OVERVIEW

Our Mission

Breathing is the essence of life, often taken for granted until it becomes a struggle. For millions of patients worldwide, respiratory diseases like asthma and COPD can turn every breath into a challenge, jeopardizing their health and well-being. Our mission is to develop innovative therapeutics that help patients breathe better.

Who We Are

We are a pioneer and emerging leader in inhalation drug delivery technology worldwide, with a focus on treating respiratory diseases. As one of the few companies in the world to have mastered major inhalation formulations — the gold standard for treating most respiratory diseases — we have developed a comprehensive product portfolio with unparalleled coverage of patients, medical specialties, and therapeutic areas. Our products strategically benchmark global blockbuster drugs, covering four of the top ten inhalation drugs worldwide in 2023 with a total sales revenue of US$4.7 billion. Moreover, we develop novel patient-centric therapeutics to treat some of the most serious respiratory and pulmonary diseases.

We have obtained five product approvals and achieved commercialization success during the Track Record Period, demonstrating our strong capabilities across clinical development, manufacturing, regulatory affairs and commercialization. More importantly, we have reached new heights in our business as we begin to generate returns on our R&D investment. This commercial success marks a new chapter in our business, enabling reinvestment in our pipeline with at least five new product approvals expected in the next four years.

Today, we stand at the forefront of global innovation with over 20 product candidates in global development for major markets including China, U.S. and/or Europe, as well as emerging markets, such as Southeast Asia and South America. We are pioneering new treatment methodologies, such as EBV, and developing potential first-in-class or first-in-China treatments for diseases that have a significant impact on patient lives, such as IPF and PAH. Our research also explores novel formulations, such as liposomes and siRNA inhalation formulations, and expands into new disease areas, including CNS disorders and anti-infectives.

Notes:

(1) BA: bronchial asthma; COPD: chronic obstructive pulmonary disease; AR: allergic rhinitis; IPF: idiopathic pulmonary fibrosis; PAH: pulmonary arterial hypertension; CE: cluster epilepsy; DES: dry eye syndrome; MAC: mycobacterium avium complex

(2) Process validation has not yet completed

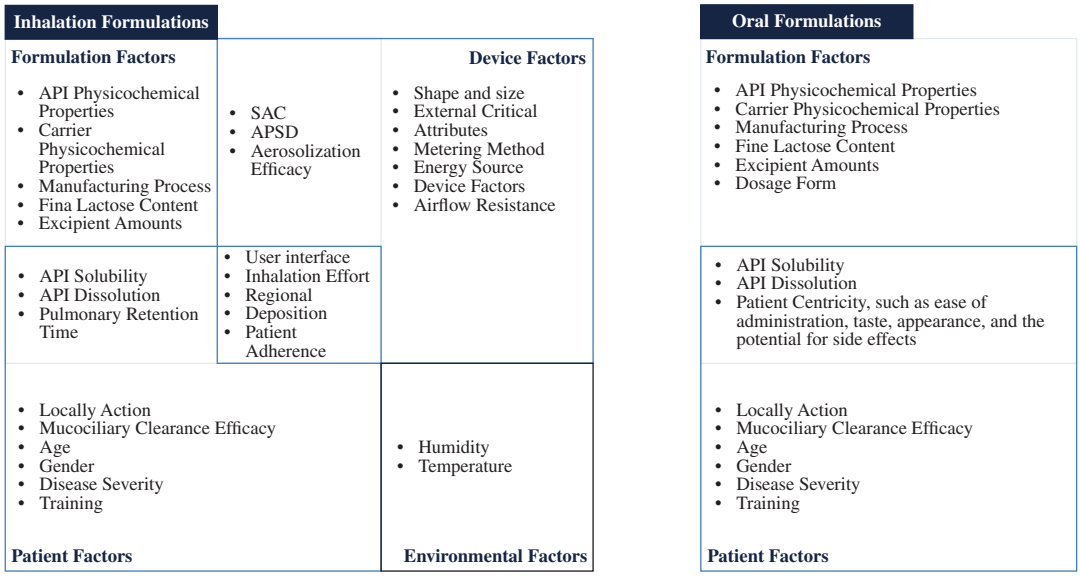
(3) Process validation is not required

Our global vision drives our business, backed by world-class manufacturing and proven commercialization strategies. Our state-of-the-art facilities, compliant with stringent regulations in our major markets, China, U.S., and Europe, coupled with team's group expertise in the U.S. pharmaceutical industries, laid down the foundation to explore global market via direct or technical service collaborations, which was validated by the successful FDA approval of GW006 in May 2024. Our well-structured marketing system and highly experienced team have propelled our first marketed product, CF017 to cover over 10,000 medical institutions in China since its approval in 2021. Our CF018 has also rapidly penetrated hospitals across multiple provinces, boosted by its inclusion in the 2023 NRDL. We are actively expanding our global commercial presence, with strategic cooperation in place for our launched products in South America, the Middle East, and Southeast Asia.

Our Market Opportunities

The global respiratory drug market is vast, driven by the increasing prevalence of respiratory diseases such as asthma, COPD and allergic rhinitis. It is estimated that nearly 2.5 billion people worldwide are living with chronic respiratory diseases today, and this number is expected to grow due to factors such as air pollution, smoking, and an aging population. The global respiratory drug market size was valued at US$94.6 billion in 2023, and it is projected to reach US$148.6 billion by 2033, growing at a CAGR of 4.6% from 2023 to 2033. China, with its large population, accounts for a sizeable share of the global market, and yet has lower diagnosis and treatment rates than countries such as the United States, indicating substantial untapped demand for treatment.

Compared to other formulation types, complex inhalation formulations are highly challenging to develop and manufacture, where the interplay of numerous factors affect the ability of the product to achieve an optimal therapeutic outcome. These factors originate from four major aspects, namely, the drug formulation, the delivery device, the patient and the environment. The chemical and physical properties of drug microparticles must be carefully engineered, then delivered in minute yet precise doses to the lungs using a compatible device that is specially designed to ensure optimal particle distribution, flow dynamics and dispersion patterns. The following diagram illustrates the complexity of inhalation formulations compared to oral formulations:



SAC: single actuation content; APSD: aerodynamic particle size distribution

As a therapeutic class, complex inhalation formulations are well-established as the most effective treatment for respiratory diseases, offering targeted delivery and superior clinical benefits compared to many other treatment options. Due to their complexity and challenges, inhalation formulations have a high entry threshold, with only a handful of established players succeeding in building out fully-fledged inhalation formulation platforms. The comprehensive technology expertise of these rare few players propels them forward in this specialized field, with potential to capture substantial market share and deliver life-changing medicines for respiratory diseases.

Our Inhalation Formulation Development Capabilities

The intricate and multifactorial nature of drug-device combinations like inhalation formulations requires us to master technologies and capabilities across multiple disciplines, especially to cover major types of formulations. Over the years, we have developed five capability platforms, which we believe encompass the most critical aspects in inhalation formulation development and serve as the foundation of our pipeline R&D.

- ***Particle engineering***. It is a cornerstone of successful inhalation formulations. Our particle engineering platform enables us to control every aspect of a drug particle, from its size, shape, density, surface characteristics, all of which can impact its delivery to the lungs. For example, our advanced particle engineering technologies controls drug particle size within the optimal range, striking the perfect balance between deep lung delivery and minimal upper airway deposition. Our proprietary techniques allow us to create uniform, stable, and high-performance particles tailored to each formulation's unique requirements.

- ***Device design***. Our devices are a testament to our scientific expertise, engineering prowess, and patient-centric design philosophy. We design devices that fit in the palm of your hand, where a complex network of over 30 components works in perfect harmony to deliver drug particles to the deepest recesses of the lungs with micron-level precision. We have developed advanced technologies, such as CFD modeling, aerosol generation and precision dose metering, to optimize particle distribution, trajectory, and dose calibration. The result is a range of devices that are not only bioequivalent to marketed products but also set new standards in terms of portability, affordability, and ease of use for patients of all ages and abilities.

- ***Product performance evaluation.*** As a drug-device combination product, it is crucial to design performance testing methodologies and parameters to evaluate the performance of the inhalation formulation products. Our state-of-the-art testing platform bridges the gap between laboratory testing and clinical performance, ensuring the safety and efficacy of our inhalation formulations prior to clinical use. We employ a suite of advanced technologies, including cascade impaction, breathing simulators, dissolution testing, imaging techniques, pulmonary function tests, and biomarkers, to rigorously assess the PK, PD, and safety of our products in animal models. This robust testing enables us to optimize our formulations and validate product performance prior to clinical trials.

- ***Clinical development***. Compared to oral and other formulation types, inhalation formulations are subject to more stringent and complex clinical development requirements across regulatory authorities in all major jurisdictions, including the FDA, EMA and NMPA. Local delivery in inhalation formulations also presents unique challenges in clinical trial design and management. We have developed robust clinical development expertise to navigate the complex landscape of inhalation formulations, from designing and managing large-scale clinical trials, controlling variability in patient factors and device use, and ensuring compliance with regulatory standards. To support clinical development, we have built a strong regulatory affairs team and a multidisciplinary team of scientists, clinicians, and statisticians for efficient trial design, patient recruitment, and high-quality data collection and analysis.

- ***Process engineering***. We have mastered the art of translating lab-scale formulations into commercially viable, industrial-scale manufacturing processes. Our deep expertise in process engineering allows us to design, optimize, and validate manufacturing processes that consistently deliver high-quality products, even as batch sizes increase from grams to tons. By leveraging statistical tools like design of experiments (DoE) and quality by design (QbD), coupled with advanced process analytical technology, we ensure tight control over critical quality attributes, such as particle size distribution, powder flow, and dose uniformity, setting new benchmarks in the industry.

COMPETITIVE STRENGTHS

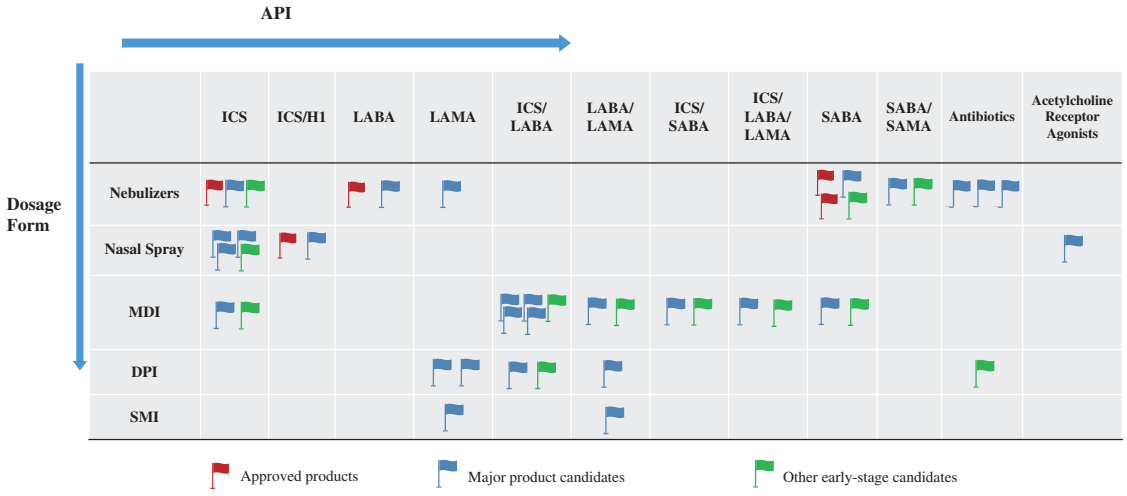
Pioneer and emerging leader in inhalation drug delivery technology with an unparalleled product portfolio to treat respiratory diseases and beyond

We are a pioneer and emerging leader in inhalation drug delivery technology worldwide, with a focus on treating respiratory diseases. We began our journey over 15 years ago as one of the few companies worldwide taking a pureplay strategy in inhalation formulation. With one of the largest specialized teams dedicated to this field, we have accumulated a wealth of formulation expertise that few in the industry can rival, built upon years of iterative advancement in inhalation formulation technology. Today, we boast one of the most comprehensive product portfolios in the world with unparalleled coverage of patients, medical specialties, and therapeutic areas.

The global respiratory drug market is vast at US$94.6 billion in 2023, driven by the increasing prevalence of respiratory diseases such as asthma, COPD and allergic rhinitis. It is estimated that nearly 2.5 billion people worldwide are living with chronic respiratory diseases today, a number that is expected to grow due to factors such as air pollution, smoking, and an aging population. Inhalation formulations, while known to be the gold-standard treatment for these diseases, are extremely difficult to develop. As a result, there are only a handful of players in the global market and even fewer capable of covering a full spectrum of formulations.

Despite the significant patient population, there remains substantial unmet needs in the treatment of respiratory diseases, including improving medication adherence, achieving better symptom control, reducing the frequency and severity of acute exacerbations, and addressing the challenges of severe or refractory cases. The key to resolving these issues lies in the innovation of formulation technologies. Over the years, inhalation formulations such as DPIs, nebulizers and SMIs have been developed. These new formulations have not only improved treatment of existing patients, but also provide therapeutic options for underserved populations, including children, the elderly, and patients with respiratory difficulties, that previously lacked effective treatment.

We are uniquely positioned as one of the few companies in the world with a comprehensive product portfolio, mastering major inhalation formulations and meeting the diverse needs of patients and healthcare providers. The following table sets forth our marketed and pipeline products by formulation and drug API.



We believe the comprehensiveness of our formulation technologies and product portfolio creates a deep competitive moat that will continue to secure our position at the forefront of the inhalation formulation industry. Our extensive expertise and wide-ranging capabilities provide us with several key advantages that set us apart from our competitors:

- ***Accelerated innovation through faster technology iteration***. Our deep understanding of various formulation technologies allows us to iterate and innovate at a faster pace. As we develop new products and improve existing ones, we accumulate valuable knowledge and experience that can be applied across our entire portfolio. This snowball effect has enabled us to stay ahead of the curve and stand at the forefront of global innovation.

- ***Comprehensive cross-specialty coverage***. Inhaled medicines are used by various medical specialties, including pulmonology, immunology, pediatrics, internal medicine, emergency, rhinology and critical care medicine. Our diverse range of inhalation formulations effectively meets the needs of healthcare providers across

multiple specialties. By providing solutions for a wide array of respiratory conditions, we establish strong relationships with hospitals and clinics, facilitating cross-selling opportunities and strengthening our presence in the healthcare system.

- ***Operating efficiencies***. Our comprehensive approach to inhalation formulations allows us to achieve significant operating efficiencies. By sharing expertise and resources across different formulation types, we optimize our research and development efforts, reduce costs and accelerate time-to-market. The knowledge gained from one formulation can often be applied to others, enabling us to streamline our processes and maximize the impact of our investments.

- ***Industry prominence and share of voice***. As we continue to expand our product portfolio and demonstrate our expertise across multiple formulation technologies and multiple medical specialties, we solidify our position as a prominent player in the industry. Our comprehensive offerings and deep understanding of the market will establish us as a key opinion leader, allowing us to shape industry trends and influence decision-making. This heightened visibility and credibility will further enhance our competitive advantage and help us maintain our leadership position in the inhalation formulation space.

Leveraging these competitive advantages, we are driving innovation as a leader in the inhalation formulation space. By pushing the boundaries of inhalation formulation technology, we aim to not only provide life-changing therapies to patients across a broad spectrum of respiratory and non-respiratory conditions but also expand our market reach and cement our position as a prominent global player.

Robust technology foundation that solidifies industry leadership and drives innovation

In the highly complex inhalation formulation field, we believe that technology leadership is the paramount factor for success. With over 15 years of unwavering dedication and specialization in this field, we have achieved industry-leading mastery of multiple key disciplines that address key challenges and pain points in formulation development. These expertise and know-how form our robust inhalation formulation technology system, encompassing the development of all major types of inhalation formulations across the entire product lifecycle, from formulation design and pre-clinical testing to clinical studies, regulatory affairs and commercial-scale manufacturing.

Our technology platforms are the foundation of our pipeline, and the driving force behind our R&D endeavors in the innovative frontiers of inhalation formulations. From established formulations such as DPIs, nebulizers and SMIs, to novel formulations such as liposomes and siRNA, from respiratory diseases to CNS conditions and anti-infectives, our technology platforms will enable us to rapidly iterate and advance at the industry vanguard.

- ***Particle engineering*** is the cornerstone of successful inhalation formulations. Compared to other routes of administration, drug delivery via the lungs demands heightened control of the drug particle. Every attribute, from particle size, shape, density, and surface characteristics, can critically impact drug effectiveness, thus adding layers of complexity to the formulation development process. These properties must be precisely engineered on a micron scale and maintain uniformity and stability across time and varied environments. We have developed a comprehensive suite of advanced particle engineering technologies, including micronization, spray drying, controlled crystallization, to engineer the exact type and form of drug particles needed for different inhalation formulations. Our extensive particle engineering expertise is substantiated by our five approved products, showcasing our ability to navigate the complexities of inhalation formulation development.

- ***Device design*** is a crucial and complex component that requires a combination of scientific expertise, engineering skills, and patient-centric design. The intricacy of delivery systems extends to their materials and formulation stability, necessitating the use of biocompatible components to prevent reactions with the medication. Within these compact devices, a sophisticated network of air passages, valves, and nozzles is engineered to consistently deliver drug particles with micron-level precision to the deepest areas of the lungs, while remaining portable, affordable, and intuitive for patients of all ages and abilities. To meet these challenges, we have developed advanced technologies, including CFD modeling, aerosol generation, and dose metering technologies, to optimize particle distribution, trajectory, and dose calibration. Our devices are patent-protected and bioequivalent to marketed products, showcasing our technological prowess and commitment to quality.

- ***Product performance evaluation*** is crucial in bridging the gap between laboratory testing and the clinical performance of inhalation formulations. Unlike oral or injectable formulations, as a combination of inhalation device and API, inhalation products navigate the complex anatomy and physiology of the respiratory tract while accounting for various patient and environmental factors. We have developed a robust testing platform that incorporates technologies such as *in vitro-in vivo* correlation (IVIVC) studies, cascade impaction, breathing simulators, and dissolution testing to simulate respiratory conditions. Additionally, we utilize a range of imaging technologies, pulmonary function tests, and biomarkers to assess pharmacokinetics, pharmacodynamics, and safety in both animal models and humans. These tests generate reliable data to ensure that our products are safe and effective, while also enabling us to validate our formulations prior to clinical trials.

- ***Clinical development*** for inhalation formulations is far more complex and stringent compared to other formulation types. Local delivery in inhalation formulations presents unique challenges. For example, variability in patient inhalation techniques can affect drug deposition, making it challenging to control dosage consistency. The potential for irritation or adverse reactions in the delicate lung tissues necessitates meticulous monitoring and control measures during trials. These complexities

demand stringent protocols, and close supervision, all of which contribute to the intricacy of clinical trials for inhalation formulations. As a result of these complexities, large-scale human clinical trials, often involving over 500 patients, are required to demonstrate bioequivalence due to the inherent variability in patient factors and device use. Inhalation formulations also demand additional studies, such as local and systemic safety assessments, device usability tests, intricate PK/PD studies, and long-term safety and efficacy evaluations. Our team has honed its expertise in navigating these challenges, designing and managing large-scale clinical trials, controlling variability, and ensuring regulatory compliance. We have assembled a multidisciplinary team of scientists, clinicians, statisticians, and regulatory affairs experts to streamline trial design, patient recruitment, and data collection and analysis, positioning us at the forefront of inhalation formulation development.

- ***Process engineering*** to translate a lab-scale inhalation formulation into a commercially viable, industrial-scale manufacturing process in a cost-effective manner presents a formidable challenge. Small variations in the manufacturing process can profoundly impact critical quality attributes, such as particle size distribution, powder flow, and dose uniformity, especially as batch sizes increase from grams to kilograms or tons. The complexity of these formulations often requires precise ratios of APIs and excipients, which can vary in compatibility and behavior at scale. To address these challenges, we utilize statistical tools such as design of experiments (DoE) and quality by design (QbD) to identify and control critical process parameters. We also implement advanced process analytical technology to monitor and control the manufacturing process in real time.

One of the most comprehensive product portfolios worldwide to address needs for the majority of patients and healthcare providers in respiratory diseases and beyond

We have developed a comprehensive product portfolio with unparalleled coverage of patients, medical specialties, and therapeutic areas. Over the past 15 years, we have taken a strategic phased approach in inhalation drug development, starting with established inhalation formulations that deliver maximum clinical impact to large patient populations or address major unmet needs. As we build up our technological foundation, in recent years, we have commenced a second phase of product development focused on innovative formulations, novel disease areas, new treatment methodologies and potential first-in-class or first-in-China treatments. Today, our portfolio includes five products approved by the NMPA or FDA, as well as over 20 in global development for major markets including China, U.S. and/or Europe, as well as emerging markets, such as Southeast Asia and South America, with at least five product approvals expected in the next four years.

The first phase of our product development has been a momentous period in our business. We strategically focused on developing products that benchmark global blockbuster inhalation products, which not only address significant areas of unmet need but also represent the gold standard in inhalation formulations. Through developing these products, we have built a robust technology and capability foundation that spans all inhalation formulations. This foundation has led to a remarkable increase in our R&D efficiency. Since our first product approval in

2021, we obtained four additional product approvals in the past three years, including one with the FDA. These products serve as a powerful testament to our capabilities across R&D, manufacturing, and commercialization. More importantly, they signify a new level of maturity in our business as we begin to generate returns on investment, allowing us to reinvest in our future success and drive further innovation in the inhalation formulation space.

Details of the major approved products and product candidates in our first phase of product development include:

- ***CF017*** is our first approved product, receiving approval from the NMPA in May 2021. As the front-line treatment for bronchial asthma, budesonide suspension for inhalation was the highest selling inhalation drug in China in 2023, generating an aggregate sales revenue of RMB5.3 billion that year. Within one month of NMPA approval, CF017 was included in the VBP list for eight provinces in China. Since then, it has achieved significant sales revenue growth, increasing from RMB29.8 million in 2021 to RMB335.9 million in 2022 and RMB547.8 million in 2023. As of the Latest Practicable Date, we had penetrated over 10,000 hospitals and medical institutions and captured a market share of approximately 20% in 2023 in terms of sales volume in China.

- ***CF018*** is the first azelastine hydrochloride and fluticasone propionate nasal spray approved for allergic rhinitis in China. Notably, our product was approved in November 2022, eight months before the originator drug was approved, by leveraging our deep technological expertise. Allergic rhinitis has a prevalence of approximately 243.0 million in China in 2023, with a diagnosis rate of only 28.8% and treatment rate of only 28.3% compared to 46.7% and 40.0%, respectively, in the United States. Compared to the existing single-compound formulations available in China, our formulation combines both the allergy control properties of azelastine hydrochloride with the anti-inflammatory effects of fluticasone, with the potential to become the mainstay treatment for moderate to severe allergic rhinitis. Since its inclusion in the NRDL in December 2023, our CF018 has penetrated over 500 hospitals and medical institutions with significant commercial upside.

- ***CF006/CF043*** is a front-line salmeterol/fluticasone aerosol for both bronchial asthma and COPD, for which we have completed a registration clinical trial and was preparing its product registration materials in China. In 2023, this drug was the third highest selling inhalation drug in China and fourth highest globally, respectively, with a sales revenue of RMB1.9 billion and US$1.9 billion, respectively. To date, the only salmeterol/fluticasone MDI approved in China is the originator drug and we are the only other developer in clinical trial. We believe we will have significant market advantages given the white space market, as well as the MDI formulation's inclusion in the treatment guidance for its clinical benefits in asthma control.

- ***GW008/GW013*** is a LAMA for the treatment of COPD, for which we are developing for China, the United States and European markets. Since the originator drug's approval in 2004, it has been one of the best-selling COPD drugs globally, generating an aggregate revenue of US$2.4 billion in 2023. We are developing a DPI formulation tiotropium bromide for the China, United States and European market,

and have commenced clinical trial in China in 2024. With know-how and insights from developing this candidate, we are also developing a soft mist version to improve patient compliance and convenience, which is a white space market with only the originator drug approved worldwide. We have designed a proprietary SMI, representative of our soft mist formulation technology platform.

Beyond our first phase of inhalation products, we are also driving global innovation in treating some of the most serious respiratory and pulmonary diseases through novel inhalation formulations. Leveraging our extensive insights and experience, we are pushing the boundaries of inhalation formulations from local delivery to systemic delivery. Through these efforts, we aim to provide life-changing therapies for patients across a broad spectrum of respiratory and non-respiratory conditions, while also expanding our market reach and cementing our position as a prominent player in the industry.

- ***Respiratory indications:*** We are designing new chemical entities for potential best-in-class treatments for pulmonary conditions that significantly impact patient lives, such as IPF and PAH. Both IPF and PAH are progressive diseases that have a significant impact on quality of life. In 2023, there were approximately 132.7 thousand IPF patients and 85.3 thousand PAH patients in China. Currently, none of the available treatments for IPF and PAH are curative. First-line treatments, antifibrotic medicine for IPF and vasodilator therapies for PAH, are associated with side effects and varying effectiveness in patients. As an inhalation formulation would directly deliver the drug to the lungs, we believe they could potentially have reduced systemic side effects and become the front-line treatment for these diseases.

- ***Treatment methodologies:*** We are pioneering new treatment methodologies, including CFQX001 to treat respiratory diseases such as severe emphysema. As an advanced form of COPD, severe emphysema most commonly results from smoking which destroys the alveoli in the lungs, causing reduced lung function, chronic shortness of breath, low blood oxygen levels and progressive lung hyperinflation. Currently, disease management mainly involves bronchodilators and ICS to manage symptoms, pulmonary rehabilitation, or oxygen therapy. We are developing an endobronchial valve that can be implanted through minimally-invasive surgery to reduce hyperinflation, improving breathing and enhancing the function of healthy lung tissue.

- ***Formulations:*** We are exploring novel formulations, such as liposomes, and developing a liposome suspension candidate, to further expand our inhalation formulation pipeline portfolio for the treatment of MAC lung disease, a type of lung disease which is more prevalent among elderly population, with a five-year mortality greater than 25%. While antibiotics are the first-line treatment for MAC, they require prolonged use of 12 to 18 months and therefore can lead to resistance and low treatment compliance. Moreover, there may be higher risk of drug-drug interactions (DDIs), especially in the elderly population. Amikacin, a novel drug treating MAC disease has a differentiated mechanism of action, however, due to its

toxicity level, the injection formulation can cause severe side effects such as kidney damage and is inconvenient given the regular injections needed. By encapsulating amikacin in a liposome, it can enable targeted delivery to specific tissues, controlled release of the drug and protection from degradation. As such, liposomal formulations can significantly reduce off-target effects, maintain therapeutic levels more effectively, and potentially allow for lower doses of the drug, thereby minimizing systemic toxicity and enhancing its safety and efficacy profiles.

- ***Delivery technology:*** We are developing siRNA therapies in inhalation formulations for delivery to the lung, which has long been a major technological challenge. RNA technology can potentially redefine the treatment landscape for respiratory diseases, with the ability to target genes or pathways that underlie the disease, in contrast to most existing treatments that only treat the symptoms. By addressing disease-causing mechanisms, siRNA therapy could modify the course of disease and achieve more sustained disease control. To date, there are no approved siRNA inhalation drugs globally. We are currently exploring opportunities to adopt siRNA technologies for the treatment of chronic respiratory diseases, with an aim to developing first-in-class siRNA inhalation drugs globally.

- ***Therapeutic pathway:*** We believe inhalation formulations have significant potential in other therapeutic areas. In recent years, the nose to brain pathway has gained significant popularity in the field of inhalation formulation. This pathway involves the direct transport of substances from nasal cavity to the brain, bypassing the blood-brain barrier and offering a non-invasive route for delivering therapeutics to the central nervous system. This pathway offers advantages in enhancing drug targeting and efficacy in treating various CNS disorders. We are currently developing two inhalation drugs for CNS diseases, including a calcitonin gene-related peptide (CGRP) receptor antagonist nasal spray for the acute treatment of migraine headaches and a diazepam nasal spray for acute treatment of seizure clusters. As nasal sprays, our CNS inhalation formulation drug candidates can bypass the slower gastrointestinal absorption of oral drugs, provide rapid relief and are easier and more convenient to administer. In addition, we are also developing CF056 for dry eye syndrome. It can bind certain receptors in the nose and activate a specific nerve pathway that increases the amount of tear film produced by the eye.

Scalable manufacturing excellence with uncompromising quality standards

Transforming a lab-scale inhalation formulation into a commercially viable, industrial-scale manufacturing process is a challenging endeavor. With over 15 years of experience, we have developed a robust manufacturing system that employs advanced techniques and expertise to produce high-quality inhalation formulations. This capability gives us a significant competitive advantage, which is further enhanced by significant in-house capacity, an integrated supply chain, and stringent quality control standards.

- ***Comprehensive formulation manufacturing.*** We have developed scalable manufacturing capabilities across major inhalation formulation types, including formulations such as SMI which very few companies in the world possess. Given the innovative nature of certain of our formulations, we have worked closely with long-time equipment suppliers to develop bespoke production equipment. Our broad manufacturing know-how allows us to persistently refine and optimize our manufacturing processes for diverse inhalation formulation types, thereby boosting manufacturing efficiency and ensuring consistent quality across our product lines.

- ***Significant in-house capacity.*** We are committed to in-house manufacturing to ensure product quality. To date, our facilities boast a production capacity with comprehensive coverage across all major formulation types, including 220.6 million vials of suspension nebulizers, 50 million vials of solution nebulizers, 4 million canisters of nasal sprays, 2 million canisters of MDI products and 24 million doses of DPI products per year, and we have earmarked space in our manufacturing base for capacity expansion. Upon completion of this expansion, we expect to hold one of the largest inhalation formulation capacities worldwide with an annual manufacturing capacity of 575 million vials of nebulizers in suspension or solution forms, 19 million canisters of nasal sprays, 14 million canisters of MDI products, 24 million doses of DPI products and 600 thousand liposome products, which will be crucial as we ramp-up sales of approved products and obtain new product approvals in the coming years.

- ***Proven industrial scale-up capability.*** We have accumulated extensive in-house manufacturing expertise in designing and calibrating our facilities to produce high-quality inhalation formulations. With the approval of five products in two formulation types, we have gained the recognition of major regulatory authorities, such as the FDA and NMPA. Our manufacturing system has been tested and validated by industrial-scale production, especially to meet the significant product demand as our products qualify for GMP standards, U.S. Pharmacopeia and EU Pharmacopeia standards. As we scale production, we have realized efficiencies that increase affordability of our products.

- ***End-to-end supply chain management.*** We implement an end-to-end supply chain management approach that covers all key stages of our process. We source raw materials exclusively from a select group of qualified suppliers, conducting thorough tests and site audits to ensure their quality. By maintaining long-term relationships with these key suppliers, we enhance the efficiency and stability of our supply chain, ensuring quality assurance and the agility to meet market demand promptly.

- ***Comprehensive quality control system.*** We implement a quality control and quality assurance system that ensures product quality in key areas of the development lifecycle meets the best practice requirements across the globe, including the United States and Europe. Within the development lifecycle, we are unwavering in our commitment to quality systems in R&D and manufacturing, building a stringent quality assurance platform with extensive testing and validation procedures and state-of-the-art equipment tailored across formulations that few in the industry can rival. This comprehensive approach ensures compliance with regulatory frameworks across various regions, establishing a reliable pathway for the global commercialization of our products.

Global commercialization strategy with a proven track record

Our ultimate goal is to provide accessible inhalation drugs that meet the needs of large patient population. With this in mind, our commercialization strategy starts with identifying medicines that bridge treatment gaps for large patient populations, or significantly improve patient quality of life. As we develop these drugs, we formulate tailored market strategies that have proven effective during the Track Record Period. Our revenue has increased from RMB42.0 million in 2021 to RMB349.1 million in 2022, and further increased to RMB556.4 million in 2023. In the six months ended June 30, 2024, our revenue increased to RMB288.7 million from RMB241.4 million in the same period in 2023.

For our first phase of drug development, we primarily focus on established inhalation drugs that have limited availability in China, such as our CF018, which was the first of its kind approved for allergic rhinitis in China, even before the originator drug. For products like this, we center our commercialization strategy on hospital penetration through various government-funded programs, conducting physician and patient education, and building up a sales network of outpatient pharmacies, specialty clinics, and e-commerce platforms. For products like CF017, for which vast market demand exists despite a few of its kind already approved, we aim to leverage programs such as the VBP to rapidly broaden market reach. We believe our scalable and synergistic manufacturing capabilities have enabled cost efficiencies that were crucial in inclusion negotiations.

We are also actively monitoring the competitive landscape for other product candidates we have, with an aim to ensure our products, once approved, to be able to enjoy the benefits from these government-funded programs once approved. Further, we are also formulating different strategies, such as combo therapies in clinics, which enable us to enjoy significant competitive advantages.

We are also preparing the market in anticipation of our innovative inhalation drugs, with a primary focus on extensive market research and analysis as we design and develop these products with a patient-centric approach. At the same time, we are actively participating in industry conferences, publishing in academic journals and collaborating with industry leaders to highlight our technological advancements and the potential benefits of our drug candidates.

Positioned with a global vision, we are expanding our presence in international markets to fully realize the commercial potential of our products. We have obtained FDA approval for our GW006 and are strategically developing several products for the European and U.S. markets. Additionally, we are exploring opportunities to collaborate with partners in various emerging markets, including South America, Middle East and Southeast Asia, to drive local commercialization.

Multi-disciplinary inhalation formulation team led by seasoned management team with global expertise and strong shareholder support

The advancement of inhalation formulations necessitates a collaborative R&D endeavor drawing expertise from various disciplines including pharmacology, chemistry, and engineering. Over the years, we have cultivated a robust multi-disciplinary team comprising more than 600 skilled professionals dedicated to inhalation formulations, covering essential technical aspects in this domain. This cohesive inhalation formulation team has empowered us to fortify an unmatched strategic advantage within this sector.

Our multi-disciplinary inhalation formulation team is led by a seasoned and renowned management team that has steered our business direction and strategy since our inception. With their guidance, we have emerged as a global leader and pioneer in complex inhalation formulation technology. Our success is largely attributed to our visionary core leadership team, whose complementary expertise in R&D, manufacturing, commercialization, and entrepreneurship have been the foundation of our achievements. Our core scientific team primarily consists of:

- ***Dr. LIANG***, our co-founder, chairperson of the Board and chief executive officer of our Company, has steered our Company since its inception while playing a pivotal role in our R&D team. Dr. LIANG spearheads the screening of novel inhalation compound targets and oversees early-stage drug efficacy validation. Notably, Dr. LIANG brings strong business acumen, industry insights and experience in entrepreneurship and investment. Dr. LIANG holds a Ph.D. in molecular and cell biology from the University of Massachusetts and master of business administration from the Universities of Southern California-Marhsall School of Business; and worked as a post-doctoral fellow at Harvard Medical School from 1996 to 1999.

- ***Dr. LI LI BOVET***, our co-founder, an executive Director, and chief scientific officer of our Company, is a pioneer in respiratory drug research with nearly three decades of experience in pharmaceutical leadership and drug development. She undertook key roles at GlaxoSmithKline and Schering-Plough, where she fronted the development of numerous inhalation formulations. She served as executive vice president of Cirrus Pharmaceuticals in the U.S.. Under her guidance, Cirrus Pharmaceuticals successfully brought to market several FDA-approved inhalation drugs. She holds a Ph.D. in physical chemistry from the University of Michigan, where she also completed her postdoctoral research, and an MBA from the University of North Carolina Kenan-Flagler Business School.

- ***Dr. Jean-Marc Bovet***, our technology director, brings nearly three decades of pharmaceutical R&D expertise to our team. As a distinguished scientist, his academic credentials include a Ph.D. from the University of Michigan. Dr. Jean-Marc Bovet's professional journey includes significant contributions as a co-founder at Cirrus Pharmaceuticals, Inc., where Dr. Jean-Marc Bovet led pioneering research in drug analysis and pharmaceutical nanotechnology from 2004 to 2012.

- ***Dr. Qi Li***, an executive Director and our chief operating officer, has over 25 years of pharmaceutical development expertise, including having successfully obtained FDA approvals for six inhalation products at Teva Pharmaceuticals, where he served as chief scientist, as well as NDAs for both improved and generic drugs in the U.S. and European markets. Dr. Li holds four international patents and has authored more than 20 academic papers. He holds a Ph.D. in chemistry from the University of Miami and completed postdoctoral research in molecular and cellular pharmacology at the University of South Florida's Cancer Center and the University of Miami School of Medicine.

Recognizing our commitment and growth potential, we have successfully completed six rounds of financing, demonstrating the ongoing trust and support from our investors, including FIIF, who will fuel our future growth with financial support and industry insights.

OUR STRATEGIES

Rapidly advance the global clinical development of our pipeline candidates and strengthen our comprehensive product portfolio to cover a wider range of clinical areas

We are accelerating the clinical development of our inhalation formulation product candidates, both domestically and internationally, with the goal of shortening development cycles and expediting commercialization. Leveraging our deep understanding of respiratory diseases, we are committed to addressing unmet clinical needs through the development of established respiratory inhalation drugs and to rapidly advancing them to the market. As we continue to advance our R&D programs, we believe that we will be able to launch at least five product approvals in the next four years.

In addition, at the forefront of innovation, we will continue to pursue programs aiming at novel formulations, molecules, and medical devices, and new therapeutic pathways. We have launched the clinical trial in China for our innovative EBV medical device for emphysema and we will continue to advance its clinical trial. Further, we plan to submit the IND application for our IPF innovative drug in China and advance its clinical trial in the near future. For the remaining product candidates, we will continue to advance their pre-clinical studies and apply for IND when appropriate. Leveraging our global resources, we plan to maximize the commercial potentials of our innovative products through various methods, such as exploring potential BD opportunities.

Enhance our commercialization capabilities to expand our market share

We are developing tailored commercialization strategies for our diverse product portfolio, aiming to leverage resources and government-funded program including the VBP and the NRDL to maximize the commercial value of our products. We also actively track the competitive landscape of our products, so that they can be qualified for such government-funded programs upon approval.

For our CF017, we will deepen market penetration by leveraging our inclusion in the VBP list, while also enhancing our presence in outpatient pharmacies, specialty clinics, and e-commerce platforms. We are actively renegotiating with the relevant government authorities to renew the VBP status for CF017. For CF018, we plan to utilize our NRDL inclusion to facilitate hospital penetration and increase market share. Additionally, leveraging the VBP list, we are exploring opportunities to commercialize CF036 and CF038, as a potential combo therapy together with our CF017 product. We believe this tailored approach will enhance our sales networks and strengthen our commercialization capabilities, ultimately expanding our market presence.

Pursue our global strategy

As a company with a global vision, we are executing an international expansion strategy to bolster our global influence and broaden our footprint. Our focus lies in leveraging global resources to elevate our R&D capabilities in inhalation formulations through initiatives such as talent recruitment, fostering collaborations, and technology transfer. Additionally, we are committed to expanding our manufacturing facilities to align with FDA and EU standards, reinforcing our dedication to quality and compliance as integral components of our global strategy.

We will also gradually advance product registration and sales in the global market. Our efforts focus on advancing product launches in major markets like Europe and the U.S., while also pursuing registration in promising emerging regions such as Southeast Asia, South America and the Middle East. To achieve this, we are continuously deepening our understanding of diverse regulatory environments and market demands worldwide, allowing us to tailor specific strategies for each product. Furthermore, we actively seek global strategic

partnerships to expedite the R&D and registration of our products abroad, leveraging these collaborations to establish robust global commercialization capabilities. Through this approach, we aim for comprehensive global integration and enhanced overseas revenue streams in business development.

Currently, we have obtained one NDA approval from the FDA, namely, GW006. We also have several product candidates targeting the European and the U.S. markets under various development stages. We will continue to advance the development of these candidates and collaborate with local partners to commercialize them in these markets. Additionally, we see significant opportunities in emerging markets, where regulators often recognize NDAs from authoritative regulatory bodies such as the NMPA and FDA. We plan to pursue product registration in these regions through partnerships with local collaborators.

As an inhalation formulation company renowned for our comprehensive product portfolio with promising clinical profiles, we plan to leverage strategic BD opportunities across the globe to maximize the commercial potential of our products candidates. These collaborations will not only enable us to bring our products to a wider population and generate new sources of revenue but also foster synergies that drive our future R&D and product innovation. Through this proactive approach to partnerships, we are poised to unlock new avenues for growth and establish a stronger presence in the market.

Further strengthen our manufacturing capabilities and quality control standards

We are expanding our production facilities and enhancing our production lines by acquiring and upgrading state-of-the-art equipment to boost efficiency and capacity. In tandem with these efforts, we will focus on improving our production management system to elevate our quality control standards. Our goal is to ensure that all products are manufactured to the highest quality, consistently meeting or exceeding international first-class standards. Through these initiatives, we aim to maintain our competitive edge and deliver superior products to the global market.

We are currently building the next phases of our manufacturing facility by adding more production lines to support more types of inhalation formulations. The phase I of our new production lines is primarily designed for the SMI and nasal spray products, which is expected to be put into use by the end of 2025. The first part of the phase II of our new production lines is primarily designed for MDI and liposome products, which is expected to be put into use by the end of 2026.

Attract, retain and cultivate a diverse and international talent pool

We believe our multi-disciplinary and specialized talent pool is crucial to our success in the long run. We are committed to continuously recruiting, retaining, and cultivating talent, especially within the inhalation formulation industry, to strengthen a diverse and international workforce that supports our ongoing innovation and growth. Our aim is to build a high-quality professional team by implementing training and career development programs to enhance our

employees' skills and knowledge. Meanwhile, we plan to recruit talents in the innovative area that we are developing our products for, such as medical device and siRNA technologies. To further motivate our team, we also plan to offer competitive compensation packages and incentive plans.

OUR CAPABILITY PLATFORMS

Since 2017, we have built comprehensive capabilities that overcome major challenges in formulation technology and place us at the vanguard of inhalation formulation development globally. Armed with these capabilities, we are equipped with critical optionality to develop the most suitable inhalation format based on the characteristics of the API and the target population group, resulting in a comprehensive product portfolio with unparalleled coverage of patients, medical specialties, and therapeutic areas. Details of our capability platforms are summarized as follows:

- ***Particle engineering*** is a cornerstone of successful inhalation formulations. We have developed a comprehensive suite of advanced particle engineering technologies, including micronization, spray drying, and controlled crystallization, to engineer the exact type and form of drug particles needed for different inhalation formulations. Our extensive particle engineering expertise is substantiated by our five approved products spanning three formulation types, showcasing our ability to navigate the complexities of inhalation formulation development.

- ***Device design*** is a crucial and complex component that requires a rare combination of scientific expertise, engineering skills, and patient-centric design. We have developed advanced technologies, including CFD modeling, aerosol generation, and dose metering technologies, to optimize particle distribution, trajectory, and dose calibration. Our devices are patent-protected and are bioequivalent to marketed products, showcasing our technological prowess and commitment to quality.

- ***Product performance evaluation*** is crucial in bridging the gap between laboratory testing and the clinical performance of inhalation formulations. We have developed a robust testing platform that incorporates technologies such as *in vitro-in vivo* correlation (IVIVC) studies, cascade impaction, breathing simulators, and dissolution testing to simulate respiratory conditions. Additionally, we utilize a range of imaging technologies, pulmonary function tests, and biomarkers to assess pharmacokinetics, pharmacodynamics, and safety in both animal models and humans. These tests generate reliable data to ensure that our products are safe and effective while also enabling us to validate our formulations prior to clinical trials.

- ***Process engineering***. We have mastered the art of translating lab-scale formulations into commercially viable, industrial-scale manufacturing processes. By leveraging statistical tools like the design of experiments (DoE) and quality by design (QbD), coupled with advanced process analytical technology, we ensure tight control over critical quality attributes, such as particle size distribution, powder flow, and dose uniformity, setting new benchmarks in the industry.

- ***Clinical development*** for inhalation formulations is far more complex and stringent compared to other formulation types and are particularly challenging. For example, variability in patient inhalation techniques can affect drug deposition, making it challenging to control dosage consistency. The potential for irritation or adverse reactions in the delicate lung tissues necessitates meticulous monitoring and control measures during trials. These complexities demand stringent protocols, and close supervision, all of which contribute to the intricacy of clinical trials for inhalation formulations. Our team has honed its expertise in navigating these challenges, designing and managing large-scale clinical trials, controlling variability, and ensuring regulatory compliance. We have assembled a multidisciplinary team of scientists, clinicians, statisticians, and regulatory affairs experts to streamline trial design, patient recruitment, and data collection and analysis, positioning us at the forefront of inhalation formulation development.

OUR PRODUCT PORTFOLIO

Specializing in inhalation formulations, we have positioned our product portfolio primarily to focus on respiratory diseases, including asthma, COPD and allergic rhinitis. We have taken a strategic phased approach in inhalation drug development. In the first phase of our product development, we focused on developing products with limited availability in China that benchmarked global blockbuster inhalation products, which not only address significant areas of unmet need but also represent the gold standard in inhalation formulations.

Beyond our first phase of inhalation products, we are also driving global innovation to push the boundaries of formulation applications. We are exploring novel inhalation formulations, such as liposomes and siRNA, and venturing into new therapeutic areas, including CNS disorders and anti-infectives. Moreover, we are pioneering new treatment methodologies like EBV and developing potential first-in-class or first-in-China treatments for diseases that have a significant impact on patient lives, such as IPF and PAH.

As of the Latest Practicable Date, we had five products approved by the NMPA or FDA and over 20 product candidates in global development for major markets including China, U.S. and/or Europe, as well as emerging markets, such as Southeast Asia and South America, with at least five product approvals expected in the next four years. The following table summarizes our product portfolio and their respective development stages as of the date of this document.

Notes:

(1) BA: bronchial asthma; COPD: chronic obstructive pulmonary disease; AR: allergic rhinitis; IPF: idiopathic pulmonary fibrosis; PAH: pulmonary arterial hypertension; CE: cluster epilepsy; DES: dry eye syndrome; MAC: mycobacterium avium complex

(2) Process validation has not yet completed

(3) Process validation is not required

The following table illustrates our revenue breakdown by product/service during the Track Record Period.

	For the year ended December 31,						For the six months ended June 30,			
	2021		2022		2023		2023		2024	
	RMB'000	*%*	*RMB'000*	*%*	*RMB'000*	*%*	*RMB'000*	*%*	*RMB'000*	*%*
							(Unaudited)			
Sales of products										
Inhalation products										
CF017	29,832	71.1	335,941	96.2	547,763	98.4	236,772	98.1	279,573	96.8
CF018	–	–	416	0.1	1,330	0.2	948	0.4	7,050	2.4
CF036	–	–	–	–	453	0.1	–	–	108	0.1
Subtotal	*29,832*	*71.1*	*336,357*	*96.3*	*549,546*	*98.7*	*237,720*	*98.5*	*286,731*	*99.3*
Consumer health products	7,611	18.1	9,635	2.8	3,686	0.7	2,154	0.9	808	0.3
Subtotal	*37,443*	*89.2*	*345,993*	*99.1*	*553,231*	*99.4*	*239,874*	*99.4*	*287,539*	*99.6*
Provision of technical services[(1)]	4,543	10.8	3,134	0.9	3,190	0.6	1,477	0.6	1,128	0.4
Total	**41,986**	**100.0**	**349,127**	**100.0**	**556,421**	**100.0**	**241,351**	**100.0**	**288,667**	**100.0**

Note:

(1) During the Track Record Period, a small portion of our revenue was generated from service fees we charge for the provision of CDMO services. For details, see "Business — Our Product Portfolio — Technical Services" and "Financial Information — Description of Certain Consolidated Statements of Profit or Loss and Other Comprehensive Income/(loss) Items — Revenue."

Established Inhalation Drugs for Respiratory Diseases

Inhalation formulations are recognized as the gold standard for managing chronic respiratory diseases such as asthma, COPD, and allergic rhinitis. According to F&S, approximately 2.5 billion people worldwide are living with chronic respiratory diseases today. However, the diagnosis and treatment rates for these diseases remain relatively low. In 2023, the diagnosis and treatment rates for asthma, COPD, and allergic rhinitis in China were significantly lower than those in the United States.

These diseases not only impact a vast number of individuals, but they also encompass various sub-populations with distinct needs. For example, patients may experience differences in disease severity, which can lead to varying management strategies for those with acute disease onset compared to those requiring long-term care. Additionally, there is a significant unmet need, particularly among populations such as children, the elderly, and individuals with comorbid respiratory conditions. This diversity in symptom presentation and patient needs underscores the necessity for inhalation formulations that are tailored to address the unique requirements of different patient populations effectively.

Inhalation drugs are generally categorized based on the drug API and device. There are three major types of APIs used in inhalation therapies for the treatment of respiratory diseases. ICS are commonly employed to effectively reduce airway inflammation. LABA and SABA are bronchodilators that relax airway muscles, improving airflow. Additionally, LAMA and SAMA prevent bronchoconstriction by blocking acetylcholine receptors in the airways; LAMAs are particularly favored for their prolonged action, providing sustained bronchodilation. Recent advancements in pharmaceutical development have also led to the creation of inhalation formulation products that incorporate two APIs in combination. This shift allows for a more comprehensive approach to treatment, addressing multiple aspects of respiratory diseases simultaneously. For instance, combining an ICS with a LABA can deliver both anti-inflammatory and bronchodilator effects, resulting in enhanced symptom control and improved lung function.

Inhalation formulations also vary by device type. Each device offers distinct advantages necessary to address the complex interplay of patient physiology and disease characteristics. For example, DPIs are propellant-free, compact, and portable but require strong inhalation effort, making them more suitable for patients who can inhale quickly and deeply. On the other hand, nebulizers are easier to use with a power source, making them more suitable for young children and the elderly who may struggle with DPIs. For more details, see "Industry Overview — Inhalation Drugs for Respiratory Diseases."

Inhalation Nebulizer

A nebulizer is an inhalation formulation that is designed to administer medication in a mist form through a nebulizer device, normally in the form of suspension or solution. The suspension consists of small liquid droplets or particles of the medication that are aerosolized by the nebulizer, allowing for easy inhalation and absorption into the lungs. This method of delivery is especially beneficial for individuals who may have difficulty using inhalers or require higher doses of medication to manage their respiratory symptoms effectively.

CF017 — Budesonide Suspension for Inhalation

We obtained NMPA approval for CF017 in May 2021, marking our first product approval. Within one month of its approval, CF017 was included in the VBP list. In September 2021, we commenced its large-scale commercial sales in China. CF017 is an ICS nebulizer that excels in its pronounced anti-inflammatory properties, ensuring enhanced efficacy in managing respiratory conditions.

First developed by AstraZeneca, budesonide suspension was approved by the FDA in 2000 under the brand name "Pulmicort Respules." Since its approval, it has been recognized as the front-line treatment for the maintenance treatment of asthma and as prophylactic therapy in children aged between 12 months to 8 years. The market of budesonide inhaler globally reached US$2.4 billion in 2023 and is expected to reach US$2.8 billion by 2033, while that in China was RMB5.3 billion in 2023 and is expected to reach RMB6.9 billion by 2033. It is also the only ICS included in the WHO Model List of Essential Medicines for Children and has been recognized as a Category B drug under the FDA Pregnancy Category, indicating that it can be used routinely and safely during pregnancy in light of its promising safety profile.

We commenced the R&D of CF017 in 2014 and successfully concluded two clinical trials in 2019 and 2020, respectively. The clinical trials demonstrated that CF017 achieved bioequivalence compared to the original inhalation drug developed by AstraZeneca. The following image illustrates our CF017 product.

As of the Latest Practicable Date, there were eight approved budesonide suspension products in China, including the originator drug and seven domestically-developed drugs. Leveraging the VBP system in China, we were able to include our product in the first batch of VBP list for eight provinces in June 2021, shortly after our product approval. There are only four of such products in the VBP list to date, which affords us a market share of approximately 20% in 2023 in terms of sales volume according to F&S. Since then, we have penetrated over 10,000 hospitals and medical institutions. In addition, we are also offering our CF017 to other provinces through our distributors. In 2021, 2022, 2023 and the six months ended June 30, 2024, revenue generated from sales of our CF017 amounted to RMB29.8 million, RMB335.9 million, RMB547.8 million and RMB279.6 million, respectively. The following table summarizes the information of the marketed budesonide suspension for inhalation drugs in China as of the Latest Practicable Date.

Dosage Form	Manufacturer	First Approval Date	Indications	VBP
Nebulizer	AstraZeneca	2001-11-22	Asthma	/
	Jiangsu Chia Tai-tianqing Pharmaceutical	2020-02-25		√
	ShenZhen Taitai/JoinCare	2020-07-21		√
	Sichuan Purity	2021-04-13		√
	Our Company	**2021-05-11**		√
	Nanjing Licheng	2024-06-18		/

Source: F&S Report

The following table summarizes the sales volume and average selling price of CF017 during the Track Record Period.

	For the year ended December 31,						For the six months ended June 30,			
	2021		2022		2023		2023		2024	
	Sales Volume	Average Selling Price	Sales Volume	Average Selling Price	Sales Volume	Average Selling Price	Sales Volume	Average Selling Price	Sales Volume	Average Selling Price
	'000	*RMB*	*'000*	*RMB*	*'000*	*RMB*	*'000*	*RMB*	*'000*	*RMB*
CF017 . .	10,911.8	2.73	120,912.4	2.78	198,264.5	2.76	84,924.0	2.79	101,335.8	2.76

CF017 was included in the VBP list for eight provinces in 2021. The VBP list has an effective period of three years. As such, we are renegotiating with the relevant authorities with respect to the renewal of the VBP status for CF017. The current batch of VBP renewal is conducted at a regional level, where several provinces form an alliance and conduct the VBP together. Currently, our bid to renew CF017's VBP inclusion status has been accepted by the Jiangsu Alliance, which consists of 11 provinces. The minimum amount of CF017 to be subscribed by public hospitals in the provinces covered by the Jiangsu Alliance had not yet been finalized. We are also preparing for the VBP renewal bidding for other alliances and provinces, which are expected to commence by the end of 2024. For details, see "Risk Factors — Risks Relating to Our Business and Industry — We face uncertainties arising from the VBP scheme in China, which could adversely affect our market share and profitability."

CF036 — Salbutamol Sulfate Solution Nebulizer

We obtained the NMPA approval for CF036 in October 2021, making our first approved SABA product. As a SABA medication, salbutamol sulfate is primarily used to provide quick relief by relaxing the muscles in the airways and improving breathing.

First developed by GSK, the salbutamol sulfate solution nebulizer was approved by the FDA in 2015 under the brand name "Ventolin." It is commonly used to manage symptoms caused by bronchial asthma and chronic bronchospasm. Since its approval, it quickly became one of the most commonly prescribed bronchodilators worldwide.

We commenced the R&D of CF036 in 2018. In October 2021, we obtained the product registration approval from the NMPA for CF036. Since the last round of negotiation for inclusion in the VBP list was concluded in February 2021 before our product was approved, CF036 was not included in the VBP list. As such, we plan to commercialize our products through cross-selling opportunities and combination therapies with our CF017. The following image illustrates our CF036 product.

Currently our bid to include CF036 in the VBP list has been accepted by the Jiangsu Alliance. The minimum amount of CF036 to be subscribed by public hospitals in the provinces covered by the Jiangsu Alliance had not yet been finalized. We are also preparing for the VBP inclusion bidding for other alliances and provinces, which are expected to commence by the end of 2024. For details, see "Risk Factors — Risks Relating to Our Business and Industry — We face uncertainties arising from the VBP scheme in China, which could adversely affect our market share and profitability."

CF038 — Terbutaline Sulfate Solution Nebulizer

We obtained the NMPA approval for CF038 in September 2023, making it our second approved SABA product. Terbutaline sulfate is a selective SABA that can relax bronchial smooth muscles, inhibit the release of endogenous spasmogenic substances and endogenous neurotransmitter-induced edema, and improve the clearance ability of bronchial mucosa cilia. As such, terbutaline sulfate solution nebulizer is widely used to relieve bronchospasm associated with asthma, chronic bronchitis, emphysema and other pulmonary diseases. Initially introduced in 1985 as a branded product under the brand name "AZ Bricanyl," the terbutaline market has evolved to include numerous generic options, reflecting its widespread use and established efficacy.

We commenced the R&D of CF038 in 2019. In September 2023, we obtained the NDA approval from the NMPA for CF038. In China, the terbutaline sulfate nebulizer market currently features over 20 marketed products. Among these products, five have been included in the VBP list. Since this product has only been recently approved and considering the competition in China's terbutaline sulfate solution nebulizer market, we plan to commercialize our products through cross-selling opportunities and combination therapies with CF017. The following picture illustrates CF038.

GW006 — Arformoterol Solution Nebulizer

We obtained the FDA approval for GW006 in May 2024, making this our first approved product in the United States. GW006 is designed to provide targeted relief for patients suffering from COPD conditions. As a LABA, arformoterol offers potent bronchodilation and symptom management.

First developed by Sunnovion Pharmaceuticals, the arformoterol nebulizer product was approved by the FDA in 2006 under the brand name "Brovana." It can activate adenylate cyclase intracellularly, which catalyzes the conversion of ATP to cAMP and ultimately leads to the relaxation of airway muscles and inhibits the release of cytokines in mast cells.

Since obtaining its FDA approval, we have been evaluating the commercialization opportunities to formulate the most suitable commercialization strategies for our product in the United States. We also plan to commercialize our products in other emerging markets that recognize its FDA approval, such as Southeast Asia and Middle East.

CF022 — Formoterol Fumarate Solution Nebulizer

CF022 represents our first drug candidate utilizing formoterol fumarate as its API, laying a solid foundation for the development of our beclomethasone formoterol MDI aerosol candidate. Formoterol fumarate, a LABA bronchodilator, functions to relax the muscles within the airways, thereby enhancing breathing and alleviating symptoms like wheezing, coughing, and breathlessness. Clinical studies have highlighted that regular use of LABAs can assist patients in reducing both the frequency and intensity of symptoms associated with asthma and COPD.

First developed by Mylan, formoterol fumarate solution nebulizer was approved by the FDA in 2007 under the brand name "Perforomist." As of the Latest Practicable Date, there were nine approved formoterol fumarate solution nebulizers globally and nine in China as well. In addition, formoterol fumarate is also marked in other inhalation formats, including DPI and MDI.

We believe there are significant clinical advantages for formoterol fumarate solution nebulizers compared to other marketed systemic formulations. This inhalation format can provide a precise and consistent dosage with each use, ensuring accurate delivery of the medication. Further, the solution nebulizer is pre-dissolved, which can lead to a quicker onset of action. Observing these opportunities, we have developed CF022 for which we have completed a bioequivalence clinical trial and submitted a manufacturing license application in China.

CF044 — Revefenacin Solution Nebulizer

CF044 is the lead LAMA drug asset we develop. It has the potential to become one of the first inhaled drugs for COPD in China to adopt a once-daily dosing regimen. Revefenacin is a LAMA that can stimulate beta-2 adrenergic receptors in the airway smooth muscle, leading to bronchodilation and improved airflow, and is often used for long-term maintenance to control symptoms and improve lung functions, such as COPD. We are developing CF044 and have obtained its IND approval from the NMPA as of the Latest Practicable Date.

First developed by Mylan/Theravance, revefenacin was approved by the FDA in 2018 under the brand name "Yupelri." It remains the only approved drug to date.

Nasal Spray

A nasal spray is an inhalation formulation administered through a pressurized container that dispenses a fine mist or spray of medication into the nostrils. Nasal sprays can provide targeted delivery directly to the nasal passages, allowing for localized treatment for nasal symptoms without the need for systemic absorption. They are also convenient to use and can provide quick relief for nasal symptoms.

CF018 — Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray

We obtained NMPA approval for our CF018 in November 2022, marking our first approved nasal spray product and the only approved product of its kind apart from the originator drug in China, according to F&S. It is an inhaled combination drug that blends the antihistamine properties of azelastine hydrochloride with the anti-inflammatory effects of fluticasone. Azelastine blocks histamine receptors in the body, thereby reducing the effects of histamine, a substance produced by the immune system during an allergic reaction. Fluticasone is an ICS medication used to treat inflammatory conditions. This inhalation formulation offers a comprehensive approach to managing allergic rhinitis by addressing both histamine-related symptoms and nasal inflammation.

First developed by Meda Pharmaceuticals, azelastine hydrochloride and fluticasone propionate nasal spray was approved by the FDA in 2012 under the brand name "Dymista." It has demonstrated statistically and significantly greater decreases in both reflective total nasal symptom score and instantaneous total nasal symptom score compared to a single azelastine hydrochloride or fluticasone inhalation drug. In 2023, Meda Pharmaceuticals' Dymista recorded a global sales revenue of US$200 million.

We commenced the R&D of CF018 in January 2015. In January 2019, we launched its phase III clinical trial in China, which was a randomized, double-blind, positive drug-controlled trial with 679 subjects enrolled. During the clinical trial, our CF018 demonstrated bioequivalence compared to Meda Pharmaceuticals' Dymista. The following image illustrates CF018.

CF018 is the first and only approved product of its kind apart from the originator drug in China, according to F&S. Notably, our product was approved by the NMPA in November 2022, eight months before the originator drug was approved, by leveraging our deep technological expertise. As there are currently only two approved products in China, azelastine hydrochloride and fluticasone propionate nasal spray is not usually included in the VBP list. As such, during the first year after its approval, CF018 was primarily sold at outpatient pharmacies through our distributors since its approval. In December 2023, CF018 became the first and the only product of its kind included in the NRDL. As of the Latest Practicable Date, CF018 has penetrated over 500 hospitals and medical institutions, and recorded sales revenue of RMB7.1 million in the six months ended June 30, 2024. The following table summarizes the information of the approved azelastine hydrochloride and fluticasone propionate nasal spray drug in China as of the Latest Practicable Date.

Dosage Form	Manufacturer	First Approval Date	Indications	2023 Medical Insurance Status	VBP
Nasal Spray	**Our Company**	**2022-11-01**	Allergic rhinitis	List B since 2023	/
	Viatris/Meda Pharmaceuticals	2023-06-30			

The following table summarizes the sales volume and average selling price of CF018 during the Track Record Period. The decrease in its average selling price in the six months ended June 30, 2024 was primarily due to its inclusion in the NRDL since December 2023.

	For the year ended December 31,						For the six months ended June 30,			
	2021		2022		2023		2023		2024	
	Sales Volume	Average Selling Price	Sales Volume	Average Selling Price	Sales Volume	Average Selling Price	Sales Volume	Average Selling Price	Sales Volume	Average Selling Price
	'000	*RMB*	*'000*	*RMB*	*'000*	*RMB*	*'000*	*RMB*	*'000*	*RMB*
CF018 . .	–	–	1.3	310	4.3	310	3.1	310	97.8	72

CF024/CF045 — Mometasone Furoate Nasal Spray

CF024/CF045 is our first steroid nasal inhaler under clinical development in China. As an ICS medication, mometasone furoate can reduce inflammation in the nasal passages, and thereby significantly improve various nasal and ocular symptoms.

First developed by Merck Sharp & Dohme, the mometasone furoate nasal spray was approved by the FDA in 1997 for the treatment of allergic rhinitis under the brand name "Nasonex." As of the Latest Practicable Date, there were six approved mometasone furoate nasal spray products in the global market, four of which were nasal sprays. In the China market, there were three approved mometasone furoate nasal spray products in China, including the originator drug. Among these approved products in China, only one product has passed the bioequivalence tests. In addition, there were seven mometasone furoate nasal spray candidates at clinical stages in China as of the same date.

We have developed CF024/CF045 for the China market. We have completed subject enrollment for its clinical trial involving 640 subjects in China. We plan to submit its product registration to the NMPA in 2025.

CF010/CF052 — Budesonide Nasal Spray

In addition to our approved budesonide suspension nebulizer, we are also developing a budesonide nasal spray candidate, which is currently under pilot testing. Through its direct delivery to the nasal mucosa, nasal spray is more suitable for allergic rhinitis maintenance treatment. In addition, nasal sprays are easy to use and generally well-tolerated, thereby improving patient adherence.

MDI

An MDI is an inhalation formulation that can deliver medications through metered-dose inhalers. It offers a convenient and effective way to deliver the medication to the lungs, providing rapid relief and improving respiratory function.

CF006/CF043 — Salmeterol/Fluticasone MDI Aerosol

CF006/CF043, an inhaled combination drug, is our lead combination drug assets under clinical development. Salmeterol is an LABA that works by relaxing the muscles in the airways, making it easier to breathe. Fluticasone is an ICS that can reduce inflammation in the airways, helping to decrease symptoms such as wheezing, shortness of breath and coughing.

First developed by GSK, the salmeterol fluticasone combination drug was approved by the FDA in 1999 under the brand name "Seretide" and has since become the current front-line combination drug for both bronchial asthma and COPD. This drug has been the third highest selling inhalation drug in China and fourth highest globally in 2023. As of the Latest Practicable Date, there were only two approved salmeterol fluticasone combination drugs in China, with GSK's Seretide being the only approved MDI product in China.

We are currently developing CF006/CF043, making us the only developer with a salmeterol/fluticasone MDI aerosol candidate under the clinical stage in China, according to F&S. Compared to DPIs, MDI aerosols do not require external force for activation, offering a simpler mechanism of delivery. They possess several advantages, including being fast-acting, accurately dosed, and relatively easy to maintain cleanliness. These characteristics make MDI aerosols particularly suitable for patients with compromised inhalation function or severe limitations in device use. As of the Latest Practicable Date, we have completed its registration clinical trial in China involving 470 subjects. We are in the process of preparing its production registration application in China, which is expected to be submitted to the NMPA in 2025.

GW009/CF064 — Beclomethasone Formoterol MDI Aerosol

GW009/CF064 is our key combination drug candidate consisting of both ICS (beclomethasone) and LABA (formoterol), which is developed solely for the European market. Beclomethasone, an ICS, functions locally to diminish inflammation in the airways, whereas formoterol, a LABA, aids in widening the bronchioles, thus facilitating improved breathing. Notably, the two APIs utilized in this candidate are in small particle form, enabling them to reach both the large and small airways concurrently. This design not only boosts the drug's bioavailability but also enhances its clinical effectiveness.

First developed by Chiesi Air, the beclomethasone formoterol combination inhalation drug was approved by the FDA in 2006 under the brand name "Fostair." As of the Latest Practicable Date, there were eight beclomethasone/formoterol MDI products approved globally, including Chiesi Air's Fostair and its generic drugs.

We believe there are significant market opportunities in Europe for beclomethasone formoterol inhalation MDI aerosol and we are developing a beclomethasone formoterol inhalation MDI aerosol product for the European market, which is currently under pilot testing.

GW015/CF049 — Beclometasone MDI Aerosol

GW015/CF049 is an inhaled drug consisting of beclometasone, an ICS, as its API. Beclometasone functions by reducing inflammation and suppressing the body's immune response, thereby alleviating symptoms associated with asthma. First developed by TEVA, the beclometasone MDI aerosol was approved by the FDA in 2012.

Currently, we are conducting pilot testing for GW015/CF049, which is primarily designed for the UK market.

DPI

DPI is an inhalation formulation used to deliver medication to the lungs in a powdered form for the treatment of respiratory conditions. DPIs are designed to convert pharmaceutical powders into an aerosol that can be inhaled directly into the lungs. Unlike MDIs, DPIs do not require coordination between actuation and inhalation, making them easier to use for many patients who may have difficulty with the coordination required for MDIs.

GW008 — Tiotropium Bromide DPI

Leveraging our abundant technologies in developing inhalation formulations in different formats, we are also developing a tiotropium bromide DPI candidate. In November 2018, GW008 was acknowledged as a "National Innovative Drug Development Project" by the NHC. The project was subsequently completed in November 2021.

As of the Latest Practicable Date, apart from the originator drug, developed by BI and marketed under the brand name "Spiriva," there were three approved tiotropium bromide DPI products in China, none of which had completed a bioequivalence test. We plan to initiate its pharmacokinetics and pharmacodynamics bioequivalence tests for GW008 in 2025 in China, which we believe will enable us to enjoy competitive advantages during negotiations for government medical reimbursement or procurement schemes in the future under the current regulatory regime. In addition, we are also conducting pre-clinical studies testing for this candidate in Europe and the United States, respectively.

CF028 — Glycopyrronium Bromide DPI

CF028 is our first LAMA drug in DPI format under development. Glycopyrronium bromide is a LAMA that can act as a bronchodilator by blocking the action of acetylcholine on muscarinic receptors in the airways. As such, glycopyrronium bromide can help improve lung function, reduce symptoms such as shortness of breath and cough, and enhance the overall quality of life for patients with COPD.

First developed by Novartis, the glycopyrronium bromide DPI product was approved by the FDA in 2015 under the brand name "Seebri Breezhaler." It was the only approved glycopyrronium bromide drug in China as of the Latest Practicable Date. In addition, there were eight glycopyrronium bromide DPI candidates under clinical development in China.

We are developing CF028 for the European market, which is currently under pilot testing.

CF037 — Indacaterol Maleate and Glycopyrronium Bromide DPI

CF037 is our first LABA and LAMA combination drug under clinical development. Studies have indicated that this LABA and LAMA combination is the only dual bronchodilator that has demonstrated clinical advantages over both LAMA/ICS and LABA/ICS combinations across multiple clinical parameters. It can effectively improve lung function, reduce the frequency of acute exacerbations, alleviate dyspnea and other symptoms, and significantly enhance the overall quality of life for patients. As such, this LABA and LAMA combination treatment has been recommended by various clinical guidelines and expert consensus, including the 2023 Global Initiative for Chronic Obstructive Lung Disease and the 2021 PRC COPD Clinical Guideline. We are conducting pilot testing for CF037, which is designed for both China and the European market.

First developed by Novartis, the indacaterol maleate and glycopyrronium bromide DPI candidate was approved by the FDA in 2013 under the brand names "Ultibro Breezhaler" and "Xoterna Breezhaler." As of the Latest Practicable Date, it remained to be the only approved drug of its kind globally. In addition, there were eight indacaterol maleate and glycopyrronium bromide candidates at clinical stage in China and Europe as of the same date.

SMI

A SMI is an inhalation formulation that can deliver medication to the lungs in the form of a soft mist spray. It provides a slow-moving, gentle mist of medication that remains in the air longer compared to traditional MDIs, allowing for improved drug delivery to the lungs. SMIs are designed to be user-friendly, making them suitable for patients who may have difficulty using other types of inhalers, such as those with limited hand strength or coordination issues.

GW013 — Tiotropium Bromide SMI

GW013 is our first and lead LAMA drug candidate under clinical development. As a LAMA medication, tiotropium bromide offers sustained relief by providing smooth muscle relaxation in the lungs, thereby enhancing airflow and easing breathing difficulties. In particular, it is a long-acting anticholinergic bronchodilator and can support a once-daily dosing regimen, thereby ensuring convenient and consistent symptom control for COPD patients.

First developed by BI, the tiotropium bromide inhalation drug was approved by the FDA in 2004 under the brand name "Spiriva" and has since become the first-line drug for the treatment of COPD. It was the third best-selling inhalation drug product in the global market in 2023. As of the Latest Practicable Date, although there were nine marketed tiotropium bromide products globally, BI's Spiriva was the only SMI product in the United States and Europe, and had not yet been approved in China. As of the same date, there was only one tiotropium bromide SMI candidate under clinical development globally.

Compared to DPI products, SMI products have several clinical advantages. It is generally easier to use for individuals with limited dexterity or coordination issues. It is more compact and convenient for carrying around, making them more suitable for on-the-go use. Further, the particle size of DPI formulations may vary, potentially affecting the deposition of the drug in the lungs. In contrast, SMI formulations can produce particles with more consistent and stable sizes. We are currently in the process of developing GW013 for both the Chinese and U.S. markets. Notably, GW013 incorporates a unique device design that is protected by our proprietary patents. Currently, we are engaged in small-scale testing for GW013.

CF050 — Tiotropium Bromide and Olodaterol Hydrochloride SMI

We are also developing CF050. It is an inhaled combination drug consisting of both tiotropium bromide, a LAMA and olodaterol hydrochloride, a LABA. The combination of these two APIs in an SMI candidate can offer dual bronchodilation for patients with COPD, leading to improved symptom management and enhanced control over COPD-related symptoms.

First developed by BI, the tiotropium bromide and olodaterol hydrochloride SMI product was approved by the FDA in 2015 under the brand names "Inspiolto Respimat" and "Spiolto." As of the Latest Practicable Date, it was the only approved tiotropium bromide and olodaterol hydrochloride SMI product globally.

We are currently conducting small-scale testing for CF050, which is designed for both the China and the United States markets.

Innovative Product Pipeline

Beyond our first phase of inhalation products, we are also driving innovation in the inhalation formulation field. Leveraging our extensive insights and experience, we are dedicated to pushing the boundaries of formulation applications, details of which are summarized as follows.

Treatment Methodology Innovation

CFQX001 — Interventional Medical Device

Emphysema, an advanced form of COPD, is a progressive, debilitating disease characterized by irreversible destruction of alveolar tissue, which normally results in reduced elastic recoil, progressive lung hyperinflation and gas trapping. In 2023, there were around 100 million patients globally suffering from emphysema. EBV interventional medical devices have recently emerged as a new treatment option for emphysema patients. EBV offers significant advantages over standard medical treatments, including improved survival rates, enhanced lung function, better quality of life, and increased exercise capacity. In 2018, Pulmonx's Zephyr valve system was approved by the FDA, becoming the first EBV interventional medical device approved for emphysema. The global market for EBV treatment is substantial, with an estimated 40,000 patients having been treated with Zephyr valves alone as of 2023. As of the Latest Practicable Date, there were two approved EBV devices globally. We are currently developing CFQX001 targeting emphysema. As of the Latest Practicable Date, we have obtained ethical review approval from the trial sites for its clinical trials in China.

New Respiratory Disease Indications

IC004 IPF Inhalation Drug

Fibrosis is a progressive and degenerative condition in human organs where normal tissues become scarred over time and loses its physiological function. Fibrosis can result from multiple pathologic processes, many aspects of which are poorly understood at cellular and molecular levels, which has made developing drugs targeting fibrosis very challenging. IPF is a specific form of chronic, progressive fibrosing interstitial pneumonia of unknown cause, which primarily occurs in older adults. Given its unpredictable but progressive evolution, the prognosis of IPF remains generally poor, with a five-year survival rate estimated at around 20%, even lower than those observed in certain types of cancer. According to F&S, IPF is one of the most common rare diseases, with approximately 596.6 thousand new cases recorded globally in 2023.

Currently, there are only two drugs approved for IPF in the US and China, namely pirfenidone and nintedanib, each being an oral medication. Both drugs are poorly tolerated with side effects, such as GI intolerance, phototoxicity and liver toxicity, which could lead to discontinuation of the treatment. Observing the significant market need for an IPF drug with

an enhanced safety profile, we are conducting pre-clinical studies for an IPF inhalation drug candidate. As an inhalation drug will directly deliver the APIs to the lungs, we believe our IC004 has significant advantages in terms of side effects as compared to currently approved IPF drugs.

IC002 and IC001 — PAH Inhalation Drugs

PAH is a type of high blood pressure that affects the arteries in the lungs. PAH is a serious and progressive condition that can be idiopathic or associated with other conditions. In 2023, the number of PAH patients in China reached approximately 85.3 thousand, and is expected to increase to 97.9 thousand in 2033, driven primarily by the aging population. Current treatment for PAH primarily focuses on symptom management to slow the progression of the disease and improve quality of life. As of the Latest Practicable Date, there were four approved PAH inhalation drugs globally, one of which was approved in China. Compared to other PAH drugs, inhalation drugs can provide targeted delivery and rapid onset of action with reduced systemic side effects. Observing the opportunities for PAH inhalation drugs, we are developing IC002 and IC001, two PAH inhalation drugs, which are currently under small-scale testing.

Therapeutic Pathway

In recent years, the nose-to-brain pathway has become a new frontier for inhalation formulations. This approach involves the direct transport of substances from the nasal cavity to the brain, effectively bypassing the blood-brain barrier. It enhances drug targeting and efficacy, making it particularly beneficial for treating various neurological and other conditions. Additionally, this pathway can potentially reduce systemic side effects and improve patient compliance compared to traditional delivery methods.

Central Nervous System Drug Candidates

CNS disorders are the leading cause of disease globally and are currently experiencing increasing prevalence, primarily attributable to population growth, prolonged lifespans and the COVID-19 pandemic. According to F&S, CNS disorders currently affect billions of people globally, including an estimated 1.2 billion people with migraine and 61.2 million with epilepsy.

In recent years, various studies have indicated that inhalation formulations also have the potential to be used to deliver drugs to the CNS. This route offers several advantages for drug delivery. For example, inhalation formulations can circumvent major pharmacokinetic obstacles typically associated with oral CNS drug delivery, including gastrointestinal/pH and enzymes, delayed/variable absorption, first-pass hepatic drug metabolism, serum-associated degradation, kidney filtration and the blood-brain barrier. Further, the nasal epithelium provides an optimal absorption surface for drug delivery due to its high permeability, leaky intercellular junctional complexes and extensive vascularization. In addition, the inhalation route is non-invasive, easy to self-administer and may be more acceptable for patients with

movement disorders. According to F&S, the global inhalation formulation drug market for CNS disorders reached US$2.8 billion in 2023, and is expected to increase to US$6.6 billion in 2033 at a CAGR of 9.0% from 2023 to 2033.

Observing the potential for inhalation formulation for CNS disorders, we are developing a calcitonin gene-related peptide (CGRP) receptor antagonist nasal spray for the acute treatment of migraine headaches namely CF070. In addition, we are also developing a diazepam nasal spray for acute treatment of seizure clusters, namely our CF069. As nasal sprays, our CNS inhalation formulation drug candidates can bypass the slower gastrointestinal absorption of the oral drugs, provide rapid relief and are easier and more convenient to administer.

CF056 — Dry Eye Syndrome Drug

We are also developing CF056 for dry eye syndrome, which is currently under small-scale testing. By stimulating the trigeminal nerve in the nasal cavity, these sprays can enhance natural tear production, providing relief without the need for topical eye drops. This method not only improves patient compliance but also targets the underlying causes of tear film instability, offering a promising alternative for those suffering from dry eye symptoms. As of the Latest Practicable Date, there was only one approved inhalation formulation drug treating dry eye syndrome globally.

Delivery Technology Innovation

CP029/CP030 — SiRNA Inhalation Drugs

We are developing siRNA molecules as novel delivery technology for our inhalation formulation products. RNAi technology can potentially redefine the treatment landscape for chronic respiratory diseases, with the ability to target genes or pathways that underlie the disease, in contrast to most existing treatments that only treat the symptoms. By addressing disease-causing mechanisms, siRNA therapy could modify the course of disease and achieve more sustained disease control. To date, there are no approved siRNA inhalation drugs globally. We are currently exploring opportunities to adopt siRNA technologies in our inhalation drugs for the treatment of chronic respiratory diseases.

Formulation Innovation

CF047 — Amikacin Liposome Suspension

CF047 is an inhaled drug candidate for the treatment of MAC lung disease. MAC lung disease is a type of non-tuberculous mycobacterial infection that affects the lungs, which typically affects individuals with underlying lung conditions such as bronchiectasis, COPD or previous lung damage. While antibiotics are the first-line treatment for MAC lung disease, they require prolonged use of 12 to 18 months and therefore can lead to resistance and low treatment compliance. Moreover, there may be higher risk of DDIs, especially in the elderly population.

Amikacin has a differentiated mechanism of action; however, the injection formulation can cause severe side effects such as kidney damage and is inconvenient given the regular injections needed. By encapsulating amikacin in a liposome, amikacin can be directly delivered to the lungs, thereby enhancing efficacy and minimizing systemic side effects. We are currently conducting pilot testing for our CF047 candidate.

Consumer Health Products

During the Track Record Period, we also developed and generated revenue from sales of several consumer health products. Our consumer health products primarily include nasal cleaner sprays and solutions and eye atomizers, among others. Revenue generated from sales of these consumer health products amounted to RMB7.6 million, RMB9.6 million, RMB3.7 million and RMB0.8 million in 2021, 2022, 2023 and the six months ended June 30, 2024, respectively, representing 18.1%, 2.8%, 0.7% and 0.3% of our revenue for the same period.

Technical Services

Leveraging our robust inhalation formulation capability platforms, we also from time to time provide R&D and manufacturing services for inhalation formulation products. Revenue generated from technical services amounted to RMB4.5 million, RMB3.1 million, RMB3.2 million and RMB1.1 million, representing 10.8%, 0.9%, 0.6% and 0.4% of our revenue in 2021, 2022, 2023 and the six months ended June 30, 2024, respectively.

RESEARCH AND DEVELOPMENT

R&D is crucial for our continuous success. As of June 30, 2024, we had over 160 employees responsible for our R&D activities, with over 90% holding bachelor's degrees or above in biology or related fields. Our R&D team is led by a number of distinguished scientists with extensive experience in inhalation formulation drug development, including our co-founder, chairperson of Board and chief executive officer, Dr. LIANG who has over 16 years of experience in supervising the development programs of both generic and new inhalation drugs and our co-founder and chief scientific officer, Dr. LI LI BOVET, who has over 30 years of experience in respiratory drug development and has led the development of several approved inhalation formulation products; Dr. Jean-Marc Bovet, who has over 20 years of experience in pharmaceutical R&D and has led the development of our manufacturing process and Dr. Qi Li, who has over 25 years of pharmaceutical development expertise, including having successfully obtained FDA approvals for six inhalation products as well as NDAs for both improved and generic drugs in the U.S. and European markets.

We have established an R&D center at our headquarters, which includes several key departments: the inhalation drug development center, technology service center, technology development department, and innovation department. Our inhalation drug development center serves as our primary R&D hub, further divided by formulation type. The technology service center is responsible for our collaborations and technical services, as well as innovative drug projects. The technology development department focuses on developing inhalation devices

suitable for our products, while the innovation department is tasked with developing novel compounds for use in our products. Our R&D expenses amounted to RMB98.8 million, RMB107.2 million, RMB132.8 million and RMB60.9 million for 2021, 2022, 2023 and the six months ended June 30, 2024, respectively. In addition, we recognized capitalized R&D costs as additional deferred development costs of RMB23.6 million, RMB16.1 million, RMB26.7 million and RMB13.5 million, respectively. As such, our total R&D costs in 2021, 2022, 2023 and the six months ended June 30, 2024 amounted to RMB122.4 million, RMB123.3 million, RMB159.5 million and RMB74.4 million, respectively.

Generally, the development of an inhalation formulation product involves the following stages:

- ***Project initiation.*** We actively follow the latest technological developments in the APIs used in inhalation formulations, particularly inhaled combination drugs, which we believe have greater commercial potential. Leveraging our ability to develop and manufacture all formats of inhalation formulations, we are confident in our capacity to select the most suitable formats for each product candidate based on the characteristics of the API and the target population group.

- ***Pre-clinical studies.*** Our pre-clinical studies typically involve four stages. First, we conduct small-scale testing, during which we primarily focus on optimizing the formulation and the manufacturing process. Next, we carry out pilot testing that focus on scalable manufacturing testing and verification. Afterwards, we conduct various assessments to evaluate the stability and consistency of our product candidate. Finally, we perform *in vitro* bioequivalence tests to simulate the clinical and safety profile of our product candidate. As of the Latest Practicable Date, we also had approximately 20 other early-stage inhalation formulation R&D projects, in addition to our products and product candidates set forth above.

- ***Clinical trial.*** In most cases, we are required to conduct clinical trials to evaluate the profile of our product candidates in human subjects. We normally select PIs and trial sites that have experience in clinical trials of similar products or are familiar with inhalation formulations. In addition, from time to time, we also engage CROs to assist us with certain ancillary tasks in relation to our clinical trials. During the Track Record Period and up to the Latest Practicable Date, we did not have any material disagreements or disputes with the PIs or trial sites in relation to the development and clinical trials of our product candidates.

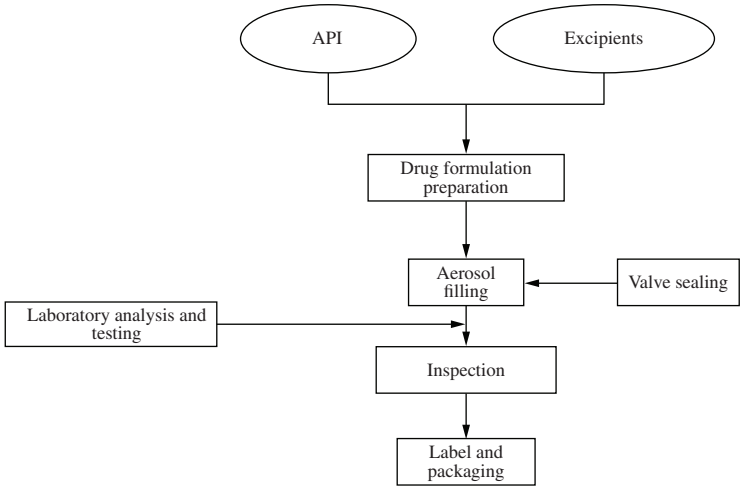
- ***Product registration.*** If the PI determines that the product candidate has met its primary endpoints in the clinical trial, we will initiate the product registration process. Leveraging our extensive regulatory affairs experience with the NMPA, EMA, and FDA, we believe we can complete the process efficiently. For our products that do not require a clinical trial, we will submit product registration if our in-house R&D team concludes that it has met the criteria for product registration in the target market.

MANUFACTURING

Production Process

As a company with a comprehensive inhalation formulation portfolio covering all existing formats, we believe that maintaining scalable manufacturing while ensuring product quality at relatively low costs is crucial for our future growth. We have developed proprietary manufacturing techniques for each major format of inhalation formulation to enhance our manufacturing efficiency and established scalable manufacturing capability. The following diagrams illustrate the production process for our major inhalation formulation.

MDI

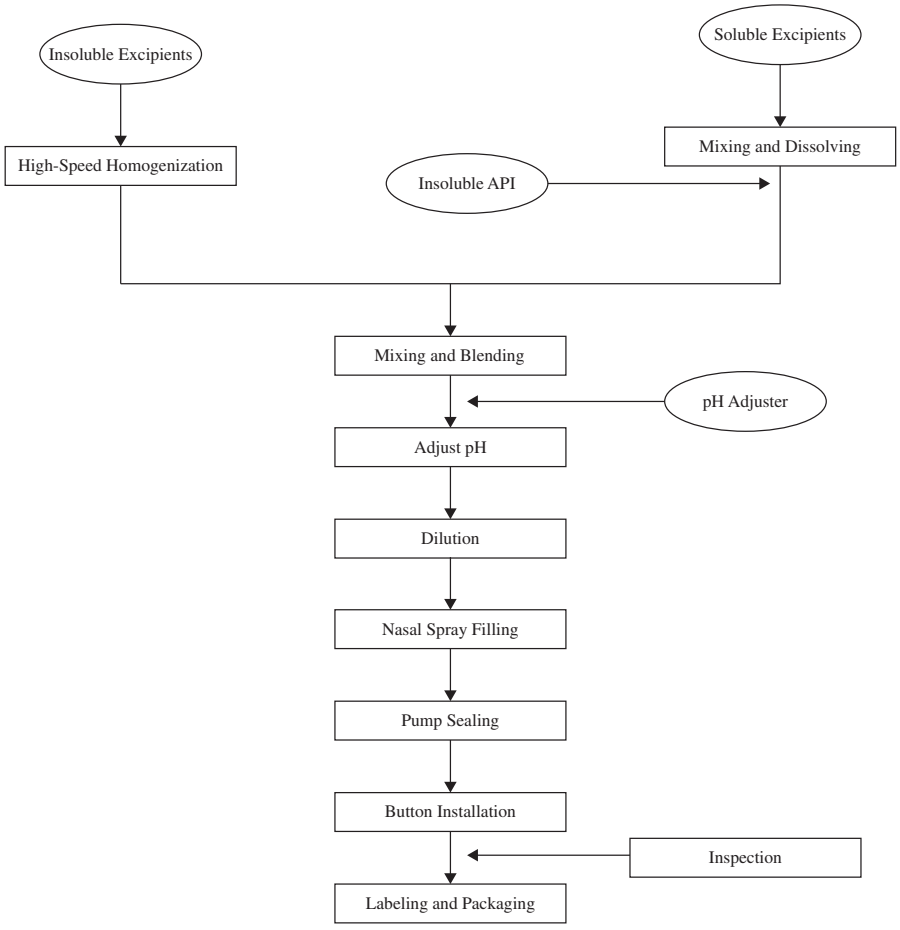


For MDI products, the major manufacturing challenge is maintaining particle stability and consistency in terms of size distribution, morphology, and characteristics of the API throughout the entire manufacturing process. Leveraging our particle engineering characterization technology, we have developed proprietary methods to achieve stable and scalable manufacturing.

Nebulizer

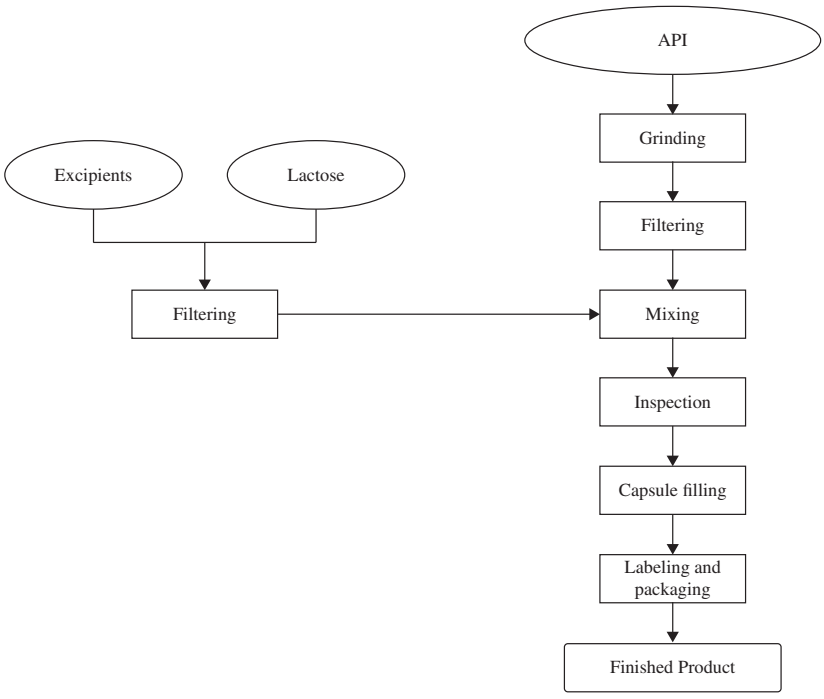
For nebulizers, the key manufacturing challenge is maintaining particle stability in terms of distribution and size during the sterilization process. Leveraging our particle engineering characterization technology and *in vitro-in vivo* correlation study technology, we have successfully maintained stable particles regarding distribution and size, as well as bioequivalence between *in vitro* and *in vivo* studies.

Nasal Spray



For nasal sprays, in addition to maintaining particle stability, the manufacturing process requires the addition of a suspension aid, which imposes greater demands on the sequence of material addition. Utilizing our proprietary inhalation formulation technologies, we have been able to maintain consistent particle stability throughout the manufacturing process.

DPI



The manufacturing of DPI products involves a combination of drug and devices. In addition to maintaining particle stability, it is also important to design and develop a suitable delivery device. We have successfully designed and developed our proprietary delivery device for our powder inhalation formulation products, which we believe is well-suited for the APIs we use and can enhance the stability of our powder inhalation products.

Manufacturing Facilities

We manufacture our products at our facilities in Suzhou, Jiangsu province. Our manufacturing facilities have a total GFA of 8,163 square meters. Currently, our manufacturing facility can support the manufacturing of 220.6 million vials of suspension nebulizers, 50 million vials of solution nebulizers, 4 million canisters of nasal sprays, 2 million canisters of MDI products and 24 million doses of DPI products per year. As of June 30, 2024, 61.4% of the total GFA has come into use, and we have a manufacturing team of 136 employees. In addition, we are expanding our manufacturing capabilities through a two-phase construction project. Phase I, scheduled for completion by the end of 2025, will primarily focus on soft mist inhaler (SMI) and nasal spray products. The first part of Phase II, expected to be operational by the end of 2026, will be dedicated to MDI and liposome products. Following these expansions, our manufacturing facilities will be able to support the manufacturing of 575 million vials of nebulizers in suspension or solution forms, 19 million canisters of nasal sprays, 14 million canisters of MDI products, 24 million doses of DPI products and 600 thousand liposome products per year.

Our manufacturing machinery and equipment primarily includes laser particle size analyzers, spray pattern and plume geometry analysis instruments, multi-stage cascade impactors, breath simulators, high-precision flow meters, critical flow controllers, and high-flow vacuum pumps, among others. We currently own all the equipment used in our manufacturing process. We perform routine and preventative maintenance on our machinery and equipment to ensure their proper functioning. During the Track Record Period and up to the Latest Practicable Date, we have not experienced any material interruptions to our production process due to machine or equipment failure.

Production Capacity

We have built scalable manufacturing capabilities for all the inhalation formulation formats that we are developing, allowing us to transform our R&D assets to successful commercial products. Considering that 71.1%, 96.2%, 98.4% and 96.8% of our revenue is generated from sales of CF017, our manufacturing line was primarily used for suspension nebulizer products, while the production lines for other inhalation formulation formats were primarily used to support our R&D activities on a by-batch and as-needed basis. The following table sets forth the production capacity, actual production volume and utilization rate for our suspension nebulizers for the period indicated.

	As of/For the year ended December 31,									As of/For the six months ended June 30,		
	2021			2022			2023			2024		
Inhalation Formulation Product	**Production capacity[1]**	**Production volume**	**Utilization rate[2]**	**Production capacity[1]**	**Production volume**	**Utilization rate[2]**	**Production capacity[1]**	**Production volume**	**Utilization rate[2]**	**Production capacity[1]**	**Production volume**	**Utilization rate[2]**
	000'	*000'*	*(%)*	*000'*	*000'*	*(%)*	*000'*	*000'*	*(%)*	*000'*	*000'*	*(%)*
Suspension nebulizer . . .	24,900	13,168	52.9%	175,600	140,849	80.2%	190,680	182,960	95.9%	110,340	106,358	96.4%

Notes:

(1) The production capacity refers the maximum doses of inhalation formulations we can produce assuming our manufacturing facilities are in operation for 25 days per month and 24 hours per day, taking into account the efficiency of our manufacturing equipment.

(2) The utilization rate is calculated by dividing production volume by designed production capacity.

COMMERCIALIZATION

Sales Model

During the Track Record Period, we primarily adopted a distribution model to commercialize our products, particularly our inhalation formulation products. To a lesser extent, we also generate revenue from direct sales of our consumer health products through e-commerce platforms. According to F&S, the adoption of a distribution model is in line with the industry norm in China.

The following table summarizes the breakdown of our revenue from sales of products by sales channels.

	For the year Ended December 31,						For the Six Months Ended June 30,	
	2021		2022		2023		2024	
	RMB'000	*%*	*RMB'000*	*%*	*RMB'000*	*%*	*RMB'000*	*%*
Distributors	35,020	93.5	341,933	98.8	550,432	99.5	286,854	99.8
Direct sales	2,423	6.5	4,060	1.2	2,799	0.5	684	0.2
Total revenue from sales of products	**37,443**	**100.0**	**345,993**	**100.0**	**553,231**	**100.0**	**287,539**	**100.0**

Movement of Distributors

We adopt a distribution model primarily because this enables us to efficiently deepen our market penetration in a cost-effective manner. We have a seller-buyer relationship with our distributors. As of December 31, 2021, 2022, 2023 and the six months ended June 30, 2024, we engaged 69, 76, 79 and 88 distributors, respectively. As of June 30, 2024, our distribution network spun over 20 provinces in China. Most of our distributors provide end-to-end delivery of our products to hospitals and pharmacies. The following table sets forth the total numbers of our distributors to whom we directly sold our products and their movement during the Track Record Period.

	For the year ended December 31,			For the six months ended June 30,
	2021	2022	2023	2024
Number of distributors at the beginning of the period	2	69	76	79
Number of new distributors during the period	67	30	14	29
Number of discontinued distributors during the period	–	23	11	20
Number of distributors at the end of the period	69	76	79	88

In 2022, we discontinued 23 distributors, primarily because we terminated certain distributors under the VBP channels in the provinces in which we intended to include our CF017 in the VBP list but failed in the negotiation in 2021. In 2023 and the six months ended June 30, 2024, we discontinued 11 and 20 distributors primarily because we continuously consolidated our distributor channels under the non-VBP channels to optimize our sales network.

Distributor Management

We primarily select our distributors based on various criteria, including their scale and geographical coverage, capabilities in pharmaceutical procurement bidding, experience with inhalation formulation products, reputation, industry track record, delivery capabilities, compliance record, financial conditions, and creditworthiness.

We primarily rely on the distribution agreements, policies, and measures we have in place to manage our distributors, ensuring that our sales to them reflect genuine market demand and their compliance with the terms and conditions of the distribution agreement. If we identify any potential non-compliance issues with a distributor, we address these issues with the relevant distributor and require them to rectify the situation within a specified period. If the non-compliance is not resolved within that timeframe, we are entitled to terminate the distribution agreement.

During the Track Record Period, to the best of our Directors' knowledge, all of our distributors were Independent Third Parties, and none were controlled by our current or former employees. None of our Directors or their respective associates or any shareholder of our Company who, to the knowledge of our Directors, owns more than 5% of the issued share capital of our Company, have any interest in any of these distributors, and none of our Directors or their respective associates and our Single Largest Group of Shareholders have any present or past relationship (other than their relationship through our Group) with any of these distributors. In addition, to our best knowledge, there was no past or present relationship or arrangement, including family, business, financing, guarantee or otherwise, between us and our distributors during the Track Record Period.

Terms of Distribution Agreement

Key terms of our distribution agreement are summarized as follows:

- **Authorization and territory.** The agreement grants the distributor authorized rights to distribute products within a specified territory.

- **Term.** Our distribution agreements normally have a term of one year.

- **Sales targets and pricing.** The agreement sets sales targets, and we may provide price discounts for distributors that meet or exceed sales targets.

- **Payment and delivery.** Payment terms require advance payments prior to shipment. After receiving the distributor's order and payment, we will deliver the goods and are responsible for transportation and costs. For certain key distributors, we may grant a credit term of 60 to 90 days.

- **Responsibility.** Currently, our distributors are primarily responsible for delivery of our products and do not carry out substantial sales and marketing activities.

- **Returns and exchanges.** Our products are not eligible for returns unless there are defects or failure to delivery.

- **Anti-bribery and anti-corruption.** Both parties are committed to adhering to anti-bribery and anti-corruption laws, ensuring ethical business practices throughout the distribution process.

Prevention of Cannibalization and Channel Stuffing

We have adopted the following measures to actively monitor inventory accumulation and usage by end-customers of our products.

- **Regular spot check and communication.** We regularly conduct spot checks on the warehouse operated by our distributor to ensure the accuracy of their sales and inventory statistics. In addition, we regularly communicate with our distributors to monitor their inventory levels of our products in the distribution channel to avoid shortages or abnormal inventory build-up.

- **Short credit term.** We normally require our distributors to make full payment prior to shipment and we only grant a short credit term of 60 to 90 days for a limited number of distributors that we consider crucial to our business.

- **Distribution restrictions.** Our distribution agreements specifically set out geographic regions where we authorize each regional distributor to sell our products and they are not allowed to sell our products in other regions.

- **Minimal product returns.** Under our distribution agreement, we only allow our distributors to return our products if there are product defects or failure to delivery. In each of 2021, 2022, 2023 and the six months ended June 30, 2024, sales returns only account for 0.12%, 0.02%, 0.06% and 0.01% of our revenue from sales of products through distributors for the corresponding periods, respectively.

In normal cases, our distributors are required to maintain an inventory level of less than two months. As we normally require our distributors to make full payment prior to shipment, we believe our distributors are incentivized to place orders based on the actual market demand. Further, we conduct audit from time to time to ensure that the inventories of our distributors are in line with their expected sales.

Impact of the two-invoice system

Since early 2017, the two-invoice system has been gradually implemented across China. The two-invoice system permits a maximum of two invoices along the sales chain from a pharmaceutical manufacturer to a public medical institution in China. It currently applies to the sales of all pharmaceuticals to public medical institutions in all provinces, municipalities and autonomous regions in China. See "Regulatory Overview — Other Laws and Regulations In Relation To Medical Industry — Two Invoice System." In accordance with the two-invoice system, we only have one-layer of regional distributors for our inhalation formulation products sold to hospitals and public medical institutions in the provinces that our products were included in the VBP list.

For our products sold to non-VBP channels, for example, pharmacies and private medical institutions, the "two-invoice" system does not prohibit us from using sub-distributors. Accordingly, we do not prohibit these distributors to engage sub-distributors. Our distributors are primarily responsible for monitoring the performance of the sub-distributors they engage. Although we do not directly enter into distribution agreement with our sub-distributors, we regularly monitor the performance of our distributors and sub-distributors and collect feedback from end-customers to ensure that these sub-distributors comply with the terms of the distribution agreement. We may require our distributors to terminate the sub-distributor if any material breach of the distribution agreement is identified. As advised by F&S, such practice is generally in line with industry norm.

Marketing

We adopt an academic approach in marketing our products, particularly our inhalation formulation products. Our in-house sales and marketing team is responsible for implementing our academic promotion activities, including participating in industry conferences, conducting market analysis and visiting end hospitals. Our academic promotion activities primarily focus on introducing the advantages of inhalation formulations in treating patients with respiratory diseases and the unique design and advantages of our inhalation formulation products.

In 2021, 2022, 2023 and the six months ended June 30, 2024, we engaged 11, 14, 14 and 15 third-party promoters. Their responsibilities primarily included gathering industry and product information, and organizing professional academic activities to communicate the pharmacological mechanisms and clinical efficacy of our products. They also worked closely with healthcare professionals, collected feedback on clinical usage and hospital demand, increased our product coverage in key regions, and provided valuable commercial channel support and insights. In 2021, 2022, 2023 and the six months ended June 30, 2024, we incurred RMB20.1 million, RMB95.8 million, RMB169.6 million and RMB88.6 million in business development expenses, primarily including service fees we paid to third party promoters.

PRICING

For our marketed products, we have formulated a competitive pricing strategy, which takes into account various factors such as our R&D, manufacturing and marketing costs and expenses, competitive landscape and our market share. In addition, our pricing strategies are also affected by the regulations in China's pharmaceutical industry, in particular the VBP list and the NRDL.

Volume-Based Procurement (VBP)

In November 2018, the PRC government launched the centralized drug procurement pilot scheme for tendering a limited number of pharmaceutical products with large procurement quantities in 11 cities in China. Subsequently, it expanded the number of drugs and geographic coverage under this scheme. Under the currently applicable PRC regulations, in principle, only originator-branded drugs or reference drugs for the Consistency of Quality and Efficacy Evaluation for Generic Drugs (GQCE), along with generic drugs that have passed the GQCE, are eligible to participate in the centralized drug procurement scheme. Only in cases where there are at least three eligible participants for the selected chemical name of a drug, a centralized tender process for the VBP list will be adopted in the procurement process. For details, see "Regulatory Overview — Other Laws and Regulations In Relation To Medical Industry — Volume-based Procurement Scheme and Bidding Process."

The VBP list only applies to drugs selected in the centralized drug procurement catalog (集採目錄). Typically, a bidding process is conducted for each category of drugs, and only the successful bidder in the process will be chosen for inclusion in the centralized drug procurement catalog. As advised by our PRC Legal Advisors, the manufacturers have the option to abstain from participating in the bidding process if they are unwilling to sell their drugs through the centralized drug procurement scheme.

Under the VBP regime, a drug procurement quota for each drug included in the centralized drug procurement catalog is determined each year on a per-hospital basis. In general, public hospitals are obligated to participate in the centralized drug procurement scheme and to meet the designated quota to the best of their capabilities. Once a hospital has met its drug procurement quota, if it has additional demand, the hospital is permitted to procure drugs not selected in the centralized drug procurement catalog from manufacturers who were not included in the centralized drug procurement scheme. According to F&S, the inclusion of a particular type of drug in the centralized drug procurement scheme can have a significant impact on the competitive landscape within the same therapeutic area. This impact is observed through changes in the drug's sales volume and selling prices. Generally, the selling prices will experience a substantial reduction, whereas the total sales volume will significantly increase.

During the Track Record Period, CF017 was included in the VBP list starting in June 2021. In 2021, 2022, 2023 and the six months ended June 30, 2024, revenue generated from CF017 through VBP channels amounted to RMB28.2 million, RMB269.4 million, RMB441.0 million and RMB234.3 million, accounting for 94.6%, 80.2%, 80.5% and 83.8% of our total revenue generated from sales of CF017. Considering that CF017 was approved in May 2021, our pricing strategy took into account the potential inclusion in the VBP list prior to its approval. Generally, under the VBP list, the ex-factory price of CF017 is determined by taking into account the prices of our competitors, our manufacturing costs and the competitive landscape of our product. In addition, we are also actively exploring opportunities to sell our products through non-VBP channels, including outpatient pharmacies, specialty clinics, and private medical institutions.

CF017 was included in the VBP list for eight provinces in 2021. The VBP list has an effective period of three years. As such, we are renegotiating with the relevant authorities with respect to the renewal of the VBP status for CF017. Meanwhile, we are also negotiating with the relevant authorities to include CF036 in the VBP list. The current batch of VBP inclusion and renewal is conducted at a regional level, where several provinces form an alliance and conduct the VBP together. For details, see "Regulatory Overview — Other Laws and Regulations In Relation To Medical Industry — Volume-based Procurement Scheme and Bidding Process." Currently, our bid to renew CF017's VBP inclusion status and to include CF036 in the VBP list has been accepted by the Jiangsu Alliance (江蘇聯盟), which consists of 11 provinces. The minimum amount of CF017 and CF036 to be subscribed by public hospitals in the provinces covered by the Jiangsu Alliance had not yet been finalized. We are also preparing for the VBP inclusion and renewal bidding for other alliances and provinces. For details, see "Risk Factors — Risks Relating to Our Business and Industry — We face uncertainties arising from the VBP scheme in China, which could adversely affect our market share and profitability."

National Reimbursement Drug List (NRDL)

The National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》), or the National Reimbursement Drug List, or the NRDL, sets forth the payment standard for pharmaceutical products under the basic medical insurance, work-related injury insurance and maternity insurance funds. On December 7, 2023, the National Healthcare Security Administration and the Ministry of Human Resources and Social Security of the PRC released an updated NRDL (effective on January 1, 2024), the scope of which was expanded to cover 3,088 drugs in total. For details of the mechanism, selection criteria, evaluation and approval procedures of the NRDL, see "Regulatory Overview — Other Laws and Regulations In Relation To Medical Industry — Medical Insurance Catalog." The inclusion of drugs into the NRDL may increase sales volume but reduce drug prices, which are negotiated on a case-by-case basis.

In December 2023, CF018 was included in the NRDL. As our product is the only one of its kind on the NRDL list, we believe this inclusion has given us a competitive edge, especially considering that allergic rhinitis patients typically need to use our product on a routine basis. Since its NRDL inclusion, the sales volume of CF018 has significantly increased. As of the Latest Practicable Date, our CF018 has penetrated over 500 hospitals and medical institutions, and recorded sales revenue of RMB7.1 million in the six months ended June 30, 2024, increasing from RMB0.9 million in the six months ended June 30, 2023.

SUPPLIERS AND PROCUREMENT

During the Track Record Period, our suppliers primarily consisted of (i) technical service providers to assist us in the design and development of inhalation formulation products; (ii) suppliers of raw materials and consumables for our inhalation formulation development and manufacturing and (iii) suppliers of equipment and devices for our manufacturing activities and construction service providers.

The raw materials procured for our inhalation formulation products primarily include APIs, device components and other ancillary materials used for our R&D and manufacturing activities. We select our suppliers by considering cost and their capability, quality, reputation, delivery and regulatory compliance. We have established a stable business relationship with our suppliers for raw materials, which we believe have sufficient capacity to meet our demands. During the Track Record Period, we did not experience any material disputes with our suppliers, difficulties in the procurement of raw materials or services, disruptions to our operations due to a shortage of or delay in supply of raw materials or services, or significant fluctuations in raw material and/or service prices. For details of our procurement process, please see "— Quality Control — Procurement Quality Control."

Purchases from our five largest suppliers, on a consolidated basis, were RMB30.7 million, RMB43.4 million, RMB52.6 million and RMB26.7 million in 2021, 2022 and 2023 and the six months ended June 30, 2024, respectively, representing 33.4%, 41.1%, 34.3% and 37.1% of our total purchases for the corresponding periods. Purchases from our largest supplier, on a consolidated basis, in 2021, 2022 and 2023 and the six months ended June 30, 2024, were RMB10.5 million, RMB13.3 million, RMB21.4 million and RMB7.1 million, respectively, representing 11.4%, 12.6%, 13.9% and 9.9% of our total purchases for the corresponding periods. Our five largest suppliers during the track record period granted us a credit term of 30 to 60 days. The following table sets forth details of our five largest suppliers for each year/period during the Track Record Period.

Suppliers	Background	Products/Services Purchased	Commencement of Business Relationship	Purchase Amount	% of Total Purchase	Listing Status
				RMB'000		
For the year ended December 31, 2021						
Supplier A	Clinical research and technical services. Registered in Beijing, China.	CRO service	2020	10,467	11.4%	Listed on the National Equities Exchange and Quotations
Supplier B	Contract manufacturer that provides services for the process of medicine development. Registered in Columbia, USA.	CMO service	2019	6,786	7.4%	Not Applicable
Supplier C	Contract research organization that provides services for the process of medicine development. Headquartered in the United States.	CRO service	2017	5,944	6.5%	Not Applicable
Supplier D	Contract research organization that provides services for the process of medicine development. Registered in Shanghai, China.	CRO service	2017	3,895	4.2%	Not Applicable
Supplier E	Biotechnology research and development. Registered in Jiangsu, China.	Raw materials	2021	3,632	3.9%	Not Applicable
Total				**30,724**	**33.4%**	

Suppliers	Background	Products/Services Purchased	Commencement of Business Relationship	Purchase Amount	% of Total Purchase	Listing Status
				RMB'000		
For the year ended December 31, 2022						
Supplier F	Contract Research Organization. Headquartered in the United Kingdom.	CRO service	2021	13,315	12.6%	Not Applicable
Supplier G	Material technology development. Registered in Shanghai, China.	Package material	2015	8,766	8.3%	Not Applicable
Supplier H	Pharmaceutical raw materials production and sale. Registered in Hubei, China.	Raw materials	2014	8,526	8.1%	Not Applicable
Supplier A	Clinical research and technical services. Registered in Beijing, China.	CRO service	2020	7,006	6.6%	Listed on the National Equities Exchange and Quotations
Supplier I	Contract Research Organization. Headquartered in the United Kingdom.	CRO service	2021	5,810	5.5%	Not Applicable
Total				**43,423**	**41.1%**	
For the year ended December 31, 2023						
Supplier F	Contract research Organization. Headquartered in the United Kingdom.	CRO service	2021	21,399	13.9%	Not Applicable
Supplier A	Clinical research and technical services. Registered in Beijing, China.	CRO service	2020	9,678	6.3%	Listed on the National Equities Exchange and Quotations
Supplier H	Pharmaceutical raw materials production and sale. Registered in Hubei, China.	Raw materials	2014	8,427	5.5%	Not Applicable
Supplier G	Material technology development. Registered in Shanghai, China.	Package material	2015	6,851	4.5%	Not Applicable
Supplier J	Product design and development consultancies. Headquartered in the United Kingdom.	Product design	2021	6,269	4.1%	Not Applicable
Total				**52,624**	**34.3%**	

Suppliers	Background	Products/Services Purchased	Commencement of Business Relationship	Purchase Amount	% of Total Purchase	Listing Status
				RMB'000		
For the six months ended June 30, 2024						
Supplier A	Clinical research and technical services. Registered in Beijing, China.	CRO service	2020	7,137	9.9%	Listed on the National Equities Exchange and Quotations
Supplier J.	Product design and development consultancies. Headquartered in the United Kingdom.	Product design	2021	6,751	9.4%	Not Applicable
Supplier F	Contract Research Organization. Headquartered in the United Kingdom.	CRO service	2021	6,710	9.3%	Not Applicable
Supplier H	Pharmaceutical raw materials production and sale. Registered in Hubei, China.	Medical material	2014	3,359	4.7%	Not Applicable
Supplier G	Material technology development. Registered in Shanghai, China.	Package material	2015	2,721	3.8%	Not Applicable
Total				**26,678**	**37.1%**	

To the best of our knowledge, (i) all of our five largest suppliers for each year/period during the Track Record Period are independent third parties, and (ii) none of our directors, their respective associates or any shareholder who owned more than 5% of our issued share capital as of the Latest Practicable Date has any interest in any of our five largest suppliers for each year/period during the Track Record Period.

CUSTOMERS

In 2021, 2022 and 2023 and the six months ended June 30, 2024, our revenue was primarily derived from the sales of inhalation formulation products to our distributors. We normally require our distributors to make full payment before shipment, except that we may grant a credit term of 60 to 90 days to distributors that we consider crucial to our business.

Our revenue from our five largest customers, on a consolidated basis, were RMB23.6 million, RMB210.4 million, RMB386.3 million and RMB188.0 million in 2021, 2022 and 2023 and the six months ended June 30, 2024, respectively, representing 56.1%, 60.2%, 69.4% and 65.2% of our total revenue for the corresponding periods. Our revenue from our largest customer, on a consolidated basis, in 2021, 2022 and 2023 and the six months ended June 30,

2024 were RMB11.5 million, RMB99.5 million, RMB174.6 million and RMB82.7 million, respectively, representing 27.3%, 28.5%, 31.4% and 28.7% of our total revenue for the corresponding periods. The following table sets forth details of our five largest customers, on a consolidated basis, for each year/period during the Track Record Period.

Customers	Background	Products/Services/ License Provided	Commencement of Business Relationship	Revenue Contribution	% of Total Revenue	Listing Status
				RMB'000		
For the year ended December 31, 2021						
Customer A	Produce and sale of medical devices. Registered in Shanghai, China.	Provides services for the process of medicine development.	2020	11,460	27.3%	Listed on the Hong Kong Stock Exchange
Customer B	Wholesale medical equipment. Registered in Tibet, China.	Sales of medical device and products.	2021	4,076	9.7%	Not Applicable
Customer C	Wholesale medicine. Registered in Hubei, China.	Provides services for the process of medicine development.	2021	3,028	7.2%	Listed on the Shanghai Stock Exchange
Customer D	Produce and sale of medicine. Registered in Hong Kong.	Provides services for the process of medicine development.	2021	2,767	6.6%	Listed on the Hong Kong Stock Exchange
Customer E	Research, produce and sale of medicine. Registered in Fujian, China.	Provides services for the process of medicine development.	2021	2,225	5.3%	Listed on the Shenzhen Stock Exchange
Total				**23,556**	**56.1%**	
For the year ended December 31, 2022						
Customer A	Produce and sale of medical devices. Registered in Shanghai, China.	Provides services for the process of medicine development.	2020	99,454	28.5%	Listed on the Hong Kong Stock Exchange
Customer C	Wholesale medicine. Registered in Hubei, China.	Provides services for the process of medicine development.	2021	36,082	10.3%	Listed on the Shanghai Stock Exchange
Customer D	Produce and sale of medicine. Registered in Hong Kong.	Provides services for the process of medicine development.	2021	26,938	7.7%	Listed on the Hong Kong Stock Exchange

Customers	Background	Products/Services/ License Provided	Commencement of Business Relationship	Revenue Contribution	% of Total Revenue	Listing Status
				RMB'000		
Customer F	Research and development of medicine and produce medical devices. Registered in Chongqing, China.	Provides services for the process of medicine development.	2021	25,751	7.4%	Listed on the Shenzhen Stock Exchange
Customer E	Research, produce and sale of medicine. Registered in Fujian, China.	Provides services for the process of medicine development.	2021	22,140	6.3%	Listed on the Shenzhen Stock Exchange
Total				**210,365**	**60.2%**	
For the year ended December 31, 2023						
Customer A	Produce and sale of medical devices. Registered in Shanghai, China.	Provides services for the process of medicine development.	2020	174,609	31.4%	Listed on the Hong Kong Stock Exchange
Customer F	Research and development of medicine and produce medical devices. Registered in Chongqing, China.	Provides services for the process of medicine development.	2021	60,629	10.9%	Listed on the Shenzhen Stock Exchange
Customer C	Wholesale medicine. Registered in Hubei, China.	Provides services for the process of medicine development.	2021	56,368	10.1%	Listed on the Shanghai Stock Exchange
Customer G	Wholesale medicine and medical devices. Registered in Zhejiang, China.	Provides services for the process of medicine development.	2021	48,677	8.7%	Not Applicable
Customer D	Produce and sale of medicine. Registered in Hong Kong.	Provides services for the process of medicine development.	2021	45,971	8.3%	Listed on the Hong Kong Stock Exchange
Total				**386,254**	**69.4%**	

Customers	Background	Products/Services/ License Provided	Commencement of Business Relationship	Revenue Contribution	% of Total Revenue	Listing Status
				RMB'000		
For the six months ended June 30, 2024						
Customer A	Produce and sale of medical devices. Registered in Shanghai, China.	Provides services for the process of medicine development.	2020	82,718	28.7%	Listed on the Hong Kong Stock Exchange
Customer F	Research and development of medicine and produce medical devices. Registered in Chongqing, China.	Provides services for the process of medicine development.	2021	28,667	9.9%	Listed on the Shenzhen Stock Exchange
Customer D	Produce and sale of medicine. Registered in Hong Kong.	Provides services for the process of medicine development.	2021	28,180	9.8%	Listed on the Hong Kong Stock Exchange
Customer C	Wholesale medicine. Registered in Hubei, China.	Provides services for the process of medicine development.	2021	26,631	9.2%	Listed on the Shanghai Stock Exchange
Customer E	Research, produce and sale of medicine. Registered in Fujian, China.	Provides services for the process of medicine development.	2021	21,818	7.6%	Listed on the Shenzhen Stock Exchange
Total				**188,014**	**65.2%**	

To the best of our knowledge, (i) all of our five largest customers for each year/period during the Track Record Period are independent third parties, and (ii) none of our directors, their respective associates or any shareholder who owned more than 5% of our issued share capital as of the Latest Practicable Date has any interest in any of our five largest customers for each year/period during the Track Record Period.

QUALITY CONTROL

We have implemented comprehensive quality control procedures and protocols that span across the entire production lifecycle from raw material sourcing till the final products are delivered to customers. This system is established and refined in accordance with the rigorous regulations and guidelines in China, the U.S. and Europe. We pay close attention to the evolving standards and regulatory developments in these target markets and update our internal procedures, accordingly, striving for the highest international standards in patient safety and regulatory compliance.

Proprietary "2+2" Quality Control System

We have developed a proprietary "2+2" quality control system, which enables us to monitor and control the entire research and development process, as well as each stage of production. The first "2" refers to our ability to oversee both research and development activities and manufacturing processes, ensuring that our products meet the highest standards of quality and regulatory compliance. The second "2" refers to our ability to ensure that our inhalation products meet the regulatory requirements of both China and overseas market, while also satisfying the needs of our customers.

Our "2+2" quality management system has accelerated the development of our project management team and reduced our reliance on individual project managers. This system ensures that our production and research activities comply with the regulatory requirements of major countries, enabling us to deliver high-quality products to patients worldwide.

Manufacturing Quality Control

Our manufacturing facilities are designed and operated to meet the highest standards of quality and compliance. We have implemented a comprehensive quality control system that includes regular testing and inspection of our products during the manufacturing process. We have invested in state-of-the-art research and development and production equipment to meet the high standards of inhalation product development and industrialization.

Our quality control procedures also include rigorous testing and inspection of our finished products to ensure they meet our quality standards and comply with regulatory requirements. We have established a comprehensive quality control system that utilizes advanced analytical techniques to evaluate the critical quality attributes of our inhalation products, including particle size and spray droplet distribution, aerodynamic characteristics, delivered dose uniformity, and spray pattern and morphology.

Additionally, we adopt a traceability system across our manufacturing process, that allows us to track and document every key stage of the production process. From raw materials to finished product storage and delivery, each step is meticulously recorded to ensure complete transparency and accountability. This traceability enables us to quickly identify and address any quality issues, ensuring the integrity and safety of our products.

Procurement Quality Control

We have established a series of management procedures to ensure the quality of the raw materials we procured. We conduct evaluations on our suppliers and supplier candidates. For each batch of the raw materials we receive, we conduct quality evaluation and inspection. In case we identify any issue, we will report to the supplier and require the supplier to implement corrective and preventive action or replace the raw materials, if necessary. If we determine the raw materials of a certain supplier cannot meet our quality standards, we will disqualify such supplier and refuse to procure any raw materials from it. We conduct due diligence on CROs

to ensure their compliance with regulatory requirements for clinical trial operations. A CRO selected by us will recommend clinical trial sites and conduct on-site visits to assess compliance of the sites with applicable regulations. Only compliant clinical trial sites will be chosen.

Integrated Risk Management and Information System

We adopt a risk-based approach in our quality management system to proactively identify, assess, and mitigate potential quality risks. By integrating risk management into our quality control processes, we ensure that potential issues are addressed before they impact product quality or regulatory compliance. This approach enhances our ability to maintain high standards and safeguard patient safety.

Our quality control processes are also seamlessly integrated with advanced information systems that facilitate real-time data collection, analysis, and reporting. These systems enable continuous monitoring of quality metrics, identification of trends, and data-driven decision-making to enhance our quality management practices. The integration of information systems ensures efficiency, accuracy, and responsiveness in our quality control operations.

By implementing these comprehensive quality control measures, we ensure that our inhalation formulation products consistently meet the highest standards of quality, safety, and regulatory compliance. Our unwavering dedication to quality excellence enables us to deliver reliable and effective solutions to patients worldwide, reinforcing our position as a trusted leader in the inhalation formulation industry.

After-sales Supervision

We have implemented a thorough management framework to oversee the quality and safety of our products in the post-marketing phase, including product complaints, product recalls, adverse drug reaction reporting, and monitoring. To this end, we have adopted a series of procedures, such as regular review of product complaints and collecting feedback from physicians to understand the clinical performance of our products, so that we can identify potential safety issues and take corrective actions promptly. We have staffed specialized personnel responsible for monitoring and reporting adverse drug reactions. These personnel systematically collect and meticulously record adverse reactions, regularly conduct drug safety risk assessments, and compile and submit safety update reports. This proactive approach allows us to swiftly implement necessary measures to mitigate risks and uphold the highest standards of product safety and patient care.

INTELLECTUAL PROPERTY

Our intellectual property rights are critical to our business. Our future commercial success depends, in part, on our ability to obtain and maintain patent and other intellectual property and proprietary protections for commercially important technologies, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid, enforceable intellectual property rights of third parties.

We have a global portfolio of patents and patent applications to protect our drug candidates and technologies. As of the Latest Practicable Date, we owned (i) 51 issued patents, including 42 in mainland China, three in Hong Kong, one in the United States and five in other jurisdictions, and (ii) 52 patent applications, including 17 in China, five in the United States, nine under the Patent Cooperation Treaty (PCT) and 21 in other jurisdictions. The following table summarizes the details of the material patents and patent applications.

Scope of Patent Protection	Patent Number/ Application Number	Jurisdiction	Patent Holder/ Applicant	Estimated Expiration Year
A method for preparing a microparticle mixture of glycopyrronium bromide and indacaterol maleate active pharmaceutical ingredients (一種格隆溴銨和茚達特羅原料藥微粉混合物的製備方法)	201911216301.7	Mainland China	Our Company	December 2039
A medicament inhalation device and associated strip foil component (藥物吸入裝置及使用在其中的泡罩條)	202011368185.3	Mainland China	Our Company	N/A*
A device for filling powders, a powder filling component, and a system for measuring powders (藥粉填充裝置、藥粉填充組件及藥粉測量系統)	2024101730607	Mainland China	Our Company	N/A*
A medicinal inhalation aerosol composition and a process for its preparation (一種藥用吸入氣霧劑及其製備方法)	201910559969.5	Mainland China	Our Company	June 2039
	DE112020003052T5	Germany	Our Company	N/A*
	PCT/CN2020/094293	U.S.	Our Company	N/A*
An automated crimping device for the filling of inhalation products (一種吸入製劑填充的自動壓蓋裝置)	201910122774.4	Mainland China	Our Company	February 2039
A manufacturing line for the filling of inhalation products (一種吸入製劑灌裝生產線)	201910124912.2	Mainland China	Our Company	February 2039
A specialized secondary formulation vessel designed for the preparation of inhalation dosage forms (一種用於配製吸入製劑的二次配料罐)	201910122768.9	Mainland China	Our Company	N/A*
A bronchial intraluminal live valve stent (一種支氣管內活瓣支架)	202211684437.2	Mainland China	Our Company	December 2042
An atomizer and a method for transporting and nebulizing fluids (噴霧器及輸送和霧化流體的方法)	18/294546	U.S.	Our Company	N/A*
	EU23812835.9	EU	Our Company	N/A*

* Patent application.

The actual protection afforded by a patent varies on a claim-by-claim and jurisdiction-by-jurisdiction basis. It depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular jurisdiction and the validity and enforceability of the patent. For details, see "Risk Factors — Risks Relating to Intellectual Property Rights" for a description of risks related to our intellectual property.

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any proceedings in respect of our intellectual property rights, and we had not received notice of any claims of infringement of any intellectual property rights that may be threatened or pending in which we may be a claimant or a respondent.

COMPETITION

We operate in a highly competitive industry. While we believe that our inhalation formulation candidates, technology platforms and management team provide us with significant competitive advantages, we face potential competition from many others who are working to develop inhalation formulations or other therapies targeting the same indications. These include multinational biopharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, academic institutions, government agencies and research institutions. Any product candidates that we successfully develop and commercialize will compete with both existing drugs and any new drugs that may become available in the future.

We believe that the primary competitive factors in our markets include the identification of promising APIs, the design of inhalation device, efficacy and safety of drug candidates, manufacturing efficiency, and commercialization activities.

EMPLOYEES

As of June 30, 2024, we had a total of 621 full-time employees in China. The following table sets forth a breakdown of our employees by function as of June 30, 2024:

Function	Number	% of Total
R&D	163	26.4
Sales and Marketing	149	24.2
Manufacturing	136	21.9
Quality Control	86	14.2
Operation	87	13.4
Total	**621**	**100.0**

Relationship with Employees

We recruit our employees primarily through online platforms, recruiting websites, headhunter referrals and job fairs. We enter into individual employment contracts with our employees covering matters such as salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clauses and grounds for termination. We also enter into separate confidentiality agreements, which contain non-competition clauses, with our senior management and certain key members of our R&D team and other employees who have access to trade secrets or confidential information about our business and may be considered possible, directly or indirectly, to compete with us. The remuneration package of our employees includes salary and bonus, which are generally determined by their qualifications, performance review, and seniority. We also offer share incentives and promotion opportunities to motivate our employees. We believe that we have maintained good working relationships with our employees. In 2022, we were recognized as the Best Employer in Suzhou by Suzhou Municipal Human Resources and Social Security Bureau.

As of the Latest Practicable Date, we have established our labor union. During the Track Record Period and up to the Latest Practicable Date, we did not experience any material labor disputes or strikes that may have a material and adverse effect on our business, financial condition or results of operations.

Training and Development

We provide our employees with a diverse array of professional development opportunities and foster a performance-driven environment. We have a comprehensive talent development mechanism that nurtures employees from entry-level to expert proficiency. Every new employee undergoes comprehensive and systematic onboarding training tailored to their specific roles and responsibilities. During daily operations, direct supervisors provide targeted training and guidance based on the employee's performance, proficiency in handling tasks, and work results. This continuous and focused training ensures that employees are well-prepared and supported in their roles, contributing to their professional growth and the overall success of our projects. We provide both internal and external training for our technical staff, which enables us to foster a diversified, multi-level, and well-structured talent pool.

Employee Benefits

We believe we offer our employees competitive compensation packages, reflecting our stakeholder-centric ethos which we believe leads to sustainable and durable growth. As required by PRC regulations, we participate in various government statutory employee benefit plans, including social insurance, namely pension insurance, medical insurance, unemployment insurance, work-related injury insurance, maternity insurance, and housing provident funds. We also adhere to legal requirements by offering maternity leave, paternity leave, and other related benefits. We ensure a safe working environment that complies with safety standards.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business to safeguard against risks and unexpected events in China. Our insurance coverage comprises personnel-related policies such as pension, medical, work-related injury, maternity, and unemployment insurance. We have also secured comprehensive property insurance to cover losses arising from natural or other disasters affecting our manufacturing facilities or other assets. For each clinical trial, we have purchased clinical trial liability insurance to ensure comprehensive protection for the safety and legal rights of trial participants. Additionally, we have voluntarily purchased insurance to address safety concerns. We believe our existing insurance coverage is adequate for our present operations and in line with the industry practice in China. For details, see "Risk Factors — Risks Relating to Our Operations — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources."

ENVIRONMENTAL, SOCIAL AND CORPORATE GOVERNANCE

We recognize our responsibility to uphold high standards in health, safety, social and environmental practices. Following our [**REDACTED**], we are committed to complying with environmental, social, and governance (ESG) reporting requirements. We understand the environmental and social-related risks that will affect our business, strategy and financial performance, and have therefore established an ESG work group for addressing such risks and formulated corresponding working rules to supervise our corporate social responsibility and measures for sustainable development. The ESG work group is responsible for coordinating ESG initiatives, ensuring compliance with ESG disclosure requirements, managing ESG risks, and overseeing the preparation of ESG reports in collaboration with third-party consultants. ESG factors will be integrated into decision-making to enhance the long-term value and resilience of our Group.

Governance on ESG Matters

The Board has collective responsibility for managing the impact of the material ESG risks and opportunities affecting the Group, formulating and establishing the Group's ESG-related mechanisms, policies and objectives, and reviewing the Group's performance against the ESG objectives on an annual basis and revising the ESG policy as appropriate if significant deviations from the objectives are identified.

The Board assesses ESG risks, reviews the Group's existing strategies, objectives and internal controls, and implements necessary improvements to mitigate the risks on a regular basis. The Board and ESG work group will continue to monitor the Group's strategic planning for risk management, including climate-related risks and those risks that were monitored as part of standard operating procedures, to ensure that appropriate mitigation measures are implemented as part of regular management reviews. Our ESG work group consists of four members, including one Director and three senior management members.

We strictly adhere to the relevant national environmental protection laws and regulations in our production and operation and have established and strictly implemented an internal control system for environmental protection. We have increased investment in pollution control, constantly optimized our processes and equipment, and reduced pollution in our production process. During the Track Record Period, our operations result in air pollution, wastewater, solid waste, or other hazardous wastes. To ensure compliance with national, industrial, and local environmental standards, laws, regulations, and policies, we have implemented internal policies for environmental risk prevention. These policies include:

- ***Air pollution***: Our manufacturing workshops generate waste gases that comply with national emission standards. These emissions are treated through appropriate gas treatment facilities and have received environmental impact assessment (EIA) approvals. Treated emissions are directly discharged outdoors through designated exhaust ducts. For workshops producing hazardous gases, such as those handling hormones, and for dust-laden emissions, we have implemented advanced filtration systems. These systems effectively remove harmful substances and particulate matter, ensuring that all treated emissions meet or exceed national discharge standards before being released into the environment. Additionally, trace amounts of toxic and harmful gases are managed through specialized exhaust ventilation systems. These emitted gases are either diluted or undergo further treatment to ensure that their release adheres to stringent environmental regulations. We conduct regular six-monthly monitoring and surveillance of our waste gas treatment processes to ensure ongoing compliance with discharge standards.

- ***Wastewater***: Wastewater generated from our production processes is recycled through our self-built sewage treatment plant, achieving zero discharge of production-related wastewater. Wastewater from office operations, domestic activities, and ground cleaning is pre-treated and subsequently discharged into the sewage treatment plant for further treatment and compliant discharge. Waste liquids from quality testing are managed as hazardous waste and are collected and disposed of by qualified units.

- ***Solid waste***: Recyclable materials are managed by our supply chain management department, which coordinates with professional recycling companies to ensure proper handling and disposal. Household garbage generated within our facilities is systematically collected and managed by licensed sanitation service providers, while general packaging materials are recycled through external vendors.

- ***Hazardous waste***: Collectable hazardous wastes are first registered with the Environmental Protection Bureau and managed through our independent "Jiangsu Province Solid Waste Dynamic Management System" account. We enter into annual treatment contracts with qualified hazardous waste disposal companies and regularly reports the types and quantities of hazardous wastes generated on a monthly basis. Additionally, volatile hazardous wastes are stored in light-proof, ventilated areas equipped with static elimination devices and fire extinguishers. The destruction of

finished pharmaceutical products is supervised by our quality assurance team to ensure compliance with all relevant standards. All operations involving hazardous waste require the use of appropriate personal protective equipment, including gloves, masks, and face shields, and must be conducted in the presence of trained personnel to prevent accidents.

Resource Consumption

In pursuit of our sustainable development objectives, we rigorously oversee our environmental protection performance across various domains, including resource efficiency and energy consumption. We closely monitor our electricity and water consumption levels and actively implement strategies to enhance energy efficiency and promote water conservation. In aggregate, our electricity consumption levels were approximately 6.3 million kWh, 7.2 million kWh, 7.5 million kWh and 3.5 million kWh in 2021, 2022 and 2023 and the six months ended June 30, 2024, respectively. Our water consumption levels amounted to approximately 127.3 thousand tons, 138.5 thousand tons, 147.2 thousand tons and 45.0 thousand tons in 2021, 2022 and 2023 and the six months ended June 30, 2024, respectively.

Climate Change

We believe that we are not susceptible to climate change. Moreover, we consider that potential changes to the regulations in the PRC regarding climate change will not adversely impact our business operations. We will continue to pay attention to risks regarding climate change and formulate emergency plans to safeguard us from climate change and extreme weather conditions. As of the Latest Practicable Date, we had not experienced any material impact on our business operations or financial performance as a result of climate change or extreme weather conditions.

Work Safety

Ensuring a secure working environment for our employees is critical to us, as we recognize that a safe and healthy workplace not only safeguards the well-being of our workforce but also underpins the long-term viability of our enterprise. We have established comprehensive and stringent company-wide work safety protocols, complemented with regular safety training initiatives to equip our employees with the requisite awareness and technical expertise to carry out their duties in a secure and efficient manner. Our comprehensive safety protocols encompass every facet of our operations, including R&D, manufacturing, and office environments, as well as our primary operational sites, such as offices, laboratories, and manufacturing plants. Moreover, we have distinct protocols governing high-risk materials and activities, and dedicated safety management roles to oversee and enforce these measures. We conduct regular meetings and periodic inspections to ensure the consistent adherence to our safety standards. During the Track Record Period and up to the Latest Practicable Date, we did not have any major workplace accidents.

In addition to proactive preventive safety management systems, we have also established a comprehensive accident reporting system. This system includes the classification of accidents, reporting requirements, and procedures for investigation and handling. The objective of this system is to ensure that any incidents are addressed promptly and efficiently, while also serving as an educational tool to prevent the recurrence of similar accidents in the future. By systematically analyzing accidents, we aim to implement corrective actions and enhance our safety protocols, thereby fostering a culture of continuous improvement and safety awareness throughout the organization.

Workplace Diversity

We are steadfast in our commitment to fostering an open and inclusive workplace that champions equality. We adhere to a corporate policy of hiring employees based solely on their merits, offering equal opportunities regardless of gender, age, race, religion, or any other social or personal characteristics.

AWARDS AND RECOGNITION

Throughout our corporate history, we have received a number of major awards and accolades. The table sets forth a summary of the major awards and recognition we received as of the Latest Practicable Date:

Year(s) of Grant	Award/Recognition	Issuing Authority
2019	High Growth Innovative Enterprise	Suzhou Municipal People's Government
2020	High-Quality Development and Innovation Talent Award	Suzhou Xiangcheng District People's Government
2021	Potential Unicorn Enterprise in Su'nan National Independent Innovation Demonstration Zone	Jiangsu Productivity Promotion Center
2022	Jiangsu Provincial Specialized and Innovative SME	Jiangsu Provincial Department of Industry and Information Technology
2022	Jiangsu Provincial Quality Credit A-Level Enterprise	Suzhou Development and Reform Commission, Suzhou Market Supervision Administration
2023	Unicorn Cultivated Enterprise in Suzhou	Suzhou Municipal People's Government
2023	Jiangsu Provincial Engineering Technology Research Center	Jiangsu Provincial Department of Science and Technology

Year(s) of Grant	Award/Recognition	Issuing Authority
2023	Jiangsu Provincial Postdoctoral Innovation Practice Base	Jiangsu Provincial Department of Human Resources and Social Security
2023	High-Tech Enterprise	Office of the Leading Group for the Identification and Administration of National High-Tech Enterprises
2024	Jiangsu Province Potential Unicorn Enterprise	Jiangsu Productivity Promotion Center
2024	Jiangsu Provincial Intelligent Manufacturing Workshop	Jiangsu Provincial Department of Industry and Information Technology

PROPERTIES

Owned Properties

Land Use Rights

As of the Latest Practicable Date, we obtained three land use right certificates for properties with an aggregate GFA of 78,638.10 sq.m. The details of these owned properties are summarized as follows.

Parcel	Address	Function	GFA
			(sq.m.)
1	No. 16 Hucundang Road, Caohu Industrial Park, Xiangcheng Economic Development Zone, Suzhou	Industrial	16,022.4
2	No. 35-113 Changjiang South Road, Wuxi	Educational and Scientific	9,956.7
3	South to Hucundang Road, East to the Yongchang Road, Xiangcheng Economic Development Zone, Suzhou	Industrial	52,659

Real Estate Ownership Certificates

As of the Latest Practicable Date, we obtained 14 real estate ownership certificates for properties with a total GFA of approximately 34,734.38 sq.m. in the PRC. These parcels of properties are mainly located in Suzhou and Guangzhou, and are primarily used as our production facilities, administrative offices and R&D buildings. Among all of our owned properties, none of land use rights with buildings on them were pledged to secure our bank borrowings.

Leased Properties

As of the Latest Practicable Date, we leased 11 properties from third parties with an aggregate GFA of approximately 12,688.07 sq.m., which were primarily used as production facilities and administrative offices. Our leases generally have a term ranging from 0.5 to 3 years. We will consider renewal of the leases upon their expiry.

Pursuant to the applicable PRC laws and regulations, both lessors and lessees must register lease agreements with the relevant authorities and obtain property leasing filing certificates. As of the Latest Practicable Date, all of the lessors of our leased properties had provided their title certificates or sublease authorization documents of the relevant properties, five of our lease agreements between us and third parties had not been registered with the relevant local authorities. As advised by our PRC Legal Advisor, failure to register an executed lease agreement will not affect its validity. However, we may be subject to a fine of no less than RMB1,000 and not exceeding RMB10,000 for each unregistered lease agreement if the relevant PRC governmental authorities require us to rectify it and we fail to do so within the prescribed time. See "Risk Factors — Risks Relating to Our Operations — Our leased properties may be subject to non-compliances or challenges that could potentially affect our future use of them."

LICENSES, PERMITS AND APPROVALS

We are subject to regular inspections, examinations and audits and are required to maintain or renew the necessary permits, licenses and certifications for our business. During the Track Record Period and as of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from the relevant government authorities that are material for our business operations. The table below sets forth the relevant details of the material licenses, approvals and permits we hold for our operations.

License/Permit	Holder	Issuing Authority	Issue Date	Expiration Date
CF017	Our Company	NMPA	May 11, 2021	May 10, 2026
CF036	Our Company	NMPA	October 26, 2021	October 25, 2026
CF018	Our Company	NMPA	November 1, 2022	October 31, 2027

License/Permit	Holder	Issuing Authority	Issue Date	Expiration Date
CF038	Our Company	NMPA	September 5, 2023	September 4, 2028
GW006	Our Company	FDA	May 17, 2024	N/A
Pharmaceutical Production License . . .	Our Company	Jiangsu Provincial Medical Products Administration	October 24, 2024	September 16, 2025

LEGAL PROCEEDINGS AND COMPLIANCE

We are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business. During the Track Record Period and as of the Latest Practicable Date, there was no litigation, arbitration or administrative proceedings pending or threatened against the Company or any of our directors which could have a material and adverse effect on our financial condition or results of operations. We believe that, during the Track Record Period and up to the Latest Practicable Date, we had complied in all material respects with the applicable laws and regulations relating to our business operations. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business. For the potential impact of legal or administrative proceedings on us, see "Risk Factors — Risks Relating to Our Operations — We may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business."

RISK MANAGEMENT AND INTERNAL CONTROL

We are committed to developing and maintaining risk management and internal control systems comprised of policies and procedures tailored to our business operations. Our dedication lies in the continual enhancement of these systems to ensure their effectiveness.

Risk Management

We recognize that risk management is critical to the success of our business operation. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the Chinese and global inhalation formulation markets, our ability to develop, manufacture and commercialize our inhalation formulation candidates, and our ability to compete with other biopharmaceutical companies. We also face various market risks. In particular, we are exposed to credit, liquidity, interest rate and currency risks that arise in the normal course of our business. See "Risk Factors" for more details.

We have adopted a comprehensive set of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an on-going basis. Risks identified by management will be analyzed on the basis of likelihood and impact and will be properly followed up and mitigated and rectified by our Group and reported to our directors. Our directors supervise the implementation of our risk management policies.

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

- formulating and implementing a risk management process covering different aspects of our business operation which includes risk identification, risk assessment, risk management strategy development, risk response development, risk monitoring and early warning, risk reporting, and risk management process improvement;

- formulating a compliance manual which stipulates the compliance obligations of different departments and their members;

- establishing an audit committee to review and supervise our financial reporting process and internal control system. Our audit committee consists of three members, namely Ms. WANG Lijuan (王麗娟) (chairperson of the committee), Dr. JIN Jian (金堅) and Mr. IP Wang Hoi (葉耘開); and

- adopting various policies to ensure compliance with the Listing Rules, including but not limited to policies with respect to risk management, connected transactions and information disclosure.

We consider that our directors and members of our senior management members possess the necessary knowledge and experience to provide outstanding corporate governance oversight in connection with risk management and internal control.

Internal Controls

Our management team is responsible for establishing our internal controls system and the audit committee of our Board is responsible for reviewing its effectiveness. We have engaged an independent internal control consultant to perform the internal review procedures in connection with the internal control of our Company and our major operating subsidiaries and to report factual findings on our Group's entity-level controls and internal controls of various processes, including financial reporting and disclosure controls, human resources and payroll management, general controls of IT system, taxation management, contract management, and other procedures of our operations. The internal control consultant performed the internal review procedures in October 2024. As of the Latest Practicable Date, there were no material outstanding issues relating to our Group's internal controls.

We are committed to establishing and maintaining risk management and internal control systems. We have adopted and implemented a comprehensive risk management policy encompassing risks that may arise in research and development, procurement management, production management, and sales management. Our risk management and internal control systems also cover the general functional operations such as human resources, financial management, asset management, warehousing and logistics management, information system management and corporate governance as well as decision-making processes. Meanwhile, we are committed to supervising and evaluating the effectiveness of risk management and internal control systems to ensure that the system is rectified and effectively controlled as our business develops.

Anti-bribery

We maintain a strict code of conduct and anti-corruption policies among our employees. We also require our distributors to bear integrity obligations pursuant to the distribution agreements with such distributors. We strictly prohibit bribery or other improper payments in our business operations. This prohibition applies to all business activities, anywhere globally, whether involving government officials or healthcare professionals. Improper payments prohibited by this policy include bribes, kickbacks, excessive gifts or entertainment, or any other payment made or offered to obtain an undue business advantage. We keep accurate books and records that reflect transactions and asset dispositions in reasonable detail. Requests for false invoices or payment of unusual, excessive or inadequately described expenses should be rejected and promptly reported. Misleading, incomplete or false entries in our books and records are not acceptable. We will also ensure that future sales team personnel comply with applicable promotion and advertising requirements, including restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

Non-Competition

We have instituted rigorous protocols to safeguard the proprietary information that arises during the development and production of our projects, which encompasses product formulations, preparation techniques, methodologies, and research strategies. The employment agreements between us and our senior management and key technical personnel include confidentiality clauses and non-compete agreements. We assign code names to our core projects in order to obscure their true nature and purpose. In addition, researchers are strictly prohibited from removing electronic or physical records of experimental results and data from the laboratory premises. Through these meticulous steps, we diligently protect our intellectual property and maintain the integrity of our innovative endeavors.