

SUMMARY

This summary aims to give you an overview of the information contained in this Document. As this is a summary, it does not contain all the information that may be important to you. You should read this Document in its entirety before you decide to [REDACTED] in the [REDACTED]. There are risks associated with any [REDACTED]. Some of the risks involved in [REDACTED] in the [REDACTED] are set out in the “Risk Factors” section 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 Rule 8.05(1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with [REDACTED] in companies like ours. Your [REDACTED] decision should be made in light of these considerations.

OVERVIEW

Established in 2013, we are a clinical-stage biopharmaceutical company with a focus on the field of live biotherapeutic products (“LBPs”), across gastrointestinal diseases, oncology, cancer therapy-related complications, metabolic diseases, and autoimmune diseases. As of the Latest Practicable Date, we have (i) one Core Product, SK08, an LBP candidate for the treatment of irritable bowel syndrome with diarrhea (“IBS-D”), acute diarrhea in children caused by rotavirus (“**pediatric rotavirus diarrhea**”), ulcerative colitis (“UC”) and advanced solid tumors in combination with anti-PD-1/L1 monoclonal antibodies; (ii) one key product, SK10, an inactivated LBP candidate for the prevention and treatment of chemotherapy-induced diarrhea (“CID”); and (iii) four other preclinical candidates in our pipeline.

THERE IS NO ASSURANCE THAT WE WILL ULTIMATELY BE ABLE TO DEVELOP AND MARKET OUR CORE PRODUCT OR ANY OF OUR PIPELINE PRODUCT SUCCESSFULLY.

We are a pioneer in the field of second-generation LBP in China, with our Core Product SK08 and key product SK10 having achieved multiple development milestones. Since our inception, our core research and development team has led or participated in six national and/or provincial major research projects. The SK08 project has been supported by key national, provincial and/or municipal research programs, including the National 863 Program (國家863計劃), the National Natural Science Foundation of China (國家自然科學基金), and the Guangdong Provincial Major Special Program for New Drug Innovation and Development (廣東省重大新藥創製專項). We have also been recognized as a Guangdong Provincial “Specialized, Refined, Distinctive and Innovative Small and Medium-sized Enterprise” (廣東省“專精特新中小企業”) and the Guangzhou Innovation Leadership Team (廣州市創新領軍團隊). In addition, the Guangdong Provincial Engineering Research Center for Live Biotherapeutic Products (廣東省活體生物藥工程技術研究中心), accredited by the Guangdong Provincial Department of Science and Technology, is an engineering research center dedicated to LBP, with us serving as the lead supporting entity. The Center focuses on the R&D and translation for LBP and supports the development, industrialization and standardization of China’s LBP sector. We are also participating in the *Akkermansia muciniphila* (“AKK”) industry standard-setting process led by the China National Research Institute of Food and Fermentation Industries (中國食品發酵工業研究院), reflecting our continued involvement in the development of industry standards for LBP and NGP.

Our products target both the global and China LBP markets with the continued demand. According to Frost & Sullivan, the global LBP market increased from USD3.0 billion in 2020 to USD4.7 billion in 2025, at a CAGR of 9.4%, and is expected to further grow to USD7.5 billion by 2030, at a CAGR of 9.8% during this period. The development of LBPs can be broadly divided into first-generation LBPs developed during the early exploratory stage before the establishment of a unified regulatory framework, and second-generation LBPs developed under a modern pharmaceutical development framework with defined indications, clinical evidence requirements and CMC controls, according to Frost & Sullivan. In addition, in recent years, the LBP industry has gradually evolved beyond live microorganisms towards broader therapeutic modalities, including inactivated microbial products, which may further expand the technological boundaries and clinical potential of LBPs.

As of the Latest Practicable Date, there are four approved second-generation LBP products and nine late-stage (Phase III and beyond) second-generation LBP candidates globally, according to Frost & Sullivan. In comparison, as of the Latest Practicable Date, (i) the 17 LBPs approved for marketing in China are first-generation products, all of which obtained marketing approval before 2010; and (ii) there are 16 clinical-stage second-generation LBP candidates in China, indicating that the LBP industry remains at a relatively early stage with significant room for further innovation and commercialization.

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OUR PIPELINE PRODUCTS

All of our pipeline candidates are biological products, as categorized by the Competent Authority, including (i) two clinical-stage products, namely (a) SK08, our Core Product, a LBP containing the novel *Bacteroides fragilis* strain ZY-312, for the treatment of IBS-D, pediatric rotavirus diarrhea, UC, and advanced solid tumors in combination with anti-PD-1/L1 monoclonal antibodies; (b) SK10, our key product, an LBP containing inactivated *Bacteroides fragilis*, for the prevention and treatment of CID; and (ii) four preclinical candidates, namely (a) TP2, a bacterial component for the treatment of autoimmune diseases; (b) SK16, an LBP for the treatment of OM; (c) SK12, an LBP for the treatment of AD and psoriasis; and (d) ZY19, an LBP for the treatment of metabolic diseases.

The following chart illustrates our pipeline and summarizes the development status of our pipeline products as of the Latest Practicable Date:

New Drug Pipeline

Project	Feature	Indication	Regulatory Authority	Pre-clinical	IND	Phase I	Phase II	Phase III	Completed/Next Milestone	Commercial Rights
SK08 ★	LBP	Irritable bowel syndrome	NMPA						To complete Phase III Primary Efficacy Endpoint Assessment in Q4 2027	Global
		Acute diarrhea in children caused by rotavirus (pediatric rotavirus diarrhea)	NMPA						To enter Phase II in Q3 2027	Global
		Ulcerative colitis	NMPA						To enter Phase II in Q4 2027	Global
			FDA						IND approved in January 2025	Global
		Advanced solid tumors (in combination with anti-PD-1/L1 monoclonal antibodies)	NMPA						To enter Phase II in Q4 2028	Global
SK10 ☆	LBP	Chemotherapy-induced diarrhea	FDA						To enter Phase II in Q1 2028	Global
			NMPA						To enter Phase II in Q4 2026	Global
TP2	Bacterial components	Autoimmune diseases	N/A						To submit the IND in Q4 2028	Global
SK16	LBP	Oral mucositis	N/A						To submit the IND in Q4 2028	Global
SK12	LBP	Atopic dermatitis/Psoriasis	N/A						To submit the IND in Q4 2029	Global
ZY19	LBP	Metabolic Diseases	N/A						To submit the IND in Q4 2029	Global

★ Core Product ☆ Key product  Exempted from this phase of clinical trial  Received the Acceptance Notice for the IND application regarding direct initiation of a Phase II clinical trial

Notes:

- In January 2025, given the relevant safety and preliminary efficacy data of SK08 obtained from Phase I and Phase II clinical trials in China, the FDA approved SK08 to directly initiate a Phase II clinical trial in the U.S. for the UC indication without the need to conduct a separate Phase I clinical trial in the U.S.;
- In March 2022, we obtained IND approval from the NMPA for a Phase Ib/II clinical trial of SK08 in advanced solid tumors in combination with anti-PD-1/L1 monoclonal antibodies. We plan to resubmit an IND application for a Phase II clinical trial of SK08 for this indication. Such direct progression to Phase II is expected to be considered by the NMPA with reference to its previous IND approval in relation to this indication and SK08’s accumulated clinical data in other indications, particularly safety and tolerability data, which are directly relevant to the primary objectives of Phase I clinical trials. Such clinical data are expected to be further supplemented by additional data from SK08’s ongoing and planned clinical trials before the resubmission. For further details, see “— Our Product Pipelines (Pharmaceutical Pipelines) — SK08, Our Core Product” — “Material Communications with Competent Authorities” in this section; and
- In June 2026, based on the safety and tolerability data obtained from the Phase I clinical trial of SK10 in the U.S., we submitted an IND application to the NMPA for a Phase II clinical trial of SK10 and then received the Acceptance Notice for this application.

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Core Product — SK08

Our Core Product, SK08, according to Frost & Sullivan, is the first LBP to obtain registrational clinical trial approvals from both the NMPA and the U.S. FDA, as well as the world’s first LBP to enter clinical development using *Bacteroides fragilis*. It is the only late-stage clinical biological drug candidate in the global IBS-D field, as of the Latest Practicable Date. If approved, SK08 may become the first marketed product in this indication. In particular, our preclinical and clinical data support the potential role of SK08 in reducing abdominal pain, the core symptom of irritable bowel syndrome (“IBS”), by alleviating visceral hypersensitivity. SK08 also exerts its effects by protecting the intestinal barrier, modulating local immune responses and enhancing the body’s ability to respond to viruses or tumors. These multi-mechanism actions underpin its therapeutic potential across IBS-D, pediatric rotavirus diarrhea, UC, and advanced solid tumors in combination with anti-PD-1/L1 monoclonal antibodies.

Clinical and Regulatory Milestones of SK08

In China, we obtained the IND approval from the NMPA for the treatment of IBS and UC in November 2019. We then completed a Phase I clinical trial in healthy subjects from May 2020 to November 2020, and a Phase II clinical trial in IBS-D patients from August 2021 to September 2022. In August 2023, we received formal confirmation from the CDE that it had no objection to our initiation of the Phase III clinical trial for the IBS-D treatment. Subsequently, we initiated a Phase III clinical trial of SK08 in March 2024. Patient enrollment is expected to be completed in the third quarter of 2027, and the primary efficacy endpoint evaluation is expected to be completed in the fourth quarter of 2027. In September 2024, we obtained the IND approval from the NMPA for a Phase II clinical trial of SK08 in pediatric rotavirus diarrhea based on the accumulated data generated from our completed clinical trials and non-clinical evaluation of SK08, without requiring an additional Phase I clinical trial for this indication. We currently plan to initiate this Phase II clinical trial for the treatment of pediatric rotavirus diarrhea in the third quarter of 2027. In addition, we obtained the IND approval from the NMPA for SK08 in combination with PD-1/L1 inhibitors for the treatment of advanced solid tumors in March 2022. We currently plan to resubmit the relevant IND application and then commence the clinical trial in the fourth quarter of 2028.

In the U.S., in January 2025, based on FDA’s review of the accumulated data generated from our completed clinical trials and non-clinical evaluation of SK08, the FDA allowed SK08 to proceed directly to a Phase II clinical trial for the treatment of UC in the U.S., without requiring an additional Phase I clinical trial for this indication.

Addressable Markets and Competitive Landscape of SK08

IBS and IBS-D. According to Frost & Sullivan, the China IBS drug market reached RMB5.8 billion in 2025 and is expected to reach RMB7.3 billion in 2030. Within the IBS market, the China IBS-D drug market reached RMB4.0 billion in 2025 and is expected to reach RMB5.1 billion in 2030. As of the Latest Practicable Date, no drugs have been approved specifically for the treatment of IBS-D and there are seven active clinical-stage drug candidates for IBS in China, of which two have advanced to Phase III, both for IBS-D. Among them, SK08 is one of the two Phase III candidates and the only biologic therapy at this stage.

Pediatric Rotavirus Diarrhea. According to Frost & Sullivan, the China pediatric rotavirus diarrhea treatment market was RMB2.0 billion in 2025 and is expected to reach RMB2.4 billion by 2030. As of the Latest Practicable Date, there are (i) seven products approved for pediatric rotavirus diarrhea globally, all of which are prophylactic vaccines designed to prevent infection rather than therapeutic products; and (ii) eleven clinical-stage drug candidates for pediatric rotavirus diarrhea globally, of which nine are prophylactic vaccines, and SK08 is the only LBP therapeutic candidate currently under development.

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UC. According to Frost & Sullivan, the global UC treatment market was USD9.7 billion in 2025 and is expected to reach USD13.2 billion by 2030, while the China UC treatment market was RMB1.9 billion in 2025 and is expected to reach RMB2.4 billion by 2030. As of the Latest Practicable Date, among LBPs for UC treatment in the clinical stage globally, SK08 is the only pipeline in China currently under clinical development.

Advanced Solid Tumor in Combination with Anti-PD-1/L1 Monoclonal Antibodies. According to Frost & Sullivan, the Chinese anti-tumor drug market is anticipated to grow from RMB197.5 billion to RMB279.1 billion, with a CAGR of 7.2%. It is estimated to achieve RMB504.0 billion in 2030, with a CAGR of 12.5% from 2025 to 2030. As of the Latest Practicable Date, there were two clinical-stage LBP products in China being developed for use in combination with PD-1 therapies for the treatment of solid tumor and SK08 is one of them.

Key Product — SK10

Our key product, SK10, is an in-house-developed, orally administered, inactivated LBP based on a novel strain of *Bacteroides fragilis* for both prevention and treatment of CID. According to Frost & Sullivan, SK10 is the first LBP candidate based on *Bacteroides fragilis* approved by the FDA for clinical development and also the first LBP candidate globally filed for CID. In addition, as of the Latest Practicable Date, SK10 is the only clinical-stage LBP candidate globally being developed for the prevention of CID.

For SK10, the relevant jurisdictions of development include China and the U.S. In the U.S., we obtained the IND approval from the FDA for the Phase I clinical trial of SK10 in October 2022 and then conducted this Phase I clinical trial from August 2023 to February 2024. In China, based on the safety and tolerability data obtained from the Phase I clinical trial of SK10 in the U.S., we submitted an IND application for the Phase II clinical trial of SK10 and received the Acceptance Notice from the CDE in June 2026. Subject to regulatory approval, we plan to commence this Phase II clinical trial of SK10 in China in the fourth quarter of 2026.

Addressable Markets and Competitive Landscape of SK10

According to Frost & Sullivan, the global CID drug market increased from USD2.1 billion in 2020 to USD2.5 billion in 2025, and is expected to reach USD3.0 billion in 2030. The China CID drug market increased from USD0.4 billion in 2020 to USD0.5 billion in 2025, and is expected to reach USD0.6 billion in 2030. According to Frost & Sullivan, as of the Latest Practicable Date, there are no approved drugs specifically for the treatment or prevention of CID globally.

OUR COMPETITIVE STRENGTHS

We believe the following strengths have contributed to our success and differentiate us from our competitors: (i) a pioneer in second-generation LBP in China; (ii) R&D platform with IP protection framework as core competitive barriers; and (iii) our Core and key products targeting diseases with traditional therapy limitations and market potential. The market potential is underpinned by the limitations of the existing therapies and our Core Product SK08 is well-positioned to redefine the future clinical guidelines and drive further market expansion. For more details, see “Business — Our Competitive Strengths.”

OUR STRATEGIES

We intend to capitalize on our competitive strengths by pursuing the following strategies: (i) advancing Core and key products from R&D to commercialization; (ii) strengthening early-stage and collaborative R&D to enrich our product pipeline; (iii) enhancing end-to-end operational capabilities from manufacturing to commercial launch; (iv) R&D-powered next-generation probiotics driving competitiveness and value; (v) strengthening R&D and management talent to sustain industry competitiveness; and (vi) pursuing strategic partnerships to expedite global business expansion. For more details, see “Business — Our Strategies.”

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RESEARCH AND DEVELOPMENT

We have continued to invest in our research and development (“**R&D**”) to support the development and commercialization of our Core Product and other product candidates. As a platform-based biopharmaceutical company, we have established ZhiYi Microbiome Innovation Research System (“**ZYMIRS**”), our proprietary microbiome innovation research system integrating strain discovery, functional validation, non-clinical evaluation, CMC development, manufacturing process development, and quality control capabilities. This system primarily supports the development of our own pipeline, while also enabling us to integrate industry resources within the industry through non-clinical CRO services and CDMO services, thereby developing an LBP ecosystem.

Our research and development expenses amounted to RMB67.6 million and RMB61.9 million in 2024 and 2025, respectively. Research and development expenses attributable to our Core Product and key product accounted for 76.8% and 79.8% of our total research and development expenses in 2024 and 2025, respectively. Our research and development cash operating costs accounted for 85.7% and 83.9% of our total cash operating costs in 2024 and 2025, respectively.

We have established an integrated in-house R&D team with expertise spanning early-stage discovery, preclinical research, medical affairs, CMC development and manufacturing operations. As of the Latest Practicable Date, under the strategic guidance of Dr. Zhi, our R&D team comprised 58 members, of whom 20 held master’s or above degrees. Our core R&D personnel (eight members) have an average of over 14 years of experience in the biopharmaceutical industry. Particularly, each of Dr. Wang, Dr. Liu Yangyang and Dr. Li Ping is a core member of the Guangzhou Innovation Leadership Team (廣州市創新領軍團隊).

[REDACTED]

SUMMARY

OUR SHAREHOLDING STRUCTURE

Our Controlling Shareholders

As of the Latest Practicable Date, our Company is owned by Zhuhai Yichangda as to 37.26%. Zhuhai Yichangda is controlled by its sole general partner, Dr. Zhi, our Chairman of the Board, who held 29.70% partnership interest in Zhuhai Yichangda, being the highest percentage of partnership interest therein, and served as its executive partner responsible for the day-to-day management of the partnership, including but not limited to the exercise of voting rights attached to the Shares held by Zhuhai Yichangda.

Immediately following the completion of the [REDACTED], Dr. Zhi through Zhuhai Yichangda will be entitled to control the exercise of approximately [REDACTED]% of the voting rights (assuming the [REDACTED] is not exercised) or approximately [REDACTED]% of the voting rights (assuming the [REDACTED] is exercised in full) of our Company and thus remain as our Controlling Shareholders.

Pre-[REDACTED] Investments

We completed several rounds of Pre-[REDACTED] Investments with our Pre-[REDACTED] Investors, including SDIC Shanghai Fund, SDIC Greater Bay Area Fund, Shenzhen Capital Group, JingDe (Guangzhou) and Yueke Qingyuan. For further details of the identity and background of the Pre-[REDACTED] Investors and the principal terms of the Pre-[REDACTED] Investments, see “History, Development and Corporate Structure — Pre-[REDACTED] Investments.” Our Sophisticated Investors which made meaningful investment to us include SDIC Shanghai Fund, SDIC Greater Bay Area Fund and Shenzhen Capital Group, which will hold approximately [REDACTED]% of our total issued share capital in aggregate upon the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised).

CMC AND MANUFACTURING

As of the Latest Practicable Date, we had a total of 45 personnel engaged in pharmaceutical research and manufacturing, with leaders possessing over 10 years of experience. We have established an LBP pilot manufacturing base in Guangzhou, Guangdong Province, the PRC with a combined floor area of approximately 4,894.8 sq.m, which comprises two pilot plants primarily used for (i) production process development; (ii) the production of materials used in clinical trials for SK08 and other LBP drug candidates; (iii) providing CRO/CDMO services to third-party clients; and (iv) the production of NGP raw material AKK AM06™. We plan to commence technical renovation of the existing manufacturing facilities in 2027, which will reduce the original two bacteria powder production lines and two formulation production lines to one of each and expand the storage, outer-packaging, and other functional areas to match the needs of commercial-scale production and quality-system upgrades.

COMMERCIALIZATION

As of the Latest Practicable Date, none of our LBP candidates have been approved for commercial sale. We intend to adopt a CSO model for the initial commercialization of SK08 and SK10, with OTC pharmacy sales expected to be a key channel for our products at a later stage. We also intend to build in-house medical affairs capabilities and pursue strategic collaboration to support the commercialization of our LBP candidates in the PRC and potentially in international markets. For details, see “Business — Commercialization.”

SALES AND MARKETING

During the Track Record Period, the primary focus of our business remained to be the R&D of our Core Product. However, as of the Latest Practicable Date, none of our LBP candidates have been approved for commercial sale. Therefore, during the Track Record Period, our limited sales activities related to our two existing revenue-generating business lines: (i) our NGP raw material business, under which we sell AKK AM06™ by both distributorship model and direct sales; and (ii) our research and development service (including CRO/CDMO services) business, under which we provide contract development, manufacturing and research services to pharmaceutical companies, biotechnology companies and academic and research institutions in the PRC.

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Our marketing activities for AKK AM06™ are conducted by a dedicated team led by the General Manager of Guangzhou Puwei Junjian and supported by our sales personnel. Our business development function for research and development services (including CRO/CDMO services) is led by our deputy general manager. As of the Latest Practicable Date, we have not commenced marketing activities for our LBP drug candidates, all of which remain in clinical development. For details, see “Business — Sales and Marketing.”

OUR CUSTOMERS AND SUPPLIERS

During the Track Record Period, our suppliers primarily included: (i) CROs; (ii) providers of research materials and consumables (including raw materials and excipients); and (iii) providers of technical services. Purchases from our five largest suppliers amounted to RMB16.9 million and RMB16.0 million in 2024 and 2025, accounting for 42.7% and 41.5% of our total purchases for the same years, respectively. Purchases from our single largest supplier amounted to RMB6.8 million and RMB6.7 million in 2024 and 2025, accounting for 17.1% and 17.3% of our purchases for the same years, respectively. For details, see “Business — Our Suppliers and Raw Materials.”

During the Track Record Period, our revenue was generated from various customers across our research and development service business and our NGP raw material business. During the Track Record Period, revenue generated from our five largest customers amounted to RMB0.7 million and RMB2.1 million in 2024 and 2025, accounting for 94.9% and 88.0% of our total revenue for the same years, respectively. Revenue from our single largest customer amounted to RMB0.3 million and RMB0.6 million in 2024 and 2025, accounting for 45.8% and 25.4% of our revenue for the same years, respectively. We believe that we maintain strong and stable relationships with our major customers. For details, see “Business — Our Customers.”

INTELLECTUAL PROPERTY

As of the Latest Practicable Date, we owned 63 issued patents and 33 pending patent applications, including 28 patent applications in China, two patent applications in the U.S., and three patent applications in other jurisdictions, relating to certain of our drug candidates and product development technologies. Further, we had 157 registered trademarks in the PRC and we are also the registered owner of two domain names as of the Latest Practicable Date. As of the Latest Practicable Date, (i) for our Core Product SK08 and its related technologies, we had 14 material patents granted in the PRC, 11 material patent applications in the PRC, two material patent applications in the U.S., and three material patent applications in other jurisdictions; (ii) for our key product SK10 and its related technologies, we had nine material patents granted in the PRC, 14 material patent applications in the PRC, two material patent applications in the U.S., and three material patent applications in other jurisdictions. For details, see “Business — Intellectual Property.”

COMPETITION

We are the only company globally to advance a *Bacteroides fragilis*-based LBP product into clinical trials, as of the Latest Practicable Date. Moreover, according to Frost & Sullivan, our Core Product, SK08, is the first LBP to obtain registrational clinical trial approvals from both the NMPA and the U.S. FDA. As of the Latest Practicable Date, our Core Product is also the only biological drug candidate for IBS-D in late-stage clinical development globally. SK10, our key product, is the first inactivated LBP in the PRC to obtain IND approval from the U.S. FDA, according to Frost & Sullivan. For our NGP raw material business, we focus on next-generation strains such as AKK AM06™, targeting a market segment distinct from conventional probiotic raw material manufacturers. According to Frost & Sullivan, our AKK AM06™ is the first and one of only two breast milk-derived AKK strains on the market to have obtained recognition from the FDA.

While we believe our pipeline of clinical and preclinical stage proprietary assets, established R&D capability and experienced management team provide us with competitive advantages, we face potential competition from various sources and expect the competition will intensify in the future as additional players enter into these segments.

SUMMARY OF HISTORICAL FINANCIAL INFORMATION

This summary historical data of financial information set forth below have been derived from, and should be read in conjunction with our historical 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 the section headed “Financial Information.” Our historical financial information was prepared in accordance with IFRS Accounting Standards.

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Summary of Consolidated Statements of Profit or Loss and Other Comprehensive Income

The following table sets forth our consolidated statements of profit or loss and other comprehensive income for the years indicated:

	For the Years Ended December 31,	
	2024	2025
	RMB'000	RMB'000
Revenue	721	2,407
Cost of revenue	(423)	(2,176)
Gross profit	298	231
Other net income	23,267	9,455
Selling and distribution expenses	(32)	(875)
General and administrative expenses	(19,307)	(15,838)
Research and development expenses	(67,570)	(61,941)
Credit loss on trade and other receivables	(145)	(5)
Loss from operations	(63,489)	(68,973)
Finance costs	(509)	(420)
Loss before taxation	(63,998)	(69,393)
Income tax expense	—	—
Loss and total comprehensive income for the year	(63,998)	(69,393)
Attributable to:		
Equity shareholders of the Company	<u>(63,998)</u>	<u>(69,393)</u>
Loss per share		
Basic and diluted (RMB)	<u>(2.33)</u>	<u>(2.47)</u>

We recorded loss for the year of RMB64.0 million and RMB69.4 million in 2024 and 2025, respectively. The increase in loss for the year of RMB5.4 million was primarily attributable to the decrease in other net income of RMB13.8 million (largely reflecting decrease in government grant), partially offset by a decrease in general and administrative expenses of RMB3.5 million and a decrease in research and development expenses of RMB5.6 million, reflecting our focus on the Core Product development, and reduction in staff costs due to structural optimization.

Our revenue increased by 233.8% from RMB0.7 million in 2024 to RMB2.4 million in 2025, primarily driven by an increase in revenue from the provision of research and development services from RMB0.4 million in 2024 to RMB1.9 million in 2025, which was largely attributable to our intensified market development efforts and the signing of new orders with additional customers, as well as an increase in revenue from the sales of NGP raw material products from RMB0.3 million to RMB0.5 million. Our gross profit margin decreased from 41.3% in 2024 to 9.6% in 2025, primarily due to a shift in our revenue mix towards research and development services, for which we strategically accepted smaller, lower-margin orders in the early stage of business development to attract new clients, resulting in a gross margin of 3.0% for such services in 2025.

Our other net income decreased from RMB23.3 million in 2024 to RMB9.5 million in 2025, primarily attributable to a reduction in government grants (including amortization of deferred income) recognized in profit or loss from RMB22.0 million to RMB8.2 million. Our research and development expenses decreased by 8.3% from RMB67.6 million to RMB61.9 million and our general and administrative expenses decreased by 18.0% from RMB19.3 million to RMB15.8 million, primarily attributable to a reduction in staff costs due to structural optimization, while our selling and distribution expenses increased from RMB0.03 million to RMB0.9 million, primarily reflecting our intensified market development efforts.

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Summary of Certain Key Items of Consolidated Statements of Financial Position

The following table sets forth certain key items of consolidated statements of financial position for the years indicated:

	As of December 31,	
	2024	2025
	RMB'000	RMB'000
Non-current assets	35,221	23,192
Current assets	122,034	83,167
Current liabilities	19,742	24,671
Non-current liabilities	9,771	7,024
Net current assets	102,292	58,496
Net assets	127,742	74,664

We had net current assets as of December 31, 2024 and December 31, 2025. Our net current assets decreased from RMB102.3 million as of December 31, 2024 to RMB58.5 million as of December 31, 2025, primarily reflecting (i) a decrease in cash and cash equivalents of RMB18.3 million as we continued to fund our R&D activities and general and administrative expenses; (ii) a decrease in prepayments and other receivables of RMB13.1 million primarily due to the receipt of a VAT refund of RMB12.3 million in 2025 and the utilization of prepayments for our SK08 Phase III clinical trial; and (iii) the maturity and full redemption of our structured deposits of RMB10.0 million; and (iv) an increase in trade and other payables of RMB4.8 million primarily due to an increase in payables for the SK08 Phase III clinical trial.

Summary of Consolidated Cash Flow Statements

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

	For the Years Ended December 31,	
	2024	2025
	RMB'000	RMB'000
Net cash used in operating activities	(45,013)	(22,676)
Net cash generated from investing activities	21,367	10,475
Net cash generated from/(used in) financing activities	77,642	(6,071)
Net increase/(decrease) in cash and cash equivalents	53,996	(18,272)
Cash and cash equivalents at the beginning of the year . . .	38,357	92,353
Cash and cash equivalents at the end of the year	92,353	74,081

In 2025, net cash used in operating activities was RMB22.7 million, primarily attributable to our loss before taxation of RMB69.4 million, as adjusted by (i) non-cash and non-operating items, which primarily consisted of equity-settled share-based payment expenses, depreciation of property, plant and equipment and right-of-use assets, amortization of intangible assets; and (ii) changes in working capital, which primarily resulted from a decrease in prepayments and other receivables of RMB13.1 million (primarily reflecting the receipt of a VAT refund of RMB12.3 million in 2025), an increase in trade and other payables of RMB4.7 million (primarily reflecting an increase in payables for the SK08 Phase III clinical trial), and an increase in contract liabilities of RMB3.9 million (primarily reflecting advances from research and development services).

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In 2024, net cash used in operating activities was RMB45.0 million, primarily attributable to our loss before taxation of RMB64.0 million, as adjusted by (i) non-cash and non-operating items, which primarily consisted of equity-settled share-based payment expenses, depreciation of property, plant and equipment and right-of-use assets, and amortization of intangible assets; and (ii) changes in working capital, which primarily resulted from an increase in prepayments and other receivables and an increase in input VAT receivable, partially offset by an increase in trade and other payables (primarily reflecting an increase in payables for the SK08 Phase III clinical trial).

Cash Operating Cost

The following table sets forth key information relating to our cash operating costs for the years indicated:

	For the Years Ended December 31,	
	2024	2025
	RMB'000	RMB'000
Research and development costs for Core Product		
Staff costs	7,361	5,188
Third-party contracting costs	19,887	20,868
Cost of materials and consumables	765	463
Utilities	1,452	893
Others	1,378	1,068
Subtotal	30,843	28,480
Research and development costs for other product candidates		
Staff costs	8,097	6,504
Third-party contracting costs	3,831	2,755
Cost of materials and consumables	834	1,137
Utilities	1,436	1,229
Others	517	357
Subtotal	14,715	11,982
Total research and development costs	45,558	40,462
Workforce employment costs⁽¹⁾	7,329	6,835
Direct production costs⁽²⁾	181	899
Non-income taxes, royalties and other governmental charges	64	20
Total	53,132	48,216

Notes:

- (1) Workforce employment cost represents total non-research and development personnel costs mainly including salaries and benefits.
- (2) We had not commenced commercial manufacturing of our LBPs as of the Latest Practicable Date.

SUMMARY

Working Capital Confirmation

Taking into account the estimated [REDACTED] from the [REDACTED] and the financial resources available to us, including cash and bank balances and considering our cash burn rate, our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs, including research and development expenses and general and administrative expenses and for at least the next 12 months from the date of this Document.

Our cash burn rate refers to our average monthly amount of net cash used in operating activities, capital expenditures, and other scheduled cash payments. Assuming an average cash burn rate going forward of 4.2 times the level in 2025, taking into account the scheduled payment of indebtedness, we estimate that our cash at bank and on hand, together with other investments as of April 30, 2026 will be able to maintain our financial viability for 9 months, or, if we also take into account the estimated [REDACTED] (based on the [REDACTED] of HK\$[REDACTED] per [REDACTED]), 54 months. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.

We currently have no immediate plan for future financing after the [REDACTED] considering our available cash, estimated [REDACTED] from the [REDACTED] and based on our cash burn rate. However, with the continuing expansion of our business and development of our products, we may require further funding through public or private equity [REDACTED], debt financing and other sources. We will comply with the applicable laws and regulations, including requirements under the Listing Rules, when we proceed with such financings.

KEY FINANCIAL RATIOS

The following table sets forth our key financial ratios for the years indicated:

	For the Years Ended December 31,	
	2024	2025
Quick ratio ⁽¹⁾	6.1	3.2
Current ratio ⁽²⁾	6.2	3.4

Notes:

- (1) Represents current assets less inventories and contract costs divided by current liabilities as of the same date.
- (2) Current ratio is calculated based on the current assets divided by current liabilities.

RISK FACTORS

Our business and the [REDACTED] involve certain risks as set out in “Risk Factors” in this Document. Some of the major risks we face include: (i) our business and financial prospects depend substantially on the success of our drug candidates, particularly our LBP candidates. If we are not able to successfully complete clinical development, obtain regulatory approval and commercialize our drug candidates, including our Core Product, or if we experience delays or cost overruns in doing so, our business prospects and financial conditions could be adversely affected; (ii) we have limited experience in large-scale manufacturing and commercialization, and any failure to effectively operate our in-house pilot plant or scale up manufacturing for LBPs could adversely affect our business; (iii) we work with various third parties to develop our drug candidates. If these third parties do not successfully fulfill their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for or commercialize our drug candidates, and our business could be severely harmed; (iv) our inability to adequately protect our proprietary microbial strains and specialized manufacturing trade secrets could erode our competitive advantage; (v) we incurred substantial losses during the Track Record Period, which

SUMMARY

may continue into the foreseeable future and expose us to liquidity risk; (vi) we are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future performance; (vii) our entire pipeline mainly consists of LBPs, a novel and emerging therapeutic class, and only a very limited number of microbiome-based therapies have received marketing approval worldwide, while the regulatory framework for evaluating LBPs is still evolving, which subjects our clinical development and business path to heightened uncertainty; (viii) if clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in, or be unable to complete, the development and commercialization of our LBP candidates; (ix) we face competition from established and emerging players in the biopharmaceutical industry, which may develop more effective or convenient treatment options and limit the market penetration of our product candidates; (x) we experienced net cash outflow in operating activities during the Track Record Period and may require additional financing to fund our operations even after the [REDACTED], and any failure to obtain such financing on acceptable terms could adversely affect our business. See “Risk Factors” in this Document for details.

DIVIDEND

We did not declare or pay any dividend during the Track Record Period. We do not currently have a formal dividend policy or a pre-determined dividend payout ratio. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. [REDACTED] should not [REDACTED] our ordinary shares with the expectation of receiving cash dividends. Any future determination to pay dividends will be made at the discretion of our Directors and may be based on a number of factors, including our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors may deem relevant. Regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits less any recovery of accumulated losses and appropriations to statutory and other reserves that we are required to make, as determined in accordance with its articles of association and the accounting standards and regulations in the PRC.

As advised by our PRC Legal Advisor, taking into account the aforesaid, we may not have sufficient or any distributable profits to make dividend distributions to our Shareholders in a given year, in view of our accumulated losses, or even if we become profitable, as we will only be able to declare or pay dividends out of our distributable profits until (i) the accumulated losses are covered by our after-tax profits; and (ii) sufficient statutory and other reserves are drawn in accordance with the relevant laws, regulations and our constitutional documents. In light of our accumulated losses as disclosed in this Document, it is unlikely that we will be eligible to pay dividends out of our profits in the foreseeable future.

[REDACTED] EXPENSES

Assuming an [REDACTED] of HK\$[REDACTED] per Share (being the mid-point of the indicative [REDACTED] stated in this Document), the [REDACTED], [REDACTED], together with the Stock Exchange [REDACTED], SFC transaction levy, AFRC transaction levy and Stock Exchange trading fee, legal and other professional fees, printing and other expenses relating to the [REDACTED], which are payable by us are estimated to be approximately RMB[REDACTED] (equivalent to HK\$[REDACTED]), of which RMB[REDACTED] are expected to be charged to our consolidated statements of profit or loss and other comprehensive income in 2026, and RMB[REDACTED] are expected to be deducted from equity following the [REDACTED]. The [REDACTED] expenses consist of RMB[REDACTED] [REDACTED]-related expenses and RMB[REDACTED] non-[REDACTED]-related expenses (including fees and expenses of legal advisors and the reporting accountant of RMB[REDACTED] and other fees and expenses of RMB[REDACTED]), representing approximately [REDACTED]% of our [REDACTED] from the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate and are provided for reference only, and actual amounts may differ.

SUMMARY

FUTURE PLANS AND USE OF [REDACTED]

We intend to use the [REDACTED] from the [REDACTED] for the following purposes and in the amounts set out below, subject to changes in light of our evolving business needs and changing market conditions:

- (i) approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the R&D and registration of our Core Product, SK08, including: (a) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund the advancement of the ongoing Phase III clinical trial, registration, and commercialization of SK08 in the PRC for the treatment of patients with IBS-D, which is expected to be completed by the third quarter of 2029; (b) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund a planned Phase II clinical trial of SK08 in combination with anti-PD-1/L1 monoclonal antibodies in the PRC for the treatment of tumor patients, which is expected to commence in the fourth quarter of 2028; (c) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund a planned Phase II clinical trial of SK08 in the PRC for the treatment of UC, which is expected to commence in the fourth quarter of 2027; and (d) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund a planned Phase II clinical trial of SK08 in the PRC for the treatment of pediatric rotavirus diarrhea, which is expected to commence in the third quarter of 2027;
- (ii) approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the R&D of our key Product, SK10, including: (a) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund the planned Phase II and Phase III clinical trials of SK10 in the PRC for the prevention and treatment of CID, which are expected to commence in the fourth quarter of 2026; and (b) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund a planned Phase II clinical trial of SK10 outside of the PRC for the prevention and treatment of CID, which is expected to commence in the first quarter of 2028;
- (iii) approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the continuous development of our technology platforms, the advancement of our existing pipeline assets, and the exploration and development of new drug candidates; and
- (iv) approximately [REDACTED]%, or HK\$[REDACTED], will be used for working capital and other general corporate purposes.

For details, see “Future Plans and Use of [REDACTED]” in this Document.

RECENT DEVELOPMENTS

Our recent developments of our drug candidates since the end of the Track Record Period and up to the Latest Practicable Date include:

For the Phase III clinical trial of our Core Product, SK08, the patient enrollment is progressing as planned. In June 2026, we received the Acceptance Notice from the CDE for our application regarding a Phase II clinical trial in China of our key product, SK10, for the prevention and treatment of CID.

We expect a significant increase in our net loss in 2026, primarily due to (i) an increase in our research and development expenses as we continue to advance the clinical development of our drug candidates, in particular the ongoing Phase III clinical trial of SK08; and (ii) an increase in general and administrative expenses, mainly attributable to the [REDACTED] expenses incurred in connection with the [REDACTED].

NO MATERIAL ADVERSE CHANGE

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, being the end date of the periods reported in the Accountants’ Report set out in Appendix I, and there is no event since December 31, 2025 that would materially affect the information shown in the Accountants’ Report set out in Appendix I to this Document.