1811 (antibody-drug conjugate) in advanced HER2-mutant non-small cell lung cancer: a multicenter, open-label, phase 1/2 study	Signal Transduction and Targeted Therapy
HR20013	Randomized, phase III trial of mixed formulation of fosrolapitant and palonosetron (HR20013) in preventing cisplatin-based highly emetogenic chemotherapy-induced nausea and vomiting: PROFIT	Journal of Clinical Oncology

Our Product(s)/ Product Candidate(s)	Article	Journal
Vunakizumab. . . .	Efficacy and safety of vunakizumab in moderate-to-severe chronic plaque psoriasis: A randomized, double-blind, placebo-controlled phase 3 trial	Journal of the American Academy of Dermatology
Recaticimab	Recaticimab Monotherapy for Nonfamilial Hypercholesterolemia and Mixed Hyperlipemia: The Phase 3 REMAIN-1 Randomized Trial	Journal of the American College of Cardiology
	Recaticimab as Add-On Therapy to Statins for Nonfamilial Hypercholesterolemia: The Randomized, Phase 3 REMAIN-2 Trial	Journal of the American College of Cardiology
Ivarmacitinib. . . .	Ivarmacitinib, a selective Janus kinase 1 inhibitor, in patients with moderate-to-severe active rheumatoid arthritis and inadequate response to conventional synthetic DMARDs: results from a phase III randomized clinical trial	Annals of the Rheumatic Diseases
SHR8028	Effect of SHR8028, a Water-Free Cyclosporine Ophthalmic Solution 0.1%, vs Vehicle for Dry Eye Disease	JAMA Ophthalmology

R&D Collaboration

As a supplement to our in-house clinical capabilities, we use services of R&D partners in limited circumstances. We have established stringent procedures for the selection, evaluation, and management of our R&D partners. We select our R&D partners based on factors such as their qualifications, credentials, professional experience, and industry reputation. Based on the service requirements of each project, we typically select multiple CROs or SMOs to participate in competitive biddings and negotiations, to ensure that we have alternative suppliers for each required service.

We collaborate with reputable, globally-leading CROs in our overseas clinical trials. In line with industry practice, these CROs support us in matters such as trial design, site selection, trial execution, data management and analysis, and compliance with regulatory requirements. As part of sponsor oversight on critical partners, we closely monitor the CROs' performance and compliance with our protocols and applicable laws, regulations, and guidelines, to ensure the high integrity and authenticity of our clinical trial data. In addition, we engage SMOs to assist in trial site management, including assisting in recruiting trial participants, coordinating site staff to confirm site process compliance, and maintaining data integrity at each site.

SALES, MARKETING AND DISTRIBUTION

Our Sales and Marketing Team

We promote our drugs primarily through our in-house sales and marketing team. As of September 30, 2024, our sales and marketing team consisted of approximately 9,000 employees across over 30 provincial-level regions in China. Meanwhile, we also have deep penetration in lower-tier cities and rural areas, which enables us to capture broader market opportunities. As of September 30, 2024, our sales network covered over 22,000 hospitals and over 200,000 offline retail pharmacies. Aside from offline retail pharmacies, our professional prescription drug sales team also covered all mainstream online pharmacy platforms as of the same date. In addition, we have established a specialized DTP team dedicated to expanding our DTP pharmacy channel to satisfy patients' diversified medical needs. We also utilize various channels and platforms to engage with patients and physicians, aiming to better serve patients with oncology and chronic diseases and improve their long-term treatment outcomes. To enhance our specialized marketing efforts, we have strategically built the following complementary functions to support our highly professional sales force:

- *Strategic planning:* formulates our commercial strategies, conducts market research and analysis, and coordinates with our production and R&D teams to support sales and marketing activities and better align R&D and manufacturing decisions with market demand.

- *Central marketing:* conducts in-depth analysis of the therapeutic areas, patient journeys, and clinical advantages of our products, develops differentiated branding strategies to effectively convey the advantages of our products to various types of healthcare professionals, thereby ensuring that our therapies are appropriately applied to maximize patients' benefits.

- *Central medical affairs*: formulates medical strategies, gathers insights from physicians' clinical practices, reviews and supports investigator-initiated trials and conducts real-world studies and medical educational training on our innovative products.

- *Central and provincial sales management:* manages and promotes the efficiency of our sales activities, implements our sales strategies, and manages and expands our sales network in local markets.

- *Sales force effectiveness:* develops methods for target setting, oversees sales roles across various regions, assesses daily activities, and formulates incentive policies to enhance the productivity and efficiency of our sales team.

- *Central and provincial market access:* negotiates with regulators on market access related matters such as centralized tender processes, VBP schemes, the NRDL, and other government-sponsored insurance programs, and works towards hospital listings for our drugs.

We have established professional academic promotion teams in various therapeutic areas to promote medical professionals' knowledge and understanding of the clinical benefits of our drugs. We provide regular training to equip our sales and marketing personnel with the latest industry knowledge, timely understanding of our innovative products, and academic promotion skills. In addition to our detailed procedures, policies, and guidelines, we conduct compliance inspections to regulate our sales and marketing personnel's interactions with, and promotion of our products to, healthcare professionals. Furthermore, we conduct regular audits of our sales and have implemented a risk warning mechanism to minimize risks in product sales and ensure that our marketing practices comply with applicable laws and regulations.

Academic Promotion

We focus on academic promotion to facilitate market adoption of our cutting-edge innovations. As early as in the drug discovery process, we would evaluate candidate molecules' commercial potential to efficiently identify promising compounds. Once we have favorable clinical results, we focus on academic promotion to prepare for the commercialization of relevant product candidates.

Leveraging our over 50 years' industry experience and our premium brand, we have built long-term academic relationships with many renowned physicians and other healthcare professionals. We have supported investigator-initiated trials and performed various post-market real-world studies to benefit more patients and collect clinical evidence to further validate our products. Physicians typically look to peer experts and key opinion leaders in the medical community for guidance in research, diagnosis and treatment. Publications of our R&D results in high-impact journals such as *The Lancet*, *Journal of Clinical Oncology, JAMA,* and *Natural Medicine* have been instrumental in raising the awareness of our differentiated innovative drugs and driving their adoption in the medical community.

Furthermore, we regularly organize and participate in a wide variety of major domestic and international academic conferences, seminars and symposia in relation to our main therapeutic areas to enhance our brand recognition. Many of our product studies have been presented at major international academic conferences such as the ASCO Annual Meeting, the European Lung Cancer Conference, the American Society of Gynecological Oncology Annual Meeting, the European Breast Cancer Conference, the World Conference on Lung Cancer, the ADA Annual Meeting, and the American Academy of Dermatology Annual Meeting, among which we have presented major research studies in the ASCO Annual Meeting for 13 consecutive years.

Moreover, as part of our branding strategy, we actively organize and participate in medical research funding initiatives to promote the development of the medical community. For example, in November 2023, we launched a program to invite cardiothoracic surgery experts from Royal College of Surgeons, the University of Cambridge to deliver lectures, analyze difficult cardiothoracic surgery cases and perform live surgeries in Shaoxing, Zhejiang Province and Shanghai, China. This program not only provided new perspectives for the improvement of medical technologies in China, but also solidified the foundation for the cooperation and academic communication between hospitals in China and around the globe.

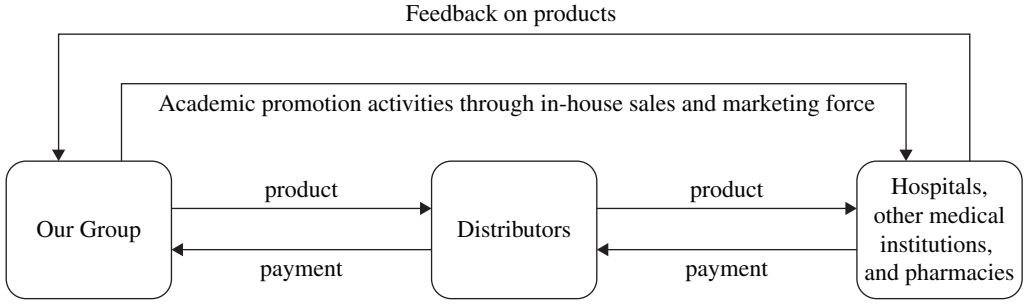
Sales and Distribution

We generate revenue from sales of pharmaceutical products in China predominantly by selling our products to distributors who, in turn, sell our products to hospitals, other medical institutions, and pharmacies. We also sell a minor portion of our APIs and drugs directly to certain pharmacies and international pharmaceutical companies, which accounted for less than 2% of our total revenue for each year/period during the Track Record Period. Our sales and distribution arrangement is in line with industry norms in the pharmaceutical industry, according to Frost & Sullivan.

Distribution

We primarily sell our pharmaceutical products through third-party distributors, who are our direct customers. We believe this distribution model helps extend our coverage in a cost-effective manner while retaining proper control over our distribution network and the marketing and promotion process.

The following diagram illustrates the relationships among us, our distributors and the hospitals, other medical institutions, and pharmacies that purchase our products from the distributors:



Distributor Network

We had established a comprehensive, tiered market coverage through our robust distribution channel. As of September 30, 2024, our distribution network comprised 603 distributors across over 30 provincial-level regions in China and for overseas markets. During the Track Record Period, our distributors in China contributed a substantial majority of our revenue from drug sales. To the best knowledge of our Directors, during the Track Record Period, all of our distributors were Independent Third Parties, and none of our distributors were wholly-owned or majority controlled by our former or current employees. In addition, to the best knowledge of our Directors, we do not have any other relationship or arrangement (including family, business, financing, guarantee or otherwise in the past or present) with the distributors engaged by us during the Track Record Period.

The following table sets forth the changes in the number of our distributors for the periods indicated below:

	For the Year Ended December 31,		For the Nine Months Ended September 30,
	2022	2023	2024
Number of distributors at the beginning of the period	580	592	579
Addition of new distributors	46	39	47
Termination of existing distributors	(34)	(52)	(23)
Net increase/(decrease) in distributors	12	(13)	24
Number of distributors at the end of the period	592	579	603

We regularly review the performance of our distributors based on their market coverage, sales growth, reputation, level of cooperation, compliance with the terms of our distribution agreement, and overall credit profiles. Based on the results of our review, we may elect to terminate distributors who fail to meet our performance criteria. In 2022, 2023, and the nine months ended September 30, 2024, a total of 34, 52, and 23 distributors were terminated, respectively. These were primarily because we continued to optimize our distribution network by terminating under-performing distributors.

Distributor Management

We screen and select our distributors mainly based on criteria such as their business qualifications, creditworthiness, distribution coverage, sales capabilities, past performance, reputation, and compliance record. We conduct inspections to evaluate the performance of distributors. We also check the qualification of our distributors to ensure that they have obtained the necessary permits, licenses, and certifications for the distribution of relevant products, including drug operation permits and GSP certifications. In addition, we carry out regular evaluations of the distributors to determine whether to adjust our list of qualified distributors and their designated distribution regions.

To optimize our product delivery and market coverage, we actively monitor the number of our distributors and our distributors' inventory levels and further track the flow of our products. Sales of our products to distributors are generally not subject to seasonal fluctuations. Our distributors are also required to maintain sufficient inventory level to ensure no shortage of supply of our products. To manage the traceability of our products, we mandate that distributors scan QR codes during the distribution process. In addition, we have also established a periodical reconciliation mechanism to ensure the accuracy of accounts. Our distributors are required to provide GSP-compliant storage conditions for our products. All of our distributors are required by GSP regulations to ensure that they only sell products to

qualified end-customers. Each of our pharmaceutical products has a specified expiry period. We are generally responsible for disposing of our pharmaceutical products that are beyond the specified expiry period after they are returned to us. We do not permit our distributors to sell any expired pharmaceutical products.

We manage cannibalization risk among our distributors through enforcement of our distribution agreements, which specify the designated products and geographic regions for each distributor. Our distributors are prohibited from distributing our products to customers outside their specified regions. In addition, for each of our products, we generally only maintain one primary distributor for each hospital.

Due to the implementation of the "two-invoice system" in China, generally our distributors are legally prohibited from engaging sub-distributors for distribution of our products to public medical institutions in the PRC. For distribution of our products to private medical institutions and pharmacies in the PRC and to overseas countries, we do not require our distributors to seek our prior approval to engage sub-distributors. We do not have contractual relationships with sub-distributors engaged by our distributors, nor do we manage such sub-distributors directly. Instead, we rely on our distributors to supervise their respective sub-distributors.

Terms of Distribution Agreements

We have a seller-buyer relationship with our distributors under the buy-out sale model. We retain no ownership over the products that we sell to them, and all significant risks and rewards associated with these products are transferred to them upon delivery to and acceptance by them.

The following sets forth salient terms of our distribution agreements.

- *Term.* The typical duration of our distribution agreements is one year for our distributors.

- *Designated distribution area.* Distributors are generally not allowed to sell our products outside of their designated distribution areas.

- *Exclusivity.* Distributors are granted the distributorship right for specified types of products in their designated distribution areas, generally on a non-exclusive basis.

- *Sales target and minimum purchase requirement.* Our agreements with distributors generally do not specify an agreed annual sales target or minimum annual purchase amount.

- *Pricing and resale price management.* Our selling prices to distributors are generally fixed during the term of the distribution agreements, and we set pricing terms for our distributors primarily based on the products' selling prices to hospitals and other medical institutions, which may vary in different regions. However, in the event of a retail price change as a result of regulatory or policy changes, centralized tender processes, or pricing negotiations with the government during the term of the distribution agreement, we and the relevant distributors typically would negotiate price adjustments accordingly.

- *Retail price management.* We generally do not control the prices at which our distributors resell our products to their customers.

- *Return of products.* Our distributors are required to inspect the products on delivery. Returns and exchanges are generally not allowed except for defective products or other reasonable requests for return that we approve. Our return policies generally comply with industry practice.

- *Credit terms.* We generally grant our distributors a credit term of 30 to 90 days, except that new customers are typically required to pay in advance.

- *Termination.* We may terminate the distribution agreements in the event of, among others, any material breach by our distributors of the agreement.

- *Others.* Our distributors are not authorized to use our trade name or any other material which may lead others to believe that they are acting on our behalf. They are required to comply with PRC laws and regulations, including anti-corruption and anti-bribery laws and regulations.

PRODUCT PRICING

We formulate reasonable pricing strategies for our commercialized products to maintain our competitiveness, market position, and profitability. When determining the prices of our commercialized products, we consider various factors including our R&D, production, sales, and marketing costs and expenses, the market potential, product innovation, products' comparative advantages, the perceived value of the products, as well as our share in the markets where the products are marketed.

The prices of our commercialized products are also affected by the laws and regulations governing the pharmaceutical industry. In China, the government regulates prices mainly by establishing a consolidated procurement mechanism, restructuring medical insurance reimbursement standards and strengthening regulation of medical and pricing practices.

We are dedicated to closely monitoring new laws and regulations affecting the pricing of pharmaceuticals in China and making timely adjustments to our pricing strategies.

Centralized Tender Process and Volume-based Procurement

Most pharmaceutical products that are sold to public hospitals and other public medical institutions in China must go through a competitive centralized tender process at the provincial or municipal level to make the price of drugs more affordable. In these centralized tender processes, pharmaceutical companies submit bids to supply their products to public medical institutions at specified prices, and the selection of winning bidders is based on multiple factors, including bid price, product quality, clinical effectiveness, and qualifications and reputation of the manufacturer. If, through these tender processes, we become a winning bidder, our relevant products will be sold to the public medical institutions at our bid price, which primarily determines the price at which we sell the products to our distributors. For more details on centralized tender process, see "Regulatory Overview—Overview of Laws and Regulations in the PRC—Drug Purchases by Hospitals." This process has created pricing pressure on us, which may decrease our revenue from relevant products and resulting in our loss of market share in regions where we failed to win bids. Our bidding and pricing strategies tailored around centralized tender process policies and our product competitiveness helped us win bids and expand our market access.

In addition, prices of certain pharmaceutical products in China sold to public hospitals and public medical institutions are affected by the VBP scheme. The VBP scheme aims to achieve a lower price of pharmaceuticals with mature, high-volume clinical usage and sufficient market competition through a competitive bidding process for large-volume procurement. The VBP scheme has been rolled out at both national and regional levels. As part of the bidding process for the VBP scheme, relevant products need to undergo an evaluation and approval procedure based on specific criteria. While the VBP scheme sometimes allows us to sell our products in larger volumes, it typically exerts downward pressure on the prices at which we sell our products to our distributors. To mitigate such impact, we continue to diversify our product matrix by introducing new innovative drugs.

NRDL

Participants in China's public medical insurance programs, along with their employers, if any, are required to contribute to these programs on a monthly basis. They are eligible for full or partial reimbursement of the cost of drugs included in the NRDL, which sets out the payment standard for drugs under the basic medical insurance, work-related injury insurance and maternity insurance funds. The National Healthcare Security Administration of the PRC, along with other government authorities, determines which drugs are included in the NRDL. Drugs listed in any government-led medical insurance program, such as the NRDL, generally undergo a pricing negotiation process with the government, which typically results in price reductions. For more details on the NRDL, see "Regulatory Overview—Laws and Regulations in Relation to New Drugs—National Reimbursement Drug List of China."

Overall, the benefits of having our pharmaceutical products included in China's national and provincial medical insurance programs significantly outweighed the countervailing factors during the Track Record Period.

MANUFACTURING AND QUALITY MANAGEMENT

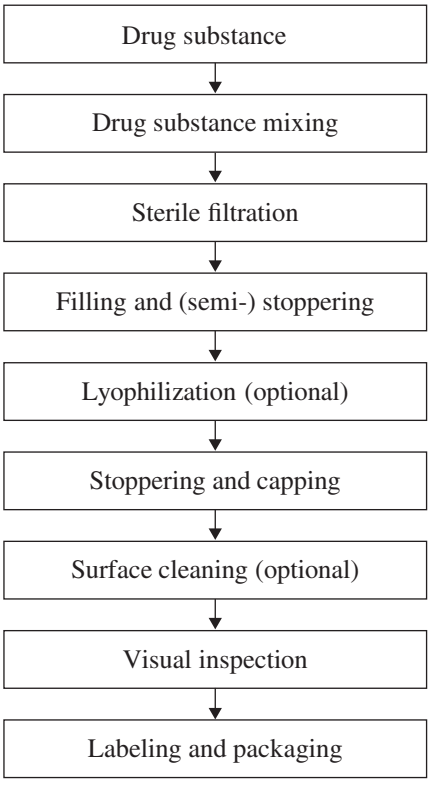
Manufacturing Process

During the Track Record Period, we manufactured our pharmaceutical products and product candidates fully in-house, except for a limited number of in-licensed products. In addition, we produced a substantial majority of the drug substances used in our pharmaceutical products. We operate tailored manufacturing processes for our pharmaceutical products in a variety of dosage forms, which primarily include injectables, oral solids, and active pharmaceutical ingredients.

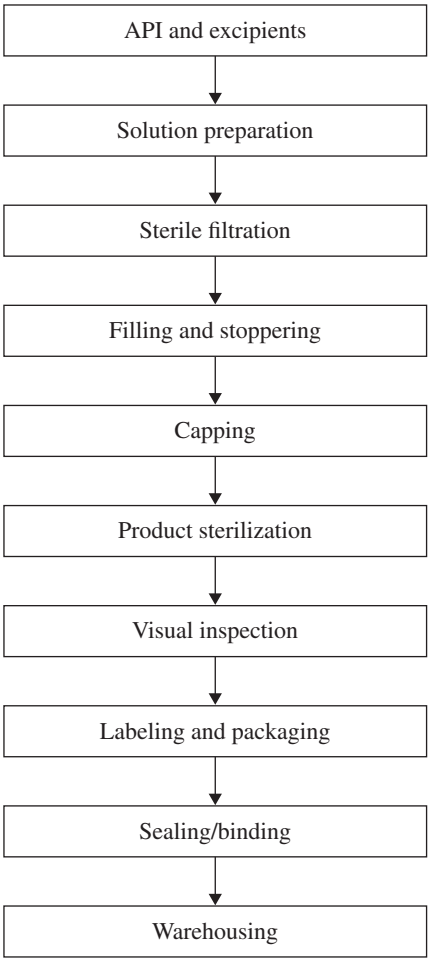
Injectable Dosage Form

The injectables we manufacture include primarily injectable solutions, powder for injection, and lyophilized powder for injection. The following diagram summarizes the production process for our biologics and small molecule drugs in injectable dosage form. Our products manufactured pursuant to the process below include, for example, adebrelimab, camrelizumab, mecapegfilgrastim, vunakizumab, remimazolam, and tegileridine.

Biologics

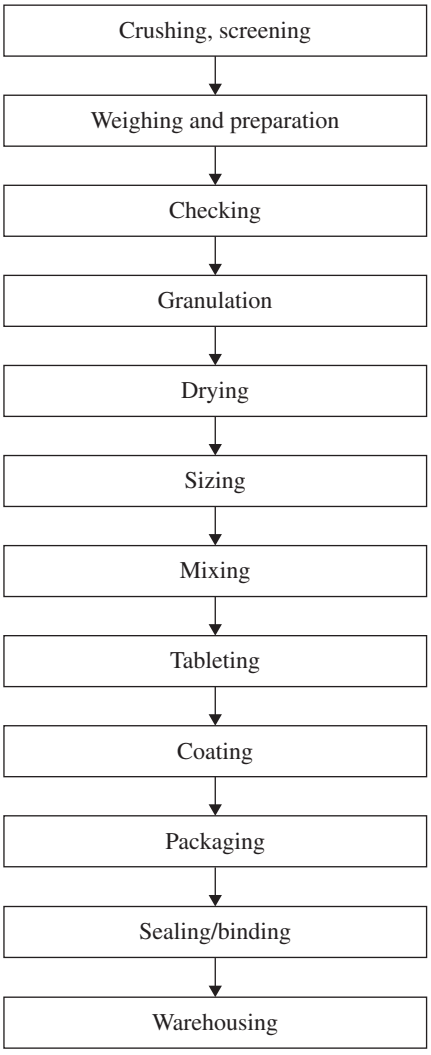


Small Molecules



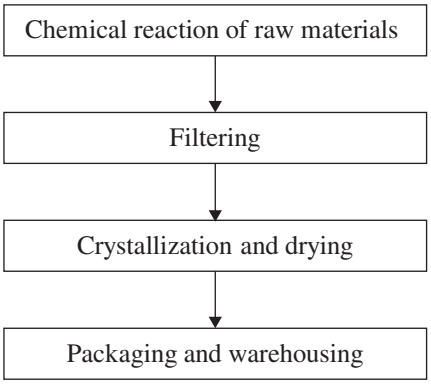
Oral Dosage Form

We manufacture a variety of oral tablets and capsules. The following flowchart summarizes the typical manufacturing process for these products. Our products manufactured pursuant to the process below include, for example, linperlisib, herombopag, and imrecoxib.



Active Pharmaceutical Ingredients

The following flowchart summarizes the typical manufacturing process for our active pharmaceutical ingredients.



Manufacturing Facilities

We currently have 12 manufacturing facilities located in nine cities across China, including four located in Lianyungang, two located in Chengdu, and one located in each of Xiamen, Guangzhou, Tianjin, Jinan, Suzhou, and Shanghai. The following table sets forth a summary of our production facilities in use as of the Latest Practicable Date:

Location	Major Production	Site Area	Gross Floor Area
		(thousand sq.m.)	*(thousand sq.m.)*
Lianyungang, Jiangsu	Biologics and small molecules	249.8	142.0
Lianyungang, Jiangsu	APIs	200.3	110.3
Lianyungang, Jiangsu	Biologics	95.0	60.6
Lianyungang, Jiangsu	Biologics and small molecules	58.3	33.7
Chengdu, Sichuan	Biologics and small molecules	100.0	43.4
Chengdu, Sichuan	APIs	66.9	32.2
Xiamen, Fujian	Peptides and nucleic acid drugs	94.2	20.7
Guangzhou, Guangdong	Biologics	65.9	23.6
Tianjin	Radioactive drugs	46.5	7.2
Jinan, Shandong	Small molecules	18.0	27.2
Suzhou, Jiangsu	Biologics	110.2	66.8
Shanghai	Small molecules	44.0	14.6

During the Track Record Period and up to the Latest Practicable Date, we obtained production licenses for all of our manufacturing facilities. Additionally, as of the Latest Practicable Date, all of our production lines for commercialized products had received the GMP certification. For details, see "—Legal and Compliance—Licenses, Permits and Certificates."

We are committed to advancing the digitalization and automation of our production management processes. During the Track Record Period, we implemented several digital systems, including our laboratory information management system, and quality management system. In addition, we implemented a supervisory control and data acquisition (SCADA) system to collect data at each stage of the manufacturing process. The integration of these systems promotes the traceability of manufacturing information, automates the production materials delivery, and enables real-time scheduling of manufacturing procedures. The SCADA system also enables one-stop control over the entire production process, facilitating an easy and automated production process.

In addition, we provide annual training sessions to enhance our quality and manufacturing team's understanding of quality assurance and production procedures, the content of which is customized based on the specific products to be manufactured and regulatory requirements. We also provide additional training to personnel who make significant mistakes during the manufacturing process to help them avoid future mistakes.

The following table sets forth our designed production capacity, actual production volume and utilization rate for production lines that are used in the production of injectables and oral solids as of the dates and for the periods indicated.

		As of/For the Year Ended December 31,						As of/For the Nine Months Ended September 30,		
		2022			2023			2024		
Production Line	Unit	Designed Production Capacity[1]	Production Volume	Utilization Rate	Designed Production Capacity	Production Volume	Utilization Rate	Designed Production Capacity	Production Volume	Utilization Rate
				(%)[2]			(%)[2]			(%)[2]
Injectables	million vials	223.6	155.4	69.5	222.5	145.3	65.3	159.6	108.7	68.1
Oral solids (including tablets and capsules)	million pieces	2,996.5	2,251.3	75.1	3,436.4	2,461.0	71.6	3,756.9	2,324.4	61.9

(1) The designed production capacity for a production line is calculated based on 255 effective production days a year on a triple shift basis (i.e., 24 hours) for oral solids, and a double shift basis (i.e., 16 hours) for other products.

(2) Utilization rate equals actual production volume divided by production capacity.

In formulating our expansion and update plan, we have taken into consideration several factors, including the projected market demand for our products, the timing of these plans, the development progress of our product candidates, technological developments that are relevant to our manufacturing process, and the estimated capital expenditures. In particular, we believe the following factors indicate sufficient market demand to support the planned increase in our production capacity: historical growth rates of our sales of commercialized innovative drugs; our robust pipeline of late-stage innovative product candidates, including those with significant market potential; and our strategy to deepen our market penetration and expand our coverage of hospitals and other medical institutions through efficient sales and marketing efforts.

Raw Materials

The principal raw materials used for the production of our pharmaceutical products primarily consist of APIs, intermediates, excipients, raw materials for biological products, chemicals, and detection reagents.

We only purchase raw materials used in our product development and manufacturing process from approved suppliers. We maintain and constantly update an approved list of qualified suppliers. We assess potential suppliers based on various factors including their credentials, product quality, occupational health and safety and environmental management, and we conduct sample tests on potential suppliers to ensure that the quality of their products meets our standard. We routinely review, assess, and rate our suppliers' performance and check their qualifications to ensure the legality and quality of our raw materials.

To efficiently regulate the access and behaviors of suppliers, our supplier management department has put in place supplier access policies, supplier performance policies, and in-process supplier management policies and adopted a digitalized supplier relationship management system to manage the whole lifecycle of procurement, from supplier registration and approval to sample collection, on-site inspections and supplier performance assessment.

Most of the raw materials used for our products are readily available in the market through multiple suppliers, and we believe we have alternative sources for such raw materials with comparable quality and prices. During the Track Record Period, we did not experience significant difficulties in maintaining stable sources of supplies, and we expect that we can continue to maintain adequate sources of qualified supplies in the future. We generally enter into supply agreements with our raw material suppliers and make procurements on an as-needed basis. The purchase price of our raw materials is generally determined through a bidding process. Upon the acceptance of the raw materials, we are typically required to make full payment to the relevant supplier within 90 days after receiving the invoice. Our suppliers are generally responsible for arranging the delivery to our designated production facilities at their own costs. We are entitled to exchange goods that do not meet our requirements or industry standards. If the exchanged goods still fail to meet relevant requirements or standards, we are generally entitled to terminate the supply agreement and request a refund. We generally contract with more than one supplier for each major type of raw material, except for very few specified raw materials for which we contract with exclusive suppliers.

We have established standardized procurement processes and a scientific procurement management system to reduce procurement costs and improve our procurement quality and efficiency. We have standardized each step of the procurement process from sourcing, to negotiation, execution and supervision. Our supply chain management department evaluates the capacity of our production lines and makes procurement plans based on our R&D results and market expectations, and timely adjusts the plans based on changes in our demand for raw materials, capacity of our production lines, and our inventory level. We have a dedicated procurement center that is responsible for the overall procurement management. Each department under our procurement center submits procurement requests through our centralized procurement management system, and such requests are integrated into our procurement center upon approval by relevant managers. To avoid unnecessary procurement and effectively control procurement costs, only the procurement requests that are approved will be implemented.

Quality Management

We believe that an effective quality management system is critical to ensuring the quality of our products, maintaining our reputation and success, and safeguarding the health of consumers. We have implemented and continuously improved our quality management system and policies to ensure our product quality. Our quality management systems are designed in accordance with applicable GMP standards, and our exported product comply with or exceed global quality standards such as EU GMP, the U.S. cGMP, and the ICH Quality Guidelines. Our quality management system complies with applicable PRC laws and regulations on drug administration.

We have established comprehensive quality management procedures and protocols, which span the entire production lifecycle from raw material procurement to final product quality testing and release. We have also been promoting the digital transformation of our quality management system, including the use of quality management software such as quality management system, Document Management System and Laboratory Information Management System, to improve the overall efficiency of our product quality management.

We have extensive compliance experience under the manufacturing and quality-related requirements of overseas regulators such as the U.S. FDA and the EMA. For example, we obtained U.S. FDA approval for a total of three ANDAs for our first-to-market generics in January, July, and October 2024. During the Track Record Period, we consistently passed various official inspections conducted by domestic and foreign drug supervision and management authorities such as the NMPA and the U.S. FDA or made rectification in a timely manner in accordance with the rectification suggestions made by regulatory authorities. Separately, we frequently receive inspections from our existing and potential global partners, leading to many long-term collaborations. These achievements reaffirm the global recognition of our quality management system.

We have recently hired our Chief Quality Officer, an industry veteran with over 30 years of global experience (including experience working at the U.S. FDA) in the pharmaceutical industry to further enhance our quality management. He was a former senior CMC reviewer at the U.S. FDA and worked as the director and senior manager of CMC in several leading Chinese and multinational pharmaceutical companies. We have established a professional quality team that actively participates in the quality management throughout the product life cycle from R&D to production and launch and marketing of the products to monitor product quality at all stages. As of September 30, 2024, we had a dedicated quality team of over 1,100 employees, most of whom had pharmaceutical, chemistry or related technical expertise.

Our employees are required to participate in multiple GMP-related trainings held by drug supervision and inspection authorities, as well as industry associations. In addition, we conduct training sessions themed on quality management to promote the awareness of quality management among our employees, and we encourage our employees to participate in the construction of our quality management system. These activities and initiatives enable our employees to continuously enhance their professional skills and knowledge while understanding the regulatory requirements for our quality and production activities and facilities.

Additionally, we have received various industry recognitions for our exceptional quality management capabilities. For example, in March 2023, we were awarded by the China Quality Association for Pharmaceuticals as "First-Batch Quality Assurance Enterprise for Sterile Drugs." In September 2023, we also won the first prize of the "China Quality Association for Pharmaceuticals Quality Team Activities." In July 2022 and November 2023, we were awarded by the Jiangsu Quality Association for Pharmaceuticals as "Excellent Enterprise of Quality Management in the Pharmaceutical Industry in Jiangsu Province." Moreover, we actively contribute to the development of industry standards and regulations for quality management, promoting systematic growth in the pharmaceutical sector while fulfilling our social responsibilities.

Key aspects of our quality management procedures are as follows:

Raw Material Quality Management

We only purchase raw materials and other components used in our product development and manufacturing process from approved suppliers. We have established comprehensive quality management policies covering various aspects of raw materials management, including raw materials receipt, examination, evaluation, release, and dispensing. After we receive the raw materials, we examine the materials in accordance with our quality standards, and only those raw materials that meet the quality standards would be evaluated and released for further processing.

Production In-process Quality Management

During the production process, we conduct quality testing for intermediates, semi-finished products, and we monitor the manufacturing process of our products. We have implemented a thorough production in-process quality management relevant system. We carry out our manufacturing processes in compliance with GMP requirements.

Final Product Quality Management

We have implemented complete final product release testing, approval and release policies to guarantee the quality of our final products. All of our final products, before their release to the market, are required to undergo sampling and release tests. To ensure sound and accurate testing of all products, we have established our in-house laboratory quality management center, which implements a comprehensive management system and strict quality testing procedures. We conduct testing on the final products in accordance with applicable national quality standards and testing methods for pharmaceutical products. After the testing results are reviewed and approved by relevant qualified personnel and the management in charge of our quality management, the final products that comply with GMP requirements and meet relevant quality standards will be released.

We monitor the quality of our products throughout their full life cycles, and implement effective quality management measures after the commercialization of our products. We have established a comprehensive pharmacovigilance system and put in place a series of after-sales policies, including the complaint handling policy, adverse drug reaction monitoring policy, and product recall policy. Our drug tracing platform uses barcodes to ensure the traceability of drug products that enter into the market. We have also stipulated detailed scenarios where products should be recalled, and set forth guidelines on product recalls. According to our product recall procedures, we will evaluate our recalled products and, based on results of our evaluation, destroy our recalled products or take other appropriate measures under regulatory agencies' supervision.

Inventory Management

Our inventory consists primarily of finished products, work in progress, and raw materials. We have established an inventory management system that monitors each stage of the warehousing process. All raw materials and products are stored in different areas in our warehouses according to their respective storage condition requirement, properties, usage and batch number. Our warehousing personnel are responsible for receiving inspection, warehousing, storage, and distribution of production materials and finished products. We generally purchase raw materials based on their shelf-lives and required lead times. At the same time, we closely monitor our inventory levels and keep appropriate levels of stock for different products. We implement inventory management policies regulating the receipt, inspection,

storage, and shipping of inventory in accordance with applicable GMP requirements. In addition, we use ERP and WMS systems for digital management of our inventory and to record the operations of our warehousing personnel, thereby enhancing the efficiency of our inventory management.

CUSTOMERS

Our customers primarily consist of distributors of our pharmaceutical products in China and around the globe and international pharmaceutical companies to which we out-licensed certain rights with respect to our drugs and drug candidates. In each of the years ended December 31, 2022 and 2023 and the nine months ended September 30, 2024, we generated revenue of RMB12,724.9 million, RMB14,163.9 million, and RMB12,392.4 million from our five largest customers, respectively, representing 59.8%, 62.0%, and 61.3% of our total revenue for the respective periods.

The following table sets forth the details of our five largest customers during the Track Record Period:

For the Year Ended December 31, 2022

Rank	Customer	Products/ Services Provided	Customer Background	Year of Commencing Business Relationship	Revenue Contribution	As a Percentage of Our Total Revenue
					(RMB million)	*(%)*
1 . . .	Customer A	Pharmaceutical products	Distributor; a public company and its subsidiaries, focused on the distribution and retail of pharmaceuticals, healthcare products, and medical devices, and related services	2005	6,126.5	28.8

Rank	Customer	Products/ Services Provided	Customer Background	Year of Commencing Business Relationship	Revenue Contribution	As a Percentage of Our Total Revenue
					(RMB million)	*(%)*
2 . . .	Customer B	Pharmaceutical products	Distributor; subsidiaries of a public company, focused on the distribution and retail of pharmaceuticals, healthcare products, and medical devices, and related services	2011	2,659.7	12.5
3 . . .	Customer C	Pharmaceutical products	Distributor; subsidiaries of a public company, focused on the manufacturing, distribution, and retail of pharmaceuticals, healthcare products, and medical devices	2001	2,335.0	11.0
4 . . .	Customer D	Pharmaceutical products	Distributor; a public company and its subsidiaries, focused on the wholesale and retail of pharmaceuticals	2000	896.4	4.2
5 . . .	Customer E	Pharmaceutical products	Distributor; subsidiaries of a public company, focused on the sale of pharmaceuticals, healthcare products, and medical devices, and related services	2000	707.3	3.3
	Total				12,724.9	59.8

For the Year Ended December 31, 2023

Rank	Customer	Products/ Services Provided	Customer Background	Year of Commencing Business Relationship	Revenue Contribution	As a Percentage of Our Total Revenue
					(RMB million)	*(%)*
1 . . .	Customer A	Pharmaceutical products	Distributor; a public company and its subsidiaries, focused on the distribution and retail of pharmaceuticals, healthcare products and medical devices, and related services	2005	6,784.5	29.7
2 . . .	Customer B	Pharmaceutical products	Distributor; subsidiaries of a public company, focused on the distribution and retail of pharmaceuticals, healthcare products and medical devices, and related services	2011	3,150.8	13.8
3 . . .	Customer C	Pharmaceutical products	Distributor; subsidiaries of a public company, focused on the manufacturing, distribution, and retail of pharmaceuticals, healthcare products, and medical devices	2001	2,498.1	10.9
4 . . .	Customer D	Pharmaceutical products	Distributor; a public company and its subsidiaries, focused on the wholesale and retail of pharmaceuticals	2000	948.5	4.2

Rank	Customer	Products/ Services Provided	Customer Background	Year of Commencing Business Relationship	Revenue Contribution	As a Percentage of Our Total Revenue
					(RMB million)	*(%)*
5 . . .	Customer E	Pharmaceutical products	Distributor; subsidiaries of a public company, focused on the sale of pharmaceuticals, healthcare products, and medical devices, and related services	2000	782.0	3.4
	Total				14,163.9	62.0

For the Nine Months Ended September 30, 2024

Rank	Customer	Products/ Services Provided	Customer Background	Year of Commencing Business Relationship	Revenue Contribution	As a Percentage of Our Total Revenue
					(RMB million)	*(%)*
1 . . .	Customer A	Pharmaceutical products	Distributor; a public company and its subsidiaries, focused on the distribution and retail of pharmaceuticals, healthcare products, and medical devices, and related services	2005	5,579.0	27.6

Rank	Customer	Products/ Services Provided	Customer Background	Year of Commencing Business Relationship	Revenue Contribution	As a Percentage of Our Total Revenue
					(RMB million)	*(%)*
2 . . .	Customer B	Pharmaceutical products	Distributor; subsidiaries of a public company, focused on the distribution and retail of pharmaceuticals, healthcare products, and medical devices, and related services	2011	2,498.5	12.4
3 . . .	Customer C	Pharmaceutical products	Distributor; subsidiaries of a public company, focused on the manufacturing, distribution, and retail of pharmaceuticals, healthcare products, and medical devices	2001	2,198.2	10.9
4 . . .	Customer F	Licensing	Pharmaceutical company; a subsidiary of a public company focused on healthcare, life science, and performance materials	2023	1,379.9	6.8
5 . . .	Customer D	Pharmaceutical products	Distributor; a public company and its subsidiaries, focused on the wholesale and retail of pharmaceuticals	2000	736.8	3.6
	Total				12,392.4	61.3

The credit terms that we provided to our five largest customers generally ranged from 30 to 90 days after the invoice date, with payments made through wire transfers or banks' acceptance bills. To the best knowledge of our Directors, during the Track Record Period, all of our five largest customers were Independent Third Parties. None of our Directors or their respective close associates, and to the best knowledge of our Directors, none of our Shareholders who own more than 5% of the Shares in issue, had any interest in any of our five largest customers in each year/period during the Track Record Period. In addition, to the best knowledge of our Directors, there is no other relationship or arrangement (including family, business, financing, guarantee, or otherwise in the past or present) between any of our five largest customers during the Track Record Period and us.

SUPPLIERS

Our suppliers primarily consist of suppliers of APIs, excipients and other raw materials. In each of the years ended December 31, 2022 and 2023 and the nine months ended September 30, 2024, our aggregate purchases from our five largest raw material suppliers amounted to RMB842.5 million, RMB957.1 million, and RMB736.4 million, respectively, representing 24.1%, 27.0%, and 26.1% of our cost of sales for these respective periods.

The tables below set forth certain details of our five largest raw material suppliers during the Track Record Period:

For the Year Ended December 31, 2022

Rank	Supplier	Products/ Services Purchased	Supplier Background	Year of Commencing Business Relationship	Purchase Amount	As a Percentage of Our Cost of Sales
					(RMB million)	*(%)*
1 . .	Supplier A	Raw materials	A public company focused on the manufacturing of pharmaceutical intermediates	2003	270.5	7.8
2 . .	Supplier B	Raw materials	A private company focused on the manufacturing and research of chemical raw materials and pharmaceutical intermediates	2021	165.1	4.7

Rank	Supplier	Products/ Services Purchased	Supplier Background	Year of Commencing Business Relationship	Purchase Amount	As a Percentage of Our Cost of Sales
					(RMB million)	*(%)*
3 . .	Supplier C	Raw materials	A private company focused on the manufacturing of basic chemical raw materials	2006	151.5	4.3
4 . .	Supplier D	Raw materials	A private company focused on the R&D of chemicals, pharmaceuticals, biology, and technical developments in the chemical industry	2017	132.5	3.8
5 . .	Supplier E	Raw materials	A subsidiary of a public company, focused on the trading and distribution of chemical products	2009	122.9	3.5
	Total				842.5	24.1

For the Year Ended December 31, 2023

Rank	Supplier	Products/ Services Purchased	Supplier Background	Year of Commencing Business Relationship	Purchase Amount	As a Percentage of Our Cost of Sales
					(RMB million)	*(%)*
1 . .	Supplier A	Raw materials	A public company focused on the manufacturing of pharmaceutical intermediates	2003	343.6	9.7
2 . .	Supplier F	Raw materials	A private company focused on the manufacturing of tablets, capsules, granules, APIs, and industrial chemical raw materials	2019	251.9	7.1
3 . .	Supplier B	Raw materials	A private company focused on the manufacturing and research of chemical raw materials and pharmaceutical intermediates	2021	137.8	3.9
4 . .	Supplier C	Raw materials	A private company focused on the manufacturing of basic chemical raw materials	2006	113.6	3.2
5 . .	Supplier G	Raw materials	A public company focused on the manufacturing of pharmaceuticals and basic chemical materials	2016	110.2	3.1
	Total				957.1	27.0

For the Nine Months Ended September 30, 2024

Rank	Supplier	Products/ Services Purchased	Supplier Background	Year of Commencing Business Relationship	Purchase Amount	As a Percentage of Our Cost of Sales
					(RMB million)	*(%)*
1 . .	Supplier B	Raw materials	A private company focused on the manufacturing and research of chemical raw materials and pharmaceutical intermediates	2021	263.2	9.3
2 . .	Supplier F	Raw materials	A private company focused on the manufacturing of tablets, capsules, granules, APIs, and industrial chemical raw materials	2019	139.1	4.9
3 . .	Supplier A	Raw materials	A public company focused on the manufacturing of pharmaceutical intermediates	2003	127.2	4.5
4 . .	Supplier G	Raw materials	A public company focused on the manufacturing of pharmaceuticals and basic chemical materials	2016	106.3	3.8
5 . .	Supplier H	Raw materials	A subsidiary of a public company, focused on the manufacturing of basic chemical raw materials	2018	100.6	3.6
	Total				736.4	26.1

The credit terms that our five largest raw material suppliers provided to us generally ranged from 30 to 90 days after receipt of the invoice, with payments made through wire transfers or banks' acceptance bills. To the best knowledge of our Directors, during the Track Record Period, all of our five largest suppliers were Independent Third Parties. None of our Directors or their respective close associates, and to the best knowledge of our Directors, none of our Shareholders who own more than 5% of the Shares in issue, had any interest in any of our five largest suppliers in each year/period during the Track Record Period. In addition, to the best knowledge of our Directors, there is no other relationship or arrangement (including family, business, financing, guarantee, or otherwise in the past or present) between any of our five largest suppliers during the Track Record Period and us.

INTELLECTUAL PROPERTY RIGHTS

As of December 31, 2024, we filed 2,609 patent applications in the Greater China region and 704 patent applications under the Patent Cooperation Treaty. As of the same date, we owned 1,084 issued patents in the Greater China region and 753 issued patents in other jurisdictions, including the United States, Europe and Japan. Our patent strategy is focused on seeking coverage for our new drug compounds, protein molecular structures, preparation processes, among others, providing a comprehensive and long-term patent protection for our products and technologies.

We rely on intellectual property rights to protect technologies, inventions, and improvements that we believe are important to maintain our product's competition. To protect our intellectual property rights, our standard employment contracts include confidentiality clauses restraining our employees from disclosing trade secrets to any third party. We may also enter into additional confidentiality agreements with certain R&D personnel, which provide that all relevant intellectual property rights developed by our R&D personnel during their employment with us should become our intellectual property and are treated as trade secrets. We also follow procedures, such as patent searches, to minimize the risk of infringing on the intellectual property rights of others.

As of the Latest Practicable Date, we were not aware of any infringement of our intellectual property rights, or any disputes or claims against us in relation to the infringement of intellectual property rights of third parties, that were pending or threatened and would, individually or in the aggregate, have a material adverse impact on our business, financial condition or results of operations.

DATA PRIVACY AND PROTECTION

We receive, collect and store de-identified codes of subjects enrolled in our clinical studies and the corresponding clinical data and we process, analyze and transfer these data within the scope of the relevant clinical studies and drug registration. In line with industry practices, some of our studies are based on published research data, which may contain de-identified individual cases. In addition, we receive, collect and store personal data from post-marketing surveillance and real-world studies, such as spontaneously reported adverse drug reactions, and submit drug safety reports as required by regulatory authorities. As such, we are bound by the relevant data privacy and protection laws and regulations that apply to our data activities in the jurisdictions where we operate and conduct our clinical studies. For instance, any transfer or processing of personal and clinical data from our clinical studies across jurisdictions, including regulatory submissions, is subject to applicable local data privacy and protection laws and regulations.

Our data privacy and protection policy includes comprehensive measures and procedures to safeguard the security and confidentiality of data we access in our operations. We collect and retain data only as permitted by law and as necessary for our clinical studies. Personal data of subjects enrolled in our clinical studies and the corresponding clinical data are collected and processed in accordance with the informed consent agreed upon by the subjects. We require our R&D partners for clinical studies in overseas markets to have data protection clauses in the agreements with us, making them responsible for safeguarding personal and clinical data handled by them. We also require employees involved in clinical studies to comply with confidentiality requirements, and our policies mandate training for our employees in the protection of personal information.

Furthermore, together with our R&D partners, we have implemented controls to govern the transfer or processing of all personal and clinical data. We have established policies and protocols to ensure compliance with data security and privacy protection requirements for the cross-border transfer of clinical data, and to ensure that the applicable filings for the export or transfer of personal data, including human genetic resources, are made with the competent government authorities in accordance with applicable laws and regulations.

During the Track Record Period and up to the Latest Practicable Date, to the best of our knowledge, we had not encountered any material data breaches or personal information leaks. Our Directors confirm that, as of the Latest Practicable Date, we were not subject to any material claims, lawsuits, penalties or administrative actions relating to non-compliance with applicable laws and regulations for data privacy and protection.

AWARDS AND RECOGNITIONS

The following table highlights notable awards and recognitions that we have received as of the Latest Practicable Date:

Year	Awards and Recognitions	Grantor
2021 to 2024	China's Top 10 Innovative BigPharma Companies (中國BigPharma創新力Top 10排行榜)	Menet
2019 to 2024	Global Top 50 Pharmaceutical Companies by Pharma Exec	Pharm Exec
2019 to 2024	Top 100 Chinese Chemical & Pharmaceutical Companies (中國化藥企業Top 100排行榜)	Menet
2018 to 2024	Among the top on the Ranking of Comprehensive Pharmaceutical R&D Capabilities in China (中國藥品研發綜合實力排行榜)	China Pharmaceutical Development Innovation Summit (中國醫藥研發創新峰會)
2013 to 2024	Among the top of R&D-driven Pharmaceutical Companies in China (中國醫藥研發產品線最佳工業企業)	China National Pharmaceutical Industry Information Center (醫藥工業信息中心)
2024	8th among the Top 25 Global Pharma Companies by Pipeline Size	Citeline
2024	Top 10 in the Global Pharmaceutical Invention Index and Top 15 in the Global Pharmaceutical Innovation Index	IDEA Pharma
2016, 2017 and 2024	State Science and Technology Progress Award (Second Prize)	The State Council
2023	Hurun Global 500 list	Hurun Research Institute
2021 and 2022	China Patent Silver Award	China National Intellectual Property Administration
2016	China Patent Excellence Award	China National Intellectual Property Administration

COMPETITION

China's pharmaceutical market is highly competitive, characterized by a number of large domestic and multinational pharmaceutical companies, as well as some smaller emerging pharmaceutical and biotechnology companies. We face competition from these companies in various aspects including brand recognition, R&D capabilities, marketing activities, sales network, product efficacy and safety, reliability, and price. Our products primarily compete with those indicated for similar conditions as our products on the basis of efficacy, price, brand recognition, and general market acceptance by medical professionals and hospitals. Our competitors may possess greater financial and R&D resources than us, and they may choose to focus these resources on developing, manufacturing, importing, and marketing substitute products in our targeted therapeutic areas. Our competitors may also have more extensive sales and marketing coverage and might be able to reach a broader market.

We believe that our competitive edge lies in our differentiated innovative product portfolio and pipeline, industry-leading technology platforms, global-standard manufacturing system, robust commercialization capabilities, increasing global presence, as well as visionary management and leadership. Our ability to stay competitive and continue our success will depend on our ability to accelerate our global expansion by addressing immense unmet medical needs worldwide; further bolster our R&D capabilities to develop more differentiated, high-quality therapeutics to the global market; further strengthen our manufacturing capabilities supported by global-standard quality system; further enhance our commercialization capabilities in China and overseas markets; and recruit and retain top-notch talent to fuel our innovation and global expansion.

LAND AND PROPERTIES

We do not engage in any property activities as defined in Rule 5.01 of the Listing Rules. The total carrying amounts of our property interests comprising buildings and construction in progress accounted for 8.8% of our total assets as of September 30, 2024, and, consequently, no single property interest had a carrying value exceeding 15% of our total assets. Accordingly, we are not required by Chapter 5 of the Listing Rules to value or include in this document any valuation report of our property interests, and, pursuant to section 6(2) of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong), this document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance and paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

Owned Properties

As of September 30, 2024, we owned and/or occupied 18 parcels of land in China (with an aggregate site area of approximately 1,296.2 thousand square meters) and 76 properties in China (with an aggregate gross floor area (GFA) of approximately 660.1 thousand square meters) that we consider as our major properties. Our major properties refer to properties that are currently used in our production or R&D activities, or are relatively large (i.e., with a GFA of at least 1,000 square meters) and used as office premises, dormitories or other ancillary facilities.

We are preparing applications to complete the as-built acceptance filings to obtain the building ownership certificates for certain major properties, including those used for our production or R&D activities and those for other purposes. In addition, we have used a major property mainly as office premises while the land is designated mainly for scientific research and design use. We have not been subject to any penalty nor received any rectification requirement from government authorities for these properties. For the properties related to our production or R&D activities not having completed the as-built acceptance filings and the property used inconsistent with its permitted use, our PRC Legal Advisor has consulted with competent government authorities, which confirmed that they would not impose any penalty on us and that we could continue to use these properties under current circumstances. Based on these confirmations, our PRC Legal Advisor is of the view that the risk for the relevant government authorities to impose any penalty on us or require us to cease our use of these properties under current circumstances is remote. On the other hand, for the properties not used for our production or R&D activities, they are immaterial to our business operations. Separately, we have used a property on a parcel of allocated land for production purposes. See "Risk Factors—Risks Related to Doing Business in the Jurisdictions Where We Operate—We are subject to risks relating to some of the properties we use" for more details on this property. Based on applicable government policies, our PRC Legal Advisor is of the view that the risk for us to be required to cease our use of this property under current circumstances is remote.

As of the Latest Practicable Date, we were not aware of any actual or contemplated actions, claims or investigations by any relevant government authorities or third parties against us with respect to the above matters. On this basis and having considered relevant government authorities' confirmations and our PRC Legal Advisor's advice, we believe that the above matters will not materially affect our business and results of operations.

Properties Under Construction

As of September 30, 2024, we had nine projects of properties under construction in China. These properties are expected to be used primarily as production and R&D facilities and office premises.

Leased Properties

As of September 30, 2024, we leased 25 major properties in China, with an aggregate GFA of 105.1 thousand square meters, which are used primarily as our production or R&D facilities, office premises, dormitories, or ancillary facilities.

Among the above leased properties, we have used one leased property as our office premises while the land is designated for scientific research and education use. Under PRC laws and regulations, for this property, the landlord may be subject to fines by relevant government authorities, and we may be unable to continue our use of the property. However, this leased property used as our office premises is immaterial to our business operations.

Lease agreements are required by applicable PRC laws and regulations to be registered with local land authorities. As of the Latest Practicable Date, we had not completed such registration for certain lease agreements for the leased properties that we held as of September 30, 2024. Although failure to do so does not in itself invalidate the leases, we may be subject to fines if we fail to rectify such non-compliance within the prescribed timeframe after receiving notice from the relevant PRC government authorities. See "Risk Factors—Risks Related to Doing Business in the Jurisdictions Where We Operate—We are subject to risks relating to some of the properties we use" for more details. We have not been subject to any penalty nor received any rectification notice from government authorities in respect of lease registrations. As advised by our PRC Legal Advisor, if the lease registration is completed within the prescribed time limit ordered by competent government authorities, the risk of government authorities to impose any penalty on us with respect to these leased properties is remote.

As of the Latest Practicable Date, we were not aware of any actual or contemplated actions, claims or investigations by any relevant government authorities or third parties against us with respect to the above matters. On this basis and having considered our PRC Legal Advisor's advice, we believe that the above matters will not, individually or in the aggregate, materially affect our business and results of operations.

INSURANCE

We maintain property insurance covering physical damages to, or loss of, our facilities, equipment, office furniture and inventory, and clinical trial insurance covering us against liabilities in the event of injury to any trial subjects caused by serious adverse events in our clinical trials. We are not required under PRC laws and regulations to, and we generally do not, purchase any employer's liability insurance or key person insurance.

During the Track Record Period and up to the Latest Practicable Date, we did not submit any material insurance claims, nor did we experience any material difficulties in renewing our insurance policies. Our Directors believe that our insurance coverage is adequate and in line with industry norm. However, the risks related to our business and operations may not be fully

covered by insurance. For details, please see "Risk Factors—Risks Related to Our Business and Industry—Our insurance coverage is limited. If we experience uninsured losses, it could adversely affect our financial condition and results of operations."

HEALTH, SAFETY, SOCIAL AND ENVIRONMENTAL MATTERS

Occupational Health and Safety

We are subject to various PRC laws and regulations with respect to occupational health and safety. We are committed to complying with PRC regulatory requirements to prevent and reduce hazards and risks associated with our operations and ensuring the health and safety of our employees as well as the surrounding communities. We have policies in place for various aspects of our operations, including R&D, sales and marketing, and production, as well as guidelines to ensure the safety of our operations and work environment. We also conduct regular checks on occupational hazards in accordance with applicable laws and regulations. In addition, we organize regular training, competitions, emergency drills, and other activities about occupational safety knowledge to enhance our employees' safety awareness and create a corporate culture that values health and safety.

As of the Latest Practicable Date, our operations had not experienced any material incidents, and we were not aware of any claims for material personal or property damage related to health and occupational safety.

Environmental Protection

Our business is subject to national, provincial and local environmental laws, and regulations in China and other jurisdictions where we operate. The relevant laws and regulations applicable to pharmaceutical production in China include those governing air emissions, water discharge, solid waste, sewage and exhaust fumes, and hazardous substances and waste. For more details, see "Regulatory Overview—Overview of Laws and Regulations in the PRC—Regulations in Relation to Environmental Protection and Fire Safety." We actively monitor and ensure compliance with the applicable environmental laws and regulations in China. As of the Latest Practicable Date, we had complied with all applicable laws and regulations relating to environmental requirements in all material respects. Our costs for compliance with the applicable environmental regulations were immaterial during the Track Record Period. We do not expect there to be substantial changes to our costs for compliance with the applicable environmental regulations in the near future.

The main pollutants generated during our production process include wastewater, waste gas and hazardous waste. We diligently monitor our energy and water consumption, take proactive measures to conserve energy, and ensure the thorough utilization of resources and materials. We also regularly carry out rigorous internal and external environmental monitoring. In addition, we engage independent third-party certification organizations to conduct audit on our environmental management systems to evaluate their effectiveness.

We continuously promote emission and consumption reductions by setting energy-saving targets and adopting energy and water conservation technologies. Our environmental, health and safety protection measures mainly include:

- establishing a standardized, science-based, and rational environmental management system;
- regularly conducting internal and external environmental monitoring and audit to ensure our compliance with applicable environmental standards and mitigate the environmental impact of our operations;
- implementing effective environmental emergency response plans and on-site management; and
- providing regular training sessions for our employees to enhance their environmental awareness.

Pollutant Emission

In 2022, 2023 and the nine months ended September 30, 2024, based on our best estimates, our greenhouse gas emissions were approximately 203,512.9 tons, 208,280.1 tons, and 204,970.7 tons and our hazardous waste generated was approximately 14,032.2 tons, 18,493.8 tons and 13,532.0 tons, respectively.

As our business expands, we plan to implement policies and practices to manage the discharge of various types of emissions, pollutants, and wastes. We have set traceable targets to manage our waste recycling levels. To achieve this goal, we have allocated environmental targets and responsibilities to each department, enabling continuous monitoring of progress of environmental protection with the support of our multi-tiered environmental management structure.

For solid waste, we follow the principle of "Reduce, Reuse and Recycle" in pursuit of waste reduction and resource utilization efficiency. For hazardous waste, we have developed special emergency response plans to mitigate the associated safety risks. We have also engaged qualified third-party service providers to process our hazardous wastes and set up a special temporary storage room for hazardous waste in accordance with relevant regulations.

To reduce carbon emissions, we are transitioning to clean energy by expanding the use of renewable resources in our production and operations and optimizing our energy mix to reduce carbon emissions. In addition, we have implemented targeted treatment measures for exhaust gases from our manufacturing workshops and laboratories to ensure compliance with applicable regulatory standards after effective treatment.

Resource Consumption

In 2022, 2023 and the nine months ended September 30, 2024, based on our best estimates, we consumed approximately 199.5 million kWh, 212.2 million kWh, and 206.8 million kWh of electricity and approximately 4,212,084 tons, 3,859,973 tons, and 3,540,652 tons of water, respectively.

We are committed to expanding our business in a sustainable manner, taking into account our forecasted growth and implementation of energy-saving measures and innovations. We diligently monitor our energy consumption, take proactive measures to conserve energy, and ensure thorough utilization of resources and materials.

In terms of energy consumption management, we have implemented a robust energy management system, establishing tailored energy consumption targets for energy efficiency and emission reduction in line with our operational and developmental needs. To achieve these targets, we have implemented several energy-saving measures to drive efficiency improvements, such as the introduction of energy-saving equipment and renovations.

Through stringent water resource management systems and policies, we aim to curtail water consumption across all aspects of our production and operations, thereby enhancing the efficiency of our water utilization. We have implemented upgraded water-saving technologies in processes with high water consumption. In addition, we have established internal policies and regulations governing wastewater management, detailing standardized treatment processes and requirements. We have also conducted projects such as reverse osmosis concentrated water recovery, dry pump replacement, and steam condensate recycling.

Climate Change

Our ESG policy places a strong emphasis on addressing the impacts of climate change. Increased frequency of meteorological disasters such as strong winds, cyclones, floods, and torrential rains can lead to significant disruptions, including power and water supply interruptions and urban waterlogging, which could impact our operational stability.

Recognizing the significant impact that climate change can have on our long-term business sustainability, we incorporate climate-related issues into our governance and decision-making processes. We proactively identify and mitigate climate-related risks, while tailoring our strategies to enhance our adaptability. For instance, we have improved our emergency response systems and contingency plans to better manage the effects of extreme weather conditions, thereby enhancing our ability to mitigate potential operational disruptions, resource shortages, and safety risks during such events. Looking ahead, we plan to monitor evolving climate-related risks, and aim to enhance our overall resilience to climate challenges by strengthening our climate change management system, leveraging green energy, and promoting a responsible supply chain.

Governance and Oversight of ESG Matters

Our corporate governance framework is designed to facilitate sound decision-making through systems and policies aligned with our corporate values and best industry practice. We have established four specialized board committees—strategy, audit, remuneration and evaluation, and nomination—each providing strategic guidance to our Board. In particular, our strategy committee serves as our ESG management body, responsible for the formulation and assessment of our ESG strategies and goals. This committee oversees the implementation of our environmental policies, tracks the progress of our environmental objectives, and reports on environmental management issues to our Board. In addition, our supervisory board exercises active oversight to prevent any irregularities that could impact our decision-making.

Moreover, we have integrated ESG into our employee management practices to ensure that our employees contribute to our sustainability goals. For instance, to effectively manage ESG issues, mitigate risks, and achieve sustainable growth, we tie executive and managerial compensation to performance metrics related to safety, environment protection, quality, and compliance.

We embrace diversity in experience and background. We believe fostering diversity and inclusion are critical for business success. We have female members on our Board, board of Supervisors, and our senior management team. Our Directors, Supervisors and senior management also span multiple age brackets. Besides, we have a dedicated policy on diversity and inclusion for our workforce. We require all employees to complete a training program and pass an assessment to ensure they understand our policies concerning diversity and inclusion. Our policies are designed to ensure that all employees, current and prospective, experience equal treatment, while discrimination against employees or job applicants is strictly prohibited. Additionally, we set specific diversity goals and regularly monitor key performance indicators to ensure ongoing improvement.

To identify ESG concerns and risks that are critical to both our Company and the relevant stakeholders, we engage in ongoing, multi-channel communication with them. This includes regular engagement with government agencies, investors, customers, employees, suppliers, and the community. Through surveys, interviews, and analysis of external market trends, we assess stakeholder priorities and identify material ESG issues. Key ESG issues that we have identified include regulatory compliance, climate change mitigation, and greenhouse gas emission. By continuously assessing and managing the social, economic and environmental impacts of our operations, we promote shared growth with stakeholders.

In recognition of our ESG performance, our MSCI ESG rating, which measures our resilience to long-term, financially relevant ESG risks, was "A" for two consecutive years since 2023.

Social Responsibility

Fulfilling social responsibility and giving back to society are our core value. We are committed to promoting people's health and making medical services more accessible to people all over the world. As such, we constantly refine and improve our product marketing plans and pricing policies to increase drug accessibility and affordability to benefit more people from different regions.

We actively participate in social welfare and charity activities. Holding a longstanding commitment to improving the lives of patients with chronic diseases such as high blood pressure, arthritis, and diabetes, we have developed long-term drug donation plans for underdeveloped regions in China. In July 2023, we donated drugs worth RMB100,000 for chronic disease treatment to Baokang County, a county in Xiangyang, Hubei Province, China. We also established various charity funds and organized charitable donations to institutions such as schools. For example, in November 2023, to support the development of education in rural areas and facilitate rural revitalization, our representatives visited the Central Comprehensive Primary School of Fengyuan village in Yunnan, China, and we donated school supplies including computers, winter school uniforms, and sports equipment to the school. In addition, after natural disasters such as earthquakes, we were consistently among the first responders to offer various forms of aid including medicines, supplies, and financial support to the affected areas. For example, in December 2023, after the earthquake in Gansu, China, we donated RMB1 million and first-aid medicine worth over RMB1 million to the affected areas. We are committed to continuing to participate in charitable events to contribute to public health construction.

EMPLOYEES

As of September 30, 2024, we had 20,298 full-time employees, with a substantial majority of our employees based in China. The following table sets forth a breakdown of our full-time employees by function as of September 30, 2024:

Function	Number of Employees	% of Total
Sales and marketing	9,027	44.4%
R&D	5,538	27.3%
Manufacturing	3,855	19.0%
General administration	1,878	9.3%
Total	**20,298**	**100.0%**

Our ability to attract, retain and motivate qualified personnel is crucial to our success. We offer remuneration packages to our employees that include a base salary and a variable portion linked to individual performance and overall company results, aiming to fully engage our employees and incentivize talent attraction, retention, and motivation. Additionally, to further incentivize our employees, we have implemented share-based awards and other incentives to further enhance employee engagement. Moreover, we provide a variety of benefits to meet the diverse needs of our workforce, including accessible facilities for disabled employees, lactation rooms for nursing mothers, specialized health screenings, regular health check-ups, medical insurance, team-building activities, hobby clubs, holiday events and gifts, and transportation and meal subsidies.

Recognizing the importance of continuous learning and professional development, we offer a robust training program designed to enhance the professional skills of our employees. This includes (i) general training in areas such as business ethics, anti-corruption, marketing practices, occupational health and safety, office software operations, and communication skills; (ii) specialized training tailored to individual job requirements, providing learning opportunities and customized courses for different functional departments; and (iii) leadership training for different levels of employees, featuring a detailed learning roadmap, online courses, and sessions with professional leadership coaches through systematic training and practical projects to equip employees with necessary leadership knowledge and skills at each stage. Furthermore, to support the growth and development of our employees, we allocate specific funds for them to participate in external training programs, professional qualifications, and certifications. Additionally, we encourage employees to pursue on-the-job degree education relevant to business needs and professional directions.

We believe we have maintained good relationships with our employees. As of the Latest Practicable Date, our employees were represented by a labor union, and we did not experience any strikes or any labor disputes with our employees which have had or are likely to have a material effect on our business.

LEGAL AND COMPLIANCE

Licenses, Permits and Certificates

As of the Latest Practicable Date, we had obtained all material licenses, permits, approvals, and certificates required for our operations in the PRC and all of these material licenses, permits and approvals were valid and remained in effect.

The following table sets forth the major licenses, permits, approvals, and certificates for our business operations as of the Latest Practicable Date (apart from those pertaining to general business requirements):

License/Permit/ Certificate	Holder	Issuing Authority	Expiration Date
Drug Manufacturing License (藥品生產許可證)	The Company	Jiangsu Provincial Drug Administration	September 20, 2025
Drug Manufacturing License (藥品生產許可證)	Shanghai Hengrui Pharmaceuticals Co., Ltd. (上海恒瑞醫藥有限公司)	Shanghai Municipal Drug Administration	December 31, 2025
Drug Manufacturing License (藥品生產許可證)	Shanghai Shengdi Pharmaceutical Co., Ltd. (上海盛迪醫藥有限公司)	Shanghai Municipal Drug Administration	October 14, 2026
Drug Manufacturing License (藥品生產許可證)	Suzhou Suncadia Biopharmaceuticals Co., Ltd. (蘇州盛迪亞生物醫藥有限公司)	Jiangsu Municipal Drug Administration	September 20, 2025
Drug Manufacturing License (藥品生產許可證)	Chengdu Xinyue Pharmaceutical Co., Ltd. (成都新越醫藥有限公司)	Sichuan Provincial Drug Administration	October 22, 2025
Drug Manufacturing License (藥品生產許可證)	Shandong Shengdi Pharmaceutical Co., Ltd. (山東盛迪醫藥有限公司)	Shandong Provincial Drug Administration	October 9, 2025
Drug Manufacturing License (藥品生產許可證)	Fujian Shengdi Pharmaceutical Co., Ltd. (福建盛迪醫藥有限公司)	Fujian Provincial Drug Administration	August 8, 2029
Drug Manufacturing License (藥品生產許可證)	Guangdong Hengrui Pharmaceutical Co., Ltd. (廣東恒瑞醫藥有限公司)	Guangdong Provincial Drug Administration	May 25, 2028
Drug Manufacturing License (藥品生產許可證)	Chengdu Suncadia Medicine Co., Ltd. (成都盛迪醫藥有限公司)	Sichuan Provincial Drug Administration	November 2, 2025

License/Permit/ Certificate	Holder	Issuing Authority	Expiration Date
Radioactive Drug Manufacturing License (放射性藥品生產許可證)	Tianjin Hengrui Pharmaceutical Co., Ltd. (天津恒瑞醫藥有限公司)	Tianjin Municipal Drug Administration	December 24, 2028
Drug Supply Permit (藥品經營許可證) . .	Jiangsu Kexin Pharmaceutical Sales Co., Ltd. (江蘇科信醫藥銷售有限公司)	Jiangsu Provincial Drug Administration	May 8, 2025

We monitor the validity status of, and make timely applications for the renewal of, relevant licenses, permits, approvals, and certificates prior to the expiration date. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material difficulty in obtaining or renewing the required licenses, permits, approvals, and certificates for our business operations. We do not expect there to be any material legal impediment in renewing these licenses, permits, approvals and certificates as they expire in future as long as we are in compliance with applicable laws, regulations, and rules.

Legal Proceedings

We have been, and may from time to time be, subject to litigation, arbitration or other legal proceedings, investigations and claims arising in the ordinary course of our business. As of the Latest Practicable Date, we had not been a party to any legal, arbitral, or administrative proceedings, nor were we aware of any pending or threatened legal, arbitral, or administrative proceedings against us or our Directors, that could, individually or in the aggregate, have a material adverse effect on our business, financial condition or results of operations.

Compliance

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any noncompliance incidents that could, individually or in the aggregate, have a material adverse effect on our business, financial condition, and results of operations.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We are committed to establishing and maintaining a robust risk management system. Our comprehensive risk management policies address potential risks that may arise in various aspects of our business, including R&D, clinical trials, production, procurement, sale activities, inventory management, financial reporting, information system management, human resources, legal and compliance matters, and corporate governance.

Our key risk management objectives include identifying and analyzing various types of risks and establishing corresponding mitigation strategies and policies. We regularly review these strategies and policies in response to regulatory updates, market conditions, and changes in our operations, ensuring that they remain relevant and effective. Applying these strategies and policies, we have put in place a risk management system to identify, assess, monitor, and mitigate various operational, financial, and legal risks. This system encompasses dedicated policies, guidelines, notices, code of conduct, and employee handbooks on an array of topics.

As part of our risk management system, our audit department leads our daily risk management work and is supported by our various business units and departments. The audit department regularly reports to our Board on risk management related matters. Its responsibilities also include setting the functions and responsibilities of our relevant business units and departments in risk management and working with our business units and departments to collect information for risk analysis and assessment. As an important part of our risk identification process, each relevant business unit and department collects information on risks related to our business, taking into consideration our strategic goals and annual business plans. The audit department then reviews this information to formulate targeted risk mitigation strategies and measures.

Internal Control

We have developed internal control policies and guidelines that specify standards for identifying internal control deficiencies, conducting internal audits, and managing follow-up actions. In line with these policies and guidelines, we conduct regular internal audits across all major aspects of our operations, and our Audit Committee oversees our internal controls and evaluates their effectiveness. Additionally, we have implemented a range of internal control measures addressing various areas including conflicts of interest, insider trading, confidentiality control, and business ethics for our employees, business partners, or other stakeholders. These measures aim to ensure comprehensive governance and ethical business conduct.

To ensure regulatory compliance, we have implemented anti-money laundering, anti-corruption, and anti-bribery related policies and procedures. We provide multiple channels for our employees to report issues, complaints, or suspicions of illegal activities, which include designated reporting emails or hotlines and direct contacts within our compliance office. In addition, to comply with applicable sanctions and export controls related regulations, we have formulated a dedicated compliance policy that sets out standard operating procedures for risk screening, identification, reporting, and assessment, compliance governance organization, and an inquiry and reporting mechanism. We have integrated this policy into our business processes, particularly in new business initiation and customer engagements.

With strong emphasis on compliance, we have established a three-tier compliance management structure under the Board's leadership. Our compliance management committee, led by our Directors and senior executives, oversees our compliance strategy and major policy implementations. The compliance office, as our central compliance department, coordinates and monitors our compliance efforts and provides guidance and oversight to all of our departments and subsidiaries. The compliance departments at all levels within our Group are responsible for the routine management of compliance within their respective areas, to ensure adherence to applicable policies and regulations.

Maintaining robust corporate governance is a primary objective of our internal controls. To this end, we have adopted policies to comply with the listing rules of the Shanghai Stock Exchange and the Hong Kong Stock Exchange, which cover aspects such as risk management, connected transactions, financial reporting, and information disclosure. We also provide periodic compliance training sessions to our senior management and employees, including training on the Listing Rules for our Directors and senior management, and offer targeted compliance training to our employees, thereby promoting sound decision-making and adherence to regulatory requirements.