SUMMARY

This summary aims to give you an overview of the information contained in this document. As it is a summary, it does not contain all the information that may be important to you and is qualified in its entirety by, and should be read in conjunction with, the full document. You should read the whole document before you decide to* [REDACTED] *in the* [REDACTED]. *There are risks associated with any* [REDACTED]. *Some of the particular risks in* [REDACTED] *in the* [REDACTED] *are set forth in the section headed "Risk Factors" of this document. You should read that section carefully before you decide to* [REDACTED] *in the* [REDACTED]. *In particular, we are a biotechnology company seeking to* [REDACTED] *on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules as we do not meet the requirements under Rules 8.05(1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with* [REDACTED] *in companies like ours. Notably, our Core Products are in the early stages of clinical development. We may continue to incur substantial costs and expenses in relation to R&D activities for the Core Products and our Core Products may not be successfully developed or marketed. Your* [REDACTED] *decision should be made in light of these considerations.

OVERVIEW

Established in 2013, 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 two Core Products, namely (i) ziresovir, a respiratory syncytial virus ("**RSV**") drug, which was originally in-licensed from Roche in January 2014 and currently under new drug application ("**NDA**") at the the National Medical Products Administration of the PRC ("**NMPA**") for the treatment of RSV infections in infants aged 1 to 24 months and (ii) AK3280, a post-phase II proof-of-concept ("**PoC**") clinical trial stage idiopathic pulmonary fibrosis ("**IPF**") drug, which was originally in-licensed from Roche, Genentech and Intermune in August 2018.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP, MARKET AND/OR GENERATE MEANINGFUL ECONOMIC VALUE FROM OUR PIPELINE PRODUCTS, INCLUDING CORE PRODUCTS ZIRESOVIR AND AK3280.

OUR DRUG PIPELINE

As of the Latest Practicable Date, we had developed a pipeline of six drug candidates. The following table summarizes our drug candidates and their respective development stage as of the Latest Practicable Date.

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	China	Ph III	NDA approval in 2026
						FDA	Global	Ph II	Initiate communications with the FDA in 2026 1H and initiate clinical trial in 2027
				RSV treatment for adult	Oral (Monotherapy)	NMPA	China	Ph III	Complete subject enrollment in 2028 Q1 and complete clinical trial in 2028
						FDA	Global	Ph II	Initiate communications with the FDA in 2026
	★ AK3280[2]	Broadly active fibrosis inhibitor	Small molecule	IPF	Oral (Monotherapy)	NMPA	China	Ph III	Complete Ph III trial in 2028
						FDA	Global	Ph II	Ph II initiation in the next 12 months
	✦ AK0610[4]	RSV F protein mAb	mAb	RSV prevention	Oral (Monotherapy)	NMPA	China	Ph II	Complete Ph II trial in 2026
	AK0705[5]	Undisclosed	Small molecule	COPD	Oral (Monotherapy)	NMPA	China	IND	Complete IND-enabling studies in 2027 Q2
	AK0406	Undisclosed	Antibody-drug conjugate (ADC)	Influenza	Oral (Monotherapy)	TGA	China	Ph I	Complete phase I clinical trial in 2027
Others	✦ AK0901[3]	Dexmethylphenidate and the prodrug serdexmethylphenidate	Small molecule	ADHD	Oral (Monotherapy)	NMPA	China	Ph III / NDA	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

Core Products

Ziresovir for treatment

Ziresovir is an 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-class RSV treatment drug candidate globally, and potentially the world's first RSV-specific antiviral drug to achieve positive results in pivotal phase III clinical trials. Due to its clinical and safety profile, ziresovir is the first non-oncology drug to receive "breakthrough therapy designation" from the NMPA. In August 2025, we submitted a NDA application for ziresovir to the NMPA for the treatment of RSV in infants aged 1 to 24 months.

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 75% greater viral load reduction than placebo with consistent daily improvements. For critically ill children requiring pediatric intensive care (PICU), 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.

- *Favorable safety profile*. Ziresovir has demonstrated a balanced and favorable safety profile. No drug-related severe adverse events were observed in healthy adults and pediatric patients as young as one month old in its completed clinical trials.

- *Sufficient drug exposure in respiratory tract*. When orally administered in pre-clinical animal studies, ziresovir demonstrated a targeted high drug exposure in the lung.

- *Patient compliance advantages*. Ziresovir offers significant compliance advantages through its innovative oral delivery method compared to existing treatments. It features a sprinkle capsule of micro pellet formulation design specifically developed for oral administration across all age groups of infants and young children.

AK3280

We have developed a post phase II PoC stage IPF drug asset, namely AK3280. AK3280 attenuates a multitude of fibrosis-related genes and proteins. We believe our AK3280 has the following competitive advantages:

- *Improved anti-fibrotic effect*. 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. We believe the potential of AK3280 in improving lung function could render its broad application in treating 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 gastrointestinal (GI) intolerance and no signs of photo-toxicity or liver toxicity in clinical trials.

- *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.

- *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 once a day (QD) or BID (twice a day), which would significantly improve patient adherence.

Key Product

AK0901

We in-licensed Azstarys®(1) (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. 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. 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 "Business — Commercialization — Commercial Collaboration with Qilu Pharma on AK0901."

We believe AK0901 has the following advantages.

- *Superior symptom control with a unique dual-component formulation*. AK0901 demonstrates more stable disease symptom control, 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.

- *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. Further, AK0901 carries no black box warning, 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.

OUR TECHNOLOGY PLATFORMS

Through years of strategic investment and development, we have built an array of integrated self-developed technology platforms internally that span key aspects of drug discovery and development. Leveraging our strong research and development capabilities and integrated technology platforms, we have developed a pipeline with strong potential. All of our technology platforms are self-developed. Our key technology platforms include pediatric drug development platform, antiviral drug screening platform, drug discovery and intelligent design platform, pharmaceutical formulation development platform and medicinal chemistry platform.

(1) Azstarys® is a registered trademark in the United States held by Commave

OUR COMPETITIVE STRENGTHS

We believe that the following competitive strengths have differentiated us from our competitors: (i) leading global RSV innovation in treatment and prevention; (ii) potentially best-in-class phase III ready IPF drug asset; (iii) a new generation of ADHD treatment, filling critical market gaps in China; (iv) dual drug development engine featuring proven global BD and multi-platform in-house R&D capabilities, driving next-generation pipeline innovation; and (v) distinguished research and development leadership backed by reputable stakeholders.

OUR DEVELOPMENT STRATEGIES

We intend to capitalize on our competitive strengths by pursuing the following development strategies: (i) accelerate the clinical development and commercialization of our pipeline products; (ii) grow our pediatric and pulmonary disease drug portfolio through internal research and development and external collaboration; (iii) maximize our drug candidates' global value through strategic partnerships; and (iv) establish our manufacturing and commercialization capacity towards a full-fledged bio-pharmaceutical company.

OUR BUSINESS MODEL

We adopt a two-pronged drug development strategy by combining in-licensing high potential candidates and in-house drug research and development effort. On one hand, we adopt a systematic and focused business development strategy to continuously scout and evaluate high quality drug candidates globally to enrich our pipeline. Leveraging the industry experience and network of our senior management team, we aim to in-license drug candidates that are scientifically sound, can address large unmet medical needs, and have synergies with our existing portfolio and disease area focus. On the other hand, our highly validated in-house research and development capabilities and drug discovery expertise in RSV and pediatric drugs have been crucial to our drug pipeline development. For both internally developed and in-licensed product candidates, we strategically allocate our R&D resources primarily toward late-stage clinical assets, particularly those that have advanced to or beyond Phase II clinical trials. Our research and development activities are led by a distinguished scientific management team with substantial experience at leading global biopharmaceutical companies and a proven track record in drug discovery and clinical development.

We have begun to build up our in-house commercialization functions, including regulatory affairs, market access, marketing, medical affairs, KOL engagement, and sales network. 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.

COMPETITION AND ADDRESSABLE MARKET

RSV

RSV is an enveloped RNA virus that is highly prevalent and infectious, which causes respiratory tract illness, especially in vulnerable populations such as children, the elderly and the immuno-compromised. RSV infection is the number one cause of LRTI in young children worldwide, infecting 90% of children under two years old with approximately 3.3 million infected and hospitalized children globally each year. In 2024, prevalence of RSV infection in children under five years old reached 91.4 million and 13.4 million globally and in China, respectively. RSV is also estimated to infect 5.5%-5.9% of adults aged 65 years or above globally, as their immune system gradually deteriorates due to aging. In 2024, prevalence of RSV infection in adults aged 65 years or above reached 46.5 million and 12.2 million globally and in China, respectively. RSV can cause severe symptoms, such as acute lower respiratory tract infections ("**ALRTI**"). Generally, among the above mentioned vulnerable population approximately 20% to 40% of RSV infection cases could develop ALRTI symptoms, and approximately 8% to 10% of these severe RSV infection cases could

require hospitalization. Notwithstanding the large number of vulnerable population, the incidence of severe RSV cases (referring to ALRTI cases caused by RSV infection) and hospitalization rate for RSV infection are relatively low. However, severe RSV infection may lead to serious consequences. Most of severe RSV infection cases are developed in young children, which require proper treatment. 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, and even death in the most severe cases. As such, it is expected that the emergence of therapeutic drug specifically targeting RSV will drive the increase in diagnostic rate of RSV infection, which will in turn drive the increase in the treatment rate of severe RSV infection cases.

RSV Therapeutic Market

According to CIC report, the RSV therapeutics market recorded only US$30.0 million as of 2024 and is projected to reach US$819.0 million in 2026. Thereafter, the RSV therapeutics drug market is expected to expand rapidly to US$8.6 billion in 2035, representing a CAGR of 67.1% from 2024 to 2035. In China, the RSV therapeutics drug market in China is projected to expand significantly from RMB43.0 million in 2024 to RMB2.0 billion in 2030, and further increase to RMB4.5 billion in 2035, representing a CAGR of 52.7% from 2024 to 2035, as new and potentially more effective drug RSV antiviral drugs becoming available in the country.

In recent years, direct-acting antiviral drugs are being developed as new therapeutic candidates for RSV, and some have shown promising results in early clinical trials. As of the Latest Practicable Date, there were seven antiviral compounds specifically targeting RSV infection under clinical development globally, details of which are summarized in the table below.

Antiviral Drugs Specifically Targeting RSV Infection under Clinical Development Globally

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

RSV Prevention Drug Market

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 6.3% during 2026 to 2035. In China, as nirsevimab was the only RSV prevention antibodies approved in China as of the Latest Practicable Date, the RSV antiviral prophylactic drug market in China remained relatively undeveloped with a market size of RMB9.6 million in 2024. According to the CIC Report, the RSV prevention drug market in China is expected to begin expanding from 2025 onwards alongside the anticipated launch of more prophylactic products reaching RMB891.3 million in 2035, with a CAGR of 51.0% from 2024 to 2035.

For RSV prevention, palivizumab, nirsevimab and clesrovimab, all being prophylactic antibodies, are currently the only three approved drugs for RSV prevention globally. However, they are only approved for prevention of RSV infection in a limited group of infants and young children with specific characteristics, and only nirsevimab is approved in China. As of the Latest Practicable Date, there were only five RSV antibodies under clinical development globally, including AK0610.

IPF

IPF is a specific form of chronic, progressive fibrosing pneumonia of unknown cause. IPF is a rare disease that affected approximately 1.9 million persons worldwide in 2024. On May 11, 2018, IPF became one of the 121 rare diseases designated by the First Catalogue of Rare Diseases in China.

The IPF drug market has grown rapidly in recent years, both globally and in China, a trend largely attributable to improved diagnosis capabilities and the availability of efficacious treatment drugs. According to the CIC Report, the market size of IPF drugs worldwide is expected to increase at a CAGR of 11.1% from US$5.8 billion in 2024 to US$18.5 billion in 2035. The market size of IPF drugs in China is expected to increase at a CAGR of 18.9% from RMB1.6 billion in 2024 to RMB10.9 billion in 2035.

There are currently only three drugs approved for IPF in the US and China. These drugs have certain clinical limitations with side effect, which could lead to discontinuation of the treatment. 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 a similar chemical scaffold and have similar mechanisms of action as pirfenidone but different chemical structure. 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 the CIC Report, as of the Latest Practicable Date, there had been three second-generation pirfenidone compounds for IPF under clinical development globally, details of which were summarized as follows.

Second-generation Pirfenidone for IPF under Clinical Development Globally

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

* Inhibitor of TGF-β induced fibrotic gene expression

Source: ClinicalTrials.gov; CDE; CIC

LICENSING ARRANGEMENTS

We adopt a systematic and focused business development strategy to continuously scout and evaluate high quality assets globally to enrich our pipeline. We have entered into certain licensing and collaboration agreements with our business partners, details of which are summarized as follows. For more details, see "Business — Overview of Licensing and Collaboration Agreements."

In-licensing Ziresovir from Roche

Ziresovir was co-invented by Dr. Wu, our Founder, when he worked at Roche R&D Center (China) Ltd. Following the departure of Dr. Wu from Roche R&D Center (China) Ltd. to found our Group, we were actively negotiating with them on the in-licensing arrangement for ziresovir. 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 and August 27, 2020 (the "**Ziresovir Agreement**"), to develop and commercialize any product containing ziresovir, including all formulations, dosages and dosage forms for all pharmaceutical and prophylactic uses and applications globally. Under the Ziresovir Agreement, Roche shall grant us sole and exclusive license, with full rights to sub-license to develop and commercialize ziresovir in all pharmaceutical and prophylactic uses and applications globally. We are obligated to make upfront, milestone and royalty payments to Roche, including (i) a one-time, non-refundable and non-creditable upfront payment of US$1 million; (ii) non-refundable and non-creditable milestone payments, up to US$96 million; and (iii) high single-digit percentage royalties on the global net sales. Roche is a Swiss multinational healthcare company that operates worldwide whose holding company is listed on the SIX Swiss Exchange. Roche is our Independent Third Party.

In-licensing AK3280 from Genentech, Intermune and Roche Basel

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. Under the AK3280 Agreement, we are granted a sole and exclusive license, with full rights to sub-license, under certain patents and know-how, to develop and commercialize AK3280 in therapeutic pharmaceutical uses for all indications, excluding diagnostic uses globally. We are obligated to make upfront, milestone and royalty payments to Roche Group under the AK3280 Agreement, including (i) a one-time, non-refundable and non-creditable upfront payment of US$5 million, (ii) non-refundable and non-creditable milestone payments, up to US$142 million, and (iii) high single-digit to one-tenth percentage royalties on the net sales of AK3280.

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

On August 2, 2021, we entered into a license agreement (the "**IMCAS Agreement**") with Institute of Microbiology, Chinese Academy of Sciences (the "**IMCAS**"). 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 and is our Independent Third Party. We will own any patent and know-how achieved independently by us, and IMCAS will own any patent and know-how achieved independently whilst providing service and guidance for us. 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 are obligated to make upfront payment and milestone payments to IMCAS under the IMCAS Agreement, including (i) two upfront payments, each in the amount of RMB5 million (ii) milestone payments in the total amount of RMB55 million, (iii) sharing 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, and (iv) sharing the drug sales revenue with IMCAS at a low single-digit percentage, during the sale commission period.

Collaboration with Calibr on AK0705

On October 18, 2017, we entered into a collaboration and option 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. 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. 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.

In-licensing of Azstarys® (AK0901) from Commave

On December 28, 2021, ArkBio HK entered into a collaboration and license agreement (the "**Commave Agreement**") with Commave Therapeutics SA ("**Commave**"). 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 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**"). 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. Pursuant to the Commave Agreement, we shall pay Commave (i) an non-refundable and non-creditable upfront payment of US$5.0 million, which had been fully settled as of the Latest Practicable Date, (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, and (iii) tiered royalty payments based on the aggregate annual net sales of Azstarys® in the Azstarys® Territory.

RESEARCH AND DEVELOPMENT

Our research and development activities are led by a team of scientists and clinicians, including Dr. Wu, our Founder and CEO and Dr. Yuan, our Chief Operating Officer, each possess over 20 years of experience in pharmaceutical research and development. They have led multiple innovative programs in antiviral, oncology and metabolic disease therapeutics, and hold numerous patents and publications in leading international journals. Most of our core R&D members hold PhD degrees from renowned universities and have prior experience in global pharmaceutical companies and research institutions. Our drug discovery, pre-clinical research, clinical development and regulatory affairs personnel work closely together to advance our research and development programs, with multi-disciplinary expertise in various fields, including biology, pharmacology, chemistry, toxicology and translational and clinical research.

The decrease in the R&D expenses for our Core Products was primarily due to the progression of these programs into less resource-intensive stages of development in 2025, as compared with in 2024. In particular, the R&D expenses for Ziresovir amounted to approximately RMB89.0 million and RMB50.3 million in 2024 and 2025, respectively, representing approximately 53.8% and 32.9% of our total R&D expenses for the respective periods. And the R&D expenses for AK3280 amounted to approximately RMB21.0 million and RMB13.8 million in 2024 and 2025, respectively, representing approximately 12.7% and 9.0% of our total R&D expenses for the respective periods. For details of the decrease in the R&D expenses for our Core Products, see "Description of Certain Key Items of the Consolidated Statements of Profit or Loss And Other Comprehensive Income — Research and Development Costs."

COMMERCIALIZATION

During the Track Record Period and up to the Latest Practicable Date, we did not have any commercialized products. We have a commercialization team covering marketing, medical affairs, regulatory affairs and commercialization preparation, and plan to further recruit and build a sales team to lead our commercialization efforts and entrance in major pediatric hospitals with which we

have established strong relationships through ziresovir's clinical trials. Considering that there are no approved RSV drugs available in the market, we plan to adopt an academic promotion approach for ziresovir by participating in industry conferences and organizing hospital seminars to introduce its competitive advantages. We have established a commercialization strategy tailored for China and global markets and plan to adopt a hybrid model combining in-house capabilities with potential 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 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. For details. please see" Business — Commercialization — Commercial Collaboration with Qilu Pharma on AK0901."

INTELLECTUAL PROPERTY

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. As of the Latest Practicable Date, in respect of ziresovir, we owned six patent applications (including one in China and five in other jurisdictions) and six issued patents (including five in China and one in other jurisdictions). We also in-licensed one patent application (none in China) and 52 issued patents (including three in China and 49 in other jurisdictions) relating to ziresovir from our global partners.

As of the Latest Practicable Date, in respect of AK3280, we owned one patent under application. We also in-licensed 21 patent applications (including two in China and 19 in other jurisdictions) and 71 issued patents (including four in China and 67 in other jurisdictions) relating to AK3280 from our global partners. 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.

Manufacturing

Given our limited resources and experience in drug product manufacturing, we have strategically decided not to maintain in-house manufacturing facilities or develop our own commercial-scale manufacturing capabilities. Instead, we have engaged third-party contract development and manufacturing organizations ("**CDMOs**") to manufacture our drug candidates for clinical trials, and we plan to continue these partnerships for commercialization activities following regulatory approval. In 2024 and 2025, we engaged 53 and 56 CROs and CDMOs, respectively. We usually only select industry leading and reputable CROs and CDMOs. We select CROs and CDMOs based on their experience, reputation and quality of service. We usually enter into service agreements with such CROs and CDMOs which stipulates their responsibilities, roles and service

fees, as well as the detailed protocol that they need to comply with. The service fees are usually determined based on the complexity of their services and the length of the service period. We usually pay these CROs/CDMOs in installments upon reaching certain key research and development milestones.

SUMMARY OF KEY FINANCIAL INFORMATION

This summary of historical financial information set forth below have been derived from, and should be read in conjunction with, our financial information, including the accompanying notes, set forth in the Accountants' Report set out in Appendix I to this document, as well as the information set forth in "Financial Information" of this document.

Summary of Consolidated Statements of Profit or Loss

	Year Ended December 31,	
	2024	2025
	(RMB in thousands, except loss per share)	
Other income and gains	26,305	7,574
Research and development costs	(165,348)	(152,942)
Selling and marketing expenses	(12,680)	(9,630)
Administrative expenses	(45,226)	(72,290)
Other expenses	(1)	(5)
Finance costs	(469)	(533)
Loss before tax	(197,419)	(227,826)
Income tax expense	–	–
Loss for the year	(197,419)	(227,826)
Other comprehensive (loss)/income		
Other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	(1,684)	2,398
Total comprehensive loss for the year	(199,103)	(225,428)
Loss per share		
Basic and diluted (RMB yuan)	(0.86)	(0.99)

During the Track Record Period, we did not have any commercialized products. Our other income and gains amounted to RMB26.3 million and RMB7.6 million for the year ended December 31, 2024 and 2025, respectively.

For more information in relation to the components of our consolidated statements of profit or loss and other comprehensive income, please refer to "Financial Information — Description of Certain Key Items of the Consolidated Statements of Profit or Loss and Other Comprehensive Income" and "Financial Information — Results of Operations."

Summary of Consolidated Statements of Financial Position

The following table sets forth a summary of our consolidated statements of financial position as of the dates indicated.

	As of December 31,	
	2024	2025
	(RMB in thousands)	
Non-current assets	124,037	141,067
Current assets	351,951	209,745
Total assets	475,988	350,812
Current liabilities	69,373	126,763
Net current assets	282,578	82,982
Total assets less current liabilities	406,615	224,049
Non-current liabilities	5,097	2,232

Our net current assets decreased from RMB282.6 million as of December 31, 2024 to RMB83.0 million as of December 31, 2025, primarily due to (i) a decrease of RMB142.2 million in our current assets, mainly reflecting a decrease of RMB127.0 million of financial assets at FVTPL in line with the decline in the overall level of funds available to our Company, and (ii) an increase of RMB57.4 million in our current liabilities, primarily attributable to an increase of RMB32.4 million in trade and other payables in line with our continuous research and development efforts and the initiation of the proposed [**REDACTED**].

As of December 31, 2024, our net assets amounted to RMB401.5 million, decreasing from RMB571.2 million as of January 1, 2024, which primarily reflected our loss for the year of RMB197.4 million in 2024. Our net assets further decreased to RMB221.6 million as of December 31, 2025, primarily reflecting our loss for the year of RMB228.0 million in 2025.

Summary of Consolidated Statements of Cash Flows

The following table sets forth the components of our consolidated statements of cash flows for the years indicated:

	Year Ended December 31,	
	2024	2025
	(RMB in thousands)	
Operating cash flows before movements in working capital	(176,580)	(161,973)
Changes in working capital	(12,154)	10,101
Net cash flows used in operating activities	(188,734)	(151,872)
Net cash flows (used in)/from investing activities	(22,396)	128,227
Net cash flows from financing activities	5,715	16,431
Net decrease in cash and cash equivalents	(205,415)	(7,214)
Cash and cash equivalents at beginning of the year	252,980	48,094
Effects of exchange rate changes, net	529	(1,876)
Cash and cash equivalents at end of the year	48,094	39,004

In 2024 and 2025, we had net cash flows used in operating activities of RMB188.7 million and RMB151.9 million, respectively. Our net cash used in operating activities were primarily resulted in our losses for the year, as we incurred significant R&D expense in relation to the development of our drug candidates. In December 2025, we obtained the NDA approval for AK0901 from the NMPA, and ziresovir is under NDA review in China, which we expect to obtain its NDA approval in 2026. We believe our net cash outflow in operating activities will improve after the sales of these drugs ramp up in the future.

Our cash burn rate refers to the average monthly amount of (i) net cash used in operating activities, including upfront and milestone fees for licensing agreements and R&D and commercialization expenditures, and (ii) capital expenditures. Assuming an average cash burn rate going forward of 3 times the level in 2025, we estimate that our cash and cash equivalents, time deposits, and financial assets at fair value through profit or loss as of December 31, 2025 will be able to maintain our financial viability for at least [**REDACTED**] months, or, if we also take into account the estimated [**REDACTED**] based on the [**REDACTED**] of HK$[**REDACTED**] per Share (being the low-end of the indicative [**REDACTED**] range), at least [**REDACTED**] months. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.

RISK FACTORS

We are a biopharmaceutical company seeking to [**REDACTED**] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. There are unique challenges, risks and uncertainties associated with [**REDACTED**] in companies such as ours, including the following: (i) we may not obtain regulatory approval for ziresovir, our Core Product, and any delay or failure to obtain such approval would materially harm our business; (ii) clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may be unable to commercialize our drug candidates on a timely basis; (iii) if our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may ultimately be unable to complete the development and commercialization of our drug candidates; (iv) our drug candidates may cause undesirable side effects; (v) we may not be able to discover new drug candidates; (vi) we invest substantial resources in research and development in order to develop our products and enhance our technologies, which we may not always be able to do successfully; (vii) if we encounter delays or difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected; (viii) if we cannot maintain or develop clinical collaborations and relationships with our PIs, KOLs, physicians and experts, our results of operations and prospects could be adversely affected; and (ix) any disagreements or delays within the joint steering committee for certain of our programs may adversely affect our product development and achievement of milestones. See "Risk Factors" for details.

PRE-[REDACTED] INVESTORS

Since our establishment, we have received nine rounds of Pre-[**REDACTED**] Investments of an aggregate of over US$220 million. Our broad and diverse base of Pre-[**REDACTED**] Investors includes Sophisticated [**REDACTED**], namely Qiming Venture Partners Funds, TF Capital and TPG Asia VII SF Pte. Ltd., all of which are established funds with a focus on investments in the healthcare sector, and will hold approximately [**REDACTED**]%, [**REDACTED**]% and [**REDACTED**]% of the issued share capital of our Company immediately upon the completion of the [**REDACTED**] respectively (assuming the [**REDACTED**] is not exercised). According to the PRC Company Law, the Shares issued by our Company prior to the [**REDACTED**] (including those [**REDACTED**] for or purchased by the Pre-[**REDACTED**] Investors) are restricted from trading within one year from the [**REDACTED**]. For further details regarding the key terms of the Pre-[**REDACTED**] Investments, including the identity and background of our Pre-[**REDACTED**] Investors, please see "History, Development and Corporate Structure — Pre-[**REDACTED**] Investments."

[REDACTED]

We estimate that we will receive [**REDACTED**] from the [**REDACTED**] of approximately HK$[**REDACTED**] after deducting the [**REDACTED**] commissions, fees and estimated expenses payable by us in connection with the [**REDACTED**], assuming no exercise of the [**REDACTED**] and an [**REDACTED**] of HK$[**REDACTED**] per Share, being the [**REDACTED**] of the indicative [**REDACTED**] range stated in this document. Assuming an [**REDACTED**] at the [**REDACTED**] of the indicative [**REDACTED**] range, we intend to apply our [**REDACTED**] for the following

purposes, subject to changes in light of our evolving business needs and changing market conditions: (i) approximately HK$[**REDACTED**] (representing [**REDACTED**]% of the [**REDACTED**]) will be allocated to the research and development of ziresovir and AK3280, our Core Products; (ii) approximately HK$[**REDACTED**] (representing [**REDACTED**]% of the [**REDACTED**]) will be allocated to the pre-clinical studies, IND filings and clinical trials for our other drug candidates, including AK0610 RSV protection, AK0901 for ADHD, AK0705 for COPD and AK0406 for influenza; (iii) approximately HK$[**REDACTED**] (representing [**REDACTED**]% of the [**REDACTED**]) will be allocated for milestone payments for existing in-licensing and other collaboration opportunities; (iv) approximately HK$[**REDACTED**] (representing [**REDACTED**]% of the [**REDACTED**]) will be allocated for the commercialization of our drug candidates in China market; and (v) approximately HK$[**REDACTED**] (representing [**REDACTED**]% of the [**REDACTED**]) will be used for our working capital and general corporate purposes.

DIVIDENDS

We did not declare or pay dividends on our Shares during the Track Record Period. We currently expect to retain all future earnings for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our Board of Directors, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions.

PRC laws and regulations permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits as determined in accordance with its articles of association and the accounting standards and regulations in China. As a result, we may not have sufficient or any distributable profits, being the after-tax profits, less any recovery of accumulated losses and appropriations to statutory and other reserves that we are required to make, to make dividend distributions to our Shareholders, even if we become profitable. Any distributable profits not distributed in a given year are retained and available for distribution in subsequent years. Our dividend distribution may also be restricted if we incur debt or losses or in accordance with any restrictive covenants in bank credit facilities, convertible bond instruments or other agreements that we or our subsidiaries may enter into in the future. See "Risk Factors — Risks Relating to Our Industry, Business and Operations — Payment of dividends is subject to restrictions under PRC law and regulations." In the future, we may rely to some extent on dividends and other distributions on equity from our principal operating subsidiaries to fund offshore cash and financing requirements.

During the Track Record Period and up to the Latest Practicable Date, we did not adopt any formal dividend policy or pre-determined dividend payout ratio. Nevertheless, the Company Law of the People's Republic of China and the Articles of Association of the Company set out certain provisions relating to the distribution of profits, which may serve as a reference for future dividend distribution. According to Article 210 of the Company Law of the People's Republic of China, when the Company records profits and proposes to distribute the profits for a given year, it shall allocate 10% of the after-tax profits to the statutory reserve fund. The Company may cease such allocations once the statutory reserve fund reaches 50% of the registered capital. Where the statutory reserve fund is insufficient to cover prior years' losses, the Company shall first use its current-year profits to offset such losses before making allocations to the statutory reserve fund. After making allocations to the statutory reserve fund, the Company may, upon a resolution of the shareholders' meeting, make further allocations to a discretionary reserve fund. The remaining after-tax profits following such allocations may then be distributed to shareholders in proportion to their shareholdings.

Based on the above, the PRC Legal Advisors are of the view that the absence of a formal dividend policy or pre-determined dividend payout ratio does not contravene any applicable PRC laws or regulations.

[**REDACTED**]

	Based on an [REDACTED] of HK$[REDACTED] per Share	Based on an [REDACTED] of HK$[REDACTED] per Share
[**REDACTED**] of our Shares[(1)]	HK$[**REDACTED**]	HK$[**REDACTED**]
Unaudited [**REDACTED**] adjusted combined net tangible assets per Share[(2)]	HK$[**REDACTED**]	HK$[**REDACTED**]

Notes:

(1) The calculation of the [**REDACTED**] is based on [**REDACTED**] Shares expected to be in issue immediately after completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised).

(2) The unaudited [**REDACTED**] adjusted combined net tangible assets per [**REDACTED**] has been arrived at after adjustments referred to "Appendix II — Unaudited [**REDACTED**] Financial Information" and on the basi s that [**REDACTED**] Shares were in issue at the respective [**REDACTED**] of HK$[**REDACTED**] and HK$[**REDACTED**], assuming the [**REDACTED**] has been completed on December 31, 2025, which does not take into account (i) any Share which may be allotted and issued upon the exercise of the [**REDACTED**], or (ii) any Share which may be allotted and issued or repurchased by our Company under the general mandates for the allotment and issue or repurchase of Shares granted to the Directors.

For further details, please refer to "Appendix II — Unaudited [**REDACTED**] Financial Information — A. Unaudited [**REDACTED**] Statement of Adjusted Consolidated Net Tangible Assets" to this document.

[**REDACTED**] EXPENSES

[**REDACTED**] expenses to be borne by us are estimated to be approximately HK$[**REDACTED**] (including [**REDACTED**] commission, assuming an [**REDACTED**] of HK$[**REDACTED**] per Share, being the mid-point of the indicative [**REDACTED**] range of HK$[**REDACTED**] to HK$[**REDACTED**] per Share), assuming no Shares are issued pursuant to the [**REDACTED**], representing approximately [**REDACTED**]% of the gross [**REDACTED**]. [**REDACTED**] expenses to be borne by us include (i) [**REDACTED**]-related expenses, including [**REDACTED**] commission and sponsor fee, of HK$[**REDACTED**], (ii) fees and expenses of legal advisors of HK$[**REDACTED**], (iii) fees and expenses of Reporting Accountants of HK$[**REDACTED**], and (iv) other fees and expenses of HK$[**REDACTED**]. During the Track Record Period, we incurred [**REDACTED**] expenses of RMB24.0 million, RMB17.7 million of which were charged to our consolidated statements of profit or loss. After December 31, 2025, approximately HK$[**REDACTED**] is expected to be charged to our consolidated statements of profit or loss, and approximately HK$[**REDACTED**] is expected to be accounted for as a deduction from equity upon the [**REDACTED**]. The [**REDACTED**] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

RECENT DEVELOPMENTS AND NO MATERIAL ADVERSE CHANGE

As of the Latest Practicable Date, we did not have any commercialized products. As we continue to incur R&D expenses in relation to our R&D activities to develop our drug candidates and administrative expenses in relation to our daily operations, we expect to record an increase in net loss in 2025 compared to 2024. Such increase was primarily attributable to our [**REDACTED**] expenses in relation to the [**REDACTED**].

In December 2025, we obtained the NDA approval for AK0901 from the NMPA.

Our Directors confirmed that during the Track Record Period and up to the Latest Practicable Date, the Company did not experience any material suspension or delay in its ongoing clinical trials or business operations due to COVID-19 and the pandemic did not have any material adverse impact on its financial performance, operations or overall drug development progress.

Our Directors confirm that, up to the date of this document, there has been no material adverse change in our financial or trading position or prospects since December 31, 2025, which is the end date of the periods reported on in the Accountant's Report included in Appendix I to this document, and there is no event since December 31, 2025 that would materially affect the information as set out in the Accountant's Report included in Appendix I to this document.

Regulatory Updates

On December 18, 2025, the U.S. legislation titled the BIOSECURE Act (the "BIOSECURE Act") was signed by President Trump. Prohibitions in the BIOSECURE Act will not take effect until the OMB issues implementing guidance and relevant federal regulations are finalized. The timing and substance of such enabling regulations remain subject to uncertainty and may differ materially from current expectations. For further details, see "Regulatory Overview – U.S. Regulation –BIOSECURE Act."

We are of the view that the BIOSECURE Act, in its current form, would not have a material adverse impact on our business, primarily because we, or any of our subsidiaries, are not a recipient of any U.S. federal government contracts, loans, grants or funding and do not anticipate applying for such contracts, loans, grants or funding in the future. Furthermore, to the best of our knowledge, none of our business partners are using any services provided by us under the respective arrangements in connection with any federal contracts, loans, grants or funding. During the Track Record Period, we procured non-clinical and clinical services and raw material for AK0610 and ziresovir from WuXi AppTec through its subsidiary. The BIOSECURE Act did not, however, have any material impact on our business and operations during the Track Record Period, given that (i) it was not enacted into law until December 18, 2025,(ii) none of WuXi AppTec or any of their affiliates with whom we had business relationship are listed as "biotechnology companies of concern" in the current version of the BIOSECURE Act, and (iii) we did not have business relationship with any entity included in the 1260H List. We will continue to closely monitor and evaluate the potential impact of the BIOSECURE Act on our business and operations, including the release of forthcoming guidance and regulations, while maintaining strong business relationships with all our existing suppliers and a list of qualified alternative suppliers capable of providing equivalent services.

During the Track Record Period and up to the Latest Practicable Date, we had not been affected by geopolitical tensions in any material respect. However, there is no assurance as to how the U.S.-China trade disputes and other geopolitical tensions might develop or whether there will be any changes to the scope and extent of businesses that will be subject to such tariffs, sanctions and export controls, and restrictive measures. See also "Risk Factors – Risks Relating to Our Operations – Future changes in laws, regulations or enforcement policies in the jurisdictions that we operate in could adversely affect our business."