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OVERVIEW

We are a biopharmaceutical company focusing on the discovery and development of therapeutics addressing the medical needs in respiratory and pediatric diseases. We have developed a pipeline of six drug candidates, including an RSV portfolio consisting of ziresovir, the first therapeutic drug specifically targeting RSV infection at NDA stage and AK0610, a phase II stage mAb for the prevention of RSV infection, an IPF drug, AK3280 at post phase II proof-of-concept (“PoC”) clinical stage, and an approved ADHD drug, AK0901.

Respiratory diseases have become a growing global public health problem and are the third largest cause of death in humans. Respiratory diseases are under-recognized, under-diagnosed, and under-treated in almost all countries, including China, especially in vulnerable populations such as children, the elderly, and the immunocompromised. Our understanding of the complex biology of respiratory diseases, and our expertise and know-how in discovery and translational development of novel pediatric and adult drugs specifically for respiratory diseases, have been crucial to our research and development achievements in the field of respiratory diseases, enabling us to rapidly and efficiently advance drugs from concept to market.

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TA	Drug code	Mechanism of Action	Modality	Indication	Route of Administration	Competent Authority	Target Markets	Pre-clinical	IND	Ph I	Ph II	Ph III	NDA	Upcoming milestones
Respiratory	★ Ziresovir ¹	RSV F protein inhibitor	Small molecule	RSV treatment for child	Oral (Monotherapy)	NMPA	🇨🇳							NDA approval in 2026
				RSV treatment for adult	Oral (Monotherapy)	FDA	🇺🇸							Initiate communications with the FDA in 2026 1H and initiate clinical trial in 2027
						NMPA	🇨🇳							Complete subject enrollment in 2028 Q1 and complete clinical trial in 2028
						FDA	🇺🇸							Initiate communications with the FDA in 2026
	★ AK3280 ²	Broadly active fibrosis inhibitor	Small molecule	IPF	Oral (Monotherapy)	NMPA	🇨🇳							Complete Ph III trial in 2028
						FDA	🇺🇸							Ph II initiation in the next 12 months
Others	+ AK0610 ⁴	RSV F protein mAb	mAb	RSV prevention	Oral (Monotherapy)	NMPA	🇨🇳							Complete Ph II trial in 2026
	AK0705 ⁵	Undisclosed	Small molecule	COPD	Oral (Monotherapy)	NMPA	🇨🇳							Complete IND-enabling studies in 2027 Q2
	AK0406	Undisclosed	Antibody-drug conjugate (ADC)	Influenza	Oral (Monotherapy)	TGA	🇨🇳							Complete phase I clinical trial in 2027
	+ AK0901 ³	Dexamethylphenidate and the prodrug serdexmethylphenidate	Small molecule	ADHD	Oral (Monotherapy)	NMPA	🇨🇳							NDA approved in 2025

★ Core product + Key product

Notes:

- 1 Company licensed in global rights of ziresovir from Roche in 2014.
- 2 Company licensed in global rights of AK3280 from Genentech, Roche and Intermune in 2018.
- 3 Company licensed in Greater China rights of AK0901 from Commave in 2021.
- 4 We in-licensed the intellectual property relating to AK0610 from Institute of Microbiology, Chinese Academy of Sciences in August 2021.
- 5 We entered into a collaboration agreement with California Institute for Biomedical Research (“Calibr”), a California non-profit corporation which is a research institute within The Scripps Research Institute, to support pre-clinical development of AK0705 and develop products for the medical needs in respiratory disease in October 2017.

Abbreviation: RSV = Respiratory Syncytial Virus; ADHD = Attention Deficient Hyperactivity Disorder; IPF = Idiopathic Pulmonary Fibrosis; COPD = Chronic Obstructive Pulmonary Disease

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Our RSV portfolio is led by ziresovir, the most advanced and potentially first-in-disease RSV treatment drug candidate globally, and the world’s first RSV-specific antiviral drug to achieve positive results in pivotal phase III clinical trial. RSV infection is the number one cause of LRTI in young children worldwide. According to CIC, the global RSV treatment market recorded only US\$30.0 million as of 2024 and is projected to reach US\$819.0 million in 2026, and is expected to expand rapidly to US\$8.6 billion in 2035, representing a CAGR of 67.1% from 2024 to 2035. The global RSV prevention drug* market (including RSV target drugs and mAbs, excluding RSV vaccine) reached approximately US\$2.7 billion in 2024, and is expected to expand to approximately US\$3.6 billion in 2026, and is projected to maintain steady growth thereafter, reaching US\$5.3 billion by 2035, representing a CAGR of 6.3% during 2026 to 2035.

We have developed AK3280, our post phase II PoC-stage IPF drug. Fibrosis is a progressive and degenerative condition that affects nearly all tissues and organ systems, where a normal tissue becomes scarred over time and loses its physiological function. IPF is one of the most common and life-threatening rare diseases affecting approximately 1.9 million individuals worldwide in 2024. According to CIC, pirfenidone and nintedanib, the only two approved treatments for IPF in the U.S. and China, together recorded US\$5.8 billion in global sales in 2024, despite their limited efficacy and poor tolerability.

We licensed Azstarys® (AK0901) from Commave in December 2021. The drug received FDA approval in the United States in March 2021, marking the first methylphenidate-class medication approved by the FDA in nearly 20 years. Through its innovative combination design of immediate-release and prodrug components, AK0901 achieves rapid onset and sustained treatment effect, delivering stable all-day ADHD symptom control with comprehensive upgrades in clinical efficacy, safety, and tolerability. Since we in-licensed AK0901 from Commave, we completed its phase I and III clinical trials in China involving 24 and 50 subjects, respectively. In December 2025, AK0901 was approved by the NMPA in China.

Leveraging the industry experience and network of our senior management team, we aim to in-license candidates, with a particular focus on preclinical candidates that are scientifically sound, can address large medical needs, and have synergies with our existing portfolio and disease area focus. Our proven track record of in-licensing and co-developing drug candidates includes ziresovir from Roche, AK3280 from Genentech, AK0901 from Commave, AK0610 from Institute of Microbiology, Chinese Academy of Sciences and partnering with The Scripps Research Institute on AK0705. Our strong R&D capabilities and clinical trial study results are recognized by renowned academic journals, including *New England Journal of Medicine* and *The Lancet Child & Adolescent Health*.

We believe our ability to design and develop therapeutics to address the medical needs in respiratory and lung diseases is validated by our strong in-house research and development capabilities and drug discovery expertise in respiratory and pediatric drugs. Our research and development programs are led by Dr. Wu, our Founder and CEO, and executed by a distinguished scientific management team with substantial experience at global biopharmaceutical companies and a proven track record in drug discovery and clinical development. We are supported by experienced clinicians and researchers who serve as our scientific advisors, together with a strong network of KOLs in respiratory and lung diseases as well as pediatric diseases.

* According to CIC, vaccines are not classified as drugs.

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COMPETITIVE STRENGTHS

Leading global RSV innovation in treatment and prevention.

RSV infection is the number one cause of LRTI in young children, which typically result in long-term sequelae for infants and pediatric patients, leading to recurrent wheezing, asthma, and declining lung function. RSV has a high global incidence rate, with an estimated 49.3 million severe RSV infection cases expected in children under 5 years old and elder adults aged 65 years old worldwide by 2035. According to CIC, the global RSV treatment market is expected to expand to US\$8.6 billion in 2035, representing a CAGR of 67.1% from 2024 to 2035. The global RSV prevention drug market (including RSV target drugs and mAbs, excluding RSV vaccine) reached approximately US\$2.7 billion in 2024, and is expected to maintain steady growth, reaching US\$5.3 billion by 2035, representing a CAGR of 8.4% during 2026 to 2035.

We are developing an RSV pipeline with two candidates for RSV treatment and prevention, details of which are set out below.

Ziresovir for treatment

Ziresovir is a RSV treatment drug that targets the F protein of RSV, a key surface protein that mediates viral entry into host cells. It is the most advanced and potentially first-in-disease RSV treatment drug candidate globally, and the world’s first RSV-specific antiviral drug to achieve positive results in pivotal phase III clinical trials. Since licensing the ziresovir molecule from Roche as a pre-clinical candidate in 2014, we have rapidly completed twelve clinical trials for ziresovir indicated for pediatric and adult patients across major markets including the U.S., China, Europe, and Australia. In August 2025, we submitted an NDA application for ziresovir to the NMPA for the treatment of RSV in infants aged 1 to 24 months. and we currently expect to receive the NDA approval in 2026 and launch the product in China afterwards.

We believe ziresovir has the following advantages:

- *Promising clinical efficacy from direct anti-viral effect.* In our phase III trials involving over 400 hospitalized infants with confirmed RSV infection, ziresovir demonstrated significant clinical benefits compared to placebo. Ziresovir demonstrated significant clinical benefits in hospitalized infants aged 1-24 months with RSV infection, showing 75% greater viral load reduction than placebo with consistent daily improvements. For critically ill children requiring PICU care, the clinical trial results achieved 2.5-day reduction in PICU stay duration compared to placebo. In addition, the two-year follow-up data for patients 6 months and under of age demonstrates that the ziresovir group showed significantly lower rates of recurrent wheezing and asthma compared to the placebo group, demonstrating its long-term clinical benefits.
- *Validated mechanism of action.* Ziresovir has a clear and validated mechanism of action to suppress RSV viral infection by specifically targeting the prefusion conformation of the RSV F protein as confirmed by the Cryo-EM structure recently obtained. Ziresovir was observed to completely inhibit F protein-induced cell fusion that is characteristic of RSV-infected cells. Demonstrating its selectivity, ziresovir is ineffective against artificially prepared RSV variants with point mutations on the F protein, confirming the molecular target of ziresovir.
- *Favorable safety profile.* Ziresovir has demonstrated a balanced and favorable safety profile. During the completed clinical trials with ziresovir, no drug-related severe adverse events were observed in healthy adults and pediatric patients as young as one month old, which was supported by the large safety window observed in pre-clinical studies. Ziresovir showed high tolerability and did not induce clinically significant drug resistance in the clinical trials.

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- *Sufficient drug exposure in respiratory tract.* When orally administered in pre-clinical animal studies, ziresovir demonstrated a targeted high drug exposure in the lung. Ziresovir was detected in patients’ respiratory specimens collected in its global phase II clinical trial, suggesting a sufficient drug exposure in RSV-infected respiratory tract and lungs in humans.
- *Patient compliance advantages.* Ziresovir offers significant compliance advantages through its innovative oral delivery method compared to existing treatments. Currently, ribavirin is the only approved drug for severe RSV infection in infants and young children, and it requires aerosol inhalation therapy lasting 12-18 hours per session over a 3-7-day treatment course, making administration inconvenient for infants and young children. In contrast, ziresovir features a sprinkle capsule of micro pellet formulation design specifically developed for oral administration across all age groups of infants and young children. We believe this formulation enables safe and convenient dosing, thereby delivering clear compliance advantages for pediatric patients and improving the treatment experience for both patients and their families.

In September 2024, the phase III clinical trial results of ziresovir were published in the globally prestigious *New England Journal of Medicine*, which demonstrated its clinical benefits and antiviral effect. In May 2025, analysis of patients aged below six months for their 2-year follow-up results during its phase III clinical trial were published in the international top-tier journal — *The Lancet Child & Adolescent Health* confirming ziresovir’s clinical efficacy in hospitalized infants 6 months of age and revealing the long-term benefits of ziresovir in reducing recurrent wheezing and asthma. These peer-reviewed publications in the world’s leading medical journals validate ziresovir’s strong clinical profile and competitive positioning, representing a significant commercial opportunity in the underserved RSV therapeutic market with potential for rapid market adoption upon regulatory approval.

Beyond pediatric applications, we are also developing ziresovir for adult RSV infection. While adults aged 65 and older and immuno-compromised individuals are high-risk populations for RSV infection, the growing aging population and increasing number of patients with chronic cardiopulmonary diseases are expanding infection risks across the broader adult population. Despite this growing need, formal clinical guidelines for treating adult RSV infection remain absent. We currently expect to initiate a phase II/III clinical trial of ziresovir in adult RSV patients in China in 2026.

AK0610 for prevention

AK0610 is a phase II stage mAb drug designed for the prevention of RSV infection in infants. It was originally isolated from a recovered pediatric RSV patient with a unique epitope and further optimized through antibody engineering. Compared to other RSV neutralizing antibodies, it maintains highly effective neutralizing activity against variant RSV strains, especially the B strains.

In preclinical studies, AK0610 has demonstrated exceptional viral neutralizing activity, showing potential to become the long-acting RSV prevention antibody for preventing RSV-induced severe lower respiratory tract infection. AK0610 exhibits superior anti-RSV efficacy in head-to-head comparisons with palivizumab, with up to 720 times stronger neutralization against RSV strains and 4 times better activity in in vivo mouse models. AK0610 also demonstrates better activity than nirsevimab in cotton rat models (1.3 times).

As of the Latest Practicable Date, we had completed the phase I clinical trial involving 136 subjects for AK0610 in China, with the maximum administered dose reaching 3,000mg. Most subjects have been followed up for 12 months and no drug-related serious adverse events have been observed during the study. AK0610 also exhibited a long half-life, and reached the highest

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maximum concentration and the highest $C_{150\text{ day}}/EC_{90}$ ratio (2.0) indicating the best pharmacokinetic parameters among similar products. We have initiated the phase II study to determine pharmacokinetics in infant subjects for AK0610.

Phase III ready IPF drug asset.

We have developed a post phase II PoC stage IPF drug asset, namely AK3280. AK3280 attenuates a multitude of fibrosis-related genes and proteins. During pre-clinical studies, AK3280 is broadly active in multiple animal models of organ fibrosis, such as lung, liver, heart and skin, suggesting its potential to support a broader clinical application in treating fibrosis in multiple organs.

We in-licensed AK3280 molecule from Genentech in 2018. Since then, we have conducted long-term GLP toxicity and other preclinical studies, tech-transfer for drug manufacturing in China, and successfully completed clinical trials for AK3280 in Europe and China. Our most advanced AK3280 program is for IPF, one of the most common and life-threatening rare diseases affecting approximately 1.9 million individuals worldwide in 2024. We plan to initiate a phase III clinical trial in China in 2026. Meanwhile, we plan to submit an IND application to the FDA in 2025 to conduct a phase II PoC clinical trial in the United States.

We believe our AK3280 has the following competitive advantages:

- *Improved anti-fibrotic effect.* AK3280 demonstrated better anti-fibrotic efficacy in the lung and liver in an array of pre-clinical studies compared to pirfenidone. Significant reductions in lung fibrosis were observed in mouse and rat models of bleomycin-induced pulmonary fibrosis. In clinical trials, AK3280 has shown the ability to improve lung function and enhance patient’s quality of life, while demonstrating good safety and tolerability profiles that favor improved patient compliance. The high dose groups demonstrated forced vital capacity (“FVC”) improvement compared to placebo, especially the 400 mg group which had the absolute FVC increased by 209.4 mL and a 6.4% adjusted %pFVC improvement compared to placebo ($p=0.002$ and 0.004 , respectively). Other lung and respiratory functions have also got better. The drug exhibited a good safety and tolerability profile without the gastrointestinal intolerance issues associated with current IPF therapeutics. We believe the potential of AK3280 in improving lung function could render its broad application in treating other ILDs, such as ILDs from targeted ADC therapies or chemotherapy for lung cancer.
- *Superior clinical safety and tolerability.* Compared to pirfenidone, AK3280 demonstrated a better safety and tolerability profile with minimal GI intolerance and no signs of photo-toxicity or liver toxicity in clinical trials. In its phase I and phase II clinical trials, most adverse events reported were mild in severity, with limited serious adverse events occurring in the AK3280 groups.
- *Broader therapeutic window.* AK3280 showed high potency and a broader therapeutic window compared to pirfenidone, suggesting that AK3280 is potentially effective at significantly lower dose levels with greatly improved safety and tolerability. Preclinical data indicate that AK3280 has an effective dose 10-30 times lower than pirfenidone, and the molecule shows no light absorption issues within its spectral range, theoretically eliminating phototoxicity concerns. AK3280 also showed superiority in pre-clinical toxicology studies, including genotoxicity and phototoxicity.
- *Improved patient compliance.* AK3280’s pre-clinical PK studies and the completed phase I study suggest a more favorable dosing regimen and a reduced pill burden of QD or BID, which would significantly improve patient adherence, compared with pirfenidone’s TID dosing regimen.

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A new generation of ADHD treatment, filling critical market gap in China.

ADHD is a neurodevelopmental disorder characterized by inattention, bouts of excessive energy, hyper-fixation, and impulsivity. ADHD affects children and may continue through adolescence and adulthood and up to 65% of children with ADHD continue to experience ADHD symptoms as adults. Despite the high overall prevalence of ADHD, only 10% of children with ADHD in China seek medical consultation and treatment. As market education advances, China is expected to see an increasing number of patients seeking medical care and pharmaceutical treatment, driving further growth in clinical medication demand for ADHD management.

We in-licensed Azstarys® (AK0901) in December 2021 from Commave with an exclusive license to develop and commercialize AK0901 in Greater China. The drug received FDA approval in the United States in March 2021, marking it the new generation of methylphenidate-class medication approved by the FDA in nearly 20 years. Through its innovative combination design of immediate-release and prodrug components, AK0901 achieves rapid onset and sustained treatment effect, delivering stable all-day ADHD symptom control. Since we in-licensed AK0901 from Commave, we completed a phase I and a phase III clinical trial in China involving 24 and 50 subjects, respectively. In December 2025, AK0901 was approved by the NMPA in China.

We believe AK0901 has the following advantages.

- *Superior symptom control with a unique dual-component formulation.* AK0901 demonstrates more stable disease symptom control compared to existing ADHD treatments, with rapid onset within 30 minutes through immediate-release d-MPH for instant core symptom management, followed by sustained 13-hour efficacy that matches patients’ full daily activity cycles from morning wake-up through evening homework. In its phase III clinical trial in China, AK0901 demonstrated statistically significant improvements compared to placebo at all visit points, achieving both primary and key secondary endpoints for both short-term and long-term treatment effectiveness.
- *Enhanced safety profile with reduced abuse potential.* The innovative prodrug technology significantly lowers addiction risk compared to other commercially available ADHD drugs, achieving a lower controlled substance classification. The prodrug mechanism prevents high d-MPH blood exposure and effectively reduce the potential for misuse or abuse through non-oral administration routes, while demonstrating promising safety and tolerability in phase III studies with no drug-related serious adverse events. Further, based on the pre-clinical and clinical data available to date and the current regulatory communications, AK0901 is not expected to carry a “black box” (most serious) safety warning label upon approval, representing a significant safety advantage with fewer tolerability issues and reduced impact on appetite and sleep patterns.
- *Improved patient compliance and convenience.* AK0901 offers superior patient adherence advantages with flexible dosing methods, including the ability to open capsules and sprinkle contents on food for drug administration, reducing compliance issues.

Dual drug development engine featuring proven global BD and multi-platform in-house R&D capabilities, driving next-generation pipeline innovation.

We have built a dual-engine approach to drug discovery and development that combines our ability to seize global BD opportunities with our comprehensive in-house research capabilities. This integrated strategy allows us to leverage the best of both worlds — established external collaborations and our own innovative research platforms — to create and advance long-awaited therapies that address significant medical needs across multiple therapeutic areas.

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We take a strategic and focused approach to business development, systematically identifying and evaluating high-quality drug candidates from around the world. Our goal is to access drug assets that are scientifically robust, address significant medical needs, and complement our existing therapeutic focus areas. Our track record demonstrates consistent success in advancing in-licensed assets through clinical development. We have transformed early-stage opportunities into late-stage clinical programs: ziresovir, in-licensed from Roche in 2014 at the pre-clinical stage, has progressed all the way to NDA application. AK3280, in-licensed from Genentech in 2018, has successfully completed the phase II trial and advanced toward phase III trials. More recently, AK0901, in-licensed from Commave in 2021, is under NDA application in China. Additionally, we have established a valuable partnership with a world leading biomedical institute — The Scripps Research Institute to co-develop AK0705 for COPD treatment. This proven ability to identify promising candidates early and guide them through successful clinical development in China forms the foundation of our dual-engine strategy.

Complementing our track record of business development is our robust in-house research and development infrastructure and capacity. For details, see “— Research and Development.”

Distinguished research and development leadership backed by reputable stakeholders.

We have assembled a distinguished team of scientists and clinicians with global perspectives, deep medical expertise, and extensive management experience. Led by our Founder and CEO, Dr. Wu, and our Chief Operating Officer, Dr. Yuan, our management team brings together an average of over 20 years of industry experience, providing steady leadership and strategic direction for our continued growth. Our leadership team combines complementary expertise across drug discovery, clinical development, and commercialization with extensive experience gained from senior positions at leading global biopharmaceutical companies. For details, see “Directors, Supervisors and Senior Management.”

Our organization is also supported by external advisers, mainly the KOLs in certain areas globally and prestigious institutional investors with a proven track record and established reputation in healthcare investment, who provided profound support in our corporate strategy and business development initiatives. For details, see “History, Development and Corporate Structure — Pre-[REDACTED] Investments.”

BUSINESS STRATEGIES

We intend to capitalize on our competitive strengths by pursuing the following business strategies.

Accelerate the clinical development and commercialization of our pipeline products.

We plan to rapidly advance the late-stage clinical trials for our core and key products, including the following:

Ziresovir

We believe ziresovir has the potential to become the first-in-disease RSV treatment drug globally, and we plan to rapidly advance its developments and commercialization in China and globally, with its China commercial launch currently anticipated in or after 2026.

- *China strategy.* In August 2025, we submitted an updated NDA application for ziresovir for the treatment of RSV in pediatric patients aged one to 24 months to the NMPA. We currently expect to receive the NDA approval from the NMPA in 2026 and launch the product in China afterwards. Upon its approval, we plan to apply for age expansion to include children aged 2-5 years leveraging the completed clinical trial in this age group. Additionally, we have initiated a Phase II/III clinical trial for adult patients in China to further broaden the eligible patient population. We plan to complete subject enrollment for this clinical trial in the 1st quarter of 2028.

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- *Global strategy.* We plan to initiate communications with the FDA to conduct a phase II or phase III, subject to agreement with the FDA, in the United States in the first half of 2026 to support its global registration. In addition, we plan to initiate communications with the FDA on the regulatory pathway for adult RSV patients by the end of 2026, and initiate phase 2 and phase 3 clinical trials following agreement with the FDA, which the Company targets to enroll approximately 80 and 200 subjects, respectively, afterwards. We intend to establish partnerships to develop and commercialize ziresovir in major overseas markets including the U.S., Europe, and Japan.

AK3280

We have initiated a phase III pivotal clinical trial of AK3280 for the treatment of IPF, and expect to complete this trial in 2028.

AK0610

As of the Latest Practicable Date, we had completed the phase I clinical trial involving 136 subjects for AK0610 in China. We have initiated the phase II clinical trial to determine pharmacokinetics in infant subjects for AK0610 and plan to complete such clinical trial in 2026.

AK0406

In February 2026, we initiated a first-in-human clinical trial for AK0406. We plan to complete this clinical trial in 2027. We are also evaluating opportunities for global collaboration with respect to this in-house developed drug asset.

Grow our pediatric and pulmonary disease drug portfolio through internal research and development and external collaboration.

We are committed to developing pediatric and pulmonary disease drugs for under-treated diseases. We plan to continue to leverage our expertise and experiences to advance the R&D of our pediatric and pulmonary disease drug portfolio. For example, we have filed CTA in Australia and obtained the EC approval for AK0406 and have initiated a phase I clinical trial in Australia in February 2026 (NCT07432698).

We will continue to leverage our dual engine for drug development — combining internal efforts with strategic partnerships — focusing on pediatric and pulmonary diseases. In the future, we plan to further explore the synergies among developing and commercializing products targeting pediatric patients, or addressing acute, chronic and end-stage respiratory and lung diseases, while reinforcing our pipeline’s full disease cycle coverage. We will also actively explore in-licensing opportunities for innovative drug candidates in mid- or late-stage clinical development or commercialized drugs, especially those targeting respiratory and fibrotic diseases or with a pediatric focus that will fit in our targeted commercial product profile.

Maximize our drug candidates’ global value through strategic partnerships.

We will remain agile in exploring partnerships in the form of licensing, partnering, co-development and co-promotion.

- *Licensing.* We will actively seek in-licensing opportunities for innovative drug candidates in early- to late-stage clinical development or commercialized drugs, especially those targeting respiratory diseases or pediatric diseases that will fit in our targeted commercial product profile.

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- *Partnering.* Outside China, we plan to explore collaborative opportunities with leading global biopharmaceutical companies for the drugs in our pipeline to maximize value for the global market. We adopt a flexible global strategy focused on capturing commercial value in major markets by exploring potential partnerships with global biopharmaceutical companies through out-licensing, co-development, or co-promotion. For example, for AK3280, we will explore options to advance development and commercialization through partnership arrangements for the global market. In addition, we have been actively exploring collaboration opportunities in our key therapeutic areas. We are open to co-development programs with partners that have synergies with us.

Establish our manufacturing and commercialization capacity towards a full-fledged biopharmaceutical company.

We aim to evolve from a research-focused biotech company into a comprehensive biopharmaceutical enterprise in the long run. To achieve this goal, we plan to gradually enhance our industrialization capabilities, delivering high-quality therapeutics to patients worldwide and establishing ourselves as a prominent player in the global biotech industry.

Manufacturing. To meet the anticipated supply chain demands for ziresovir and other late-stage product candidates, we plan to continuously utilize reputable CDMO partnerships with whom we maintain stable, long term partnership to support the supply of our commercialized products in the future.

Commercialization. We have begun to build up our in-house commercialization functions, including regulatory affairs, market access, marketing, medical affairs, KOL engagement, and sales network. To prepare for our products’ near-term commercial launch, we plan to adopt a hybrid commercialization approach. While we will continue to develop our in-house commercialization capabilities, we are also exploring opportunities to seek partnership with reputable pharmaceutical companies to leverage their sales network for our commercialization activities. We will continue to collaborate with KOLs, HCPs, leading medical institutions, and professional medical associations to advance the development and delivery of clinically meaningful therapies to patients. To support successful commercialization, we intend to invest in comprehensive disease awareness initiatives focused on the conditions addressed by our pipeline candidates, particularly RSV infection and ADHD, thereby expanding market recognition and facilitating patient identification and treatment.

OUR PRODUCT PIPELINE

We are a biopharmaceutical company focusing on the discovery and development of therapeutics addressing the medical needs in pediatric patients and for respiratory diseases. Under the leadership of Dr. Wu, our Founder and CEO and distinguished scientific management team, we have developed a pipeline of six drug candidates. Our pipeline features an RSV portfolio consisting of ziresovir, the first therapeutic drug specifically targeting RSV infection at NDA stage and AK0610, a phase II stage mAb for the prevention of RSV infection, an IPF drug, AK3280 at post phase II PoC clinical stage, and an ADHD drug, AK0901 at NDA stage.

RESPIRATORY DISEASE PORTFOLIO

RSV

RSV infection is the number one cause of LRTI in young children, which could ultimately lead to chronic respiratory diseases, including asthma, wheeze and COPD, if not properly treated. The virus causes seasonal epidemics in children, as well as in the elderly and immunocompromised population. Bronchodilators, epinephrine, steroids and non-specific anti-viral agents are not recommended by major clinical practice guidelines as they either only address symptoms or have very limited therapeutic effect. As of the Latest Practicable Date, palivizumab, nirsevimab and clesrovimab were the only three approved RSV prophylactic drugs globally but they were only available for selected high-risk infants and young children. There is a significant need for effective RSV treatment and prevention. According to CIC, the global RSV treatment market recorded only

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US\$30.0 million as of 2024 and is projected to reach US\$819.0 million in 2026, and is expected to expand rapidly to US\$8.6 billion in 2035, representing a CAGR of 67.1% from 2024 to 2035. The global RSV prevention drug market (including RSV target drugs, excluding RSV vaccine) reached approximately US\$2.7 billion in 2024, and is projected to maintain steady growth thereafter, reaching US\$5.3 billion by 2035, representing a CAGR of 8.4% during 2026 to 2035.

Ziresovir — NDA Stage Core Product

Overview

Ziresovir, is a highly selective and potent small molecule inhibitor of RSV fusion protein, namely RSV F protein, which regulates viral entry into host cells and cell-cell fusion. Ziresovir was originally discovered by Roche where our Founder, Dr. Wu, co-invented the molecule and led its early development. We had entered into a license agreement with Roche pursuant to which we obtained the exclusive global rights of ziresovir. For details, see “— Overview of Licensing and Collaboration Agreements — In-licensing Ziresovir from Roche.” At the time of in-licensing, ziresovir was a pre-clinical drug candidate. Since in-licensing the ziresovir molecule from Roche in 2014, we have rapidly advanced ten clinical trials for ziresovir indicated for pediatric and adult patients across major markets including China, the U.S., Europe and Australia, and have submitted the NDA application to the NMPA for the treatment of RSV in infants aged one to 24 months. It is the first RSV drug worldwide to enter phase III clinical trial in hospitalized infants and young children, according to CIC. In July 2025, ziresovir was included in the newly released “Pediatric drug optimization for respiratory syncytial virus (PADO-RSV) meeting report” by Global Accelerator for Pediatric formulations (GAP-f), a WHO host network. Ziresovir is the first and only RSV antiviral drug included in the list, and this is the first time the WHO includes an anti-RSV drug in the pediatric drug optimization priority list.

In September 2024, the phase III clinical trial results of ziresovir were published in the globally prestigious *New England Journal of Medicine*, which demonstrated its clinical benefits and antiviral effect. In May 2025, analysis of patients aged below six months for their 2-year follow-up results from its phase III clinical trial were published in the international top-tier journal — *The Lancet Child & Adolescent Health* marking the first validation of ziresovir’s clinical efficacy in hospitalized infants 6 months of age and revealing the long-term benefits of ziresovir in reducing recurrent wheezing and asthma. These peer-reviewed publications in the world’s leading medical journals validate ziresovir’s strong clinical profile and competitive positioning, representing a significant commercial opportunity in the underserved RSV therapeutic market with potential for rapid market adoption upon regulatory approval.

Market Opportunity and Competition

According to CIC, incidences of severe RSV infection in children under five years old reached 34.1 million globally in 2024. In the same year, incidence of severe RSV infection in adults aged 65 years or above reached 9.1 million globally.

The current treatment guidelines in the U.S. and China advise supportive care through oxygen supplement, nasal decongestion, nutrition and hydration, and the use of bronchodilators, epinephrine and steroids as the main standard of supportive care. Ribavirin was approved for RSV infection. But it was not recommended by the American Academy of Pediatrics (AAP) and the experts’ consensus in China due to its lack of clinical efficacy and significant adverse side-effects, especially teratogenicity and hematologic anemia.

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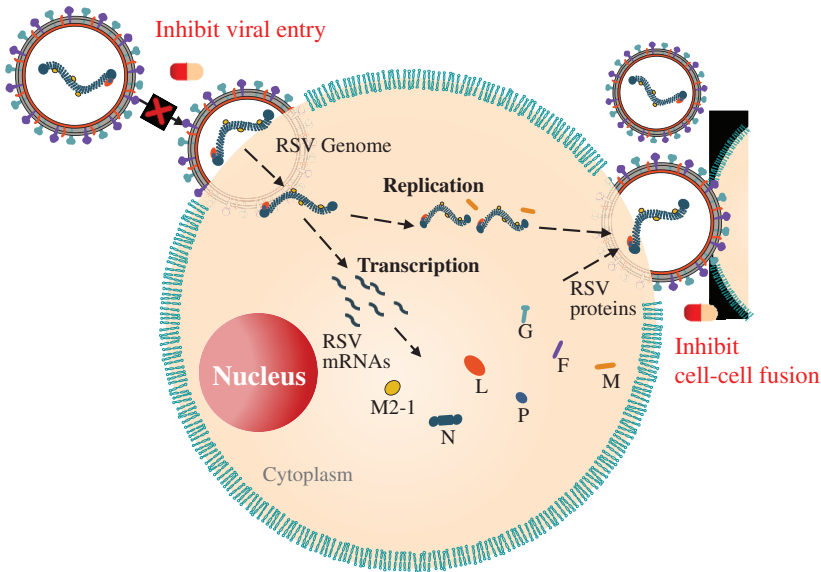
Small molecule antiviral drugs have shown to be a promising modality for RSV infection treatment. While there are multiple RSV antiviral drugs in development, only a few have reached clinical stage. The following table summarizes RSV-targeted antiviral compounds in active clinical development as of the Latest Practicable Date¹. Ziresovir was the first RSV-specific antiviral drug to achieve positive results in pivotal phase III clinical trials.

Trial number	Candidate	MoA	Company	Clinical phase	First posted date	Indication	Location
NCT04231968	Ziresovir	F protein	ArkBio	NDA	2020/01/18	RSV for children	China
NCT06942299	Ziresovir	F protein	ArkBio	II	2025/04/24	RSV for adults	China
NCT06585150	GS-5245	RdRp	Gilead Sciences	II	2024/09/05	RSV for adults	US
NCT05568706	EDP-938	N protein	Enanta	IIb	2022/10/06	RSV for adults	US
NCT06170242	EDP-323	RdRp (L protein)	Enanta	IIa	2023/12/14	RSV for adults	US
NCT04816721	EDP-938	N protein	Enanta	II	2021/03/25	RSV for children	US
NCT06270511	S-337395	RdRp (L protein)	Shionogi/UBE Corporation	I	2024/02/21	RSV for adults	US
NCT06206720	VV116	RdRp	Vigonvita Life Sciences	II/III	2024/01/16	RSV for children	China
NCT06328400	VV116	RdRp	Vigonvita Life Sciences	I	2024/03/25	RSV for adults	China
CTR20253751	SYH2066	/	CSPC	I	2025/09/19	RSV for adults	China

Source: ClinicalTrials.gov; CDE; CIC

Mechanism of Action

The RSV fusion (F) protein is a glycoprotein expressed on the surface of the viral membrane. It plays an important role in RSV infection, where it induces viral entry and promotes syncytia formation between infected cells and adjacent healthy cells for viral transmission, a process for which the name of the virus is coined. Ziresovir inhibits RSV F protein-induced viral entry into host cells as well as cell-cell fusion. This mechanism of action was validated by the mutation assays where identification of certain ziresovir-resistant mutations in the RSV F protein upon artificial selection pressure. We have recently solved the ziresovir F protein complex structure by Cryo-EM method. The RSV replication cycle and ziresovir’s mechanism of action by inhibiting viral entry and cell-to-cell fusion are illustrated below.



¹ Unless otherwise specified, a clinical trial is considered inactive, and hence not included in this and other pipeline charts, if (1) the latest phase of the clinical trial had been completed over five years ago, and (2) it has not entered into the next phase.

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Source: Company Information

Clinical Development Strategy

Ziresovir was co-invented by Dr. Wu, our Founder, during his tenure at Roche China, where he led its early development journey. Following Dr. Wu’s departure from Roche China to found our Group, our subsidiary, ArkBio Cayman, in-licensed the global rights to ziresovir from Roche in January 2014. We subsequently executed a series of pre-clinical R&D programs to advance ziresovir into clinical trials.

We adopted a phased approach in formulating the clinical development strategy for ziresovir, targeting different patient groups, including adults, children, infants and PICU patients. Ziresovir applied to different patient groups adopt the same molecule and API with different dosage levels. Our clinical development strategy for ziresovir consists of the following:

China Market

- ***Infants and Young Children Aged 1-24 Months – NDA under Review.*** Following the completion of its phase III clinical trial and supplementary phase III clinical trial in China, we have submitted the NDA application to the NMPA in August 2025, which is currently under technical review. As of the Latest Practicable Date, we had submitted the necessary documents for manufacturing inspection and clinical data verification. Based on the normal review timelines (12-15 months) according to CIC, we expect to obtain its NDA approval in 2026.
- ***Children Aged 2-5 Years – Age Expansion Planned.*** We intend to expand our indication to children aged 2 to 5 years via a label expansion approach following our initial NDA approval, supported by a bridging PK study we completed involving 48 subjects. We plan to submit its age expansion application to the NMPA by the end of 2027, after the NDA approval for ziresovir is obtained.
- ***Adults – Phase II/III Clinical Trial Underway.*** In the past, we initiated two Phase II clinical trials of ziresovir targeting adult patients, both of which were discontinued. The first trial (CTR20181808), initiated in March 2019, was discontinued as subject enrollment was significantly impeded by the COVID-19 pandemic, which limited hospital access and deterred patients from site visits due to infection risks, resulting in a total enrollment of only one subject. The second trial (CTR20230657) commenced in July 2023 and enrolled 25 subjects during the 2023–2024 RSV season. We discontinued this trial following a strategic review to prioritize the execution of the supplemental Phase III clinical trial of ziresovir, thereby facilitating our NDA submission. In October 2025, we held communications with The CDE, during which the CDE confirmed that they had no objection to our initiating a combined phase II/III clinical trial for adult RSV patients and we shall arrange another round of communication prior to the initiation of phase III part of this clinical trial. In March 2026, we initiated subject enrollment for this phase II/III clinical trial and aim to complete subject enrollment in the next two RSV seasons (2026Q4/2027Q1 and 2027Q4/2028Q1) and complete this clinical trial in 2028. We anticipate accelerating patient enrollment in the upcoming Phase II/III trial compared to the previously terminated trials by leveraging recent technological advancements to adopt more advanced and suitable diagnostic kits for patient screening and enrollment, concurrently with an expansion of the number of participating clinical trial sites.

Ex-China Market

We have completed various clinical trials to develop ziresovir in ex-China market, including a phase 1 first-in-human clinical trial, mass balance and drug-drug interaction studies and a global multi-regional phase II clinical trial in pediatric patients; and a phase I U.S. clinical trial in the United States. Particularly, we view the U.S. market as a significant opportunity, with its RSV treatment market size expected to reach US\$3,705.5 million by 2035 according to CIC.

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U.S. Pediatric Population Development Strategy

In January 2023, we initiated communications with the FDA regarding our clinical trial plan to support the NDA for ziresovir in the United States. These communications were supported by our then-available clinical trial data, which included results from our Phase I first-in-human clinical trial in Australia, our Phase II global clinical trial, our Phase III clinical trial in China, and our completed Phase I clinical trial in adults in the United States. During these communications, the FDA requested that we complete a Thorough QT (TQT) study to provide additional clinical data on the cardiac safety profile of ziresovir prior to initiating studies in the pediatric patient population. We successfully completed the TQT study (NCT06591845) in December 2024, which concluded that ziresovir did not have a clinically relevant effect on heart rate or cardiac conduction. We submitted the results of the TQT study to the FDA in June 2025. Subsequently, in October 2025, the FDA requested an amendment regarding chemistry, manufacturing and control design in relation to ziresovir’s future clinical trial in the United States. We do not anticipate any material difficulties in addressing the FDA’s comments.

We plan to request a meeting with the FDA in the first half of 2026 to seek regulatory guidance on our clinical development strategy and trial design, including the target study population and clinical endpoints. Recognizing that ziresovir is a novel chemical entity targeting a medically vulnerable population (infants under two years of age) and that there are currently no globally approved direct anti-viral drugs for RSV, we plan to propose a Phase II clinical trial involving approximately 80 subjects to the FDA. Concurrently, during these communications, we intend to seek the FDA’s concurrence to bypass the Phase II study and proceed directly to a pivotal Phase III clinical trial. The phase III clinical trial is expected to enroll approximately 168 subjects, using a 2:1 randomization ratio. The primary endpoints for these phase II and III trials would be the proportion of participants demonstrating clinical improvement as measured by the Clinical Progression Scale for Pediatrics (CPS-Ped), with secondary evaluations of symptom improvement utilizing the Wang Bronchiolitis Clinical Score (WBCS). As of the Latest Practicable Date, we are actively consulting with leading key opinion leaders (KOLs) in the U.S. in the fields of pediatric respiratory medicine and pediatric intensive care units (PICU) to further refine our study design and development strategy prior to our formal FDA submission.

Concurrently, we are in the process of identifying prospective trial sites equipped with the requisite patient populations and operational expertise. Subject to FDA feedback and agreement, we anticipate initiating the relevant clinical trial in the United States in the first half of 2027. We anticipate that the phase II clinical trial would take 12 months to complete.

U.S. Adult Clinical Development Strategy

Furthermore, we are evaluating clinical development opportunities in the U.S. adult RSV patient market. We currently plan to initiate communications with the FDA regarding the regulatory pathway for this indication by the end of 2026, supported, where applicable, by data from our adult trials conducted in China. Subject to reaching an agreement with the FDA, we plan to proceed with Phase II and Phase III clinical trials in the U.S. thereafter. The planned Phase II trial is expected to enroll approximately 80 subjects, and the planned Phase III trial is expected to enroll approximately 200 subjects.

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Key Milestones

The following summarizes key milestone during the development of ziresovir after in-licensing it from Roche.

Time	Milestone
January 2014	We in-licensed ziresovir from Roche.
October 2014 to June 2015	We conducted and completed the phase I first-in-human clinical trial in adults in Australia.
October 2017 to May 2018	We conducted and completed the NMPA-regulated phase I clinical trial in adults in China.
January 2018 to February 2018	We conducted and completed the phase I mass balance study in the UK.
April 2019	We completed the phase II global clinical trial in infants and young children in multi jurisdictions.
October 2019 to January 2020	We conducted and completed the phase I DDI study in Australia.
September 2020	We initiated the NMPA-regulated phase III clinical trial in China in infants and young children aged one to 24 months (“ AirFLO ”).
March 2021 to June 2021	We conducted and completed the phase I clinical trial in adults in United States. Under the existing FDA rules and regulations, before a novel drug can be approved for marketing in the US, a series of clinical studies are required to fully characterize the safety and efficacy of such drug. These could typically include multiple Phase I studies such as mass balance study, drug-drug-interaction (DDI) studies, and thorough QT (“ TQT ”) study, among other studies. Although we have previously completed multiple clinical trials for ziresovir, following FDA’s suggestion, we have initiated and completed a phase I pharmacology study in preparation for a potential TQT study in the United States.
February 2022	The phase III AirFLO clinical trial in China in infants and young children was completed.
December 2022	We submitted the NDA application for ziresovir to the NMPA for treatment of RSV in infants and young children one to 24 months.
April 2023	The NMPA published a new clinical guideline for the development of RSV antiviral drugs.
December 2023	We had a face-to-face meeting with the NMPA regarding the NDA application for ziresovir. During the meeting, the NMPA suggested conducting a supplemental phase III study.

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Time	Milestone
January 2024	Upon discussion and following NMPA’s suggestion, the trial design for the supplemental phase III clinical trial to support the NDA application for ziresovir was agreed by the NMPA.
February 2024	We withdrew the NDA application for ziresovir in agreement with the NMPA to initiate the supplemental phase III clinical trial AirFLO 2 in infants and young children in China to gather additional clinical data to support the NDA application.
March 2023 to May 2024	We completed a bridging PK study in RSV-infected hospitalized children aged 2 to 5 years old.
June 2024.	The phase II clinical trial in hospitalized adults in China was completed.
December 2024.	We completed a phase TQT study in the United States to support future clinical trial as requested by the FDA.
April 2025	The supplemental phase III AirFLO 2 clinical trial was completed.
June 2025.	The TQT study results were submitted to the FDA.
August 2025	We submitted the NDA application for ziresovir for the treatment of RSV in infants and young children aged one to 24 months to the NMPA.
	The NDA application for ziresovir for the treatment of RSV in infants and young children aged one to 24 months was accepted by the NMPA.

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Summary of Clinical Trial Results

The following table summarizes the clinical trials of ziresovir we initiated with ziresovir as of the Latest Practicable Date.

Country/Region	Clinical Trial	NCT/CTR Number	No. of Subjects	Start Date	Completion Date	Safety Results	Key Findings
Australia . . .	FIH trial to evaluate safety, tolerability, PK and food effect in healthy volunteers	NCT02297594	64	October 2014	June 2015	Grade 3 and above TEAE: None Discontinuation due to TEAE: None Withdrawal due to TEAE: None SAE: None	The proportion of subjects experiencing at least one adverse effect was similar between ones who received ziresovir (52%) and placebo (57%). The most commonly reported AEs were nervous system disorders and gastrointestinal disorders. A single asymptomatic abnormal liver function test result was reported. No clinically significant changes and concerns of safety data were noted from the trial.
Australia . . .	Phase Ib clinical trial in infants and young children	NCT02460016	1	November 2015	N/A	Grade 3 and above TEAE: None Discontinuation due to TEAE: None Withdrawal due to TEAE: None SAE: None	A six-month female was enrolled in the trial. During the trial, no adverse event occurred, and we did not observe any abnormal lab test results with clinical significance. In November 2015, following HREC's suggestion, the clinical trial was closed in favor of a Phase II global clinical trial in infants and young children.
China	Phase I trial to evaluate safety, tolerability, PK and food effect in healthy Chinese volunteers	NCT03322800/ CTR20171145	50	October 2017	May 2018	Grade 3 and above TEAE: None Discontinuation due to TEAE: None Withdrawal due to TEAE: None SAE: None	No serious adverse events were observed. The drug was well tolerated with no grade 3 or above AE, and no withdrawal due to adverse events. The most frequently reported adverse events were thrombin time prolongation and prolonged activated partial thromboplastin time, which were attributed to laboratory heparin contamination of samples according to post hoc investigation. No subjects withdrew from the clinical trial. No trend or clinically significant changes were noted.

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Country/Region	Clinical Trial	NCT/CTR Number	No. of Subjects	Start Date	Completion Date	Safety Results	Key Findings
China	Phase II clinical trial to evaluate ziresovir in the treatment of RSV in adult patients	NCT03699202/ CTR20181808	1	March 2019	Terminated	Grade 3 and above TEAE: None Discontinuation due to TEAE: None Withdrawal due to TEAE: None SAE: None	We originally plan to accelerate subject enrollment in the RSV season starting from 4 th quarter of 2019. However, enrollment coincided with the COVID-19 pandemic, during which patients were generally reluctant to visit hospitals due to concerns about exposure to respiratory illnesses, including RSV. As a result, only one subject was enrolled before the trial was discontinued.
China	Phase II clinical trial to evaluate ziresovir in hospitalized RSV adult patients	NCT06942299/ CTR20230657	25	July 2023	Terminated	Grade 3 and above TEAEs: A total of 7 cases (28.0%), comprising 4 cases (23.5%) in the Ziresovir group and 3 cases (37.5%) in the placebo group. None of the 4 cases in the Ziresovir group were related to the study drug. Discontinuation due to AEs: None. Withdrawal due to AEs: None. SAEs: A total of 4 cases (16.0%), comprising 2 cases (11.8%) in the Ziresovir group and 2 cases (25.0%) in the placebo group. None of the SAEs were related to the study drug.	We only enrolled 25 subjects during the first RSV season (4 th quarter of 2023 and 1 st quarter of 2024) and obtained preliminary clinical trial data for this clinical trial. As a seasonal respiratory disease, we believe it would be difficult to enroll subjects in the 2 nd and 3 rd quarter of 2024. In the meantime, we had to conduct a supplementary phase 3 clinical trial of ziresovir to support its NDA submission for infants aged 1-24 months. Therefore, we shifted our focus to such clinical trial. Accordingly, we decided to discontinue this phase 2 clinical trial.
UK	Phase I trial to evaluate mass balance in healthy volunteers	NCT03400995	7	January 2018	February 2018	Grade 3 and above TEAE: None Discontinuation due to TEAE: None Withdrawal due to TEAE: None SAE: None	Ziresovir and its metabolite are shown to have no preferential distribution to red blood cells. Following a single oral dose of ziresovir, 75% of the radio-labelled dose was recovered on day 8.

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Country/Region	Clinical Trial	NCT/CTR Number	No. of Subjects	Start Date	Completion Date	Safety Results	Key Findings
Australia . . .	Phase I trial to assess effect of itraconazole and fluoxetine on ziresovir PK in healthy volunteers	ACTRN 12619001413112	28	October 2019	January 2020	Grade 3 and above TEAEs: 1 case. Discontinuation due to TEAEs: 1 case. Withdrawal due to TEAEs: None. SAEs: 1 case, which was not related to the study drug.	During the clinical trial, 28 subjects were divided into two group with 14 in each group to evaluate the potential drug-drug interaction of ziresovir with itraconazole or fluoxetine. Generally, ziresovir was moderately rapidly absorbed from the gastrointestinal tract. In addition, the PK data comparisons between the two groups indicate co-administration of itraconazole results a 1.8-fold increase in ziresovir exposure and peak concentration.
U.S.	Phase I trial to evaluate safety, tolerability and PK of single dose escalation in healthy volunteers	NCT04788017	24	March 2021	June 2021	Grade 3 and above TEAE: None Discontinuation due to TEAE: None Withdrawal due to TEAE: None SAE: None	Single oral doses of 300, 600, and 900 mg of ziresovir were generally well tolerated in healthy adult subjects. Plasma ziresovir exposure increased in an approximately dose proportional manner for the dose range of 300 to 900 mg.
U.S.	Phase I safety clinical pharmacology (TQT) trial in healthy volunteers	NCT06591845	31	September 2024	December 2024	Grade 3 and above TEAE: None Discontinuation due to TEAE: None Withdrawal due to TEAE: None SAE: None	The most commonly reported treatment emergent adverse events (TEAEs) were headache and nausea, reported predominantly in the ziresovir 500 mg group. All TEAEs were mild (Grade 1) intensity. Cardiodynamic evaluation demonstrated that ziresovir at the studied doses did not have a clinically relevant effect on HR or cardiac conduction. The effect on the QTc interval was small and not clinically significant.

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Country/Region	Clinical Trial	NCT/CTR Number	No. of Subjects	Start Date	Completion Date	Safety Results	Key Findings
Australia, Hong Kong, Israel, Lebanon, Malaysia, Poland, Taiwan and Turkey . . .	Phase II Global Clinical Trial in Hospitalized Infants and Young Children	NCT02654171	74	May 2016	April 2019	Grade 3 and above TEAEs: A total of 3 cases (4.1%), comprising 2 cases (4.1%) in the Ziresovir group and 1 case (4.2%) in the placebo group. None of the cases were related to the study drug. Discontinuation due to TEAEs: None. Withdrawal due to TEAEs: None. SAEs: 2 cases (4.1%) in the Ziresovir group, none of which were related to the study drug	• WBCS reduced to baseline within 72 hours in 2mg/kg ziresovir group • Up to 1.7 log, or 98% decrease in viral load reduction in treatment group compared with the placebo group
China	Phase II Bridging PK Study in Hospitalized Children Aged 2-5 Years	CTR20223276	46	March 2023	May 2024	Grade 3 and above TEAEs: None. Discontinuation due to TEAEs: 1 case in the Ziresovir group due to rash, which was related to the study drug. Withdrawal due to TEAEs: None. SAEs: 1 case in the Ziresovir group due to rash, which was not related to the study drug.	• Virologically, subjects in both stages exhibited a consistent trend of rapid followed by slower reduction in RSV viral load relative to baseline.

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Country/Region	Clinical Trial	NCT/CTR Number	No. of Subjects	Start Date	Completion Date	Safety Results	Key Findings
China	Phase III clinical trial in infants and young children in China (“AirFlo”)	NCT04231968/ CTR20200215	302	September 2020	February 2022	Grade 3 and above TEAEs: A total of 13 cases (4.3%), comprising 8 cases (4.0%) in the Ziresovir group and 5 cases (4.9%) in the placebo group. The only Grade 3 or above drug-related TEAE in the Ziresovir group was one case of rash. Discontinuation due to TEAEs: A total of 6 cases (2.0%), all of which (6 cases, 3.0%) occurred in the Ziresovir group. Withdrawal due to TEAEs: A total of 3 cases (1.0%), all of which (3 cases, 1.5%) occurred in the Ziresovir group. SAEs: A total of 8 cases (2.6%), comprising 4 cases (2.0%) in the Ziresovir group and 4 cases (3.9%) in the placebo group. None of the SAEs in the Ziresovir group were related to the study drug.	• In the ziresovir group, WBCS improved 30% more than placebo within 48 hours of treatment. • Viral loads significantly reduced in the ziresovir group, including a 77% reduction on day 5 • Lower rate of recurrent wheezing and asthma compared to the placebo group.
China	Supplemental Phase III clinical trial in infants and young children in China (“AirFlo 2”)	NCT06775405/ CTR20240557	180	February 2024	April 2025	Grade 3 and above TEAEs: A total of 8 cases (4.4%), comprising 6 cases (6.7%) in the Ziresovir group and 2 cases (2.2%) in the placebo group. None of the 6 cases in the Ziresovir group were related to the study drug. Discontinuation due to TEAEs: None. Withdrawal due to TEAEs: None. SAEs: A total of 16 cases (8.9%), comprising 9 cases (10.0%) in the Ziresovir group and 7 cases (7.8%) in the placebo group. None of the SAEs were related to the study drug.	• Ziresovir subjects showed significantly greater RSV viral load reductions from baseline on each day through day three to day six compared to placebo • In terms of PICU stay duration for infants when combined with AirFLO clinical trial data, ziresovir maintained the 2.5-day reduction advantage in PICU stay duration compared to placebo.

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Summary of Key Clinical Trial Data

China

Infants and Young Children Aged one to 24 months

Phase III Clinical Trial in Infants and Young Children in China (“AirFLO”)
(NCT04231968/CTR20200215)

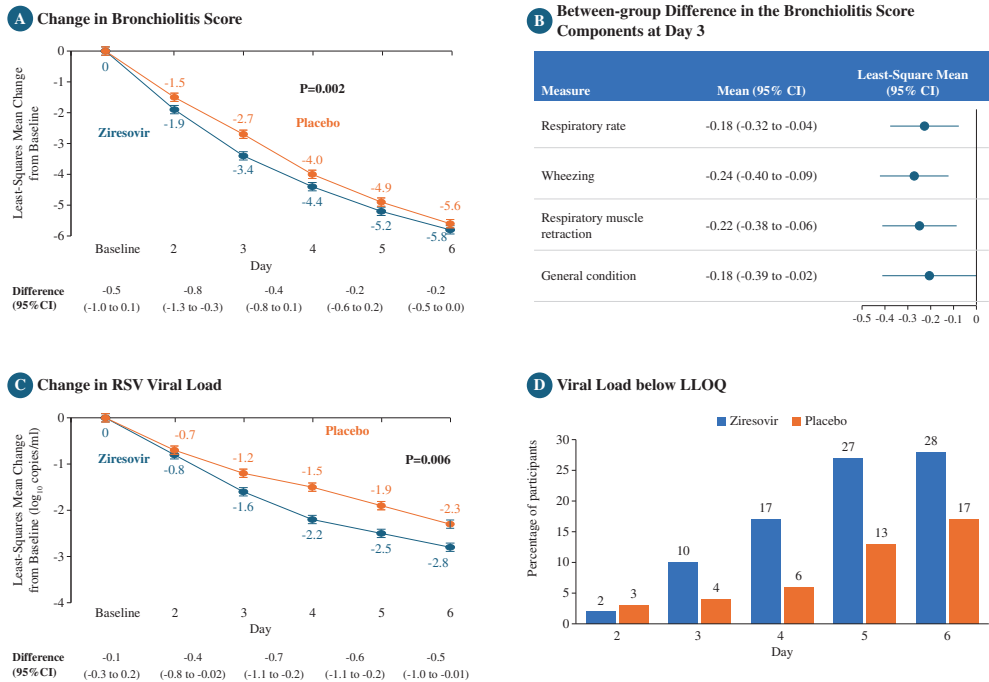
- *Trial design.* From September 2020 to February 2022, we completed an NMPA-regulated regulated, randomized, double-blind, placebo- controlled, multi-center phase III clinical trial in infants and young children aged one to 24 months who are infected by RSV to assess the clinical efficacy, safety, tolerability, PK, and antiviral effect of ziresovir in pediatric patients with RSV infection in China. A total of 302 subjects were enrolled in the trial. The clinical trial was divided into two parts. Each part of the study included a visit schedule with two stages: 1) main study stage, including a 36-hour screening period prior to first dosing, a 5-day treatment period, and a 9-day safety follow-up period; 2) subsequent information collection stage: collecting information on respiratory sequelae (number of recurrent wheezing episodes, duration, treatment, and asthma diagnosis) from the end of the safety observation period through two years. The clinical trial report was finalized in May 2022, upon which the PI and we concluded that the primary and secondary endpoints are reached.

During the first part of this study, ziresovir or placebo were orally administered twice-daily based on a weight-based regimen. If no safety issues were identified or dose adjustments required after completion of the first part, the second part of the study would proceed. 302 subjects were enrolled in the clinical trial, including 200 subjects receiving treatment by ziresovir and 102 subjects receiving placebo.

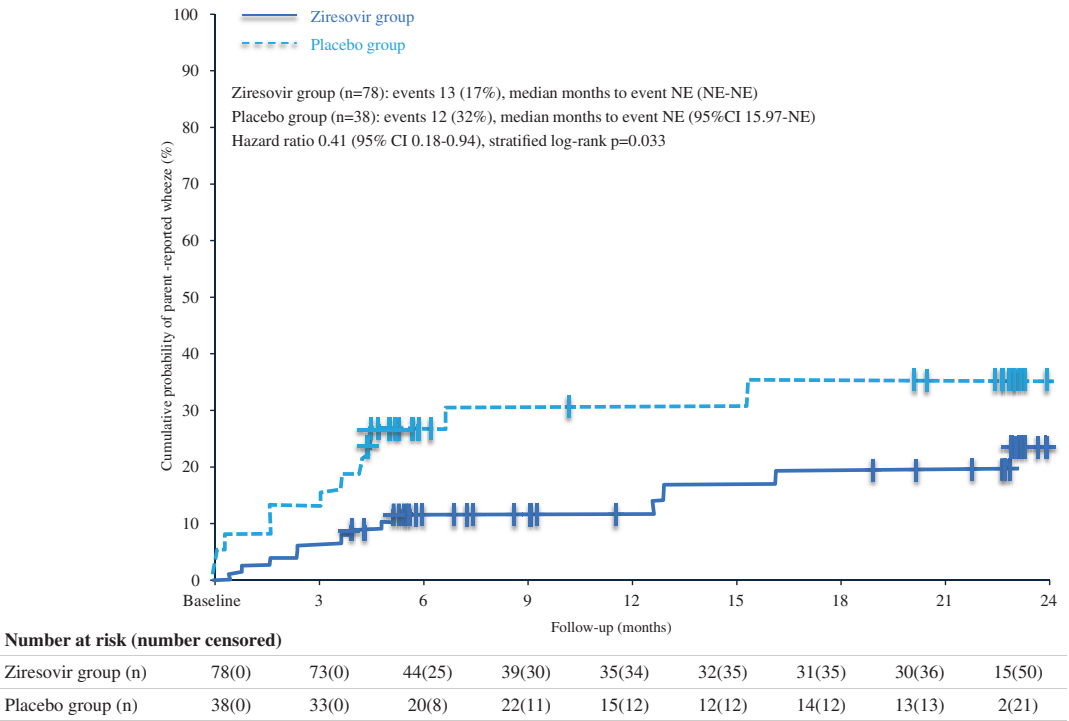
The primary outcome measure was the difference of the change in WBCS score. Secondary outcome measurements include differences of viral load change, differences of frequency of PICU admission and of length of PICU stay, differences of frequency of non-invasive positive pressure ventilation or mechanical ventilation, differences of the duration of supplemental oxygen administration.

- *Safety data.* During the clinical trial, ziresovir demonstrated comparable overall tolerability to placebo in the study population. A total of 122 (61.0%) subjects in the ziresovir group and 54 (52.9%) subjects in the placebo group reported adverse events after medication, with similar incidence rates between the two groups. There were no deaths in this clinical study, and the proportion of subjects experiencing serious adverse events in the ziresovir group (4/200, 2.0%) was lower than in the placebo group (4/102, 3.9%), with all serious adverse events being unrelated to the study medication. Drug-related adverse events occurred in 31 (15.5%) subjects in the ziresovir group and 13 (12.7%) subjects in the placebo group, with similar proportions between the two groups.
- *Efficacy data.* Clinical studies showed that ziresovir had rapid onset of action, with WBCS improving 30% more than placebo within 48 hours of treatment (P=0.002). In infants under 6 months of age, ziresovir demonstrated more significant clinical benefit, with WBCS improving 55% more than placebo (P<0.001). Additionally, ziresovir showed significant antiviral effects, with viral loads significantly reduced during treatment compared to placebo, including a further 77% reduction in viral load on Day 5 compared to placebo (P=0.006).

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The two-year follow-up data for patients ≤ 6 months of age demonstrates that the ziresovir group showed significantly lower rates of recurrent wheezing and asthma compared to the placebo group. This highlights ziresovir’s long-term protective benefit in preventing respiratory sequelae in infants treated for RSV infection.



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- *Conclusion.* The clinical trial report was finalized in May 2022, upon which the PI and we concluded that the primary and secondary endpoints are reached. For infants and young children infected with RSV, ziresovir can significantly reduce WBCS and viral loads, with a good safety profile.

Supplemental Phase III Clinical Trial in Infants and Young Children in China (“AirFLO 2”) **(NCT06775405/CTR20240557)**

- *Trial design.* Following the discussion with the NMPA, we decided to conduct a supplementary phase III clinical trial in infants and young children aged between 1 months to 24 months (“AirFLO 2”). Compared to AirFLO, AirFLO 2 adopted a similar study design including the same primary endpoint compared to AirFLO. A total of 180 subjects with virologically confirmed RSV infection were enrolled. Each participant’s study period included a 36-hour screening period before first dosing, a 5-day treatment period, and a 9-day post-treatment safety follow-up period. The primary endpoint was the change in WBCS from baseline at Day 3 after initiation of first dose. The secondary endpoints included changes in RSV viral load from baseline, proportion of subjects achieving viral load below quantification limits, time to clinical improvement, changes in clinical sub-scores, and time to recovery of individual symptoms (respiratory rate, wheezing, retractions, and general symptoms). The AirFLO 2 clinical trial was initiated in February 2024 and completed in April 2025. The clinical trial report was finalized in July 2025, upon which the PI and we concluded that the primary and secondary endpoints are reached.
- *Efficacy data.* Ziresovir demonstrated significant antiviral efficacy with RSV viral load showing continuous and significant decline over the treatment period. When combined with the AirFLO clinical trial results, ziresovir subjects showed significantly greater RSV viral load reductions from baseline on each day through day three to day six compared to placebo. The proportion of subjects achieving RSV viral load below the lower limit of quantification (LLOQ) was consistently higher in the ziresovir group.

Combined with the AirFLO clinical trial results, ziresovir demonstrated that it significantly reduced WBCS compared to placebo. For sustained clinical recovery, the combined analysis revealed that ziresovir subjects achieved shortened recovery with approximately 1 day earlier compared to placebo.

In terms of PICU stay duration for infants when combined with AirFLO clinical trial data, ziresovir maintained the 2.5-day reduction advantage in PICU stay duration compared to placebo. These results indicate that ziresovir demonstrates potential clinical value in promoting accelerated recovery and discharge for PICU patients.

- *Safety data.* Ziresovir demonstrated a favorable safety and tolerability profile in this clinical trial. When combined with the AirFLO clinical trial results, 61.0% of subjects experienced TEAEs, with drug-related TEAE rates of 22.1% in the ziresovir group and 24.0% in the placebo group. With respect to severity and correlation, drug-related TEAEs observed in both the ziresovir group and the placebo group were mild in severity, primarily Grade 1-2, with similar incidence proportions between groups. Drug-related TEAEs with incidence rates $\geq 2\%$ in the ziresovir group that exceeded those in the placebo group included creatine phosphokinase MB increased (8.9% vs. 3.3%), rash (3.3% vs. 2.2%), hypertriglyceridemia (2.2% vs. 1.1%), functional gastrointestinal disorder, anemia, and neutrophil percentage decreased (each 2.2% vs. 0%). No incidences of adverse events led to patients withdrawal or study discontinuation was observed.

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- **Conclusion.** These phase III clinical results establish that ziresovir provides excellent safety, significant anti-RSV viral effects, effective improvement of clinical symptoms, and accelerated disease recovery, with particularly pronounced clinical benefits in the most vulnerable patient populations.

Children Aged 2 to 5 Years Old

Phase II Bridging PK Study in Hospitalized Children Aged 2-5 Years (CTR20223276)

- **Trial Design.** We initiated the clinical trial in March 2023 and completed it in May 2024. This is a multi-center, open-label, single-arm trial designed to evaluate the pharmacokinetics, safety, and efficacy of ziresovir in hospitalized pediatric RSV patients aged two to five years. In the first phase, 24 subjects were enrolled, who received ziresovir twice daily for five consecutive days, with dosing stratified by body weight, followed by a nine-day safety follow up period. Subsequently, in the second phase, 24 additional subjects were enrolled using a dosage regimen adjusted based on the PK data derived from the first phase, while maintaining the same study procedures. The clinical trial report was completed in March 2025 and the PI and us concluded that all the primary and secondary endpoints were reached.
- **Efficacy Results.** Ziresovir demonstrated significant antiviral activity and symptom alleviation in hospitalized pediatric patients aged two to five years. Virologically, subjects in both stages exhibited a consistent trend of rapid followed by slower reduction in RSV viral load relative to baseline, with maximum inhibitory effects generally achieved by days 4 to 5 of dosing. Clinically, ziresovir treatment effectively mitigated acute respiratory symptoms, showing high alleviation rates for fever, wheezing, and rales, with fever resolving fastest at a median time of 2.0 days across both stages.
- **Safety Results.** Ziresovir demonstrated a favorable safety and tolerability profile in hospitalized pediatric patients aged two to five years. Treatment-emergent adverse events (TEAEs) were reported in 25 subjects (54.3%), with incidence rates of 62.5% in the first stage and 45.5% in the second stage. Drug-related TEAEs occurred in 29.2% and 13.6% of subjects in the first and second stages, respectively, with hypertriglyceridemia being the most frequently reported. Importantly, no TEAEs of Grade 3 or higher were observed. There were no deaths, and the single reported serious adverse event (SAE) (2.2%), a case of Grade 2 norovirus acute gastroenteritis, was assessed by the investigator as unrelated to the study drug. Only one subject (2.2%) discontinued treatment due to a TEAE (Grade 2 rash), and no subjects withdrew from the study due to adverse events.

Adults

Phase II Clinical Trial in Adults in China (Discontinued Due to Prolonged Subject Enrollment) (NCT06942299/CTR20230657)

- **Trial design.** From July 2023 to June 2024, we initiated, and later discontinued an NMPA-regulated phase II randomized, double-blind, placebo-controlled clinical trial in China to evaluate drug's safety, efficacy and PK properties in hospitalized high-risk Chinese RSV adult patients. Prior to its discontinuation, a total of 25 subjects were enrolled in the clinical trial. During the preliminary trial, 25 subjects were randomized to orally receive ziresovir or placebo. As a seasonal respiratory disease, we believe it would be difficult to enroll subjects in the 2nd and 3rd quarter of 2024. In the meantime, we had to conduct a supplementary phase 3 clinical trial of ziresovir to support its NDA submission for infants aged 1-24 months. Therefore, we shifted our focus to such clinical trial. Accordingly, we decided to discontinue this phase 2 clinical trial.

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- *Safety data.* The drug was well tolerated with no withdrawal due to adverse events. Most TEAEs identified during the clinical trial were grade 1 and grade 2 in severity.
- *Efficacy data.* Based on the respiratory infection severity questionnaire analysis, subjects in the treatment group demonstrated varying degrees of improvement across all eleven symptom indicators compared to baseline, with notably greater improvement than the placebo group. Particularly significant improvements were observed in systemic symptoms including sleep disruption, neck pain, body aches, and lower respiratory tract wheezing, where the proportion of subjects showing improvement exceeded the placebo group by more than 20%, with the highest improvement reaching 69%.
- *Conclusion.* This study demonstrates that ziresovir exhibits good safety and tolerability profiles for treating RSV infections in hospitalized adult patients with underlying health conditions. The study shows that ziresovir has potent and sustained viral clearance effects against RSV infections in adults and can improve respiratory symptoms in hospitalized adult patients with RSV infection, with symptom relief becoming increasingly evident over extended treatment duration.

Global Market

Phase II Global Clinical Trial in Hospitalized Infants and Young Children (NCT02654171)

- *Trial design.* From May 2016 to April 2019, we completed a randomized, double blind, placebo-controlled, multi-center phase II clinical trial to evaluate the safety, tolerability, PK and antiviral effect of single and multiple doses of ziresovir in hospitalized infants and young children with RSV infection aged from one to 24 months. The clinical trial was conducted at 28 trial sites in Australia, Hong Kong, Israel, Lebanon, Malaysia, Poland, Taiwan and Turkey. Australia TGA and the applicable HREC per TGA’s Clinical Trial Notification (“CTN”) scheme were the lead regulatory authorities for this trial and the clinical trial also obtained the local IND approvals from local regulatory bodies in all the countries and regions it was conducted. We strategically selected these countries and regions for several scientific and operational reasons. First, RSV infection exhibits distinct seasonal patterns across different geographic locations, with peak infection periods occurring at different times of the year in the Northern Hemisphere, Southern Hemisphere, and tropical regions. By conducting the trial across multiple countries spanning different hemispheres and climate zones, we were able to maintain continuous patient enrollment throughout the year rather than being limited to a single RSV season, thereby substantially accelerating trial completion timelines and reducing overall development costs and time to market. The geographic and ethnic diversity of the participating countries enabled us to evaluate Ziresovir’s efficacy and safety profile across different patient populations including Caucasian, Asian, Middle East, and other ethnic groups. A total of 74 subjects were enrolled and randomized, with 73 subjects dosed in the clinical trial. The primary objective was to evaluate safety and tolerability of ziresovir in pediatric patients. Secondary objectives included (i) to characterize single- and multi-dose PK of ziresovir in infants and young children; (ii) to determine antiviral effects in pediatric patients by measuring the RSV viral load area under the curve in nasal, pharyngeal and tracheal washes or aspirates; and (iii) to evaluate clinical benefits of ziresovir by determination of the WBCS of these pediatric patients. The trial was conducted in multiple jurisdictions and trial sites with quite different medical practice and insurance policy, among others. As such, the duration of hospitalization and ICU stay would be highly variable and would not provide meaningful information to evaluate the efficacy of ziresovir. The efficacy endpoints used in the trial primarily included WBCS scores, which is one of the suggested measures of drug efficacy according to FDA’s guidance. The clinical trial report was finalized in May 2021, upon which the PI and we concluded that the primary and secondary endpoints are reached.

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- *Efficacy data.* A clear trend of ziresovir’s therapeutic effect was demonstrated in both WBCS and viral load. The 2 mg/kg ziresovir group had their WBCS reduced virtually to baseline within 72 hours, whereas placebo group only showed gradual reduction. Strong anti-viral effects were also observed in the trial, with an up to 1.7 log or 98% decrease in viral load in treatment group compared with the placebo group.
- *Safety data.* During the clinical trial, the proportion of subjects experiencing treatment emergent adverse events (TEAEs) was similar between treatment groups (49%) and placebo group (42%). Only three subjects (4%) experienced drug related TEAEs and none of the three had experienced severe emergent adverse events. No emergence of clinically significant drug resistant mutation was observed during the clinical trial.
- *Conclusion.* Ziresovir was well tolerated in hospitalized RSV-infected infant patients. The efficacy profile of ziresovir demonstrated that it can reduce viral load and improve clinical symptoms. The results of this clinical trial was published as an academic paper on *Influenza and Other Respiratory Viruses*, a peer-reviewed scientific journal published by John Wiley & Sons for the International Society for Influenza and other Respiratory Virus Diseases

Although this global phase II clinical trial was not directly conducted within China, the trial design, conduct, and data were subject to NMPA regulatory oversight as part of our overall clinical development strategy for the Chinese market. We submitted the complete trial data from this clinical trial as core supporting evidence in our application to initiate phase III clinical development in China. Based on the efficacy and safety data generated from this phase II global clinical trial and together with our proposed Phase III trial design tailored to the Chinese pediatric RSV patient population, NMPA has no objection for us to proceed with our Phase III clinical trial in China.

Next Steps

China – Infants aged 1-24 months. For ziresovir’s current NDA application in China, we expect we will be able to obtain such NDA approval by the end of 2026. As of the Latest Practicable Date, the NDA application had entered technical review stage. As part of the regular review process, the NMPA will conduct manufacturing site inspection and clinical trial data sampling verification, and we have submitted all the necessary information for such inspection and verification process. As of the Latest Practicable Date, we had not received any feedback from the NMPA, which is consistent with the standard market practice. Based on the standard NMPA review period for innovative drugs, which typically ranges from 12 to 15 months from the date of acceptance, and the current stage of the review process, we expect that we can obtain the NDA approval for ziresovir in infants aged 1-24 months in 2026.

China – Children aged 2-5 years old. Supported by the completed phase II bridging PK clinical trial in China in this age group (CTR20223276), we plan to adopt an age expansion approach for ziresovir for this age group, after we obtain the NDA approval for ziresovir in infants aged 1-24 months. As advised by CIC, this approach is in line with practice of pharmaceutical companies developing other respiratory antiviral drug (e.g. influenza drugs). We currently expect to submit such age expansion application to the NMPA by the end of 2027, utilizing the data from the completed phase II bridging PK clinical trial.

China – Adults. In October 2025, we re-initiated communications with the Center for Drug Evaluation (CDE) regarding the future development plan for ziresovir in adult patients. As part of this consultation, we submitted clinical data from our prior pediatric trials and from the discontinued Phase II clinical trial (CTR20230657). The CDE concluded that they had no objection to the initiation of a Phase II/III clinical trial for adult RSV patients in China. We have designed this as a seamless combined Phase II/III trial to allow for the determination of an optimal dose to support the Phase III portion, a strategy intended to minimize the overall development timeline and enhance the probability of success. The CDE has requested a consultation meeting prior to the

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commencement of the Phase III portion to align on requirements for future NDA approval. In March 2026, we initiated subject enrollment for this phase II/III clinical trial and aim to complete subject enrollment in the next two RSV seasons and aim to complete subject enrollment in the upcoming two RSV season (2026Q4/2027Q1 and 2027Q4/2028Q1) and complete in 2028. We anticipate accelerating patient enrollment in the upcoming Phase II/III trial compared to the previously terminated trials by leveraging recent technological advancements to adopt more advanced and suitable diagnostic kits for patient screening and enrollment, concurrently with an expansion of the number of participating clinical trial sites.

U.S. – Pediatric Patients. We plan to initiate communications with the FDA in the first half of 2026 to finalize our clinical strategy, during which we will propose an 80-subject Phase II trial while concurrently seeking regulatory concurrence to bypass it and proceed directly to a pivotal 168-subject Phase III trial. If the FDA request us to complete the phase II clinical trial before initiating the phase III clinical trial, we anticipate that it will take 12 months to complete the phase II clinical trial. Subject to FDA agreement, we anticipate to initiate such clinical trial in the first half of 2027. We are currently consulting U.S. key opinion leaders and identifying prospective trial sites to refine our study design.

U.S. – Adults. Furthermore, we are evaluating clinical development opportunities in the U.S. adult RSV patient market. We currently plan to initiate communications with the FDA regarding the regulatory pathway for this indication by the end of 2026, supported, where applicable, by data from our adult trials conducted in China. Subject to reaching an agreement with the FDA, we plan to proceed with Phase II and Phase III clinical trials in the U.S. thereafter. The planned Phase II trial is expected to enroll approximately 80 subjects, and the planned Phase III trial is expected to enroll approximately 200 subjects.

Material Communications and Next Steps

China

With an aim to rapidly capture the market opportunities in China market, in December 2019, we had a meeting with the CDE after the completion of the phase II global clinical trial for hospitalized infants and young children. Based on the available CMC, pre-clinical, and clinical data, CDE agreed to waive the phase II study for hospitalized infants and young children in China and allowed us to proceed directly to a phase III clinical study. We subsequently obtained approval for phase III clinical study from the CDE in May 2020 and launched the phase III AirFLO clinical trial in China in September 2020. The phase III AirFLO clinical trial was completed in February 2022. Following its completion, in August 2022 we held communications with the NMPA regarding the NDA application for ziresovir, during which the NMPA confirmed that we can submit the NDA application based on the existing clinical trial results, including the results from phase III AirFLO clinical trial. Accordingly, we submitted the NDA application for ziresovir to the NMPA in December 2022. Following the submission of the NDA application, the NMPA conducted an onsite inspection on our clinical trials for ziresovir in May 2023 and did not identify any material findings during such inspections.

In December 2023, we had a face-to-face meeting with the NMPA. During the meeting, the NMPA proposed, that, in April 2023, following the publication of the FDA guideline on RSV antiviral drugs development, the NMPA also published the clinical trial guideline for RSV drug development, which recommended the inclusion of at least 300 subjects to receive the trial drug in the phase III clinical trial for the treatment of RSV infection and we were suggested to take into account such NMPA guideline, especially considering that there are no approved RSV antiviral drugs globally. Under the AirFLO clinical trial, only 200 subject received ziresovir. Accordingly, we agreed to conduct supplementary phase III clinical studies for ziresovir to better support its NDA application in China. We have not received any comments from NMPA indicating that they have material concerns with respect to ziresovir’s safety and efficacy profile of the AirFLO clinical trial and NMPA later confirmed with us regarding the proposed supplemental phase III clinical trial

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design. We voluntarily withdrew the previous NDA application, which was in agreement with the NMPA, in February 2024, approximately 14 months after the initial submission of the NDA and shortly after the face-to-face meeting with the NMPA. According to CIC, it is not uncommon for the NMPA to require pharmaceutical companies to conduct supplementary Phase III clinical trials during the review of their NDA submissions in order to test novel drug candidates in an expanded patient population. In such cases, it is not uncommon for pharmaceutical companies to withdraw its NDA applications. Other than the communication mentioned above, we did not have any material communications with the NMPA from December 2022 to January 2024.

We submitted the supplementary phase III clinical trial design for ziresovir in infants and young children (AirFLO 2) to the NMPA in January 2024 and initiated the supplementary phase III clinical trial in February 2024. We completed the supplementary phase III clinical trial for ziresovir in infants and young children (AirFLO 2) in April 2025. In August 2025, we submitted the NDA application to the NMPA for ziresovir for infants and young children aged 1 to 24 months, which was accepted by the NMPA in the same month. As of the Latest Practicable Date, our NDA application had entered the technical review stage, and we have submitted information for manufacturing site inspection and clinical trial data sampling verification. Based on the standard NMPA review period for innovative drugs, which typically ranges from 12 to 15 months from the date of acceptance, and the current stage of the NDA review process, we expect that we will obtain the NDA approval for ziresovir in 2026.

Dosage and Drug Labels

Based on communications with the CDE during its previous NDA application, we believe that ziresovir, once approved, will be administered orally based on body weight: patients weighing 2.5 to <5.0 kg receive 10 mg (1 capsule of 10 mg formulation) twice daily for 3 days; those weighing 5.0 to <10.0 kg receive 20 mg (2 capsules of 10 mg formulation) twice daily for 3 days; and patients weighing 10.0 to <20.0 kg receive 40 mg (1 capsule of 40 mg formulation) twice daily for 3 days. However, the drug label includes important warnings contraindicating use in patients with severe liver dysfunction, renal impairment, or hematological disorders. The product contains excipients that may trigger allergic reactions in susceptible individuals; such reactions can be managed with antihistamines, 10% calcium gluconate injection, corticosteroids, or epinephrine as needed. Patients should expect symptom improvement within 12 hours and seek immediate medical attention if symptoms worsen within 30 minutes of administration.

U.S.

We have maintained regular and ongoing communications with the FDA regarding the development of ziresovir since 2018. Initial PIND inquiries in 2018 and January 2020 resulted in general agreement on non-clinical and CMC programs, with the FDA advising on clinical pharmacology and clinical virology recommendations, including DDI, TQT, and antiviral testing in extensive clinical RSV A and B isolates, and requiring a pivotal phase 3 study in the target population for NDA approval. We filed an IND application with the FDA in November 2020 and obtained the IND approval in December 2020. As discussed with the FDA, the IND application follows FDA's recommendation to firstly conduct a clinical pharmacology study. We have since completed the recommended safety clinical pharmacology study in U.S. with good results. Following IND submissions and supplements from late 2020 through 2025, key milestones included: acceptance of the CQT protocol with a partial clinical hold requiring definitive QT prolongation risk results prior to patient trial initiation; requirement for a TQT study (subsequently completed and accepted with no comments in December 2024); acceptance of negative TQT study results in June 2025; and a request for CMC amendment in October 2025. Based on these communications, we need to seek FDA's clearance before initiation of next phase clinical trials. We plan to have a meeting with the FDA to discuss and clear the regulatory pathway of market approval of ziresovir in the U.S. based on available clinical data. For pediatric population, we plan to initiate communications with the FDA in the first half of 2026 for a phase II clinical trial, and may also seek

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the FDA’s concurrence to bypass the Phase II study and proceed directly to a pivotal Phase III clinical trial. For adult population, we plan to initiate communications with the FDA by the end of 2026 for a phase II and phase III clinical trial in the United States.

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

AK0610 — Phase II Stage RSV Prevention Candidate

AK0610 was originally discovered by Institute of Microbiology, Chinese Academy of Sciences in collaboration with Beijing Children’s Hospital through screening antibodies isolated from a recovered pediatric RSV patient. We participated in the early characterization of the antibodies. We in-licensed the intellectual property relating to AK0610 from Institute of Microbiology, Chinese Academy of Sciences in August 2021 and engineered and optimized the original antibody to AK0610. Since then, we conducted various preclinical and clinical studies, and advanced AK0610 to a phase II stage mAb drug for the prevention of RSV infection. It is promising in preventing RSV viral infection in the pediatric population by binding to the pre-fusion conformation of the RSV F protein at a site distinct from that of palivizumab or nirsevimab. The enhanced neutralizing activity both *in vitro* and *in vivo* as well as a projected prolonged half-life of AK0610 should support a once-a-season dosing regime, protecting infants and young children from RSV for the whole RSV season.

We obtained the IND approval for AK0610 in September 2023. In February 2024, we initiated the phase I clinical trial in China. The clinical trial enrolled 136 subjects and consisted of two parts to test the safety of AK0610 in healthy adults. The first part involves gradually increasing doses up to 3,000mg across five groups. The second part expanded testing to 96 additional subjects across two dose groups (300mg and 600mg by muscle injection, 48 subjects each) to collect more safety data at doses expected to be effective. Each subject completed treatment and a regular follow-up visits for six months. Those who were dosed with AK0610 continued in an extended follow-up period for additional six months. This comprehensive approach ensured thorough safety evaluation before the drug can be tested in infants and young children with RSV infections.

As of the Latest Practicable Date, AK0610 achieved very high yields of 7g/L in pilot production in CMC development. We had completed the phase I clinical trial, and no drug-related serious adverse events have been observed during the study, demonstrating long half-life and good drug safety. The antibody drug reached expected effective protective concentrations, with AK0610 showing the longest time to maximum concentration and the highest $C_{150\text{-day}}/EC_{90}$ ratio (2.0), indicating the best pharmacokinetic parameters among similar products on the market. We have initiated a phase II study to determine pharmacokinetics in infant subjects for AK0610 in the second half of 2025 and plan to complete this clinical trial in 2026.

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AK3280 — Post Phase II PoC Stage Lung Fibrosis Core Product

Fibrosis is a progressive and degenerative condition in human organs where a normal tissue becomes scarred over time and loses its physiological function. It affects nearly all tissues and organ systems. 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.

ILD is a group of fibrosis-related lung diseases characterized by progressive deterioration in lung function, physical performance, and quality of life in patients. 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, even lower than those observed in many types of cancer. IPF accounts for approximately 33% of all cases of ILD. IPF is one of the most common and life-threatening rare diseases, affecting approximately 1.9 million patients globally in 2024.

There are only two approved treatments for IPF in the U.S. and China, pirfenidone and nintedanib, and both with limited efficacy and poor tolerability. There are significant unmet medical needs for better IPF treatment options. The global IPF drug market has increased from US\$2.6 billion in 2018 to US\$5.8 billion in 2024 and is expected to reach US\$18.5 billion in 2035.

AK3280 was originally licensed from Genentech in 2018. Since then, we have conducted long-term GLP toxicity studies and other preclinical studies, tech-transfer for drug manufacturing in China, and successfully initiated clinical trials in Europe and China. AK3280 is a phase-III ready candidate broadly active in several different animal models of organ fibrosis. Our most advanced program for AK3280 is for IPF. We are also advancing programs to expand indications to other ILDs, such as PF-ILD, as well as liver fibrosis and other fibrotic diseases. For details on our in-licensing arrangement with Genentech Inc. on AK3280, see “— Overview of Licensing and Collaboration Agreements — In-licensing AK3280 from Genentech, Intermune and Roche Basel.”

Market Opportunity and Competition

There are currently only three drugs approved for IPF in the U.S. and China, all of which have certain clinical limitations with side effect, such as GI intolerance, which led to discontinuation of the treatment in up to 50% of the patients. In 2024, pirfenidone and nintedanib together recorded US\$5.8 billion in global sales, despite their limited efficacy and poor tolerability.

Currently, there is a growing portfolio of candidates that target different pathways involved in the complex pathogenesis of IPF. Among the candidates, second generation pirfenidone drugs share the similar pharmacophore structure but could have a diverse chemical structure and different pharmacological profile. Second-generation pirfenidone drug candidates aim to improve the safety profile of pirfenidone, especially side effects such as GI intolerance and phototoxicity that could result in discontinued use of the drug, and to achieve better efficacy and patient compliance. According to CIC, as of the Latest Practicable Date, there were three second-generation pirfenidone compounds under clinical development for the treatment of IPF globally.

Trial number	Candidate	MoA	Company	Clinical Phase	First posted date	Indication	Location
NCT05060822	Yinfenidone (HEC585)	TGF-β	Sunshine Lake Pharma	III	2025/07/02	IPF	China, US
NCT05321420	Deupirfenidone (LYT-100)	TGF-β	PureTech	III	2025/12/16	IPF	US
NCT05424887	AK3280	TGF-β	Ark Biosciences	II	2022/06/21	IPF	China

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* Inhibitor of TGF- β induced fibrotic gene expression

Source: *ClinicalTrials.gov*; *CDE*; *CIC*

Mechanism of Action

AK3280 is an optimized molecule based on pirfenidone, an approved therapy for IPF but with a chemical structure. Similar to pirfenidone, the molecular target of AK3280 is not fully characterized. Pre-clinical data has demonstrated that AK3280 exerts a strong anti-fibrotic effect and can significantly reduce fibrotic biomarkers in rodent models of pulmonary, hepatic fibrosis, and other organs.

Competitive Advantages

- *Improved anti-fibrotic effect.* AK3280 demonstrated better anti-fibrotic efficacy in the lung and liver in an array of pre-clinical studies compared to pirfenidone. Significant reductions in lung fibrosis were observed in mouse and rat models of bleomycin-induced pulmonary fibrosis. In clinical trials, AK3280 has shown the ability to improve lung function and enhance patient’s quality of life, while demonstrating good safety and tolerability profiles that favor improved patient compliance. The high dose groups demonstrated forced vital capacity (“FVC”) improvement from placebo, especially the 400 mg group which had the absolute FVC increased by 209.4 mL and a 6.4% adjusted %pFVC improvement compared to placebo ($p=0.002$ and 0.004 , respectively). Other lung and respiratory functions have also got better. The drug exhibited a good safety and tolerability profile without the gastrointestinal intolerance issues associated with current IPF therapeutics. We believe the potential of AK3280 in improving lung function could render its broad application in treating not only IPF, but also other ILDs, such as ILDs resulted from targeted ADC therapies or chemotherapy for lung cancer.
- *Superior clinical safety and tolerability.* Compared to pirfenidone, AK3280 demonstrated a better safety and tolerability profile with minimal GI intolerance and no signs of photo-toxicity or liver toxicity in clinical trials. In its phase I and phase II clinical trials, most adverse events reported were mild in severity, with limited serious adverse events occurring in the AK3280 groups.
- *Broad clinical application.* AK3280 attenuates a multitude of fibrosis related genes and proteins, and is broadly active in animal models of lung, liver, and skin fibrosis. For Example AK3280 demonstrated efficacy in the CCl_4 -induced rat model of liver fibrosis with significant, dose dependent reductions in serum liver enzymes as well as histopathological evaluation of fibrosis scoring in the liver, indicating significant potential in the treatment of liver fibrosis. Hence, AK3280 may be effective in treating fibrosis in other organs, including the liver, heart, and kidneys. Moreover, AK3280’s potentially broader therapeutic window, improved efficacy and PK profile may enable it to be used in combination with other anti-inflammatory or anti-fibrotic drugs with complementary mechanisms of action for synergistic effects.
- *Improved patient compliance.* AK3280’s pre-clinical PK studies and the completed phase I study suggest a more favorable dosing regimen and a reduced pill burden of QD or BID which would significantly improve patient adherence, compared with pirfenidone’s TID dosing regimen.

Clinical Development Plan

AK3280 was originally licensed from Genentech in 2018. Since then, we have completed a phase I safety clinical pharmacology clinical trial in Sweden in order to further understand AK3280 based on the same race of subjects as the existing clinical trial involving

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80 subjects in the UK completed prior to the in-licensing arrangement, a phase I bridging PK study to assess the safety, tolerability, and PK of AK3280 in healthy Chinese adults, and a phase II PoC clinical trial in IPF patients in China.

After its in-licensing, we conducted its phase I study in Sweden. We strategically selected Sweden as the location for our Phase I bridging study for several important reasons. First, by conducting our phase I trial in a Scandinavian population that shares similar ethnic, genetic, and demographic characteristics with the UK population from the original Phase I study conducted by the original developer, we were able to generate PK, safety, and tolerability data under comparable conditions, thereby providing greater certainty and confidence in our ability to interpret and bridge the results across studies and reducing the risk of unexpected population-specific differences that could complicate development planning. Second, we would like to explore further on the nephrotoxicity therefore we conducted a trial in a Swedish site which has reputable track record in nephrotoxicity study. Sweden also possesses highly mature and well-established clinical trial infrastructure.

The following table summarizes clinical trials we initiated and completed with AK3280 as of the Latest Practicable Date.

Country/ Region	Clinical Trial	NCT/CTR Number	Start Date	Completion Date	No. of Subjects	Safety results	Other Key Findings
Sweden . . .	A Phase I Study to Assess the Effect of AK3280 on Renal Function in Healthy Subjects	NCT03990688	October 2019	September 2020	48	Grade 3 and above AEs: one case in the placebo group. SAEs: None. Discontinuation due to AEs: 3 cases. Withdrawal due to AEs: None.	The study concluded that AK3280 demonstrated AK3280 has generally favorable safety profile. AK3280 demonstrated no clinically significant changes in glomerular filtration rate at Day 7 and Day 14 compared to baseline, with mostly mild adverse events (headache, nasopharyngitis, oropharyngeal pain, and elevated serum creatinine) and no serious adverse events reported.
China	A Phase I Bridging PK Study of AK3280 in Chinese Healthy Volunteers	NCT04926116	June 2021	September 2021	24	Grade 3 and above TEAEs: None. SAEs: None. Discontinuation due to TEAEs: 3 cases. Withdrawal due to TEAEs: 3 cases.	The study concluded that AK3280 demonstrated no dose-limiting toxicities, with all TEAEs being Grade 1, and showed favorable pharmacokinetic properties including rapid absorption, moderate half-life, and steady-state achievement across the 100mg and 200mg BID dosing levels.

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Country/ Region	Clinical Trial	NCT/CTR Number	Start Date	Completion Date	No. of Subjects	Safety results	Other Key Findings
China	Phase II Clinical Trial in China	NCT05424887	108	July 2022	July 2025	Grade 3 and above TEAEs: 18 cases (21.7%) in the active dose groups and 5 cases (20.0%) in the placebo group. Drug-related SAEs: 6 cases (7.2%) in the active dose groups and 1 case (4.0%) in the placebo group. Discontinuation due to TEAEs: 10 cases (12.0%) in the active dose groups and 1 case (4.0%) in the placebo group. Withdrawal due to TEAEs: 8 cases (8.3%) in the active dose groups and 1 case (4.0%) in the placebo group.	• The high dose groups demonstrated FVC improvement from placebo, especially the 400 mg group • which had the absolute FVC increased by 209.4 mL and a 6.4% adjusted %pFVC • improvement compared to placebo

Phase II Clinical Trial in China

- *Trial design.* We initiated the phase II clinical trial for AK3280 in China in July 2022 and the clinical trial was completed in July 2025. The phase II clinical trial for AK3280 in China was a randomized, double-blind, placebo-controlled, multi-center trial to evaluate the safety and efficacy of different doses of AK3280 compared to placebo in patients with IPF. The study enrolled 108 IPF patients with confirmed IPF clinical and imaging diagnosis and includes a main study period of 24 weeks treatment, followed by an optional 24-week open-label extension study, plus 4 weeks safety follow-up. The trial was conducted in two parts. Part 1 randomized 54 patients in a 1:1:1 ratio to receive AK3280 100mg, AK3280 200mg, or placebo twice daily, with a data monitoring committee (DMC) safety review after 30 patients complete 12 weeks of treatment. Based on the DMC’s safety assessment, we added Part 2 study of 54 additional patients, who were randomized to higher doses of AK3280 300mg, AK3280 400mg, or placebo. Clinical efficacy endpoints included forced vital capacity of lung (FVC and %pFVC), diffusing capacity of lung for carbon monoxide (DLco), the 6-minute walk test (6MWT) and patient reported St. George’s Respiratory Questionnaire (SGRQ) scores.
- *Efficacy data:* The phase II clinical trial 24-week data demonstrated AK3280’s capability to improve lung function and enhance patient quality of life. The high dose groups demonstrated FVC improvement from placebo, especially the 400 mg group which had the absolute FVC increased by 209.4 mL and a 6.4% adjusted %pFVC improvement compared to placebo (p=0.002 and 0.004, respectively). Other lung and respiratory functions have also got better. The drug exhibited a good safety and tolerability profile without the gastrointestinal intolerability issues associated with current IPF therapeutics. We believe the potential of AK3280 in improving lung function could render its broad application in treating not only IPF but other organ fibrous, including ILD resulted from targeted ADC therapies or chemotherapy for lung cancer.

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- *Safety data:* AK3280 was generally well tolerated in patients with IPF. During the 24-week double-blind treatment, the overall incidence of TEAEs and drug-related TEAEs in AK3280 groups was comparable to placebo. The incidence of grade ≥ 3 TEAEs and SAEs was slightly higher in AK3280 groups than in placebo. Overall, AK3280 demonstrated a favorable safety and tolerability profile.
- *Conclusion.* During the clinical trial, AK3280 demonstrated efficacy across all primary and secondary clinical endpoints. The clinical trial report was finalized in July 2025, upon which the PI and we concluded that all the primary and secondary endpoints are reached. The clinical trial demonstrates AK3280’s potential to improve both lung function and quality of life, and also highlights its good safety profile that supports long-term use.

Phase I Bridging Clinical Trial in China

- *Trial Design.* We initiated the phase I bridging clinical trial in China in healthy adults in June 2021, which was completed in September 2021. The clinical trial is a randomized, double-blind, placebo-controlled study evaluating AK3280 in 24 healthy adult volunteers aged 18-45 years. The study consists of two cohorts, with 12 subjects enrolled in each cohort. Cohort 1 receives AK3280 200mg BID, and based on safety review committee (SRC) assessment of tolerability and pharmacokinetics, subsequent cohorts may be dose-escalated to 300mg BID or 400mg BID, or dose-reduced to 100mg BID if the 200mg BID dose is not well-tolerated. Following completion of the 200mg cohort and SRC approval, the study proceeds to a 100mg dose cohort, with all patients undergoing sequential study phases including screening/baseline, treatment period (divided into single-agent and combination therapy phases), and safety follow-up for up to 20 days following the first dose. The clinical trial report was finalized in January 2022, upon which the PI and we concluded that the primary and secondary endpoints are reached.
- *Safety Data.* The safety profile of AK3280 demonstrated acceptable tolerability across dose levels. A total of 76 TEAEs were reported, of which 22 (91.4% of the 24 patients) experienced 71 TEAEs considered treatment-related, distributed across the AK3280 100mg, 200mg, and placebo groups with 8 cases (100%), 7 cases (87.5%), and 7 cases (87.5%) respectively, with 22, 23, and 26 individual events reported in each group. Treatment-related serious adverse events (SAEs) occurred in 3 patients (12.5%), specifically one patient in the AK3280 100mg group experiencing skin drug eruption and two patients in the AK3280 200mg group experiencing skin-related reactions and urinary infections. The most common TEAEs associated with AK3280 included diarrhea, increased blood bilirubin, headache, anemia, decreased appetite, abdominal pain, low-grade fever, and elevated blood bilirubin.
- *Conclusion.* The study concluded that AK3280 demonstrated no dose-limiting toxicities, with all TEAEs being Grade 1, and showed favorable pharmacokinetic properties including rapid absorption, moderate half-life, and steady-state achievement across the 100mg and 200mg BID dosing levels.

The fundamental difference and justification for the Chinese bridging study as compared with previous phase I studies lies in the ethnic-specific pharmacokinetic assessment. These PK parameters are different from those observed in Caucasian populations due to genetic polymorphisms in drug-metabolizing enzymes (particularly CYP3A enzymes), differences in body composition, and other ethnic-specific factors. The NMPA requires such bridging studies to ensure that dosing recommendations are appropriate for Chinese patients and that the safety and efficacy profile established in Western populations is applicable to Chinese patients.

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Material Communications with the NMPA

We obtained the IND approval for AK3280 from NMPA in January 2021. After that, we have completed the phase I bridging PK studies in China. Based on the clinical trial results of the phase I bridging PK study in healthy adults in China, we initiated a phase II clinical trial in IPF patients in China. The study design incorporated NMPA suggestions in the IND approval letter to include suitable efficacy endpoints such as lung diffusion capacity and progressive free survival. Specifically, the NMPA confirmed that we did not need to seek their confirmation again as long as we implemented their comments in the clinical trial design before initiating the phase II clinical trial. Accordingly, we followed these comments in the design of phase II clinical trial and initiated the phase II clinical trial in China in July 2022.

In July 2025, we completed the phase II clinical trial in China and the PI and us concluded that all the primary and secondary clinical endpoints have been met. Following the completion of the phase II clinical trial, we requested an EOP2 meeting with the NMPA and submitted the clinical data from AK3280’s phase II clinical trial in China demonstrating that all the primary and secondary clinical endpoints have been met. In November 2025, the EOP2 meeting was held, during which the NMPA, after reviewing the phase II clinical trial data and our proposed phase III clinical trial design, did not raise any material questions on our phase II trial data and phase III trial design. The NMPA also confirmed that we may proceed with AK3280’s phase III clinical trial in China.

In December 2025, we submitted an IND application to initiate a phase II proof-of-concept clinical trial in the United States to the FDA, supported by AK3280’s available clinical trial data in China. In January 2026, the IND was cleared by the FDA, enabling us to initiate a Phase II proof-of-concept clinical trial of AK3280 in the United States.

Next Steps

For AK3280’s phase III pivotal clinical trial in China, we plan to initiate subject enrollment in the third quarter of 2026, with an aim to complete this clinical trial by the end of 2028. For the phase II proof-of-concept clinical trial in the United States, we plan to initiate such clinical trial in the United States in the next 12 months, which is expected to enroll approximately 140 subjects.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AK3280 SUCCESSFULLY.

AK0705 — IND-Stage COPD Candidate

COPD has become growingly popular, with an estimated 509.8 million incidences in 2024. There is no approved drug to treat the underlying cause of COPD. COPD is often treated through pharmacological therapy to reduce symptoms, reduce the frequency and severity of exacerbations and improve exercise tolerance and health status.

AK0705 is a highly potent and selective small molecule inhibitor of an enzyme implicated in the pathogenesis of COPD and other inflammatory lung diseases. It displays pico-molar activity in the enzymatic assay and maintains activity in the presence of patient sputum. AK0705 is capable of reversible covalent binding to the target, resulting in prolonged action time on the target. The molecule was originally discovered at The Scripps Research Institute and was reported in a paper published on Science. We are collaborating with California Institute for Biomedical Research, a research institute within the Scripps Research Institute for AK0705. For details, see “Overview of Licensing and Collaboration Agreements — Collaboration with Calibr on AK0705.”

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AK0406 — Phase I-Stage Influenza ADC

Influenza is an acute respiratory infection caused by the influenza virus. Influenza A and B viruses cause annual seasonal epidemics, with Influenza A capable of triggering global pandemics. In 2024, the incidence of influenza in China amounted to 25.1 million, which is expected to steadily grow to 51.2 million in 2035 at a CAGR of 6.7%.

Leveraging our medicinal chemistry platform and biologic discovery capabilities, we have been able to extend the application of ADC technology to infectious disease with a non-toxic payload design. In this way, we have developed AK0406 and initiated its phase 1 clinical trial in Australia in February 2026. The clinical trial is a Phase I, first-in-human, randomized, double-blind, placebo-controlled trial designed to assess the safety, tolerability, and pharmacokinetics of AK0406 administered via subcutaneous injection at escalating doses (150 mg, 300 mg, 600 mg, and 900 mg) in 32 healthy adult participants across four cohorts. We currently expect to complete this phase I clinical trial in 2027.

ADHD

AK0901 — Approved ADHD Candidate

ADHD or attention deficit/hyperactivity disorder is a neurodevelopmental disorder characterized by inattention, bouts of excessive energy, hyper-fixation and impulsivity. It is one of the most common childhood disorders. ADHD may continue through adolescence and adulthood and up to 65% of children with ADHD continue to experience ADHD symptoms as adults.

We in-licensed Azstarys® (AK0901) in December 2021 from Commave. For details, see “— Overview of Licensing and Collaboration Agreements — In-licensing Azstarys® (AK0901) from Commave.” As the world’s first and currently only approved combination formulation containing immediate-release dexamethylphenidate (d-MPH) and the prodrug serdexmethylphenidate (SDX), AK0901 represents a next-generation innovative treatment for ADHD patients. The drug received FDA approval in the United States in March 2021, marking the first ADHD medication approved by the FDA in nearly 20 years. AK0901 is a central nervous system stimulant prescription medicine for the treatment of ADHD. D-MPH is an immediate-release medication that has been used for the treatment of ADHD for over 20 years globally. SDX is a prodrug, which has a delayed onset of action and a prolonged duration of effects compared to d-MPH, its parent compound. Being the first and the only product containing SDX globally, AK0901 can provide an enhanced therapeutic efficacy, a delayed release and a once-a-day dosing regimen.

Market Opportunity and Competition

ADHD is one of the most common mental disorders of childhood and can even continue through adolescence and adulthood. In 2024, the prevalence of ADHD in China was 34.0 million. With growing awareness and diagnosis rate for ADHD, especially in adults and expected approval of novel ADHD therapeutic drugs, China’s ADHD drug market is expected grow from US\$1.1 billion in 2024 to US\$13.1 billion in 2035 at a CAGR of 24.9% during 2024 to 2035.

Treatment of ADHD can generally be divided into drug therapy and non-drug therapy. For children aged six years or older, the current recommended treatment is a combination of drug and non-drug therapy. Drug therapy of ADHD contains either a stimulant, targeting receptors of the brain chemical dopamine with rapid onset, or a non-stimulant, targeting the brain chemical norepinephrine with a delayed onset. Although generally stimulant can achieve better clinical efficacy, one of its major limitations is its shorter duration of therapy, which increases the risks of drug abuse and dependence.

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As of the Latest Practicable Date, there were 15 approved ADHD therapeutic drugs in China, most of which are older-generation products or generic formulations of previously approved molecules.

Mechanism of Action

AK0901 contains a prodrug of serdexmethylphenidate (SDX) and immediate-release dexamethylphenidate (d-MPH). d-MPH is the pharmacologically active d-enantiomer of methylphenidate. Methylphenidate blocks the re-uptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the intraneuronal space. It is an immediate-release medication that has been used for the treatment of ADHD. SDX is a prodrug of d-MPH and is pharmacologically inactive until being gradually converted to active d-MPH in the lower intestinal tract. SDX has a delayed onset of action and a prolonged duration of effects compared to d-MPH, its parent compound. After oral administration, early exposure is governed primarily by the d-MPH component, and mid- to late-day exposure is determined primarily by the gradual conversion of inactive SDX to active d-MPH.

Summary of Clinical Trials

Since the in-license of AK0901 from Commave in December 2021, we had completed a phase I bridging study and a phase III clinical trial for AK0901 in China.

Phase I Bridging Study in China

- *Trial Design.* From June 2024 to July 2024, we completed the phase I bridging study for AK0901 in healthy adults in China. The clinical trial is a single-center, randomized, open-label parallel-controlled study to evaluate the pharmacokinetics, safety and tolerability of a single dose of AK0901. The study enrolled 24 participants who were randomly assigned in a 1:1:1 ratio across three dose groups, with each group including two female participants. The study lasted up to 38 days and consisted of three phases: a screening period of up to 28 days to determine participant eligibility, a 5-day treatment period to receive a single dose of the study drug and undergo blood sampling and safety monitoring, and a follow-up visit 3 days after discharge to assess ongoing safety.
- *Safety data.* The drug demonstrated a favorable safety profile, with only two participants (8.3%) experiencing three mild to moderate adverse events that were assessed by investigators as related to AK0901. These side effects included hives, while the other adverse events resolved on their own without requiring medical intervention. Importantly, no serious adverse events occurred during the treatment period. As expected for this type of stimulant medication, participants experienced temporary increases in heart rate after taking AK0901. All other safety measurements including electrocardiograms, vital signs (except heart rate), and physical examinations showed no clinically significant abnormalities or changes related to AK0901, indicating that AK0901 was generally well-tolerated by healthy adult participants.
- *Pharmacokinetics data.* Following a single oral dose of AK0901, the drug demonstrated predictable absorption and elimination patterns across all tested dose levels. The SDX was rapidly absorbed and quickly eliminated from the body with a half-life of about seven hours, while d-MPH showed a more complex pattern with initial rapid absorption followed by sustained release from the intestinal conversion of SDX, resulting in a longer half-life of approximately 11 hours.
- *Conclusion.* AK0901 demonstrated good overall safety and tolerability in healthy subjects with a single dose, and all observed adverse events were consistent with the known side effect profile of methylphenidate medications. In addition, the pharmacokinetic profile suggests that AK0901’s combination formulation worked as intended, providing sustained delivery of the active medication over time, which could potentially allow for less frequent dosing compared to immediate-release formulations.

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Phase III Clinical Trial in China

- *Trial Design.* From May 2024 to January 2025, we conducted a phase III clinical trial for AK0901 in China. The clinical trial was a multi-center, dose-optimization, randomized, double-blind, placebo-controlled Phase III bridging study designed to evaluate the effectiveness, safety, and tolerability of AK0901 capsules in Chinese children aged 6-12 years with ADHD. The study consists of a screening period of up to 28 days, a 28-day double-blind treatment period, and a 5-day follow-up period for safety monitoring. During the treatment phase, a total of 55 subjects were enrolled and were randomly assigned in a 1:1 ratio to receive either AK0901 or placebo once daily for 4 weeks, with all participants starting at the same dose during the first week and then having their dose adjusted weekly based on individual response and tolerability. The primary efficacy endpoint was the changes in the ADHD Rating Scale. Safety is monitored through comprehensive assessments including tracking of side effects, vital signs, physical examinations, weight changes, heart function tests, laboratory blood work, sleep patterns, and suicide risk evaluations throughout the study period.
- *Safety data.* Most of the adverse events observed during the trial were mild to moderate in severity. The most common drug-related adverse events were consistent with known effects of methylphenidate-type stimulant medications. The overall safety monitoring including heart function, laboratory tests, physical examinations, suicide risk assessments, and sleep evaluations showed no significant safety concerns.
- *Efficacy data.* The study showed that AK0901 was consistently more effective than placebo in reducing ADHD symptoms throughout the treatment period. Children taking AK0901 experienced significantly greater improvement in their ADHD symptoms compared to those taking placebo, with meaningful benefits in real-world terms for children and their families. Children taking AK0901 also showed better improvements in attention problems, hyperactivity and impulsivity issues, overall clinical condition, and morning and evening behaviors compared to the placebo group, indicating that the medication provided broad-based benefits across different areas of ADHD-related difficulties that affect daily life at home and school.
- *Conclusion.* AK0901 effectively reduced ADHD symptoms in Chinese children aged 6-12, working quickly and maintaining benefits throughout treatment. The medication was generally well-tolerated, with side effects similar to other methylphenidate stimulants and no significant sleep disruption observed in participants.

Next Steps

After the completion of its phase III clinical trial in China, we held a pre-NDA meeting with the CDE during which the CDE agreed that based on preliminary assessment, AK0901 met the criteria for priority review. Subsequently, we submitted the NDA application for AK0901, which were granted priority review designation by the NMPA. We obtained the NDA approval for AK0901 in December 2025.

In December 2025, we entered into commercialization collaboration with Qilu Pharma Co., Ltd. (齊魯製藥有限公司), a nationwide pharmaceutical company in China, for the commercialization of AK0901 in Chinese Mainland (“**Qilu Agreement**”). Pursuant to the Qilu Agreement, we granted Qilu Pharma an exclusive license for the develop, manufacture and commercialization of AK0901 in Chinese Mainland. Under the agreement, we are eligible to receive up to RMB110 million in R&D milestone payments upon NDA approval and technology transfer, up to RMB360 million in sales milestones based on achieving specific annual sales targets, and tiered royalty payments in the low-to-mid teens as a percentage of aggregate annual net sales. For details, please see “— Commercialization — Commercial Collaboration with Qilu Pharma on AK0901.”

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OVERVIEW OF LICENSING AND COLLABORATION AGREEMENTS

We have entered into certain licensing and collaboration agreements with our business partners, details of which are summarized as follows. To our best knowledge, all the licensing and collaboration parties are Independent Third Parties.

In-licensing Ziresovir from Roche

Ziresovir was co-invented by Dr. Wu, our Founder, when he worked at Roche R&D Center (China) Ltd. During that time, Dr. Wu was actively involved in the development of ziresovir and led its early development. Dr. Wu was the co-author of several academic papers in relation to ziresovir, including *Discovery of Benzoazepinequinoline (BAQ) Derivatives as Novel, Potent, Orally Bioavailable Respiratory Syncytial Virus Fusion Inhibitor* published on *Journal of Medicinal Chemistry* and *Discovery of Ziresovir as a Potent, Selective, and Orally Bioavailable Respiratory Syncytial Virus Fusion Protein Inhibitor* published on *Journal of Medicinal Chemistry*. In addition, Dr. Wu was listed as one of the co-inventors for patents in relation to ziresovir, including compounds for the treatment and prophylaxis of respiratory syncytial virus disease (US 2013/0196974 A1; WO2013/020993 A1).

On January 28, 2014, ArkBio Cayman entered into a license and transfer agreement with Hoffmann-La Roche Inc. and F. Hoffman-La Roche Ltd (collectively, “**Roche**”), as amended on January 15, 2019 (pursuant to which, Japan, the only jurisdiction excluded in the original agreement was included as part of the in-licensing arrangement) and August 27, 2020 (pursuant to which ArkBio Cayman assigned all of rights and obligations under the original agreement in Mainland China to our Company, and all of rights and obligations outside Mainland China to ArkBio HK) (the “**Ziresovir Agreement**”). Pursuant to the Ziresovir Agreement, we are granted the exclusive right to develop and commercialize any product containing ziresovir, including all formulations, dosages and dosage forms for all pharmaceutical and prophylactic uses and applications globally. Roche is a Swiss multinational healthcare company that operates worldwide whose holding company is listed on the SIX Swiss Exchange.

Scope and Exclusivity of the Licensing. Under the Ziresovir Agreement, Roche shall grant us sole and exclusive license, with full rights to sub-license at no additional costs to develop and commercialize ziresovir in all pharmaceutical and prophylactic uses and applications globally. Roche shall not transfer, assign, sub-license or grant other access to the right to develop and/or commercialize any compound, the composition of matter of which is claimed under the patents in relation to ziresovir to any third party without first notifying us in writing and giving us the first right to negotiate a license. We have the right to transfer, assign, sub-license or grant any other access to ziresovir or any formulations, dosages and dosage forms in relation to ziresovir to a third party by informing Roche and Roche shall enjoy a first negotiation right on this.

Rights and Obligations. Pursuant to the Ziresovir Agreement, we are obligated to use commercially reasonable efforts to develop and commercialize ziresovir, including obtaining the necessary approvals from regulatory agencies. While we are required to provide a development plan to Roche and submit annual written reports on the development progress of ziresovir, such development plan is prepared solely by us and is not subject to Roche’s approval or negotiation. The annual reports are submitted for informational purposes only, to provide Roche with updates on the latest development progress. The development plan may be reasonably modified and updated at any time at our sole discretion as deemed necessary. Furthermore, the Ziresovir Agreement provides that we are solely responsible, at its own cost, for the manufacturing of ziresovir and for obtaining any third-party licenses that may be useful or necessary for the development and commercialization of ziresovir. In addition, the national science and technology major project related to ziresovir does not involve Roche or any of its research and development personnel. We retain final decision-making authority over the development, manufacturing, and commercialization of ziresovir.

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Intellectual Property. All patent rights and knowhow under the Ziresovir Agreement shall remain to be owned by Roche and Roche shall, at its own expense, prosecute and maintain such patent rights and knowhow. Any future invention or knowhow made, developed or conceived by our employees and all intellectual property rights therein shall be owned by us and any future invention or knowhow made or developed by Roche’s employees and all intellectual property rights therein shall be owned by Roche. The parties should jointly own any inventions jointly made, developed or conceived by both parties. Each party has the right to prosecute and maintain future patent application at its own expense within its own patent rights.

Payment Arrangement. As partial consideration for the license grant to us, we are obligated to make upfront, milestone and royalty payments to Roche. Following the execution of the Ziresovir Agreement, we should pay Roche a one-time, non-refundable and non-creditable upfront payment of US\$1 million. Moreover, we are obligated to pay Roche non-refundable and non-creditable milestone payments at ten triggering events, including (i) a total of US\$15 million at six triggering events commencement of phase IIb clinical trial (excluding phase II clinical trial in China), commencement of phase III clinical trial, first NDA filing and first regulatory approval in the U.S., Europe and Asia, respectively; and (ii) the sales based events payments up to a total of US\$81 million upon the achievement of sales milestones (first time annual sales reaching US\$100 million, US\$300 million, US\$1 billion and US\$3 billion) globally. We are also required to pay Roche high single-digit percentage royalties on the global net sales (ranging from approximately 6.0% to 10.0% of net sales on a tiered basis). The royalty payment obligation for a given country shall expire at the later of (i) there no longer exists in such country a valid patent protection or application over the manufacture, use, sale or importation of ziresovir; or (ii) ten years after the date of first commercial sale of ziresovir. As of the Latest Practicable Date, the upfront payment and the development milestone payment upon commencement of the Phase IIb clinical trial, in an aggregate amount of US\$2.0 million, had been fully settled (in February 2014 and March 2021, respectively). The development milestone payments upon commencement of the Phase III clinical trial and the first NDA filing, in an aggregate amount of US\$3.0 million, had become due but remained unsettled, which we expect to settle in 2026. Such payments have been or are expected to be funded by internal resources, external financing (including [REDACTED] from the [REDACTED]) and/or future commercialization revenue. The amount of such payments was determined after arm’s length negotiations with reference to the development stage, commercial potential, scope of licensed rights, comparable transactions and prevailing market practice.

The following table summarizes the payment terms as well as our historical and expected payments to Roche under the Ziresovir Agreement as of the Latest Practicable Date.

Payment	Triggering Event	Amount	Payment Schedule
		<i>US\$ in million</i>	
Upfront payment . . .	Payable within 30 days after the effective date of the agreement	1.0	Paid in February 2014
Development milestone	Commencement of Phase IIb clinical trial (excluding Phase II trial in China)	1.0	Paid in March 2021
	Commencement of Phase III clinical trial	1.0	Expected to be settled in 2026
	First NDA filing	2.0	Expected to be settled in 2026
Approval milestone .	First regulatory approval in the U.S.	5.0	Not yet triggered
	First regulatory approval in EU	3.0	Not yet triggered
	First regulatory approval in Asia	3.0	Not yet triggered

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Valid Term and Termination. The Ziresovir Agreement will remain in effect until the expiration of all of our royalty payment obligations, after which the license shall become perpetual and irrevocable. In addition, we may terminate the agreement in its entirety at any time with prior written notice. Further, each party may terminate the agreement in its entirety with written notice in the event of the other party’s material breach and such party failing to cure the breach.

Non-Competition. No express non-competition provision is contained.

Joint Steering Committee. No JSC has been established under the Ziresovir Agreement. Following our acquisition of the relevant rights under the agreement, we have independently conducted the development and commercialization of the relevant product, and accordingly no formal JSC mechanism has been put in place.

Since entering into the Ziresovir Agreement, we have paid a total of US\$2.0 million to Roche in accordance with the Ziresovir Agreement. In 2024 and 2025, we did not record any milestone fees to Roche in accordance with the Ziresovir Agreement. Following December 31, 2025, we had not made any other payment to Roche in accordance with the Ziresovir Agreement.

In the worst-case scenario, for example in the event of early termination of the license in relation to ziresovir granted us, we may no longer continue the development of ziresovir as a Core Product.

In-licensing AK3280 from Genentech, Intermune and Roche Basel

Building on our ongoing collaboration with the Roche after the in-licensing of ziresovir, we were introduced by Roche to GDC3280 (currently as AK3280) for IPF as an out-licensing opportunity, which we decided to in-license after due consideration to enhance our pipeline in the respiratory diseases. On August 23, 2018, ArkBio Cayman entered into a license agreement (the “**AK3280 Agreement**”) with F. Hoffman-La Roche Ltd, (“**Roche Basel**”) and Genentech, Inc. (“**Genentech**”) and Intermune, Inc. (“**Intermune**”), as amended on August 27, 2020 (pursuant to which ArkBio Cayman assigned all of rights and obligations under the original agreement in Mainland China to our Company, and all of rights and obligations outside Mainland China to ArkBio HK).

Scope and Exclusivity of the Licensing. Under the AK3280 Agreement, we were granted a sole and exclusive license, with full rights to sub-license at no additional costs, under certain patents and know-how, to develop and commercialize AK3280 in therapeutic pharmaceutical uses for all indications, excluding diagnostic uses (the “**AK3280 Field**”) globally. Genentech is an American biotechnology corporation and Intermune is a biotechnology company focused on the research, development and commercialization of innovative therapies in pulmonology and orphan fibrotic diseases. Each of Genentech, Intermune and Roche Basel owns certain knowhow and GMP materials in relation to AK3280 and were wholly-owned subsidiary of Roche Group. Roche Basel, Genentech and Intermune are collectively referred as “**Roche Group**.”

Rights and Obligations. Under the AK3280 Agreement, we have the right to (i) grant written sub-licenses to our affiliates without prior approval of Roche Group, (ii) sub-contract the work with disclosing certain information including a copy of the sub-contract agreement and related confidential information to Roche Group, and (iii) enter into a partner agreement in the AK3280 Field globally and to sub-license rights granted to us under the AK3280 Agreement with prior written notice and subject to the first negotiation right of Roche Basel.

Pursuant to the AK3280 Agreement, we are obligated to use commercially reasonable efforts to develop AK3280 at our sole cost. While the AK3280 Agreement contains a development plan for AK3280 and we are required to develop AK3280 in accordance with such plan, we may make changes to the development plan at our sole discretion and are only required to provide prompt notification to Roche in the event of any major changes. With respect to manufacturing, we are

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solely and exclusively responsible, at its own expense, for the commercial manufacturing and supply of AK3280 for sale, whether conducted by ourselves or through third parties. We also have sole responsibility for the marketing, promotion, sale, and distribution of AK3280. Although we are required to provide updates to Roche regarding the commercialization of AK3280, Roche is not entitled to request such updates more frequently than twice per calendar year. We retain final decision-making authority over the development, manufacturing, and commercialization of AK3280. We, at our sole costs and expenses, are also solely and exclusively responsible for the research and development, manufacturing, supply, commercialization and regulatory matters of AK3280 in the AK3280 Field.

Payment Arrangement. We are obligated to make upfront, milestone and royalty payments to Roche Group under the AK3280 Agreement. After execution of the AK3280 Agreement, we should pay Roche Group a one-time, non-refundable and non-creditable upfront payment of US\$5 million. Moreover, we are obligated to pay Roche Group non-refundable and non-creditable payments at nine triggering events, including (i) a total of US\$17 million at seven triggering events, including phase III clinical trial initiation, NDA filing in the United States, Europe and China and NDA approval in the United States, Europe and China; and (ii) the sales based events payments up to a total of US\$125 million upon the first achievement of certain annual sales target of US\$500 million and US\$2 billion globally. We are also required to pay Roche Group high single-digit to one-tenth percentage royalties on an incremental basis on the net sales of AK3280. As of the Latest Practicable Date, the initial payment of US\$5.0 million had been fully settled in September 2018. The development milestone payment upon initiation of the Phase III clinical trial had become due, which we expect to settle in 2026. Such payments have been or are expected to be funded by internal resources, external financing (including [REDACTED] from the [REDACTED]) and/or future commercialization revenue. The amount of such payments was determined after arm’s length negotiations with reference to the development stage, commercial potential, scope of licensed rights, comparable transactions and prevailing market practice.

The following table summarizes the payment terms under the AK3280 Agreement as well as our historical and expected payments, as of the Latest Practicable Date.

Payment	Triggering Event	Amount	Payment Schedule
		<i>US\$ in million</i>	
Upfront payment . .	Payable within 20 days after the effective date of the agreement	5.0	Paid in September 2018
Development milestone	Phase III initiation	2.0	Expected to be settled in 2026
	NDA filing in the U.S.	3.0	Not yet triggered
	NDA filling in EU	1.5	Not yet triggered
	NDA filling in China	0.5	Not yet triggered
	Regulatory Approval in the U.S.	6.0	Not yet triggered
	Regulatory Approval in EU	3.0	Not yet triggered
	Regulatory Approval in China	1.0	Not yet triggered

Intellectual Property. Pursuant to the AK3280 Agreement, any inventions or knowhow made or developed by our employees solely or jointly with third party other than Roche Group shall be owned by us and any inventions or knowhow made or developed by Roche Group’s employees solely or jointly with third party other than us (“**Roche’s Patent Rights**”) shall be owned by Roche Group. For inventions or knowhow made or developed jointly by our and Roche Group’s employees jointly shall also be owned by us. Moreover, both parties agree to claim the unlimited use of any inventions made, developed or conceived under German Statute on Employee’s Inventions in the event that an affiliate of us or Roche Group is organized under the German Law and such affiliate

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shall be responsible for fulfilling the obligations towards their employees under German Law. Roche shall be responsible for prosecuting and maintaining all of Roche Group’s patent rights specified in the appendix of the AK3280 Agreement, and we shall be responsible for prosecuting and maintaining all patent rights other than Roche’s Patent Rights, with informing the other party of the prosecution status on a regular basis.

Valid Term and Termination. The AK3280 Agreement will remain in effect unless early terminated due to customary termination events stipulated in the agreement, such as material breach, insolvency or change of control. Either party may also terminate this agreement in its entirety or on a country-by-country basis with written notice for other party’s material breach if such party fails to cure the breach. Further, the AK3280 Agreement may also be terminated by either party due to insolvency of the other party. We have the right to terminate the AK3280 Agreement at any time on a product-by-product basis with prior written notice within a certain period.

Non-Competition. No express non-competition provision is contained.

Joint Steering Committee. No JSC has been established under the AK3280 Agreement. Following our acquisition of the relevant rights under the agreement, we have independently conducted the development and commercialization of the relevant product, and accordingly no formal JSC mechanism has been put in place.

In 2024 and 2025, we did not record any milestone fees to Roche Group in accordance with the AK3280 Agreement. Following December 31, 2025, we had not made any other payment to Roche Group in accordance with the AK3280 Agreement.

In-licensing AK0610 from Institute of Microbiology, Chinese Academy of Sciences

We have maintained research collaborations with the Institute of Microbiology, Chinese Academy of Sciences (the “**IMCAS**”) and Beijing Children’s Hospital in the field of anti-viral drug development, under which we supported the evaluation of antibody candidates using our proprietary anti-viral screening platform. Through this collaboration, we became aware of the antibody RV11 (currently as AK0610), which showed promising potential for RSV prevention. On August 2, 2021, we entered into a license agreement (the “**IMCAS Agreement**”) with IMCAS.

Scope and Exclusivity of the Licensing. Under the IMCAS Agreement, we are granted a sole and exclusive license in relation to AK0610, to globally develop and commercialize mAb drugs for preventing and curing RSV. Institute of Microbiology, Chinese Academy of Sciences is a leading academic institution in China.

Rights and Obligations. Under the IMCAS Agreement we have the right to grant sub-licenses, with prior notice to IMCAS, to any third parties other than our affiliates outside mainland China. IMCAS is obligated to (i) select appropriate third-party agency and timely transfer certain know-how to such agency designated by us, (ii) assign specific personnel to guide the third-party agency entrusted by us on pre-clinical study, and (iii) provide continuous technical guidance in our subsequent research and development. Under the IMCAS Agreement, we are obligated to have IMCAS informed in advance if we develop new drugs based on the molecules under the IMCAS Agreement, and both parties will reach a new agreement in this regard. We are also obligated to use commercially reasonable efforts to apply the patent under the IMCAS Agreement and to inform IMCAS with a justifiable explanation if no material progress after six months since the effective date.

Payment Arrangement. As partial consideration for the license granted to us, we are obligated to make upfront payment and milestone payments to IMCAS under the IMCAS Agreement. We will pay IMCAS two upfront payments, each in the amount of RMB5 million after the execution of the IMCAS Agreement and six months after verifying the molecule of AK0610 and concluding that the molecule of AK0610 has the potential to conduct clinical trials. We will pay IMCAS milestone

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payments in the total amount of RMB55 million at five triggering events in relation to the development status including IND approval, ethical approval from the leading site for phase II study, ethical approval from the leading site for phase III study, NDA submission and NDA approval of AK0610 in China. We are also required to share profits with IMCAS, in the event that we sub-license the right under the IMCAS Agreement to any third parties other than our affiliates outside China, at a drug-development based milestone payment. Moreover, IMCAS has the right to share the drug sales revenue at a low single-digit percentage, during the sale commission period. As of the Latest Practicable Date, the two upfront payments and the first development milestone payment upon IND approval, in an aggregate amount of RMB15.0 million, had been fully settled in August 2021, July 2022, and January 2024, respectively. We expect to settle the development milestone payment upon ethical approval from the leading site for the Phase II clinical trial by the end of 2026. Such payments have been or are expected to be funded by internal resources, external financing (including [REDACTED] from the [REDACTED]) and/or future commercialization revenue. The amount of such payments was determined after arm’s length negotiations with reference to the development stage, commercial potential, scope of licensed rights, comparable transactions and prevailing market practice.

The following table summarizes the payment terms under the IMCAS Agreement as well as our historical and expected payments, as of the Latest Practicable Date.

Payment	Triggering Event	Amount	Payment Schedule
		<i>RMB in million</i>	
First upfront payment	30 days after execution of the agreement	5.0	Paid in August 2021
Second upfront payment	Six months after the execution of the agreement and upon our completion of verification as to whether the molecule can advance to clinical development	5.0	Paid in July 2022
Development milestone	Obtained Approval of IND	5.0	Paid in January 2024
	Obtained ethics approval from the leading site for the Phase II study	7.0	Expected to be settled in 2026
	Obtained ethics approval from the leading site for the Phase III study	10.0	N/A
	Submission of NDA	13.0	N/A
	Obtained Approval of NDA	20.0	N/A

Intellectual Property. Under the IMCAS Agreement, any new patents and know-how independently discovered, invented or developed by us under the IMCAS Agreement will be owned by us, and any new patents and know-how independently discovered, invented or developed by IMCAS in performing its obligations under the IMCAS Agreement will be owned by IMCAS. Each party is required to notify the other of any intellectual property infringement, and we have the first right, but not the obligation, to take action against such infringement at our own cost.

Valid Term and Termination. The IMCAS Agreement shall remain effective until we cease to manufacture or sell AK0610 globally, unless early terminated due to customary termination events stipulated in the agreement, such as material breach, insolvency or change of control. Either party may also terminate this agreement with written notice for other party’s material breach if such party fails to cure the breach.

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Non-Competition. No express non-competition provision is contained.

Joint Steering Committee. No JSC has been established under the IMCAS Agreement. In lieu of a formal JSC, the parties maintain regular communication through designated personnel to coordinate the technical implementation of the collaboration and monitor project progress. The parties consider this arrangement adequate for the current stage of the collaboration.

Amendment. On October 29, 2021, the IMCAS Agreement was further amended and entered into by IMCAS, Beijing Children’s Hospital, Capital Medical University (the “**BCHCMU**”) and us, pursuant to which BCHCMU shall provide IMCAS with relevant materials for screening human neutralizing antibodies against RSV, assist us in conducting clinical assessment while offering necessary technical guidance to us for obtaining the IND approval. Beijing Children’s Hospital, Capital Medical University is one of China’s leading pediatric hospitals. This collaboration aims to advance the pre-clinical development and industrialization of human neutralizing antibody drugs for preventing and curing RSV.

In 2024 and 2025, we recorded milestone fees to IMCAS in the amount of nil and RMB5.6 million in accordance with the IMCAS Agreement. Following December 31, 2025, we had not made any other payment to IMCAS in accordance with the IMCAS Agreement.

In-licensing Azstarys® (AK0901) from Commave

By 2021, we had established ourselves as a biotechnology company focused on developing therapies for respiratory and pediatric diseases with high unmet needs through both internal R&D and external partnerships. As part of our partnership strategy, we sought to strengthen our pipeline with late-stage or commercial products aligned with our focus and the commercialization prospects of ziresovir for pediatric use. During this process, we identified AK0901 (currently as Azstarys in the U.S.), a newly approved FDA drug with significant clinical value for ADHD, which affects approximately 6–7% of children in China, and began detailed evaluation and discussions regarding its potential introduction into China. On December 28, 2021, ArkBio HK entered into a collaboration and license agreement (the “**Commave Agreement**”) with Commave Therapeutics SA (“**Commave**”).

Scope and Exclusivity of the Licensing. Under the Commave Agreement, we are granted an exclusive, payment-bearing license by Commave (the “**Commave Technology**”) in relation to the development, commercialization and manufacture of Azstarys® with respect to attention deficit hyperactivity disorder (the “**ADHD**”) and other indications as may be approved by the FDA or any regulatory authority in mainland China, Hong Kong, Macau, and Taiwan (the “**Azstarys® Territory**”).

Rights and Obligations. In addition, we have the right to (i) grant sub-licenses to our affiliates with prior written notice to Commave, and (ii) grant sub-licenses to third parties with prior written consent from Commave. Commave is a Switzerland-based pharmaceutical company and an affiliate of Gurnet Point Capital, a private investment firm focused on the life sciences and medical technology sectors. Commave is our Independent Third Party.

Payment Arrangement. Pursuant to the Commave Agreement, we shall pay Commave (i) an non-refundable and non-creditable upfront payment of US\$5.0 million, which has been settled in January 2022, (ii) milestone payments up to a total of US\$100.5 million following the first occurrence of certain development and triggering events such as obtaining the NMPA approval and achieving certain annual sales targets, at each of US\$25 million, US\$50 million, US\$75 million, US\$100 million, US\$250 million and US\$500 million, and (iii) tiered royalty payments based on the aggregate annual net sales of Azstarys® reaching sales threshold that is equal to or greater than from US\$10 million to US\$200 million in the Azstarys® Territory with royalty rates ranging progressively from 7% to 14%, increasing as sales reach higher thresholds. Such royalties may be subject to reduction as approved by Commave if we, upon Commave’s approval, obtain a license

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from third parties for the development or commercialization of Azstarys® in the Azstarys® Territory. Such payments have been or are expected to be funded by internal resources, external financing (including [REDACTED] from the [REDACTED]) and/or future commercialization revenue. The amount of such payments was determined after arm’s length negotiations with reference to the development stage, commercial potential, scope of licensed rights, comparable transactions and prevailing market practice.

The following table summarizes the payment terms under the Commave Agreement as well as our historical and expected payments, as of the Latest Practicable Date.

Payment	Triggering Event	Amount	Payment Schedule
		US\$ in million	
Upfront Payment . .	45 days after execution of the agreement	5.0	Paid in January 2022
Development milestone	NDA approval in China	2.0	Expected to be settled in 2026

Intellectual Property. Under the Commave Agreement, Commave generally retains ownership of the licensed intellectual property. Any new inventions generated by or on behalf of us in connection with the Commave Agreement shall be assigned to Commave. Commave is also granted a license to certain intellectual property developed by or on behalf of us during the term, subject to the terms of the the Commave Agreement.

Valid Term and Termination. The Commave Agreement shall remain in effect until the expiration of the later of (i) ten years after the first commercial sale of Azstarys® in the Azstarys® Territory; and (ii) the expiration of the last-to-expire valid claim in patents owned by Commave in the Azstarys® Territory. The Commave Agreement may be terminated by either party upon a material breach by the other party, subject to the applicable cure period, or upon the bankruptcy or similar insolvency events of the other party. Commave may also terminate the agreement upon a change of control of the licensee in certain circumstances.

Non-Competition. Under Commave Agreement, we are not obliged, without Commave’s prior written consent, to directly or indirectly develop or commercialize any product that competes with AZSTARYS® in the licensed territory during the term.

Joint Steering Committee. Under the Commave Agreement, a JSC has been established to oversee overall project management and key development matters. A deadlock resolution mechanism is in place pursuant to which, if the JSC fails to reach consensus within the prescribed period, the relevant matter will be escalated to the chief executive officers or board representatives of both parties. If the matter remains unresolved, we have final decision-making authority over development, manufacturing and commercialization matters, while Commave retains final decision-making authority over safety, efficacy and regulatory matters. As of the Latest Practicable Date, there had been no material disagreements between us and Commave, and no material matters had been escalated beyond the JSC.

In 2024 and 2025, we did not record any milestone fees to Commave in accordance with the Commave Agreement. Following December 31, 2025, we had not made any other payment to Commave in accordance with the Commave Agreement.

To accelerate the commercialization activities of AK0901 in China, we have obtained consent from Commave and in December 2025, strategically entered into a commercialization collaboration with Qilu Pharma Co., Ltd. (齊魯製藥有限公司) for the commercialization of AK0901 in Chinese Mainland. For details, please see “— Commercialization — Commercial Collaboration with Qilu Pharma on AK0901.”

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Collaboration with Calibr on AK0705

Through Dr. Wu's long-standing connections with researchers at The Scripps Research Institute, we were introduced to AK0705, an early discovery molecule with potential applications in inflammatory lung diseases such as COPD. Recognizing our expertise in advancing early-stage programs through pre-clinical and clinical development, on October 18, 2017, we entered into a collaboration and option agreement (the "**Calibr Agreement**") with California Institute for Biomedical Research ("**Calibr**"), a California non-profit corporation which is a research institute within The Scripps Research Institute, to support pre-clinical development of AK0705 and develop products for the medical needs in respiratory disease.

Pursuant to the Calibr Agreement, the parties should establish a JSC, initially consisting of two members with one designated by each party, governing the overall performance of each party during the collaboration. Each party should have only one vote in the JSC and all decisions of JSC should be made by unanimous vote from both parties. If a unanimous agreement on a particular matter within JSC's authority cannot be reached, we are entitled to have the final decision making authority with respect to profiling as an early lead to assess suitability, analog design and synthesis, formulation work/feasibility assessment, PK/PD studies via inhaled route of administration and preliminary non-GLP toxicology studies at our own budgets and expenses; and Calibr shall have the final decision making authority for analog design and synthesis, preliminary PK/PD studies and guidance on our PK/PD studies, *in vitro* assays and *in vivo* efficacy essays at their own budget and expenses. For the remaining pre-clinical matters, the status quo shall persist until the parties reach agreement. Calibr and us shall mutually agree on a detailed work plan for development and regulatory approval by stage. As of the Latest Practicable Date, there had been no material disagreements between us and Calibr, and no material matters had been escalated beyond the JSC.

Under the Calibr Agreement, each party is obligated to use commercially reasonable efforts under the research collaboration framework and each party should solely own its respective background intellectual property rights. Governed by U.S. patent law standards, we and Calibr agreed to jointly own all worldwide right, title and interest in and to all inventions and project results with each party having equal, undivided right and interest. In addition, we are entitled to have the first option to obtain an exclusive license to (i) Calibr's interest in inventions and project results, (ii) Calibr lead compounds listed in the Calibr Agreement, (iii) any Calibr background intellectual property useful and/or necessary to research, develop, manufacture and/or commercialize products and/or (iv) Calibr's interest in a product under the Calibr Agreement, which is further subject to our compliance and prior written notice to Calibr within certain period and approval from JSC. In the meantime, we also granted Calibr a back-up option to acquire an exclusive, worldwide license upon the expiration of our first option period. Each party is responsible for prosecuting and maintaining its own background intellectual property at its own cost and expense. Each party shall direct and control the preparation, filing, prosecution and maintenance of patent applications and patents within the patent filed by such party at its cost and expenses and the other party shall have full rights of consultation with the filing party on all matters relating to the patent. Each filing party shall deliver to the other party copies of all patent applications, amendments, office actions and responses thereto, issued patents, related correspondence and other related documents. Each filing party shall also consider in good faith the other party's timely and reasonable comments and suggestions regarding the preparation, filing, prosecution, and maintenance of such patent.

Pursuant to the Calibr Agreement, Calibr shall have the option (but not the obligation) to fund up to 50% of the cost of IND-enabling studies and following first-in-human clinical trial. In the event of Calibr elects to exercise these options in full, Calibr shall be entitled to a percentage in the range of 45% to 55% of revenue from AK0705. If Calibr does not exercise its option with respect to the IND-enabling studies, then the parties shall renegotiate, in good faith a percentage Calibr shall be entitled to. If Calibr elects to partially, or not to exercise its option with respect to the first-in-human clinical trial, the percentage of revenue sharing shall be subject to a pro rata adjustment based on the actual co-funding contribution of Calibr.

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The Calibr Agreement will remain in effect unless early terminated due to customary termination events stipulated in the agreement, such as material breach, insolvency or change of control. In addition, either party (i) may terminate the Calibr Agreement with written notice upon other party’s material breach, if such party fails to cure the breach, and (ii) may terminate the Calibr Agreement if project results are insufficient to support continuation under JSC’s review.

To date, our business strategy in selecting product candidates and therapeutic areas for licensing and collaboration opportunities is guided by the alignment with our overall R&D focus and scientific strategy, as well as the clinical and commercial potential of the underlying assets. In assessing potential programs, we consider factors such as target biology, therapeutic differentiation, clinical feasibility, unmet medical needs, and synergy with our technological strengths and disease area focus. Accordingly, our decisions to advance, in-license or discontinue product candidates are driven by scientific merit, development potential, commercial value and resource allocation priorities, rather than the source of the program. We also maintain effective control over all material aspects of our in-licensed product candidates, supported by our technical expertise, experienced teams and internal capabilities spanning biology, chemistry, preclinical studies, process development, clinical development, regulatory affairs, intellectual property, manufacturing and commercialization, ensuring that each in-licensed program is managed and advanced under our leadership.

RESEARCH AND DEVELOPMENT

As a company focusing on the research and development, manufacturing and commercialization of innovative drugs, research and development is crucial to our continued growth. Our research and development activities primarily focus on anti-fibrotic, respiratory and anti-viral drugs.

The following summarizes the research and development process in drug candidate development.

- *Scientific discovery.* During scientific discovery stage, we will first determine the specific therapeutic area and the disease we target. We will conduct a comprehensive analysis based on the market size, patentability, competitive landscape and potential risks involved before commence testing. After we determine to proceed with the research and development project, we will conduct *in vitro* pharmacological study for the drug candidate. Then, we will conduct testing to evaluate its druggability and safety profile. After that, we will conduct animal studies to assess its toxicity and *in vivo* pharmacological profile. Only drug candidates that can pass all the tests can proceed to the pre-clinical stage.
- *Pre-clinical stage.* During pre-clinical stage, we will conduct animal studies to fully assess the PK performance, toxicity, pharmacological and safety profile of the candidate, aiming to ensure a smooth transition from molecule to drug candidate. We have a novel drug research and development committee to determine whether we shall proceed the research and development for drug candidates and supervise the whole research and development progress. The novel drug research and development committee will conduct regular meetings to review the research and development progress of such drug candidates. The novel drug research and development committee will also determine the timeline for IND application for our drug candidates.
- *Clinical studies.* We usually select reputable GCP-certified hospitals based on their quality, resources, experiences, reputation and availability of leading PI and subjects for our clinical trials. During the clinical trial, we maintain regular communication with clinical trial sites and PIs to ensure the clinical trial is conducted in accordance with the study protocol and ICH GCP guidelines in a timely manner. Further, we also maintain communications with regulatory bodies including the NMPA and the FDA from time to time to ensure our clinical trial data collected can meet the requirements for NDA application.

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R&D Strategy

We adopt a highly synergistic, “dual-engine” R&D strategy that balances in-house discovery with targeted in-licensing to continuously enrich our pipeline. When seeking licensing and collaboration opportunities, we systematically scout and evaluate global assets, prioritizing scientifically validated, late-stage product candidates, or early-stage clinical assets with significant commercial potential. We specifically target therapeutic areas where we possess deep domain expertise — namely pediatric therapeutics and respiratory diseases like RSV — ensuring that newly acquired assets seamlessly integrate with our existing R&D infrastructure and future commercialization channels. Regarding our strategic focus and prioritization between self-development and in-licensing, we do not view these approaches as mutually exclusive; rather, our capital and resource allocation is primarily driven by the clinical stage of the asset rather than its origin. By consistently directing our R&D resources toward our most mature, late-stage clinical assets — whether internally discovered to maximize long-term proprietary value or in-licensed to rapidly mitigate development risks and accelerate time-to-market — we aim to efficiently advance our pipeline toward commercialization.

R&D Team

Our research and development team are led by distinguished scientists and clinicians, including our Founder and CEO, Dr. Wu, our Chief Operating Officer, Dr. Yuan, who lead our research and drug development and guide our business direction and pipeline development strategy. As of the Latest Practicable Date, we had 86 employees in total, among whom 62 employees were engaged in our research and development activities. Among these R&D personnel, 34 individuals held a master’s degree or above in biology or other related fields, representing approximately 54.8% of our total R&D personnel.

The following table summarizes the key R&D personnel (including the resigned personnels) for the R&D of our product candidates.

Name	Responsibility	Time of Joining our Group	Core Products R&D Participated
Jim Zhen Wu	Overall R&D management and supervision	August 2013	Ziresovir and AK3280
Haiqing Yuan	Overall R&D execution	May 2017	Ziresovir and AK3280
Gu Feng	Overall clinical trial execution and pharmacovigilance	August 2015	Ziresovir and AK3280
Gao Zhao	Viral biology and clinical virology research	October 2020	Ziresovir
Zou Gang*	Viral biology and clinical virology research	November 2017	Ziresovir
Stephen Tooney*	Overseas clinical trial design	April 2014	Ziresovir
Wu Yan*	Clinical design of AirFLO clinical trial	November 2020	Ziresovir
Peng Cheng*	Early-stage drug manufacturing process development	June 2014	Ziresovir
Na Zhao	Drug manufacturing process development	March 2023	Ziresovir
Ki Rito*	Phase II clinical trial management	June 2022	AK3280

* These R&D personnels identified have departed from us as of the Latest Practicable Date.

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Change of Key R&D Personnels

Since our inception, we have experienced changes in our chief medical officer (“CMO”) position, details of which are summarized as follows.

Background

Since 2014, we have engaged three CMOs to guide our clinical strategies, adapting our leadership to align with the evolving focus of our development pipeline. Dr. Stephen Tooney served as our CMO from April 2014 to July 2020, overseeing the early development of ziresovir and AK3280 in international jurisdictions. While Dr. Tooney possessed strong expertise in international clinical trials, we subsequently identified China as the primary market for our Core Products. Consequently, we determined it was necessary to appoint a new CMO with specialized experience in the PRC regulatory landscape.

Following this strategic shift, Mr. Wu Yan (吳龔) served as CMO from November 2020 to January 2023, overseeing the AirFLO Phase III clinical trial of ziresovir and the Phase 1 clinical trial of AK3280 in China. Dr. Wu Yan resigned in January 2023 to pursue opportunities in private equity investment as he transitioned toward retirement. Dr. Ki Rito served as CMO from January 2023 to March 2024. Dr. Rito was originally responsible for the Phase II clinical trial of AK3280 when he joined us in June 2022 and, following Dr. Wu Yan’s departure, assumed responsibility for ziresovir, leading our first NDA submission and initiating the supplemental Phase III clinical trial. Dr. Rito resigned in March 2024 due to personal reasons.

Impact on the R&D of Our Core Products

Our Directors are of the view that these changes have not resulted in, and are not expected to result in any material adverse impact on our business, financial condition and results of operations, particularly regarding the R&D of our Core Products, ziresovir and AK3280, for the following reasons.

The scientific direction and clinical execution of ziresovir and AK3280 have been continuously anchored by key scientific leaders with deep historical ties to the programs, ensuring that the departure of any single CMO did not result in a hiatus between trials or delay the initiation of subsequent study phases. Notably, Dr. Wu, our Founder, Chairman, and CEO, is the original inventor of ziresovir from his tenure at Roche China, providing foundational continuity to the drug’s development lifecycle. Together with Dr. Yuan, our Chief Operating Officer who has been with the Group for over a decade, they have ensured that our clinical strategies remain consistent and robust throughout our history.

Notably, our clinical development activities have remained continuous despite changes in leadership. The transition from Dr. Tooney to Dr. Wu Yan in late 2020 seamlessly bridged our early-stage global studies and pivotal development in China; immediately following Dr. Wu Yan’s appointment, we successfully initiated the AirFLO Phase III clinical trial in RSV-infected infants in China in 2021 without any suspension of the R&D plan. Similarly, during the handover from Dr. Wu Yan to Dr. Rito, our R&D momentum accelerated rather than slowed, with Dr. Rito continuously assuming responsibility for AK3280 and assuming responsibility for ziresovir after Dr. Wu Yan left us without adverse impact on the development of either asset.

To further mitigate transition risks and ensure long-term stability, we have established a Development Committee to govern clinical stage product development activities and decision making, which is composed of Dr. Wu, Dr. Yuan, and the heads of key departments, including CMC, marketing, regulatory affairs, R&D, business development and project management, to oversee the development of ziresovir and AK3280. Following the departure of Dr. Rito in March 2024, the R&D function has been under the direct supervision of Dr. Wu. Given his deep scientific expertise as the inventor of ziresovir, his direct oversight ensures that clinical execution remains strictly aligned

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with our strategic goals. Our critical late-stage studies — specifically the supplemental AirFLO 2 Phase III trial of ziresovir and the Phase II proof-of-concept study of AK3280 — have continued to advance through 2024 and 2025 without interruption. We believe this demonstrates that we possess sufficient internal technical capabilities and leadership depth to sustain our clinical development plan independently of a standalone CMO.

Impact on Our Overall R&D Capabilities

Our Directors are of the view that the changes in the CMO position do not reflect a deficiency in our overall R&D capabilities. Although our current portfolio includes four in-licensed products, our ability to identify promising early-stage assets and independently advance them through critical value-inflection milestones is well-established. Notably, only AK0901 was a commercialized drug at the time of in-licensing. For our other key assets — ziresovir, AK3280, and AK0610 — we acquired rights at very early stages of development and have since driven their progression internally:

- Ziresovir: Originally discovered by Dr. Wu during his tenure at Roche China, we acquired global rights to ziresovir when it was merely a pre-clinical asset. We have since independently advanced the drug through all phases of development to NDA filing.
- AK3280: Acquired as a Phase 1 candidate, we have successfully advanced AK3280 into pivotal clinical trials in China
- AK0610: Licensed as an early-stage laboratory molecule without established druggability, we completed all IND-enabling studies and successfully moved the compound into clinical development.

These achievements demonstrate that we possess the internal technical capabilities to develop drugs independently of a standalone CMO, rather than relying solely on the acquisition of late-stage products.

In addition to the three CMOs previously disclosed, Mr. Zou Gang and Mr. Peng Cheng have departed from us for personal reasons. Mr. Zou Gang’s responsibilities have been assumed by Mr. Gao Zhao, who has served with us for over five years and possesses the requisite experience and institutional knowledge to ensure operational continuity. Mr. Peng Cheng’s primary responsibility pertained to early-stage drug manufacturing process development for Ziresovir, which has been substantially completed as such product candidate has advanced to the NDA stage. We do not believe that these departures will have a material adverse effect on our business, results of operations, or financial condition.

External Scientific Advisors

We also maintain cooperation with leading KOLs, and we may consult with these KOLs for issues arising from our research and development activities. From time to time, we may engage leading scientists and practitioners in pulmonary and pediatric diseases as our external scientific advisors, who provide us abundant industry insights and clinical research expertise. The following summarizes background of our major scientific advisors.

- *Peter Barnes*, one of the world’s highly cited respiratory researchers. Dr. Barnes was a professor at Imperial College London. Dr. Barnes has published over 1,500 peer-reviewed papers on asthma, COPD and related topics. He was elected as a Fellow of the Royal Society in 2007. He has been a member of the Scientific Committee of Global Guidelines on Asthma and COPD.
- *Richard Whitley*, a veteran in development of antiviral therapies. Dr. Whitley is a Distinguished Professor of Pediatrics and co-director at University of Alabama. Dr. Whitley served as the president of the Infectious Diseases Society of America in 2010 and has served as chair at several FDA and NIH committees.

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- *Borje Darpo*, a drug safety pharmacology expert with over 25 years of industry experience. Dr. Darpo is a member of the Division of Cardiovascular Medicine, Department of Clinical Science at the Karolinska Institute in Sweden. Dr. Darpo has extensive experience in atrial fibrillation and has published over 100 papers and articles in leading academic journals. He is the chief scientific officer of eResearch Technology, Inc., a global leading data and technology company specializing in clinical trial services.

These external scientific advisors bring decades of combined experience in academic medicine, clinical research, regulatory affairs, and drug development, and their ongoing involvement enhances the scientific rigor of our development programs, strengthens our regulatory submissions, expands our access to global clinical research networks, and validates our strategic approach to building a differentiated respiratory and antiviral product portfolio. Professor Richard Whitley, a leading authority in respiratory diseases, antiviral drug development, and pediatric medicine, has provided invaluable consultation on the overall clinical development strategy for ziresovir’s overseas clinical research programs and has assisted us in establishing a network of key opinion leaders and PIs critical to advancing our global development initiatives. Dr. Borje Darpo, a renowned expert in drug-induced cardiac safety, has contributed his specialized expertise in reviewing and advising on the design of clinical pharmacology studies for both ziresovir and AK3280, ensuring that our cardiac safety assessment protocols meet the highest regulatory standards and incorporate best practices for QT interval evaluation and cardiovascular risk assessment. Professor Peter Barnes, a world-leading respiratory disease and drug development expert, has played a pivotal role in guiding our strategic decisions regarding indication selection for our respiratory portfolio including AK0705, providing critical input on clinical trial design to optimize regulatory pathways and commercial potential, and conducting rigorous technical evaluations of potential in-licensing candidates to ensure alignment with our therapeutic focus and development capabilities.

Our Technology Platforms

We have developed a strong product pipeline by leveraging our strong research and development capabilities and the integrated technology platforms, which spans across key aspects of drug discovery and development. Our key technology platforms are summarized as follows.

- *Pediatric drug development platform.* We have gained extensive expertise in the areas where special considerations or regulatory requirements are warranted for drugs designated for infants and young children, involving pediatric drug discovery and formulation, population pharmacokinetics (PK) and allometric scaling, juvenile animal toxicity, pediatric clinical study design, and pediatrician KOL network. Building on strict adherence to international regulations and industry-leading standards, we have developed distinctive capabilities in pediatric clinical study design and execution. This specialized platform has delivered significant clinical success with ziresovir for RSV infection in infants and young children, advancing the drug candidate from an early-stage molecule to an NDA-stage drug asset. Leveraging this platform, our pediatric drug development capabilities have garnered significant recognition from leading medical journals and global health organizations, as evidenced by the publication of our infant clinical trial results in the New England Journal of Medicine and The Lancet Child & Adolescent Health, as well as the World Health Organization’s (WHO) inclusion of ziresovir on its Pediatric Drug Optimization priority list. These highlights our ability to develop innovative treatments that address critical needs in pediatric populations where safe and effective therapeutic options are often limited.
- *Antiviral drug screening platform.* Equipped with a biosafety laboratory for virological assays, we have established an antiviral drug screening platform to assess and evaluate the antiviral activity of drug candidates. We have a collection of a wide range of viruses, especially respiratory viruses for drug discovery and screening in the areas of RSV, MPV influenza, parainfluenza, coronavirus, rhinovirus, adenovirus and HBV. We are also experienced in *in vivo* virus challenge pharmacological animal models to assess antiviral effects.

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- *Drug discovery and intelligent design platform.* This platform showcases the convergence of computational biology in modern drug development. This sophisticated platform integrates intelligent drug design, medicinal chemistry optimization, and antibody discovery and engineering to accelerate the identification and development of both small molecule and biologic therapeutic candidates. This approach not only speeds up the traditional drug development timeline but also improves our success rates by making more informed decisions at each stage of development, further strengthening our ability to deliver innovative therapies to patients faster and more efficiently. The platform has already produced two clinical-stage programs that showcase its capabilities.
- *Pharmaceutical formulation development platform.* We have established a pharmaceutical formulation development platform that enables the design and optimization of different forms of drug products, including small molecules and biologics suitable for specific applications. This sophisticated platform encompasses core technologies including multi-layer coating for micro-pellets, enteric coating systems, nano-milling for particle size optimization, and solid dispersion techniques to address complex formulation challenges. Our formulation expertise has been successfully applied across multiple pipeline assets, including ziresovir, AK0610 and AK3280, where we have enhanced drug stability profiles and reduced side effects through innovative delivery approaches. Ziresovir’s innovative sprinkle capsule micro-pellet formulation represents the first pediatric-specific drug delivery system of its kind in China. This capability ensures that our therapeutic candidates not only demonstrate clinical efficacy but also offer optimal patient experience and compliance through thoughtfully designed drug products.
- *Medicinal chemistry platform.* We have established an internal medicinal chemistry platform for the discovery of patentable molecules with favorable drug-like properties, including both small molecule and ADC. We have established unique platforms, namely the CarBoX platform and the StabOx platform and the AFC (antiviral FC conjugate platform) platform for use of ADC technology in application to infectious diseases with a non-toxic payload. Through these platform technologies, we have discovered our lead molecules and have advanced the manufacturing processes of our drug candidates. For example, we have advanced the development of an IND-ready ADC candidate, namely AK0406, and plan to file its IND application to the NMPA in 2025.

Our R&D Efforts to Bring In-licensed Compounds to Drug Candidates

Currently, a significant portion, including our Core Products are in-licensed from third parties. We possess comprehensive research and development capabilities that have enabled us to independently advance these products through systematic clinical and non-clinical development programs. Since in-licensing these product candidates at various early stages of development, we have applied our core technology platforms and clinical development expertise to generate significant value through our independent R&D activities, transforming early-stage compounds and technologies into advanced clinical-stage or NDA-ready product candidates. The following summary demonstrates the substantial independent research outcomes and clinical achievements we have accomplished for each in-licensed product candidate, evidencing our core competitiveness in drug development.

Ziresovir

Following the in-licensing of compound patent rights for Ziresovir at our inception, our R&D team has conducted nearly ten years of independent and systematic non-clinical and clinical research, advancing the product to NDA filing stage. We independently completed comprehensive preclinical studies demonstrating nanomolar-level broad-spectrum antiviral efficacy against dozens of RSV viral strains and significant therapeutic efficacy in our proprietary RSV-infected mouse

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disease model. We successfully developed an openable enteric-coated pellet capsule formulation suitable for pediatric administration that effectively addressed Ziresovir’s instability and susceptibility to gastric acid degradation. We adopted an innovative pediatric-first development strategy and utilized quantitative pharmacology technology to establish population pharmacokinetic models and exposure-response analysis models for infants and young children, enabling rational dose selection and clinical trial design. We independently initiated and conducted nine clinical trials in infant, young children, and adult populations both domestically and internationally.

AK3280

Following in-licensing of AK3280 from Roche/Genentech at the Phase I clinical trial stage for treatment of idiopathic pulmonary fibrosis, our R&D team independently designed, conducted and completed the domestic Phase I bridging clinical trial in China, as well as API and drug product process validation and optimization. As of the Latest Practicable Date, we had completed a domestic Phase II clinical trial for IPF indication. Through in-depth mechanism of action research, we confirmed that AK3280 exerts broad-spectrum anti-fibrotic effects by inhibiting TGF β , LPA and other genes.

AK0610

Following in-licensing of an early-stage antibody (internal designation RV11) from the Institute of Microbiology, Chinese Academy of Sciences at the drug discovery stage, we applied our neutralizing antibody discovery and optimization technology platform and, through manufacturing process optimization and antibody engineering, successfully established the clinical candidate antibody drug AK0610. Following optimization and engineering, AK0610’s in vivo half-life was significantly extended and its neutralization activity substantially exceeded marketed products overseas.

These independent R&D achievements demonstrate that we possess comprehensive drug development capabilities spanning preclinical research, formulation development, manufacturing scale-up, clinical trial design and execution, and new indication expansion, enabling us to create substantial value through systematic development of in-licensed assets.

Considering the above, we believe we are capable of advancing our R&D programs for the development and commercialization of our drug candidates, including the Core Products.

- **Proven Track Record of Clinical Execution:** We have demonstrated a robust capability to identify high-potential early-stage assets and successfully advance them through complex clinical development pathways toward commercialization. For example, we advanced our Core Product, ziresovir—originally discovered by our Founder, Dr. Wu—from the pre-clinical stage to NDA submission in China. Similarly, for our Core Product, AK3280, we identified the optimal therapeutic indication and advanced the asset from Phase I to a pivotal clinical trial in China. This track record validates our ability to independently drive clinical programs from early development to late-stage regulatory milestones. Our strong R&D capabilities and clinical trial study results are recognized by renowned academic journals, including *New England Journal of Medicine* and *The Lancet Child & Adolescent Health*.
- **Integrated R&D Platform and Strategic Resource Allocation:** Our proprietary technology platforms underpin our ability to efficiently advance multiple product candidates simultaneously. We view the engagement of external scientific advisors as a strategic lever to access specialized domain expertise and global best practices. This approach—standard among leading biotechnology companies—enhances our internal capabilities rather than substituting for them. It allows us to access deep sub-specialty expertise efficiently without the fixed costs of maintaining full-time personnel in every niche area, representing a prudent and scalable resource allocation strategy.

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- **Stability of Core Leadership and Operational Continuity:** While we have optimized our workforce composition and suspended certain early-stage programs to prioritize our most promising assets, we have maintained unwavering continuity in our core R&D leadership. Under the strategic direction of Dr. Wu and Dr. Yuan, our R&D operations have remained focused and effective, and the development of our Core Products has not been materially and adversely affected by personnel turnover.
- To maximize operational efficiency and capital returns, we have adopted a focused development strategy that prioritizes our late-stage clinical assets — specifically our Core Products, ziresovir and AK3280 — and the commercialization of our recently approved product, AK0901. This disciplined approach ensures that our resources are concentrated on achieving high-value regulatory and commercial milestones.
- **Ziresovir:** Our immediate priority is the successful completion of the NDA review process by the NMPA for the treatment of infants aged 1–24 months. Concurrently, we are pursuing a label expansion strategy. We plan to apply for an expansion of the indication to cover children aged 2 to 5 years, leveraging positive data from our completed Phase II bridging PK study in China. Furthermore, we intend to initiate a Phase II/III clinical trial in China for adult patients, as well as U.S. clinical trials for both pediatric and adult populations, following our scheduled communications with the FDA. While the anticipated NDA approval for the infant indication represents a significant near-term commercial milestone, our phased development approach allows us to systematically de-risk subsequent indications while expanding the total addressable market, thereby maximizing the asset’s long-term commercial potential.
- **AK3280:** We are aggressively advancing the Phase III clinical trial for AK3280 in China. We target the completion of patient dosing by the end of 2026 and the conclusion of follow-up studies by the end of 2027, with the aim of submitting an NDA in China in 2028. Internationally, having obtained an IND from the FDA in February 2026, we plan to initiate a proof-of-concept Phase II clinical trial in the United States within the next 12 months.
- **AK0901:** Following the receipt of NDA approval in December 2025, we have transitioned AK0901 into the commercialization phase. To ensure rapid market penetration and efficient distribution, we have entered into a strategic partnership with Qilu Pharma, a leading nationwide pharmaceutical company to promote and distribute the product across China.

By balancing the immediate revenue potential of AK0901 with the near-term regulatory milestones of ziresovir and the medium-term global expansion of AK3280, we have structured a diversified but focused portfolio. We believe this tiered development strategy enables us to manage our cash runway efficiently while delivering sustainable value growth, demonstrating our capability to operate as a fully integrated biopharmaceutical company.

CROs and CDMOs

In line with the industry practice, we outsourced certain non-core research and development work and pre-clinical testing to reputable third parties. In 2024 and 2025, we engaged 53 and 56 CROs and CDMOs, respectively. We usually only select industry leading and reputable CROs and CDMOs. The costs incurred for CROs and CDMOs amounted to RMB61.9 million and RMB55.9 million in 2024 and 2025. We select CROs and CDMOs based on rigorous criteria, including extensive industry experience and track record in pharmaceutical development and manufacturing, advanced technical capabilities and infrastructure, and robust quality assurance systems and regulatory compliance history. Our service providers typically possess comprehensive capabilities essential to our drug development programs, including pre-clinical research platforms, both

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GMP-compliant and non-GMP production facilities, and established analytical and validation expertise. These capabilities enable them to support critical activities across the drug development lifecycle, from drug substance production and process development to analytical method establishment and stability studies. We enter into detailed service agreements with our CROs and CDMOs that clearly stipulate the specific terms of engagement, including pre-clinical research protocols, production requirements, and testing specifications. The scope of services typically encompasses non-GMP and GMP pilot-scale production, multi-batch process validation and optimization, analytical method development, verification and validation, long-term and accelerated stability studies for drug candidates, as well as quality control testing and release services. These agreements establish clear quality standards, timelines, and deliverables to ensure that our drug candidates are manufactured and tested in accordance with applicable regulatory requirements and industry best practices. The consideration is usually determined based on the type of testing and analysis they need to perform. To ensure our outsourced research and development activities are conducted in a timely manner, we usually stipulate the research and development schedule required for each type of testing or analysis. We usually pay these CROs/CDMOs in installments upon reaching certain key research and development milestones.

While our collaborations with CROs and CDMOs are important for enhancing operational efficiency and ensuring the high-quality execution of specific pre-clinical and chemistry, manufacturing, and controls procedures, we do not rely on any single external service provider for the development of our product candidates. We maintain an in-house research and development team that is responsible for designing and supervising all research and development activities, determining experimental protocols, and reviewing and verifying all key deliverables from our external service providers. This approach ensures that we retain full control over our core scientific and technical decisions while leveraging the specialized capabilities of our CRO and CDMO partners. We also retain the flexibility to engage alternative qualified CROs and CDMOs with comparable technical capabilities should the need arise, thereby mitigating dependency risks associated with our outsourcing strategy.

In addition, we also engage CROs to support our clinical trials. We select our CROs based on various factors, including service quality, capability, reputation, cost-effectiveness and research experience. We usually enter into master service agreements with our CROs with a detailed scope of work for each study or trial, establishing specific and detailed metrics on working methods, procedures, standards and timelines to further ensure the quality of the outcomes. We will organize periodic meetings with them and ask them to prepare reports from time to time. We closely monitor their performance to ensure they perform their duties with a standard in line with our protocols and industry benchmark to safeguard the integrity of the data collected from the trials. All the clinical trial results are only accessed by our responsible employees and the employee of the CRO in charge of the clinical trial.

Research and Development Facilities

During the Track Record Period and up to the Latest Practicable Date, our research and development activities were primarily conducted at our Shanghai headquarters and Suzhou Research and Development Center. Laboratories in our research and development facilities are built in compliance with the applicable legal requirements in China.

Third Party Collaboration

We also from time to time engage third parties to support our research and development activities. For early-stage molecule we discovered, we may engage third party companies to help us design the inhalation formulation and related manufacturing process to ensure that such potential drug candidates can meet the clinical and commercial standard. For example, we engaged Shanghai Omni Pharmaceutical Co., Ltd., an innovative pharmaceutical company focusing on drug delivery

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technologies, to design the inhalation formulation and related manufacturing activities of an early-stage drug candidate. As such, they are listed as one of the co-inventors for certain patent/patent application in relation to the preparation method for this drug candidate. For details, see “— Intellectual Property.”

MANUFACTURING

During the Track Record Period and up to the Latest Practicable Date, all of our drug candidates, including their APIs were manufactured by reputable CDMOs we engaged with whom we have a stable, long-term relationships. Our contracts with these CDMOs will stipulate detailed manufacturing procedures and requirements to ensure our drug samples used in the clinical trial can meet our stringent quality standards. To meet the anticipated demand for ziresovir, we will explore opportunities to build our own manufacturing facility over the next several years.

We expect to continuously strengthen our drug manufacturing and formulation capability in the future. In line with our commercialization schedule, we will continue to engage CDMOs to implement certain manufacturing processes, such as the production of APIs, to improve cost and compliance efficiency.

INTELLECTUAL PROPERTY

As a company focusing on the research, development and commercialization of innovative drugs, we believe intellectual properties are crucial to our business. We actively seek patent protection for our drug candidates in China and major jurisdictions and file additional applications, when appropriate, to cover certain strains, proteins, formulations and production processes, and method of use for our drug candidates. We have developed a significant portfolio of intellectual property rights to protect our technologies and products. As of the Latest Practicable Date, we owned 42 issued patents (including 37 in China and five in other jurisdictions) and 53 patent applications (including 26 in China and 27 in other jurisdictions). As of the Latest Practicable Date, we also in-licensed 134 issued patents (including 11 in China and 123 in other jurisdictions) and 31 patent applications (including four in China and 27 in other jurisdictions) from our global partners. For details of our collaboration and in-licensing agreements, see “— Overview of Licensing and Collaboration Agreements.” Before entering these in-licensing arrangements, we have conducted due diligence on the respective patents, and we only enter into in-licensing agreements or collaboration agreements after we are satisfied that the other party legally and validly owns all the intellectual properties subject to these agreements. We also have dedicated personnel monitoring the status of the patents subject to these collaboration and in-licensing agreements from time to time. We believe we have exclusive license rights under a compound patent and a method of manufacture of the compound patent, own a formulation patent and an intermediate compound patent application and a method of manufacture of the intermediate compound patent application in relation to ziresovir in our primary target market, such as China. As such, our Directors are of the view that we own all required intellectual property rights to cover all key characteristics of our Core Products in light of the future commercial launch. Our Directors confirm that we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that might be threatened or pending as claimant or respondent during the Track Record Period and up to the Latest Practicable Date. As of the Latest Practicable Date, our Directors were of the view that our patents/patent applications are currently not subject to any claim or invalidation request from any other party on the underlying technology in respect of these patents/patent applications.

For the purpose of the [REDACTED], we have engaged a reputable intellectual property counsel (“IP Counsel”) to conduct a freedom-to-operate analysis on (i) ziresovir and AK3280, our Core Products, in China and the United States and (ii) AK0901 and AK0610 in China. Based on such analysis, the IP Counsel is not aware of any third-party issued patents that would be infringed by the Company with respect to these drug candidates in their respective target jurisdictions as stated above.

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The following table summarizes material patents and patent applications we owned or co-owned as of the Latest Practicable Date, including three granted patents in relation to ziresovir and one patent application for AK3280.

Number	Patent	Related Product Candidate	Owner/ Applicant	Patent Type	Jurisdiction	Status	Expiration Date/ Application Date
1. . . .	Enteric-coated pellet containing RSV inhibitor and preparation method thereof	Ziresovir	The Company	Invention	China	Granted	December 7, 2034
2. . . .	Preparation method for compounds for the prevention and treatment of RSV	Ziresovir	The Company	Invention	China	Granted	April 10, 2035
3. . . .	Synthesis method of [3- (aminomethyl) -oxetane-3-yl] carbamic acid p-methoxybenzyl ester p-chlorobenzoate	Ziresovir	The Company	Invention	China	Granted	November 3, 2036
4. . . .	Treatment method for IPF ⁽²⁾	AK3280	The Company	Invention	China	Applied	May 13, 2025
5. . . .	Preparation method of oseltamivir carboxylate and atomizing agent thereof ⁽¹⁾	Undisclosed	The Company and Shanghai Omni Pharmaceutical Co. Ltd.	Invention	China	Granted	July 27, 2036
6. . . .	Preparation method for oseltamivir carboxylic acid hydrochloride and its atomizing agent ⁽¹⁾	Undisclosed	The Company and Shanghai Omni Pharmaceutical Co., Ltd.	Invention	China	Granted	July 27, 2036
7. . . .	A prodrug of an elastase inhibitor and its use	AK0705	ArkBio Suzhou	Invention	China	Granted	March 8, 2040
8. . . .	A capsule design	N/A	The Company	Design	China	Granted	August 23, 2030

Notes:

- (1) These patents are registered in relation to a drug candidate, which is at very early pre-clinical stage. For these patents, Shanghai Omni Pharmaceutical Co., Ltd., an innovative pharmaceutical company focusing on drug delivery technologies, are responsible for design of the inhalation formulation and related manufacturing activities of this drug candidate and therefore is one of the co-owners of these patents/patent applications for the preparation method for this drug candidate.
- (2) This patent application is a priority application we made in China.

The following table summarizes the material Chinese patents we in-licensed from our business partners as of the Latest Practicable Date.

Number	Patent	Related In-licensing Agreement	Patent Type	Jurisdiction	Status	Expiration Date	Owner
1. . . .	Compounds for the treatment and prophylaxis of Respiratory Syncytial Virus disease	Ziresovir Agreement	Invention	China	Granted	August 7, 2032	F. Hoffmann-La Roche AG
2. . . .	Process for the preparation of compounds for the prevention and treatment of RSV	Ziresovir Agreement	Invention	China	Granted	January 20, 2035	F. Hoffmann-La Roche AG
3. . . .	Anti-fibrotic pyridinone	AK3280 Agreement	Invention	China	Granted	September 30, 2033	INTERMUNE INC.
4. . . .	Anti-fibrotic pyridinone	AK3280 Agreement	Invention	China	Granted	March 30, 2035	INTERMUNE INC.

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We believe we owns all the intellectual properties in relation to our Core Products independently developed by ourselves, for the following reasons:

- Under the Ziresovir Agreement, while Roche retains ownership of the existing patent rights and background know-how covering the original compound, we own all inventions, improvements, know-how, data and other intellectual property generated solely by our employees through our clinical development, manufacturing and commercialization activities. Any inventions jointly developed by our employees and Roche’s employees are jointly owned, with each party responsible for prosecuting and maintaining its own patent rights at its own expense.
- Under the AK3280 Agreement, we own all inventions and know-how developed (i) solely by our employees; (ii) jointly by our employees with third parties other than Roche Group; and (iii) jointly by both our employees and Roche Group’s employees, as the agreement grants us sole ownership of such joint inventions. Roche Group retains ownership only of inventions developed solely by its employees or jointly with third parties other than us.

COMMERCIALIZATION

We have formulated a comprehensive commercialization strategy for our Core Products in key domestic and regional markets to drive effective market entry, sustainable revenue growth, and broad patient access. Leveraging both internal capabilities and external partnerships, we intend to adopt a phased approach — initially targeting regions with significant unmet medical needs and favorable market dynamics, and progressively expanding our coverage in tandem with regulatory approvals, production capacity, and market readiness. To ensure efficient product promotion, logistics, and market reach, our commercialization model integrates a dedicated inhouse commercial team with qualified regional distributors and strategic partners. Furthermore, our marketing initiatives will focus on academic promotion, medical conferences, real-world data dissemination, and digital engagement to enhance brand awareness and clinical acceptance. Concurrently, we plan to implement pricing and reimbursement strategies that reflect the clinical and pharmacoeconomic value of our Core Products, actively engaging with healthcare authorities to secure reimbursement inclusion and improve patient affordability. We believe this integrated, staged commercial framework will facilitate rapid market penetration and lay a robust foundation for the long-term commercial success of our Core Products.

We have a commercialization team which covers key functions of marketing, medical affairs, regulatory affairs and commercialization preparation. We will further recruit and build up the sales team to lead commercialization efforts and entrance in major pediatric hospitals in which we have established a strong working relationship through ziresovir’s clinical trials. Considering that there are no approved RSV drugs available in the market, we plan to adopt academic promotion approach in enhancing market share of ziresovir, such as actively participate in industry conferences and organize hospital seminars to introduce the competitive advantages of ziresovir as compared to other treatment for RSV infections. Our academic promotion activities will primarily focus on top 30 pediatric hospitals and leading general hospitals with pediatric respiratory department in tier-one cities. We plan to gradually increase our academic promotion activities, in anticipation of the expected NDA approval and following commercialization of ziresovir in China. Meanwhile, we are actively seeking to partner with established contract sales organizations to leverage their sales networks for nationwide commercialization in China. After commercial launch of ziresovir in China, we plan to seek inclusion of ziresovir in the NRDL. For risks associated with the potential inclusion of ziresovir in the NRDL, see “Risk Factors — Risks Relating to Commercialization of Our Drug Candidates — Even if we are able to commercialize any approved drug candidates, reimbursement may be limited or not immediately available for our drug candidates.”

We have established a commercialization strategy tailored for China and global markets to realize near-term value of our pipeline, especially our lead candidates ziresovir, AK3280 and AK0901. To prepare for our products’ near-term commercial launch, we plan to adopt a hybrid

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commercialization approach. While we will continue to develop our in-house commercialization capabilities, we are also exploring opportunities to seek partnership with reputable pharmaceutical companies to leverage their sales network for our commercialization activities, which is evidenced by our recent-entered collaboration with Qilu Pharma.

As the ex-China global rights holder of most of our products, we adopt a flexible global strategy focused on capturing commercial value in major markets by exploring potential partnership with global biopharmaceutical companies through out-licensing, co-development or co-promotion. We have conducted global clinical trials for ziresovir in major markets including the US, Europe, Asia, Middle East and Australia, and may consider advancing ziresovir globally through partnerships. For ziresovir and AK3280, we will explore options to advance development and commercialization through partnership arrangements for global market. For more details, see “— Business Strategies — Maximize our drug candidates’ global value through strategic partnerships.”

Commercial Collaboration with Qilu Pharma on AK0901

On December 12, 2025, we entered into a commercialization collaboration with Qilu Pharma Co., Ltd. (齊魯製藥有限公司) (“**Qilu Pharma**”), a nationwide pharmaceutical company in China, for the commercialization of AK0901 in Chinese Mainland (“**Qilu Agreement**”). Pursuant to the Qilu Agreement, we granted Qilu Pharma an exclusive license within Chinese Mainland for the develop, manufacture and commercialization of AK0901 in Chinese Mainland. Qilu Pharma may subcontract or engage affiliates or third parties (such as CSOs) to perform its obligations, provided such parties comply with terms, confidentiality of the Qilu Agreement, and applicable laws, and Qilu Pharma remains responsible for their actions.

A JSC will be established to oversee development, regulatory affairs, manufacturing, and commercialization. While decisions require consensus, Qilu Pharma generally holds the final decision-making power for development and commercialization of AK0901 within Chinese Mainland, except that neither party shall have final decision-making authority with respect to annual sales targets in Mainland China.

Qilu Pharma shall prepare an annual commercialization plan each year, with the first such plan to be prepared within six months following NDA approval of AK0901. Each annual commercialization plan shall be submitted to the JSC for review and approval and shall include the sales target and work plan for Qilu Pharma’s sales team. Any revisions to an annual commercialization plan shall also be submitted to the JSC for review and approval. Qilu Pharma has the sole right and responsibility to commercialize the product in Mainland China, bearing all associated costs, and is required to use commercially reasonable efforts and meet the specified sales targets. Failure to meet 80% of the sales targets set forth in the commercialization plan for two consecutive years may result in compensation payable to us.

Qilu Pharma is obliged to pay us (i) R&D milestone payments up to a total of RMB110 million following occurrence of NDA approval, and completion of the manufacturing technology transfer (ii) sales milestone payment up to a total of RMB360 million following AK0901 achieves certain annual sales targets (ranging from RMB200 million to RMB3.6 billion); and (ii) tiered royalty payments based on aggregate annual net sales, at rates ranging from low-to-mid teens as a percentage of net sales.

QUALITY MANAGEMENT SYSTEM

Our quality management system includes quality control and quality assurance, which are crucial to us, and we endeavor to ensure the quality of our operations through a comprehensive quality management system, which was formulated in accordance with the GLP, GCP and GMP standards as required by the NMPA, covering substantially every aspect of our operations including discovery, pre-clinical research and development, clinical trial, supply chain and manufacturing, among others.

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We have established an independent quality management system and devote significant attention to quality control and assurance for the clinical development, manufacturing and testing of our drug candidates. Our quality management team monitors and drives our quality performance, allocates sufficient resources to implement the quality management system and sets the quality governance mechanism. Any quality or regulatory issues identified by the quality team are documented in writing, and documentation is archived based on regulatory requirements. We also document and investigate each quality incident or issue pursuant to our quality management system.

The primary responsibilities of our quality management team include the following:

- maintaining quality assurance policy and standard operating procedures and coordinating and performing risk evaluations for our Company and individual projects to ensure adequate quality metrics and timely reporting to our senior management team.
- adopting and implementing audit plans for investigator site audits, system audits and supplier audits to ensure our compliance with applicable regulatory requirements.
- maintaining our supply chain management system, which includes establishing appropriate processes for the assessment of our suppliers, monitoring their performance, reviewing and approving quality agreements and other duties; and
- ensuring patient safety and well-being during our clinical trials and the credibility of our clinical trial data.

SUPPLIERS

During the Track Record Period, our suppliers primarily consisted of (i) CROs and CDMOs, (ii) suppliers of equipment and devices for our research and manufacturing facility development, and (iii) other service providers, such as decoration.

During the Track Record Period, we engaged a number of CROs and CDMOs to support our pre-clinical and clinical research and development activities. For details, see “— Research and Development — CROs and CDMOs.” In addition, we procure raw materials from numerous suppliers around the world according to our product development plans. Our raw materials for our drug candidates primarily include chemical materials. Most of our raw materials are widely available. We have established stable collaboration relationships with qualified suppliers for key services in relation to our pre-clinical and clinical research and development activities as well as raw materials, which we believe have sufficient capacity to meet our demands. Nevertheless, we believe that adequate alternative sources for such supplies exist. To monitor the quality of supplies, we implemented a standardized operating system, setting out the procedures and guidelines for the procurement of raw materials, quality control inspection, warehousing, testing, and storage. During the Track Record Period and up to the Latest Practicable Date, we did not experience any shortage or delays in the supply of raw materials.

We select our suppliers by considering their qualifications, compliance with relevant regulations and industry standards, production facilities, production quality, prices, business scale, market share, reputation, and after-sales service quality. During the Track Record Period, we did not experience any material disputes with suppliers, difficulties during the procurement of raw materials, interruptions in our operations due to a shortage or delay of raw materials, or significant fluctuations in raw material prices.

For the years ended 2024 and 2025, our purchases from our five largest suppliers in aggregate amounted to RMB51.1 million and RMB53.9 million, accounting for 48.3% and 34.9% of our total purchases for the same period, respectively. The following table sets forth details of our five largest suppliers during the Track Record Period.

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Rank	Supplier	Amount (RMB'000)	Credit Term	Background of Supplier	Product/ Service procured	Years of business relationship ⁽¹⁾
<i>For the year ended December 31, 2025</i>						
1 . . .	Supplier A	17,797	30 days	A private company founded in 2017 that provides medical services	License-in of AK0901	Four years
2 . . .	Supplier B	14,422	180 days	A company founded in 2010 and listed on the Stock Exchange with approximately US\$277.6 million registered capital that develops and commercialize innovative oncology drugs and therapies	Clinical services, non-clinical services and raw material and formulation production for AK0406	Four years
3 . . .	Supplier C	10,070	30 days	A company founded in 2004 and listed on the Shenzhen Stock Exchange with approximately RMB861.0 million registered capital that provided CRO services	Clinical services for AK3280 and ziresovir	Eight years
4 . . .	Supplier D	5,995	30 days	A company founded in 2000 and listed on the Stock Exchange with approximately RMB2.9 billion in registered capital that provides pharmaceutical research and development services	Non-clinical services, clinical services and raw material and formulation production for AK0610 and ziresovir	Six years
5 . . .	Supplier E	5,600	30 business days	An institution founded in 1958 that engages in microbiology research and microbial technology development	License-in of AK0610	Five years
Total		53,884				
Percentage of total purchases		34.9%				

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Rank	Supplier	Amount (RMB'000)	Credit Term	Background of Supplier	Product/ Service procured	Years of business relationship ⁽¹⁾
<i>For the year ended December 31, 2024</i>						
1 . . .	Supplier F	14,755	30 days	A private company founded in 2016 with approximately 311.0 million registered capital that provides CDMO services	Raw material production and non-clinical services for ziresovir	Five years
2 . . .	Supplier G	13,676	30 days	A private company founded in 2000 that provides CRO and biopharmaceutical services	Clinical services for ziresovir	Two years
3 . . .	Supplier C	8,974	30 days	A company founded in 2004 and listed on the Shenzhen Stock Exchange with approximately RMB861.0 million registered capital that provided CRO services	Clinical services for AK3280 and ziresovir	Eight years
4 . . .	Supplier D	8,563	30 days	A company founded in 2000 and listed on the Stock Exchange with approximately RMB2.9 billion in registered capital that provides pharmaceutical research and development services	Non-clinical services, clinical-services and raw material and formulation production for AK0610 and ziresovir	Six years
5 . . .	Supplier H	5,165	30 days	A public hospital founded in 1960 with approximately RMB610.9 million start-up capital that engages in medical research and provides medical services	Clinical services for AK0610 and AK0901	Two years
	Total	51,133				
	Percentage of total purchases	48.3%				

Note:

- (1) “Years of Business Relationship” represent the number of years we entered into business relationship with such suppliers as of the end of the year indicated.

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All of our five largest suppliers during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates nor any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers during the Track Record Period.

COMPETITION

The biopharmaceutical industry is highly competitive and subject to rapid and significant change. While we believe that our pipeline of innovative drug candidates in clinical and pre-clinical trials, strong research and development capability and distinguished leadership team provide us with competitive advantages, we face potential competition from many different sources working to develop therapies targeting the same indications for which we develop our drug candidates, in particular in respiratory and lung diseases. These include major pharmaceutical companies as well as specialty pharmaceutical companies of various sizes and academic research institutions. Any drug candidates that we successfully develop and commercialize will compete both with existing drugs, if any and with any new drugs that may become available in the future. For more information on the competitive landscape of our drug candidates, see “— Our Product Pipeline” and “Industry Overview.”

INSURANCE

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. In line with industry practice in China, we maintain different types of insurance policies, such as insurance covering clinical trials. Our Directors consider that our existing insurance coverage is sufficient for our present operations. See “Risk Factors — Risks Relating to Our Industry, Business and 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” for details.

EMPLOYEES

As of the Latest Practicable Date, we had 86 employees. All of our employees are based in China. The table below sets forth our employees by function as of the Latest Practicable Date.

Function	Number
Management and administrative	20
Research and development	62
Medical affair and commercialization	4
Total	86

We recruit our employees through recruitment websites, recruiters and internal referrals. For all of our employees, we will provide on-board training for them, and we also provide periodic training or seminars to ensure their self-development. The remuneration package of our employees includes salary and bonus, which are generally based on their qualifications, industry experience, position and performance. We may also provide share-based incentives to our employees from time to time. We consider the remuneration package of our employees to be competitive among our domestic competitors. We make contributions to social insurance and housing provident funds as required by the PRC laws and regulations.

In compliance with the relevant PRC laws and regulations, we entered into employment contracts with our employees to cover matters such as wages, benefits and grounds for termination. We enter into standard confidentiality agreements with all of our employees. We enter into

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non-compete agreements with employees of the departments that we consider crucial to our business, such as research and development. Such non-compete agreements prohibit employees to conduct any business competing with us after twelve months following the termination of his or her employment.

We have not established a labor union. During the Track Record Period and as of 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. During the Track Record Period, we confirm that there were no shortfalls in our contributions to social insurance and housing provident funds.

PROPERTIES

We are headquartered in Shanghai. As of the Latest Practicable Date, we did not own any properties and we leased a number of properties with an aggregate GFA of 3,159.52 square meters. We believe our current facilities are sufficient to meet our near-term needs, and additional space can be obtained on commercially reasonable terms to meet our future needs. We do not anticipate undue difficulty in renewing our leases upon their expiration. The following table sets forth the details of our leased properties in China currently.

Item Number	Location	Use	GFA (sq.m.)	Expiry date
1	No. 25, Lane 338 Shengrong Road, Zhangjiang Town, Pudong New Area, Shanghai	Scientific research design	1,897.49	December 31, 2026
2	F/2, No. 53 and 57, Huale Road, Yuxiu District, Guangzhou, Guangdong	Office	8.75	December 31, 2026
3	Unit 406, Building B2, BioBay, No. 218 Xinghu Street, Suzhou Industrial Park, Suzhou, Jiangsu	R&D, office and production	345.00	March 19, 2026
4	Unit 705, Building B2, BioBay, No. 218 Xinghu Street, Suzhou Industrial Park, Suzhou, Jiangsu	R&D, office and production	345.00	July 21, 2026
5	Unit 706, Building B2, BioBay, No. 218 Xinghu Street, Suzhou Industrial Park, Suzhou, Jiangsu	R&D, office and production	378.00	April 24, 2028
6	F/1-18, Building 100, East Third Ring South Road, Chaoyang District, Beijing (Rooms 805-806 for F/8)	Office	185.28	January 9, 2027

As of the Latest Practicable Date, we had not completed lease registration with the relevant regulatory authorities for all of the leases. Our PRC Legal Advisors are of the view that the non-registration of lease agreements will not affect the validity of such lease agreements, but the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and we may be subject to a fine between RMB1,000 and RMB10,000 per lease for any delay in making these registrations. Therefore, we have the right to use such properties in accordance with the lease agreements, but we may be subject to the risks of fines if the lease registration is not completed as required by the relevant local housing administrative authorities. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of the lease agreements.

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According to section 6(2) of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice, this document is exempted from compliance with the requirements of section 342(1)(b) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which require a valuation report with respect to all our Group’s interests in land or buildings, for the reason that, as of December 31, 2025, we had no single property with a carrying amount of 15% or more of our total assets.

SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

We believe our sustained growth lies in our contribution to the society. Since our inception, we have adopted as our long-term strategic goal to promote environmental sustainability, support and participate in socially responsible projects, and adhere to a high standard of corporate governance.

ESG Governance

We attach great importance to environment, social and governance (“ESG”) practice, and we have adopted a detailed ESG reporting procedure. Our Board is fully responsible for setting up ESG policies and strategies, assessing the ESG risks associated in our day-to-day operations, monitoring and reviewing of progress made against targets to ensure mechanism effectiveness, and fostering a culture of acting in accordance with our core ESG values. To strengthen our sustainability capabilities, improve our governance structure and enhance our ESG performance, we also had an ESG working team consisting of senior executives, heads of various functional departments and staff with a solid understanding of current and emerging ESG-related issues, which shall report to our Board on all the ESG-related matters and shall be responsible for executing the ESG strategies implemented by the Board. The duties and responsibilities of the ESG working team include the following:

- Develop and implement ESG framework, policies and initiatives aligned with our long-term business strategy, and regularly review and adjust as needed.
- Ensure compliance with the latest ESG-related laws and regulations, and update ESG policies promptly based on regulatory changes.
- Identify, assess and manage material ESG-related risks on a regular basis, and implement timely measures to mitigate potential impacts.
- Engage external ESG experts when necessary to provide professional advice and support in fulfilling our ESG targets.
- Review and monitor the effectiveness of our stakeholder communication channels and collect their feedback to optimize our ESG strategies.
- Arrange ongoing ESG training for directors and senior management to ensure awareness of the latest trends and compliance requirements on ESG-related matters; and
- Monitor and evaluate our performance and progress against ESG targets and regularly report to the Board.

Environmental Protection

We are committed to sustainable development and environmental stewardship across all aspects of our operations. With this in mind, we pay close attention to the global trend and China’s national strategy of addressing environmental issues and related risks and prioritize eco-conscious practices and take proactive and effective measures to control and reduce pollutant emissions and energy consumption, striving to minimize our environmental footprint while supporting long-term

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business growth. We are actively strengthening our capabilities to respond to climate-related risks and will, following our [REDACTED], formulate policies to systematically identify, assess and manage climate change-related risks and develop corresponding response strategies.

GHG Emissions and Resource Consumption Management

Our greenhouse gas (“GHG”) emissions during the Track Record Period were relatively limited, as the major sources of our GHG emissions and energy consumption were primarily attributable to electricity usage in the ordinary course of our business operations. We have not engaged in any manufacturing activities to date, as we remain in the process of exploring various manufacturing arrangements in preparation of the future commercial launch.

We closely monitor water consumption levels at our offices and have implemented various policies and measures to conserve water resources. These include timely repairing any dripping faucets to minimize water wastage and posting reminder stickers in restrooms to raise employees’ awareness on water conservation. Through these efforts, we target to further promote water-saving practices and reduce overall water usage.

The following table sets out the breakdown of our electricity and water consumption for the periods indicated.

	For the Year Ended December 31,	
	2024	2025
Energy Consumption		
Electricity consumption (MWh)	185.61	216.46
Water Consumption		
Water consumption (t)	359	207

Waste Management

We are fully committed to sustainable waste management practices, ensuring that all waste is handled with the utmost care and efficiency. Given that our operations involve the use of hazardous and flammable chemical materials, which in turn generate hazardous waste, we have formulated a comprehensive and robust management framework to mitigate associated risks and ensure regulatory compliance.

As part of the framework, we have appointed part-time safety management personnel and established a comprehensive hazardous waste management system to regulate the entire process from generation to disposal. Our day-to-day hazardous waste is divided into four categories, namely organic solvents, spent activated carbon medical waste and other waste. For each category, dedicated personnel from the respective functional departments are assigned and report directly to the safety management personnel for the daily management of such hazardous waste.

In alignment with our environmental objectives, we have also set clearly defined pollutant emission targets. For example, the total wastewater we dispose each year shall not exceed 721.3 tons per year. The pH values of the wastewater shall be within the range of 6 to 9 and the Chemical Oxygen Demand (COD) wastewater shall not exceed 300 mg/L. For waste gas, the ethyl acetate shall not exceed 0.0007 ton per year and the total volatile organic compounds shall not exceed 0.02 ton per year. All hazardous materials and waste are disposed of through licensed third parties, ensuring that our waste management practices remain compliant with applicable laws and environmental standards.

BUSINESS

Social Responsibility

Employment and Labor Practice

We deeply value our people and respect the dignity, character, privacy and personal interest of our employees. We enter into employment contracts with our employees in accordance with the applicable PRC laws and regulations, and foster inclusion and equality among employees regardless of their gender, age, race, religion or any other social or personal characteristics. Moreover, we encourage everyone within our organization to pursue professional development by offering both training and mentorship programs, supporting continued education, as well as providing opportunities to participate in industry conferences, to enhance their knowledge, skills, and competencies. As of the date of this Document, we have not engaged in any illegal activities in employment such as hiring child labor or forced labor, and we have timely paid social insurance contributions for our full-time employees.

We fully empower women in recruitment and employment, training and promotion, employee well-being, workplace environment and communication channels. For example, we set up multi-dimensional communication channels to actively address concerns from female employees, helping create a diverse and inclusive work environment. As of the Latest Practicable Date, 56% of our full-time employees were female.

Occupational Health and Safety

We are subject to various health, work safety and environmental laws and regulations and our operations are regularly inspected by local government authorities. We strive to provide a safe working environment for our employees and have implemented company-wide work safety guidelines setting out safety practices, accident prevention and accident reporting procedures. To mitigate risks and safeguard the well-being of our employees, we have also established emergency response plans and provide relevant safety training for our employees to promote a culture of safety. Our employees responsible for laboratory work are required to hold relevant qualifications, as well as wear the proper safety gear when working. In addition, we conduct regular safety inspections and maintenance for our research and development facilities to ensure ongoing compliance and risk prevention. During the Track Record Period and up to the Latest Practicable Date, we had complied with health, work safety and environmental laws and regulations applicable to our operations in all material respects, and we did not encounter any environmental or occupational health related incidents or complaints that would materially and adversely affect our business, financial condition or results of operations during the same period.

Corporate Governance

Patient Data Protection and Prevention of Data Manipulation

We strive to safeguard sensitive information and ensure the protection of clinical trial participant information in compliance with applicable laws, regulations, and industry standards. We require CROs to maintain strict confidentiality of all documents, data, records, and information provided by us or generated during the trial. CROs are also obligated to ensure that their employees, consultants, and other professionals who access such confidential information are bound by the same confidentiality obligations. Without our prior written consent, CROs are prohibited from disclosing or disseminating any confidential information to third parties in any form. Furthermore, we require CROs to implement protective measures that are at least equivalent to those they use for their own confidential information, to prevent unauthorized use, disclosure, or leakage of the clinical trial data. We also enter into standard confidentiality agreements with all of our employees, adding an extra layer of security for the confidential information.

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To reinforce our commitment to data integrity and prevent data manipulation, we have established comprehensive internal policies regarding detecting and responding to data breaches, tampering, and data loss, and set forth consequences for policy violations. Together, these policies form a robust framework to safeguard the authenticity and reliability of our research and clinical trial data, while promoting strong standards of confidentiality and data protection throughout the clinical trial process.

Business Ethics and Integrity

We are committed to upholding high standards of corporate governance and fostering a healthy corporate culture. We believe that strong governance and ethical values are essential to the well-being of our employees and the sustainable development of our business. To this end, we have put in place a series of internal regulations to set forth the guidelines for compliance with laws and regulations and promote honest and ethical conduct, prevent corruption practices and conflicts of interest, and maintain operational transparency and fairness, including our code of business conduct and ethics, anti-corruption compliance policy, and internal control manual. These measures foster an ethical and transparent business environment while safeguarding our interests and those of all stakeholders.

LICENSES AND PERMITS

We are subject to regular inspections, examinations and audits by local regulators and are required to maintain or renew the necessary permits, licenses and certificates for our business. Our PRC Legal Advisors are of the view that, during the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from the relevant government authorities that are material for our business operations in China. The following table summarizes material licenses and permits we held as of the Latest Practicable Date. We plan to renew all the material license and permit upon its expiration if applicable.

License/Permit	Holder	Time of Grant	Time of Expiration
IND approval from NMPA for ziresovir (10/40mg dose) . . .	Company	May 26, 2020	Not applicable
IND approval from NMPA for ziresovir (100mg dose)	Company	November 8, 2016	Not applicable
IND approval from NMPA for ziresovir (API)	Company	November 11, 2016	Not applicable
IND approval from NMPA for AK3280	Company	January 26, 2021	Not applicable
IND approval from NMPA for AK0901	Company	September 18, 2023	Not applicable
IND approval from NMPA for AK0610	Company	September 28, 2023	Not applicable
Pharmaceutical Manufacturing License	Company	April 29, 2024	June 30, 2027
Biosafety Laboratories Filing Certificate	Company	August 26, 2025	August 25, 2027

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LEGAL PROCEEDINGS

We may be involved in legal proceedings in the ordinary course of business from time to time. During the Track Record Period and up to the Latest Practicable Date, none of us or our Directors were involved in any litigation, arbitration or administrative proceedings which could have a material adverse impact on our business, financial condition or results of operations. As of the Latest Practicable Date, we were not aware of any pending or threatened litigation, arbitration or administrative proceedings against us or our Directors which may have a material and adverse impact on our business, financial condition or results of operations.

RISK MANAGEMENT AND INTERNAL CONTROL

We recognize that risk management is critical to the success of our business operation. See “Risk Factors” for a discussion of various risks and uncertainties we face. We also face various market risks. In particular, we are exposed to currency, interest rate, credit and liquidity risks that arise in the normal course of our business. See “Financial Information — Quantitative and Qualitative Disclosure about Market Risk” for a discussion of these market risks. We have adopted a consolidated set of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an on-going basis. Our audit committee, and ultimately our Directors, shall supervise the implementation of our risk management policies. Risks identified by management will be analyzed on the basis of likelihood and impact and will be properly followed up and mitigated by our Group and reported to our Directors.

Our policies and procedures are aimed at managing and monitoring our business performance. We have adopted, or will continue to adopt, among other things, the following risk management measures:

- establish an audit committee to review and supervise our financial reporting process and internal control system. Our audit committee consists of three members: Dr. Ziyue ZHAO, the chairperson of the committee, Ms. Audrey RAO and Dr. Wenfang WU. For the qualifications and experiences of these members, see “Directors, Supervisors and Senior Management;”
- adopt various policies to ensure the compliance with the Listing Rules, including but not limited to policies in respect of risk management, connected transactions and information disclosure;
- provide regular anti-corruption and anti-bribery compliance training for senior management and employees in order to enhance their knowledge of and compliance of applicable laws and regulations; and
- arrange our Directors and senior management to attend training seminars on Listing Rules requirements and the responsibilities as directors of a Hong Kong-listed company.

As a crucial part of our internal control procedures, we value the protection of personal data of the patients enrolled for our clinical trials. In accordance with the relevant laws and regulations in China, we have formulated a detailed internal procedure with respect to the protection of patients’ data. Our clinical operation department is responsible for supervising the data protection practice during clinical trials. We have also formed a data protection team, which is responsible for analyzing the latest laws and regulations in these areas and upgrading and managing our private data protection system. In particular, when collecting any patient’s private data, we will inform them the types of personal data collected, purpose, processing method, the storage period and whether the data may be transferred abroad. We strive to only collect personal data and store them for the period necessary for our clinical purpose. We also provide on-board training with respect to the handling of personal data to all of our employees when they join us.

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We have also formulated a series of anti-bribery compliance policy in accordance with the applicable laws and regulations as part of our internal control procedure. We have established an employee code of conduct, which covers anti-bribery compliance requirements in our business operations. Our employees involved in the accounting and finance function shall be alert to any suspicious transactions and are required to report such suspected violations they identified to the Chief Financial Officer of our Company. We also encourage all the employees to report any suspicious violations in this area.

In preparation for the [REDACTED], The Group engaged an internal control consultant (the “**Internal Control Consultant**”) to perform internal control review over selected areas in August 2025. The selected areas including entity level controls, financial reporting, purchase, payables and payment, inventory and logistic management, research and development project management, fixed assets and intangible assets management, intellectual property management, treasury and investment, human resource and payroll, tax management, insurance, management and general controls of information technology. The Internal Control Consultant performed the follow-up review in September 2025. As of the Latest Practicable Date, there was no material issue remaining based on our internal control review procedure in relation to the internal controls of our Group.

The Group has been advised by the Internal Control Consultant that, during the course of its review, a number of material internal control deficiencies were identified, including: (i) the absence of a formalized policy governing securities dealings by employees, management and Directors; (ii) the lack of a corporate governance framework aligned with the requirements of the listing venue; (iii) the need to further enhance our training and professional development policies; (iv) the absence of a systematic risk assessment mechanism; (v) the lack of policies and procedures relating to overseas economic sanctions compliance; and (vi) the absence of a comprehensive sales management system.

We have rectified the above deficiencies by (i) formulating and adopting corresponding internal policies and procedures addressing each of the areas identified, including securities dealing policy, corporate governance policies, training management system, risk assessment mechanism, overseas sanctions compliance procedures and sales management policy; and (ii) conducting relevant internal trainings, including anti-money laundering and finance-related professional training, with reference to the Internal Control Consultant’s recommendations. We further confirm that all such policies will be formally adopted prior to [REDACTED].

Based on the follow-up review performed by the Internal Control Consultant, save for the deficiencies identified above and subsequently rectified, no other material deficiencies have been identified.